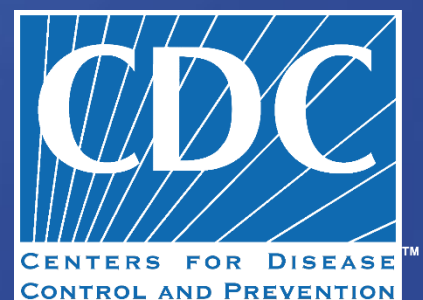


2022

CDC

INFECTIOUS DISEASES LABORATORY TEST DIRECTORY

April 2022, Version 12.8



This document was created under National Center for Emerging and Zoonotic Diseases/ Office of Infectious Diseases (NCEZID/OD). The printed version of CDC's Infectious Diseases Laboratory Test Directory contains information that is current as of April 13, 2022. All information contained herein is subject to change.

For the most current test information, please view the CDC's Infectious Diseases Laboratory Test Directory on: <http://www.cdc.gov/laboratory/specimen-submission/list.html>.



Test Order
***Acanthamoeba* Molecular Detection**
CDC-10471

Synonym(s) Free-living amoeba, parasite, *Acanthamoeba*, granulomatous amoebic encephalitis (GAE), keratitis

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information Required **Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis, prior to submitting specimen for molecular identification. Contact dpx@cdc.gov for more information about submitting images.**

Supplemental Form **Not Applicable**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For suspected cases of granulomatous amoebic encephalitis (GAE) due to *Acanthamoeba* species by *Acanthamoeba* molecular detection, brain tissue is the preferred specimen type; however, these amoebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of *Acanthamoeba* keratitis (AK), deep corneal scraping and ocular fluid is an acceptable specimen. For suspected cases of *Acanthamoeba* skin lesion, skin tissue is an acceptable specimen.

Minimum Volume Required 0.2 g tissue; 1 mL fluids; 5 mm corneal scraping

Collection, Storage, and Preservation of Specimen Prior to Shipping Tissue or corneal scraping (in 0.5x phosphate-buffered saline (PBS)), or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days or frozen (-20°C or lower, in absence of PBS buffer), for up to 60 days.

Transport Medium Small piece of tissue or corneal scraping should be transported in small amount (e.g., 1 mL) of 0.5x phosphate-buffered saline (PBS) to prevent dryness.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen at room temperature, not on dry ice, as an etiologic agent, unless the specimen has been previously frozen. Frozen specimens may be shipped in cold with ice-packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred. Additionally, CSF is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection, because a negative CSF test result does not completely rule out infections with these amebae.
Additional Information	None
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov

Version 2.6

Test Order
Aerobic *Actinomyces* - Identification
CDC-10148

Synonym(s) *Nocardia*, *Streptomyces*, *Tsukamurella*, *Gordonia*, *Rhodococcus*, *Williamsia*, *Dietzia*, *Nocardiopsis*, *Actinomadura*, *Pseudonocardia*, *Dermatophilus*, *Kroppenstedtia*, and other related genera

CDC Pre-Approval Needed **None**

Supplemental Information Required **Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.

Transport Medium Not applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 17
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry

Turnaround Time 3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Aerobic *Actinomyces* - Identification and Antimicrobial Susceptibility Testing
CDC-10149

Synonym(s)	Nocardia, Tsukamurella, Gordonia, Rhodococcus, Streptomyces, Actinomadura
CDC Pre-Approval Needed	None
Supplemental Information Required	Please provide as much information as possible on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Antimicrobial Susceptibility Testing by broth microdilution, Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Alkhurma Hemorrhagic Fever Testing
CDC-10274

Synonym(s) AHFV

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/nceid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For molecular and/or serology testing the accepted specimen types are whole
for Testing blood (EDTA) or serum. CDC POC contact is required prior to sending any
specimens.

Animal specimens or human research specimens may be submitted with
approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Molecular testing specimens must be placed in plastic screw capped vials, frozen
of Specimen Prior to Shipping to -70 °C, and sent on dry ice. Serology testing specimens must be kept cold (at
or below 4 °C) and shipped with a cold pack, or on dry ice in a plastic tube. See
link to supplemental submission form for specific information on various
specimen types. Contact the CDC POC for approval prior to sending any
specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens.
Testing subject to CLIA regulations requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Ameba Identification (*Acanthamoeba*, *Balamuthia*, *Naegleria*)
CDC-10286

Synonym(s) Free-living ameba, *Acanthamoeba*, *Balamuthia*, *Naegleria fowleri*, primary amebic meningoencephalitis (PAM), granulomatous amebic encephalitis (GAE), *Acanthamoeba* keratitis (AK), brain-eating ameba

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
ibne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information Required **Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**

Supplemental Form Not Applicable

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Real-time PCR: Fresh, unfixed tissue, cerebrospinal fluid (CSF), biopsy specimen, deep corneal scrapings, and ocular fluids
 Indirect immunofluorescence (IIF) assay: Paraffin-embedded and formalin-fixed unstained tissue slides (if available, include H&E-stained slides)

Minimum Volume Required 0.2 mL fluids (preferred 1 mL); 0.1 g tissue (preferred 0.2 g); 3 unstained slides (preferred 6); 5-10 mm corneal scraping; 1 H&E-stained slide

Collection, Storage, and Preservation of Specimen Prior to Shipping CSF and fresh, unfixed tissue should be kept and shipped at (a) refrigerated within 7 days, or (b) frozen within 60 days. Unstained tissue slides should be kept and shipped at room temperature within 30 days. Send 1-2 Hematoxylin and Eosin-stained (H&E-stained) slides (if available) along with 3- 6 unstained slides for IIF assay.

Transport Medium For deep scraping and brain or skin biopsy materials, transport in a small volume of 0.5x phosphate-buffered saline (PBS) to prevent dryness for refrigerated temperature shipment with ice-packs. However, addition of 0.5x PBS is not needed if specimen is stored and shipped frozen

Unfixed deep corneal scraping and brain or skin biopsy materials for identification of free-living ameba are usually very small and may dry if they are not stored in proper fluid such as 0.5x PBS. However, frozen tissue can be shipped frozen on dry-ice without adding 0.5x PBS.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship all fresh specimens such as CSF, tissue biopsy (e.g., brain, lungs, skin) and all deep corneal scraping, etc., as an etiologic agent, within 7 days of collection. Fresh, unfixed specimens (i.e., CSF and tissue), should be sent at refrigerated temperature with refrigerated or frozen cold packs, or frozen temperature with dry-ice by overnight priority mail. Unstained slides should be sent at room temperature with room-temperature cold packs. Please ship these specimens separately from other chilled or frozen samples being shipped. Care should be taken to pack glass slides securely, as they can be damaged in shipment if not packed in a crush-proof container.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 53
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Polymerase Chain Reaction (PCR), Indirect Immunofluorescence (IIF), Immunohistochemical (IHC) staining plus microscopy, Microscopy, real-time polymerase chain reaction (PCR), indirect immunofluorescence (IIF)
Turnaround Time	7 Days
Interferences & Limitations	For molecular detection, CSF is the preferred specimen type for <i>N. fowleri</i> only, and it is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection. A negative CSF test result does not completely rule out infection with <i>Acanthamoeba</i> or <i>Balamuthia</i> . Fresh or frozen (unfixed) tissue specimens are preferred for <i>Balamuthia</i> or <i>Acanthamoeba</i> detection. Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred over the formalin-fixed specimens.
Additional Information	<p>Include the address of sender and physician contact information with the specimen.</p> <p>For deep scraping and biopsy materials, provide the following information: patient name (first, last and middle initials), age & date of birth, sex, date specimen collected, specimen source (cornea, vitreous fluid), specimen type (deep scraping, biopsy, vitreous fluid), suspected infection (keratitis, conjunctivitis, endophthalmitis), transport medium used.</p>

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov
If calling outside of regular please call the CDC Emergency
(770) 488-7100

Version 2.0

Test Order
Ameba Serology (*Acanthamoeba*, *Balamuthia*, *Naegleria*)
CDC-10287

Synonym(s) Free-living ameba, *Acanthamoeba*, *Balamuthia*, *Naegleria fowleri*

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information Required **Please provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results**

If images are available please upload to: <http://www.cdc.gov/dpdx>

Supplemental Form Not Applicable

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum; Two serum specimens collected at least 2 weeks apart preferred.

Minimum Volume Required 0.5 mL; 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum specimens can be collected from the patient in a red top tube (plain vacuum tube with no additive) or a serum-separator tube (red/gray speckled top i.e. tiger top, with gel in the tube). Centrifuge the specimen, and send serum only. If using a plain red top tube, separate the serum before shipping and send the serum only. Serum should be kept frozen (-20°C or lower).

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum samples should be shipped frozen on dry ice. Samples must reach the CDC laboratory within 60 days of collection. Please contact laboratory prior to shipping any specimen.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Indirect Immunofluorescence Antibody (IFA) assay

Turnaround Time 14 Days

Interferences & Limitations The Ameba Serology test has limited diagnostic value for three reasons:

1. This test cannot differentiate between an old infection (or exposure) and an acute infection.
2. For immunocompromised patients (which is the case for most *Acanthamoeba* infections, and some of the *Balamuthia* infections), there may not be any antibody response in the infected patients.
3. There may not be enough time to mount an antibody response during an active *N. fowleri* (PAM) infection since the time from the onset of infection to fulminant disease (and death) is usually only 2-8 days.

Additional Information Include the address of sender and physician contact information with the specimen

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov
If calling outside of regular please call the CDC Emergency
(770) 488-7100

Version 3.2

Test Order
Ameba Special Study
CDC-10288

Synonym(s)

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
lbne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov
If calling outside of regular please call the CDC Emergency
(770) 488-7100

Version 1.3

Test Order
Anaerobic Bacteria Identification (ID)
CDC-10227

Synonym(s)	Anaerobe ID, Bacterial Identification, Anaerobe, Anaerobic <i>Actinomyces</i> Identification, <i>C. difficile</i> toxin, <i>C. difficile</i> , <i>C. diff</i> , Clostridioides (Clostridium) <i>difficile</i>
CDC Pre-Approval Needed	None
Supplemental Information Required	The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information and both the specimen source (type) and specimen source site. The CDC 50.34 Specimen Submission Form or GFAT must also include the date the submitted culture was inoculated onto transport media, the name of the suspected agent and include confirmation that isolate does not contain <i>Clostridium botulinum</i>.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of anaerobic bacteria from clinically relevant sources
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure culture isolates prepared in broth and incubated for 18-24 hours anaerobically: store anaerobically sealed vial at room temperature (15-25°C) and ship within 24 hours, or at refrigerated temperature (2-8°C) and ship within 48 hours. Alternatively, aliquot pure culture isolate to cryogenic media within 7 days, store at -20°C or lower until shipped. Pure culture isolates shipped on commercial semi-solid media: store sealed vials in accordance with the manufacturer's instructions for use.
Transport Medium	Transport specimens in Chopped Meat Glucose broth at room temperature or refrigerated. Transport commercial anaerobic semi-solid agar tube transport media (i.e. Anaerobe Systems Transport Media) at room temperature. Transport frozen specimens in Tryptic Soy Broth (TSB) plus glycerol or sterile skim milk plus glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship all samples for overnight delivery.

Pure culture isolates, ship anaerobically sealed vials at room temperature within 24 hours with room-temperature cold packs. If shipment must be delayed, anaerobically sealed vials at can be stored and shipped refrigerated within 48 hours on cold packs with refrigerated or frozen cold packs. Frozen anaerobically sealed vials should be shipped on dry ice within a month.

Pure culture isolates on commercial semi-solid media, ship sealed vials in accordance with the manufacturer's instructions for use.

Ship To:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 13

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	16S ribosomal ribonucleic acid (rRNA) gene sequencing and additional phenotypic testing
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Turnaround Time	4 Weeks
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Interferences & Limitations	Specimens from respiratory, vaginal, and fecal sources are not acceptable.
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Additional Information	If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
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CDC Points of Contact	David Lonsway (404) 639-2825 dul7@cdc.gov Ashley Paulick (404) 639-4761 wnk1@cdc.gov
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Version 3.1

Test Order
Anaplasma Molecular Detection
CDC-10290

Synonym(s) Human granulocytic anaplasmosis

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- **Test order name (one per submission form)**
- **SPHL point of contact including phone number of the person responsible for sample submission and follow-up**
- **Patient full name, sex, birth date**
- **Date of onset (of symptoms)**
- **Specimen collected date**
- **Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)**
- **Therapeutic agent and dates (specific antibiotic therapy and initiation date)**
- **State of illness**
- **Brief clinical summary (include signs, symptoms, and underlying illnesses if known)**

Requested additional information:

- **Previous laboratory results (physical exam findings and pertinent laboratory values)**
- **Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)**
- **Exposure history (including animals and arthropods)**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute whole blood (taken within 14 days of illness onset or while symptomatic): EDTA-treated, or ACD-A treated.
 Acute serum: Serum separator tube, or cryo-tubes. Vascularized tissue biopsies, including skin biopsy specimens from the site of rash or eschar. Swab specimen of eschar, using a dry, sterile cotton swab (include eschar scab when available). Samples must be collected before or within 72 hours of initiation of a tetracycline-class antibiotic, e.g., doxycycline (within 48 hours is preferred), or, if occurring outside of this established time frame, patients must be symptomatic at the time of collection.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For swab, place in sterile specimen container without any medium.

Transport Medium For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline. For swab, place in sterile specimen container without any medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Samples in saline buffer have decreased sensitivity and are subject to rejection. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with nucleic acid extraction.

Additional Information Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.

The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Molecular detection of other rickettsial disease organisms including Ehrlichia, Rickettsia, Coxiella, and Orientia may be performed. Results are reported directly to SPHLs.

Additional RZB specimen and shipping information can be found at the following address:

<https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iwv7@cdc.gov

Version 2.7

Test Order
Anaplasma Serology
 CDC-10292

Synonym(s) Human granulocytic anaplasmosis

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimen should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	<p>Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.</p> <p>The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Ehrlichia, Coxiella, and Orientia may be performed. Results are reported directly to SPHLs.</p> <p>Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</p>
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov

Test Order
Anaplasma Special Study
CDC-10291

Synonym(s)	Human granulocytic anaplasmosis
CDC Pre-Approval Needed	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov
Supplemental Information Required	As determined during pre-approval consultation.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	As determined during pre-approval consultation.
Minimum Volume Required	As determined during pre-approval consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	As determined during pre-approval consultation.
Transport Medium	As determined during pre-approval consultation.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice. <p style="text-align: center;">CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p style="text-align: center;">Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p style="text-align: center;">All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	As determined during pre-approval consultation.
Additional Information	As determined during pre-approval consultation.

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iwv7@cdc.gov

Version 2.6

Test Order
***Angiostrongylus cantonensis* Molecular Detection**
CDC-10472

Synonym(s)	Angiostrongyliasis, Rat lungworm, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Specimens should be stored in leak-proof tubes. Specimens not meeting the following conditions will not be accepted for testing, and a new specimen will be required.</p> <p>Specimen will be received at CDC within 7 days from collection: store refrigerated (2-8°C) at all times.</p> <p>Specimen will be received at CDC more than 7 days from day of collection: store frozen temperature (-20°C or lower).</p> <p>Specimens not meeting these conditions will not be accepted for testing, and a new specimen will be required.</p>
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens shall be shipped to CDC by same- or next-day courier as etiologic agent. Refrigerated specimens should be shipped with refrigerated or frozen cold packs and received at CDC within 7 days of collection. Frozen specimens should be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 52
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Real-time Polymerase Chain Reaction (PCR)
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Turnaround Time	2 Weeks
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Interferences & Limitations

Formalin-fixed specimens are not suitable for this test order. Please see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov regarding testing of formalin-fixed specimens.

Additional Information	None
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CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tg5@cdc.gov
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Version 2.5

Test Order

Antimicrobial Resistant Bacteria - Colonization Screening CDC-10521

Synonym(s) point prevalence survey (PPS), carbapenemase-producing organism (CPO) surveillance, processing of surveillance swabs, surveillance screening for antimicrobial resistant (AR) bacteria, Cepheid Xpert Carba-R assay, infection prevention and control (IPC) surveillance

CDC Pre-Approval Needed **Natashia Reese**
(404) 718-5584
nfu2@cdc.gov
Rocio Balbuena
(404) 718-6627
nyq0@cdc.gov

Supplemental Information Required **All submissions: the CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information and previous testing results that identify the isolated microorganism as Enterobacterales, *Acinetobacter baumannii* or *Pseudomonas aeruginosa* and demonstrate carbapenem-non-susceptibility. Swab submissions: the CDC 50.34 Specimen Submission Form or GFAT must include the date of swab collection. Pure culture isolate submissions: the CDC 50.34 Specimen Submission Form or GFAT must include the date the submitted culture was inoculated into transport media**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Cepheid Xpert Carba-R assay: rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370) or pure culture isolate of Enterobacterales, *Acinetobacter baumannii* or *Pseudomonas aeruginosa* which are carbapenem non-susceptible.
Culture-based methods: rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370) and/or tracheal, axilla, groin or composite axilla/groin swabs on Elution Swab (ESwab) with liquid Amies swab collection and transport system.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370): store at 15-28°C and ship within 24 hours of collection. Do not freeze.
For non-rectal swabs on Elution Swab (ESwab) with liquid Amies swab collection and transport system: store at 20-25°C or at 4-8°C and ship within 24 hours of collection. Do not freeze.
For pure culture isolate: store at 15-25°C and ship within 24 hours of the 18-24 hour incubation of the culture being submitted, or store at 2-8°C and ship within 48 hours. Alternatively, freeze culture within 7 days of 18-24 hour incubation and store at -20°C or lower until shipped.

Transport Medium	<p>Rectal swabs: Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370)</p> <p>Non-rectal swabs: Elution Swab (ESwab) with liquid Amies swab collection and transport system.</p> <p>Pure culture isolate: trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar if at room temperature or refrigerated. If frozen, use trypticase soy broth (TSB) plus 15% glycerol</p>
Specimen Labeling	<p>Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.</p> <p>Rectal swabs (Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370): ship at room temperature within 24 hours of swab collection to arrive at CDC overnight with room-temperature cold packs.</p> <p>Non-rectal swabs (Elution Swab (ESwab) with liquid Amies swab collection and transport system): ship refrigerated with refrigerated or frozen cold packs or at room temperature with room-temperature cold packs within 24 hours of swab collection to arrive at CDC overnight.</p> <p>Pure culture isolates: ship overnight at room temperature with room-temperature cold packs within 24 hours after the 18-24 hour incubation of the culture being submitted. If shipment must be delayed, cultures can be shipped refrigerated with refrigerated or frozen cold packs within 48 hours of 18-24 hour incubation. Cultures frozen within 7 days of 18-24 hour incubation should be shipped on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	<p>Molecular Method: Polymerase chain reaction (PCR)-based detection of blaKPC, blaNDM, blaVIM, blaOXA-48-like, and blaIMP-1 group genes; Culture-based Method: Outbreak strain identification and characterization of antimicrobial resistance mechanisms, Cepheid Carba-R Assay: real-time polymerase chain reaction (PCR)-based detection of blaKPC, blaNDM, blaVIM, blaOXA-48-like, and blaIMP-1 group genes.</p> <p>Culture-based method: characterization of antimicrobial resistance mechanisms (broth enrichment, RT-PCR and phenotypic testing).</p>
Turnaround Time	5 Days

Interferences & Limitations Cepheid Carba-R assay: interfering substances include barium sulfate at >0.1% w/v, Pepto-Bismol at >0.01% w/v; or fecal fat at 0.25% w/v (for blaVIM detection). Level of detection (LOD) of targets for Cepheid system (per package insert) ranged from 74-815 cfu/swab (specificity reported as 100%). If more than one PCR target is present in the sample, one target may not be detected. Culture-based methods: no significant interferences or limitations are currently known.

Additional Information Contact the CDC POC for approval prior to submitting any specimen. If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Prior epidemiologic consultation with CDC/DHQP Prevention and Response Branch (haioutbreak@cdc.gov) is also required. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed. Note: turnaround time for culture-based methods is 3 weeks.

CDC Points of Contact
Natashia Reese
(404) 718-5584
nfu2@cdc.gov
Rocio Balbuena
(404) 718-6627
nyq0@cdc.gov

Version 2.4

Test Order
Antimicrobial Susceptibility Testing (AST) - Bacteria
CDC-10223

Synonym(s)	Antimicrobial Susceptibility Testing (AST), sensitivity, resistance, Minimum Inhibitory Concentration (MIC) testing
CDC Pre-Approval Needed	None
Supplemental Information Required	For all submittals, the CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information as well as documentation of specific antibacterial agent(s) of interest and previous results and testing method on the CDC 50.34 Specimen Submission Form or GFAT. For pure culture isolate submittals, the CDC 50.34 Specimen Submission Form or GFAT must include the date the submitted culture was inoculated onto transport media.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of bacteria demonstrating unusual resistance or unusual isolates on which the submitter cannot perform susceptibility testing.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure culture isolates: store at room temperature (15-25°C) and ship within 24 hours after the 18-24 hour incubation of the culture being submitted, or store at refrigerated temperature (2-8°C) and ship within 48 hours. Alternatively, freeze culture within 7 days after 18-24 hour incubation and store frozen (-20°C or lower) until shipped.
Transport Medium	Pure culture isolates room temperature or refrigerated: trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Frozen submissions: trypticase soy broth (TSB) plus 15% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Pure culture isolates: ship overnight at room temperature with room-temperature cold packs within 24 hours after the 18-24 hour incubation of the culture being submitted. If shipment must be delayed, cultures can be shipped refrigerated within 48 hours of 18-24 hour incubation with refrigerated or frozen cold packs. Cultures frozen within 7 days of 18-24 hour incubation should be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 13
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Broth Microdilution (BMD), Disk Diffusion, Molecular Detection of Antimicrobial Resistance Markers, additional phenotypic testing, broth microdilution (BMD), disk diffusion, molecular detection of antimicrobial resistance markers, additional phenotypic testing
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
CDC Points of Contact	David Lonsway (404) 639-2825 dul7@cdc.gov Rocio Balbuena (404) 718-6627 nyq0@cdc.gov

Version 3.1

Test Order

Arbovirus Isolation and Identification

CDC-10281

Synonym(s) Arbovirus, Arbo Isolation, Barmah Forest virus (BFV), Bourbon virus (BRBV), Cache Valley virus (CVV), Chikungunya virus (CHIKV), Colorado tick fever virus (CTFV), Deer tick virus (DTV), Dengue virus (DENV), Heartland virus (HRTV), Jamestown Canyon virus (JCV), Japanese encephalitis virus (JEV), La Crosse virus (LACV), Mayaro virus (MAYV), Murray Valley encephalitis virus (MVEV), O'nyong nyong virus (ONNV), Powassan virus (POWV), Ross River virus (RRV), Saint Louis encephalitis virus (SLEV), Severe fever with thrombocytopenia syndrome virus (SFTSV), Sindbis virus (SINV), Snowshoe hare virus (SSHV), Tahyna virus (TAHV), Toscana virus (TOSV), West Nile virus (WNV), Western equine encephalitis virus (WEEV), Yellow fever virus (YFV), Zika virus (ZIKV)

CDC Pre-Approval Needed None

Supplemental Information Required Onset date, specimen collected date, travel dates, and travel location(s)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum, plasma, cerebrospinal fluid (CSF), and fresh frozen tissue specimen. All specimens should be acute (0-5 days post onset date) for most arboviruses.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen should be kept refrigerated at 4 °C and shipped cold on gel ice-packs. Frozen specimens (less than or equal to -20 °C) should be shipped on dry ice. Tissue specimens should be approximately one cm³, frozen as soon as possible (less than or equal to -20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.

CDC does not accept routine shipments on weekends or holidays. Please ship Monday - Thursday and make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Isolation in cell culture
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	Minimum Volume Required: Additional volume would allow the use of additional cell lines.

For additional information regarding the fields above, please see this link:
<https://www.cdc.gov/ncezid/dvbd/specimensub/arboviral-shipping.html>

CDC Points of Contact Jason Velez
(970) 225-4262
jdv4@cdc.gov
Amanda Panella
(970) 225-4237
ahf6@cdc.gov

ADBBDiagnostics@cdc.gov

Version 2.0

Test Order

Arbovirus Molecular Detection

CDC-10280

Synonym(s) Arbovirus, Arbo reverse transcriptase-polymerase chain reaction (RT-PCR), Alphavirus, Bourbon virus (BRBV), Bunyavirus, Cache Valley virus (CVV), Chikungunya virus (CHIKV), Colorado tick fever virus (CTFV), Deer tick virus (DTV), Dengue virus (DENV), Eastern equine encephalitis virus (EEEV), Flavivirus, Heartland virus (HRTV), Jamestown Canyon virus (JCV), La Crosse virus (LACV), Mayaro virus (MAYV), Powassan virus (POWV), Saint Louis encephalitis virus (SLEV), Severe fever with thrombocytopenia syndrome virus (SFTSV), Venezuelan equine encephalitis virus (VEEV), West Nile virus (WNV), Western equine encephalitis virus (WEEV), Yellow fever virus (YFV), Zika virus (ZIKV)

CDC Pre-Approval Needed None

Supplemental Information Required Onset date, specimen collected date, travel dates, and travel location(s)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum, plasma, cerebrospinal fluid (CSF), and fresh frozen tissue specimen. For HRTV, BRBV, SFTSV, and CTFV, whole blood is acceptable. For ZIKV, urine, and amniotic fluid is also acceptable. All specimens should be acute (0-7 days post onset date) for most arboviruses. For HRTV, BRBV, SFTSV, and CTFV, acute samples (0-14 days post onset date) will be acceptable.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen should be kept refrigerated at 4 °C and shipped cold on gel ice-packs. Frozen specimens (less than or equal to -20 °C) should be shipped on dry ice. Tissue specimens should be approximately one cm³, frozen as soon as possible (less than or equal to -20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.

CDC does not accept routine shipments on weekends or holidays. Please ship Monday - Thursday and make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Reverse transcriptase (RT)-Polymerase Chain Reaction (PCR); real-time RT-PCR (rRT-PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Hemolysis can affect the test results.
Additional Information	Turnaround Time: Molecular testing for each virus is typically performed once a week but will take longer time to have results interpreted and reported to state health department. For additional information regarding the fields above, please see this link: https://www.cdc.gov/ncezid/dvbd/specimensub/arboviral-shipping.html

CDC Points of Contact Jason Velez
(970) 225-4262
jdv4@cdc.gov
Amanda Panella
(970) 225-4237
ahf6@cdc.gov

ADBiagnostics@cdc.gov

Version 2.0

Test Order
Arbovirus Neutralization Antibody
CDC-10283

Synonym(s) Arbovirus, Arbo plaque reduction neutralization test (PRNT), Barmah Forest virus (BFV), Bourbon virus (BRBV), Cache Valley virus (CVV), Chikungunya virus (CHIKV), Colorado tick fever virus (CTFV), Dengue virus (DENV), Eastern equine encephalitis virus (EEEV), Heartland virus (HRTV), Jamestown Canyon virus (JCV), Japanese encephalitis virus (JEV), La Crosse virus (LACV), Mayaro virus (MAYV), Murray Valley encephalitis virus (MVEV), O'nyong nyong virus (ONNV), Powassan virus (POWV), Ross River virus (RRV), Saint Louis encephalitis virus (SLEV), Severe fever with thrombocytopenia syndrome virus (SFTSV), Sindbis virus (SINV), Snowshoe hare virus (SSHV), Tahyna virus (TAHV), Tick-borne encephalitis virus (TBEV), Toscana virus (TOSV), Venezuelan equine encephalitis virus (VEEV), West Nile virus (WNV), Western equine encephalitis virus (WEEV), Yellow fever virus (YFV), Zika virus (ZIKV)

CDC Pre-Approval Needed None

Supplemental Information Required Onset date, specimen collected date, travel dates, travel location(s), and IgM test results for requested virus

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum and cerebrospinal fluid (CSF)

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen should be kept refrigerated at 4 °C and shipped cold on gel ice-packs. Frozen specimens (less than or equal to -20 °C) should be shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include All specimens should be submitted to CDC through state health departments and Specimen Handling Requirements NOT submitted directly to CDC.

CDC does not accept routine shipments on weekends or holidays. Please ship Monday - Thursday and make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Plaque reduction neutralization test (PRNT)
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolysis can cause non-specific binding in serological tests and can have an effect on laboratory results.
Additional Information	For additional information regarding the fields above, please see this link: https://www.cdc.gov/ncezid/dvbd/specimensub/arboviral-shipping.html
CDC Points of Contact	Amanda Panella (970) 225-4237 ahf6@cdc.gov Jason Velez (970) 225-4262 jdv4@cdc.gov

ADBBDiagnostics@cdc.gov

Version 1.3

Test Order

Arbovirus Serology

CDC-10282

Synonym(s) Arbovirus, Arbo serology, Arbovirus immunoglobulin M (IgM), Barmah Forest virus (BFV), Chikungunya virus (CHIKV), Dengue virus (DENV), Eastern equine encephalitis virus (EEEV), Heartland virus (HRTV), Jamestown Canyon virus (JCV), Japanese encephalitis virus (JEV), La Crosse Encephalitis virus (LACV), Mayaro virus (MAYV), Murray Valley encephalitis virus (MVEV), O'nyong nyong virus (ONNV), Powassan virus (POWV), Ross River virus (RRV), Saint Louis encephalitis virus (SLEV), Sindbis virus (SINV), Snowshoe hare virus (SSHV), Tahyna virus (TAHV), Venezuelan equine encephalitis virus (VEEV), West Nile virus (WNV), Western equine encephalitis virus (WEEV), Yellow fever virus (YFV), Zika virus (ZIKV)

CDC Pre-Approval Needed None

Supplemental Information Required Onset date, specimen collected date, travel dates, and travel location(s)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum and cerebrospinal fluid (CSF)

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen should be kept refrigerated at 4 °C and shipped cold on gel ice-packs. Frozen specimens (less than or equal to -20 °C) should be shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.

CDC does not accept routine shipments on weekends or holidays. Please ship Monday - Thursday and make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 Arbovirus Diagnostic and Reference Laboratory
 3156 Rampart Rd
 Fort Collins, CO 80521
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Enzyme-linked immunosorbent assay (ELISA) immunoglobulin (Ig) M,
Microsphere immunoassay (MIA) IgM

Turnaround Time 4 Weeks

Interferences & Limitations Hemolysis can cause non-specific binding in serological tests and can have an effect on laboratory results.

Additional Information Turnaround Time: turnaround time is impacted by whether the specimen tests positive for immunoglobulin (Ig) M antibodies, as all IgM positive samples will have plaque reduction neutralization test performed (see CDC-10283 Arbovirus Neutralization Antibodies).

For additional information regarding the fields above, please see this link:
<https://www.cdc.gov/ncezid/dvbd/specimensub/arboviral-shipping.html>

CDC Points of Contact Amanda Panella
(970) 225-4237
ahf6@cdc.gov
Jason Velez
(970) 225-4262
jdv4@cdc.gov

ADBBDiagnostics@cdc.gov

Version 1.3

Test Order
Arbovirus Special Study
CDC-10284

Synonym(s)	Arbovirus
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please ship Monday-Thursday and make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	To be determined
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined

CDC Points of Contact Amanda Panella
(970) 225-4237
ahf6@cdc.gov
Jason Velez
(970) 225-4262
jdv4@cdc.gov

ADBDiagnositics@cdc.gov

Version 2.1

Test Order
Arenavirus (New World) Testing
CDC-10293

Synonym(s) New World *Arenavirus*, South American hemorrhagic fever viruses

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For serology testing, the accepted specimen types are whole blood (EDTA) or
for Testing serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or
of Specimen Prior to Shipping below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order

Atypical Bacterial Pneumonia Agents (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Legionella* species) Molecular Detection CDC-10157

Synonym(s) *C. pneumoniae*, *Chlamydophila pneumoniae*, *Chlamydia*, *Chlamydophila*, *M. pneumoniae*, *Mycoplasma*, *Legionella pneumophila*, *L. pneumophila*, *Legionella*, Atypical pneumonia, Community acquired pneumonia, CAP, Legionnaires' disease, LD, Legionellosis, Pontiac fever, Walking pneumonia

CDC Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.

Minimum Volume Required 0.4 mL preferred, 0.2 mL minimum

Collection, Storage, and Preservation of Specimen Prior to Shipping Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Specimens should be refrigerated (2–8°C) after collection and frozen (-20°C or lower) within 96 hours of collection.

Transport Medium Viral transport medium (VTM) for NP and OP swabs

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	All specimens in which <i>Mycoplasma pneumoniae</i> is detected will also be tested using test order <i>Mycoplasma pneumoniae</i> Macrolide Susceptibility Genotyping (CDC-10513). Specimens in which <i>Legionella</i> species is detected will also be tested using test order <i>Legionella</i> species Detection and Identification (CDC-10159) and/or <i>Legionella</i> species Molecular Subtyping (CDC-10160).
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov

Version 3.2

Test Order
***Babesia* Molecular Detection**
CDC-10473

Synonym(s)	Babesiosis; <i>Babesia microti</i> ; <i>Babesia duncani</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	Please submit the blood smear slides with the whole blood, each with their own 50.34. Microscopy examination of blood smears is mandatory prior to performing molecular detection.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored in leak-proof containers and kept refrigerated (2-8°C) at all times. Ship to CDC within 7 days of collection. Specimens not meeting these conditions will not be accepted for testing, and a new specimen will be required.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent and shall remain refrigerated with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Conventional and Real-time Polymerase Chain Reaction (PCR) and Sanger sequencing
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	None

CDC Points of Contact Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
Theresa Benedict
(404) 718-4124
tgd5@cdc.gov

Version 2.3

Test Order
Babesiosis Serology
CDC-10456

Synonym(s) *Babesia microti*; *Babesia duncani*; *Babesia divergens*, babesiosis, parasite

CDC Pre-Approval Needed None

Supplemental Information Required **CDC 50.34 Specimen Submission Form must include exposure and travel history, any relevant risk factors (ticks, transfusion); clinical symptoms, treatment and relevant lab results.**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 57
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Indirect Fluorescent Antibody assay, Antibody detection

Turnaround Time 3 Weeks

Interferences & Limitations Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin

Additional Information Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.5

Test Order
Bacillus anthracis Detection in Clinical Specimens
CDC-10204

Synonym(s) Anthrax PCR

CDC Pre-Approval Needed **William Bower**
(404) 639-0376
wab4@cdc.gov
EOC Duty Officer (After hours)
(770) 488-7100
eocreport@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results.**

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Whole blood, serum, cerebral spinal fluid (CSF)

Minimum Volume Required 0.10 mL (prefer 0.5-1.0 mL)

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerated (2-8°C) for up to 14 days post- collection and frozen (-20°C or lower) for up to 28 days. Specimens should not exceed 3 freeze/thaw cycles.

Transport Medium Dependent on specimen type submitted. For more information, reference the Additional Information field.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Culture, Polymerase Chain Reaction (PCR), Immunohistochemistry (IHC), Toxin detection
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Turnaround Time	2 Weeks
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Interferences & Limitations	Varies depending on tests used. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin). Tissues for IHC should be formalin fixed.
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Additional Information

Turnaround time will vary depending on methods selected for detection at CDC. Some methods may require up to 2 weeks. Information on specimens, storage, and shipping can be found at:
http://www.cdc.gov anthrax/labs/recommended_specimen.html

Pre-approval required from state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance.

CDC Points of Contact	<p>Zoonoses and Select Agent L (ZSAL) (404) 639-1711 ZSAL@cdc.gov Cari Kolton (404) 639-2065 fts3@cdc.gov
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Version 3.2

Test Order
Bacillus anthracis Genotyping and AST
CDC-10203

Synonym(s) Anthrax, Anthrax Gamma phage, Anthrax PCR, Anthrax typing

CDC Pre-Approval Needed **William Bower**
(404) 639-0376
wab4@cdc.gov
EOC Duty Officer (After hours)
(770) 488-7100
eocreport@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**

Supplemental Form **Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).**
<https://www.selectagents.gov/forms.html>

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing *B. anthracis* isolates

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolates can be kept at room temperature prior to shipping.

Transport Medium Appropriate microbiological media for *Bacillus*

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements

Isolates should be shipped at room temperature.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 91

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state, and federal regulations.

Methodology	Genotyping (i.e., MLVA and genome sequence), Broth Microdilution, Rapid Antimicrobial Susceptibility Test (AST)
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Turnaround Time	2 Weeks
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Interferences & Limitations	No significant interferences or limitations are currently known.
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Additional Information

Rapid AST turnaround is 1 day or less. Genotyping and broth microdilution is approximately 7 days. Note: More extensive characterization by whole genome sequencing may take longer. Times may be shorter in public health emergencies.

Link to our website:

http://www.cdc.gov/anthrax/labs/recommended_specimen.html

Pre-approval required from state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance.

CDC Points of Contact	Zoonoses and Select Agent Labo (ZSAL) (404) 639-1711 ZSAL@cdc.gov David Lonsway (404) 639-2825 dul7@cdc.gov Cari Kolton (404) 639-2065 fts3@cdc.gov
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Version 2.2

Test Order
Bacillus anthracis Serology
CDC-10196

Synonym(s) Anthrax ELISA, Anthrax serology, Bacillus serology

CDC Pre-Approval Needed **William Bower**
(404) 639-0376
wab4@cdc.gov
EOC Duty Officer (After hours)
(770) 488-7100
eocreport@cdc.gov

Supplemental Information Required **Provide the following Specimen Information on the CDC 50.34 Specimen Submission form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results, date of onset, and specimen collection date for both acute and convalescent sera samples.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Contact CDC POC prior to specimen submission for specimen acceptance, collection, storage and preservation requirements.

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum may be stored at refrigerated temperature (2-8°C) for up to 28 days post-collection and frozen (-20°C or lower) for up to 28 days. Specimens should not exceed 3 freeze/thaw cycles.

Transport Medium Not applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice. For additional information, reference the Additional Information field.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Antibody detection by enzyme-linked immunosorbent assay (ELISA)
Turnaround Time	2 Weeks
Interferences & Limitations	Requires acute and convalescent serum for analysis.

Additional Information

Additional information on Shipping Instructions which Include Specimen Handling Requirements.

http://www.cdc.gov/anthrax/labs/recommended_specimen.html

Pre-approval required from state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at 770-488-7100 for additional guidance.

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov
Chung Marston
(404) 639-4057
cdk5@cdc.gov

Version 3.3

Test Order
Bacillus anthracis Study
 CDC-10205

Synonym(s)	
CDC Pre-Approval Needed	Alex Hoffmaster (404) 639-0852 amh9@cdc.gov Cari Kolton (404) 639-2065 fts3@cdc.gov
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).
Supplemental Form	Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/forms.html
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]
	All samples must be shipped in accordance with all applicable local, state, and federal regulations
Methodology	
Turnaround Time	
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information To be determined

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Cari Kolton
(404) 639-2065
fts3@cdc.gov

Version 2.1

Test Order
Bacillus cereus Detection - Foodborne Outbreak
CDC-10104

Synonym(s) *B. cereus*

CDC Pre-Approval Needed **Haley Martin**
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Supplemental Information Required **Only specimens from foodborne outbreaks accepted. Consult with CDC POC before sending specimens. Include a CDC 50.34 Specimen Submission Form with each specimen. For food or environmental samples (including derived isolates), provide the following information: specimen collected date, material submitted, specimen source site, and if applicable, transport medium/specimen preservative and any preliminary laboratory results available. For human specimens (including derived isolates), provide the following information: date of onset, if fatal, specimen collected date, material submitted, specimen source (type), and if applicable, transport medium/specimen preservative and any preliminary laboratory results available.**

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Only implicated food (preferred sample type), vomitus and stool specimens (collected within 48 hours of illness onset), and their derived isolates are acceptable. Consult with CDC POC prior to sending specimens.

Minimum Volume Required 25 g (food) and 10 g (stool)

Collection, Storage, and Preservation of Specimen Prior to Shipping Collect stool and vomitus while patient is symptomatic (within 48 hours after illness onset). Separate foods into individual containers or bags. Refrigerate samples promptly after collection and maintain at 2-8°C. Ship samples within two weeks from collection date. Food or stool stored longer than two weeks are not acceptable. If samples cannot be shipped within 2 weeks, promptly freeze upon collection at <-20°C, and ship frozen.

Transport Medium Transport medium not applicable with food. Ship stool raw or in transport medium (e.g. Cary-Blair, Enteric Transport Medium). Ship isolates on non-selective agar.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with ice packs and ship frozen specimens on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Toxin Detection (Food only), Culture (Food and Stool), Polymerase Chain Reaction (Isolates)

Turnaround Time 13 Weeks

Interferences & Limitations Incorrect storage and/or spoilage of food may affect results. Reduced toxin detection and/or culture occurs in food older than two weeks. Stools collected 48 hours after illness onset and/or after patient recovery are not suitable for testing as they may not contain detectable organism.

Additional Information Direct toxin detection requires food (toxin testing is not performed on stool).

The test methods(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Haley Martin
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Version 1.5

Test Order
Bacillus cereus Genotyping
 CDC-10206

Synonym(s)	<i>Bacillus</i> MLST
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates can be kept at room temperature prior to shipping.
Transport Medium	Any medium can be submitted, but preferably agar slants.
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>Isolates should be shipped at room temperature.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state, and federal regulations.</p>
Methodology	Multilocus sequence typing (MLST)
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information Testing can be done on *B. cereus* and *B. thuringiensis*.

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov

Version 2.1

Test Order
Bacillus species Identification (Not *B. anthracis*)
 CDC-10142

Synonym(s)	Gram-positive bacilli
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Bacterial Identification of Unknown Isolate (Not Strict Anaerobe)
CDC-10145

Synonym(s)	Bacterial Identification
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
***Balamuthia* Molecular Detection**
CDC-10474

Synonym(s) Free-living amoeba, parasite, granulomatous amoebic encephalitis (GAE), *B. mandrillaris*

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information Required **Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpx@cdc.gov for more information about submitting images.**

Supplemental Form **Not Applicable**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For suspected cases of granulomatous amoebic encephalitis (GAE) due to *Balamuthia mandrillaris* detected by *Balamuthia* molecular detection, brain tissue is the preferred specimen type; however, these amoebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of *Balamuthia* skin lesion, skin tissue is an acceptable specimen.

Minimum Volume Required 0.2 g tissue; 1 mL fluids

Collection, Storage, and Preservation of Specimen Prior to Shipping Tissue (in 0.5x PBS) or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower, in absence of PBS buffer) for up to 60 days.

Transport Medium Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen at room temperature, not on dry ice, as an etiologic agent, unless the specimen has been previously frozen. Frozen specimens may be shipped in cold with ice-packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred. Additionally, CSF is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection, because a negative CSF test result does not completely rule out infections with these amebae.
Additional Information	None
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov

Version 2.5

Test Order
Bartonella henselae/*B. quintana* Indirect Fluorescent Antibody (IFA) test
 CDC-10486

Synonym(s) *B. henselae*/cat scratch disease, *B. quintana*/trench fever

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Upon collection and serum separation, serum specimens should be held at 2-8 °C. Serum samples can be stored at 2-8 °C for up to 14 days and shipped on gel ice packs. If testing is delayed longer than 14 days, serum samples may be frozen (-20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If serum can be shipped to CDC within 14 days of sample collection, serum samples should be kept refrigerated and shipped on gel ice packs. If serum specimens are frozen, they should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 Bacterial Diagnostic and Reference Laboratory
 3156 Rampart Road
 Fort Collins, CO 80521
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Indirect Fluorescent Antibody (IFA)

Turnaround Time 2 Weeks

Interferences & Limitations Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.7

Test Order
Bartonella quintana Molecular Detection
CDC-10554

Synonym(s) Trench fever

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing EDTA-treated whole blood or suspect isolate

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen refrigerated (2-8 °C) prior to transport.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship specimens refrigerated on gel ice packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase chain reaction (PCR)

Turnaround Time 3 Weeks

Interferences & Limitations Prior antibiotic treatment may reduce sensitivity by decreasing the amount of bacterial DNA present in specimens.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.0

Test Order
Bartonella Special Study
CDC-10297

Synonym(s) Cat scratch fever, *B. henselae*, Trench fever, *B. quintana*, Oroya fever, *B. bacilliformis*

CDC Pre-Approval Needed **Jeannine Petersen**
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- **Test order name (one per submission form)**
- **Patient full name, sex, birth date**
- **Date of onset (of symptoms)**
- **Specimen collected date**
- **Specimen source (type)**
- **Submitting agency address, contact name, phone number and email address for each submitter**
- **Brief clinical summary (include signs, symptoms, and underlying illnesses if known)**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Contact the CDC POC for appropriate guidance/relevant information.

Minimum Volume Required Contact the CDC POC for appropriate guidance/relevant information.

Collection, Storage, and Preservation of Specimen Prior to Shipping Contact the CDC POC for appropriate guidance/relevant information.

Transport Medium Contact the CDC POC for appropriate guidance/relevant information.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 2.3

Test Order
Baylisascariasis Serology
CDC-10457

Synonym(s)	Baylisascariasis, Raccoon roundworm, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors (raccoon) clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and CSF for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum and CSF can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera and CSF specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.6

Test Order
Bio-Rad Avidity-based Incidence (BRAI) Assay
CDC-10535

Synonym(s) BRAI, Recency assay

CDC Pre-Approval Needed **Jeff Johnson**
(404) 639-4976
jlj6@cdc.gov
Bill Switzer
(404) 639-0219
bis3@cdc.gov

Supplemental Information Required **Additional information will be requested after the specimen is approved for testing at CDC.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum, plasma or whole blood

Minimum Volume Required 10 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen stability is affected by elevated humidity temperature. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping.

Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Plasma can be collected using plasma preparation tubes (PPT) or EDTA or ACD. Serum can be collected in serum tubes. Follow sample tube manufacturer's instructions. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health, management of the individual patient, nor recorded in patient medical records.

Shipping Instructions which Include Specimen Handling Requirements Shipping of specimens the same day of collection is preferred. Shipment of specimens plasma or serum specimens stored at 2-8 °C within 7 days of collection should be sent with cold packs, and frozen specimens sent on dry-ice. For EDTA whole blood, tube must be shipped overnight on the date of collection at ambient temperature.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday (overnight shipping preferred).

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 74
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimens that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	This test order is Research Use Only (RUO). The results reported should NOT be used for diagnosis, treatment, assessment of health, management of the individual patient nor recorded in patient medical records.
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Jeff Johnson (404) 639-4976 jlj6@cdc.gov

Version 1.0

Test Order
Biodefense R&D Study
CDC-10487

Synonym(s) Biodefense Research and Development Laboratory Study

CDC Pre-Approval Needed **Linda Weigel**
(404) 639-1497
lew9@cdc.gov
David Sue
(404) 639-4027
btx6@cdc.gov

Supplemental Information Required **For isolates from human specimens, prior approval is required. Consult with the lab for details.**

Select Agent Form 2 required for submission of all confirmed Select Agents. The Form 2 can be found at <http://www.selectagents.gov/forms.html>

Supplemental Form **<http://www.selectagents.gov/forms.html>**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates on agar plate or slant, consult with lab for details.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Consult with lab for details

Transport Medium Pure culture isolates (only) on sheep blood or Mueller-Hinton agar

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Select agents that have been identified need form 2 approval prior to shipping. Form 2 may be found at: <http://www.selectagents.gov/forms.html>

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 206
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Modified Broth Microdilution

Turnaround Time 2 Days

Interferences & Limitations Isolates from human specimens may be tested only under Emergency Use Authorization.

Additional Information Turnaround time can vary depending on age/purity of isolate received

CDC Points of Contact David Sue
(404) 639-4027
btx6@cdc.gov
Julia Bugrysheva
(404) 639-4892
vol5@cdc.gov

Version 2.4

Test Order
BioFire Respiratory Panel
CDC-10556

Synonym(s) Respiratory 2.1 Panel

CDC Pre-Approval Needed **Everardo Vega**
(404) 639-2396
evega@cdc.gov
Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required minimum 0.3 mL; 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping

- At room temperature (15 - 25° C) for up to 4 hours
- Refrigerated up to 3 days (2 - 8° C)
- Frozen (\leq -15 °C) for up to 30 days

Transport Medium Specimens must be in viral transport medium or saline.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 84
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology This Respiratory Pathogen PCR Panel is used to detect:

Adenovirus, coronavirus (HKU1, NL63, 229E, OC43, SARS-CoV-2), human metapneumovirus, human rhinovirus/enterovirus, influenza A (A, A/H1, A/H3, A/H1-2009), influenza B, parainfluenza (1-4), human respiratory syncytial virus, Bordetella (*Bordetella parapertussis*, *Bordetella pertussis*), *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information nasopharyngeal swabs should not be spun down

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Hannah Kirking
(404) 718-8345
hrj7@cdc.gov
Brett Whitaker
(404) 639-1519
ijr4@cdc.gov

Version 1.0

Test Order
Biothreat Event
CDC-10432

Synonym(s)

CDC Pre-Approval Needed Jennifer Thomas
(404) 639-4259
fsu8@cdc.gov
Nazia Kamal
(404) 639-4733
ird7@cdc.gov

Supplemental Information Required To be determined

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling To be determined

Shipping Instructions which Include Specimen Handling Requirements To be determined

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Jennifer Thomas
(404) 639-4259
fsu8@cdc.gov
Nazia Kamal
(404) 639-4733
ird7@cdc.gov

Version 2.1

Test Order
Bordetella pertussis and Related Species Detection and Identification
 CDC-10163

Synonym(s) *Bordetella pertussis*, *B. parapertussis*, *B. holmesii*, *B. bronchiseptica*, whooping cough, pertussis

CDC Pre-Approval Needed None

Supplemental Information Required **Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of cough, recent antibiotic history and pertussis-containing vaccine status.**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Nylon, rayon, or polyester-tipped nasopharyngeal swab; nasopharyngeal aspirate; pure culture isolate of suspected *Bordetella pertussis*, *B. parapertussis*, *B. holmesii*, or *B. bronchiseptica*.

Minimum Volume Required 0.5 mL of nasopharyngeal aspirate

Collection, Storage, and Preservation of Specimen Prior to Shipping Nasopharyngeal swab for culture and PCR: collect from patient and immediately place in a Regan-Lowe semi-solid agar or Amies charcoal gel transport tube and store within 30 minutes of collection, refrigerated (2-8°C) until shipment. Ship within 24-72 hours of collection.

Nasopharyngeal aspirate for culture and PCR: collect from patient in physiological saline and immediately place in leak-proof plastic tube and store within 30 minutes of collection, refrigerated (2-8°C) if it will be shipped within 72 hours of collection; otherwise, freeze the aspirate (-20°C or lower) within 30 minutes of collection.

Nasopharyngeal swab for PCR only (no culture): collect from patient and immediately place in a dry, sterile tube or in a tube of liquid universal transport medium (UTM) and store frozen (-20°C or lower) within 30 minutes of collection.

Pure culture isolate for confirmation by culture and/or PCR: inoculate on Regan-Lowe solid agar slant or plate, Bordet Gengou solid agar slant or plate, or 5% sheep blood solid agar slant or plate and incubate in an aerobic atmosphere at 35-37°C until growth is observed (typically 48-72 h). After observed growth, store slant or plate refrigerated (2-8°C) until shipped. Ship within 24-48 hours after growth is present.

Alternatively, growth of a pure culture isolate may be collected from a Regan-Lowe, Bordet Gengou, or 5% sheep blood solid agar plate within 72 hours of plate inoculation using a nylon, rayon, or polyester-tipped swab and placed in a tube of Regan-Lowe semi-solid agar or Amies charcoal gel transport. Regan-Lowe semi-solid agar or Amies charcoal gel transport should not be incubated prior to shipping; instead, store the inoculated transport tube refrigerated (2-8°C) until shipped. Ship within 24-48 hours of transport inoculation.

Transport Medium Nasopharyngeal swab for PCR only (no culture): Dry in sterile tube without transport medium or in liquid Universal Transport Medium (UTM).

Nasopharyngeal swab for culture and PCR: Regan-Lowe semi-solid agar transport medium or Amies charcoal gel transport medium.

Nasopharyngeal aspirate for culture and PCR: Transport medium not required.

Pure culture isolate for confirmation by culture and/or PCR: Regan-Lowe solid agar slant or plate, Bordet Gengou solid agar slant or plate, 5% sheep blood solid agar slant or plate, Regan-Lowe semi-solid agar transport, or Amies charcoal gel transport.

Specimen Labeling Test subject to CLIA regulation and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Nasopharyngeal swabs for culture and PCR: ship overnight with refrigerated or frozen cold packs within 24-72 hours of collection.

Nasopharyngeal aspirate for culture and PCR:

- If stored refrigerated, ship overnight with refrigerated or frozen cold packs within 24-72 hours of collection.
- If stored frozen, ship frozen overnight with dry ice within 1 week of collection. Once frozen, do not allow aspirate to thaw.

Nasopharyngeal swab for PCR only (no culture):

- Ship frozen with dry ice within 1 week of collection. Once frozen, do not allow swab to thaw.

Pure culture isolate for confirmation by culture and/or PCR:

- Ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours after growth is present.
- Pure culture in Regan-Lowe semi-solid agar or Amies charcoal gel transport: ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours of transport inoculation.

Note: The original isolate should be retained by the submitter for the duration of testing at CDC.

Ship To:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 12

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Culture, Multi-target Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Bordetella</i> spp. Patients coughing more than two weeks will likely not be culture positive. Specimens collected from patients with more than 4 weeks of cough are not appropriate for culture or PCR. Specimens should not be tested if they have incurred more than 2 freeze-thaw cycles. Amies Charcoal transports are acceptable, but may decrease the probability of isolation. Specimens in Regan-Lowe can be tested by both culture and PCR.
Additional Information	None

CDC Points of Contact Pam Cassidy
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Version 2.3

Test Order
Bordetella pertussis Serology
CDC-10166

Synonym(s) IgG against pertussis toxin, Pertussis ELISA, whooping cough

CDC Pre-Approval Needed Lucia Pawloski
(404) 639-4506
ecz6@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Supplemental Information Required Specimens are for research or surveillance testing only. Provide the following limited patient information on the CDC 50.34 Specimen Submission Form: patient age, duration of cough, recent pertussis-containing vaccination status. Do not include Personally Identifiable Information (PII).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing The following are criteria for serum submission:
- Adolescent and adult individuals
- Cough of at least 2 weeks, up to 12 weeks
- Not vaccinated with a pertussis-containing vaccine in the previous 6 months

The age cut-off is designed to exclude children who are still receiving their primary pertussis vaccination series. Vaccination with a pertussis-containing vaccine within 6 months of serology test may confound results. Cough of at least 2 weeks and up to 12 weeks is required for IgG antibody detection in this test.

Minimum Volume Required 0.2 mL; 0.5 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Blood should be collected using a serum separation tube with no additives. Centrifuge the tube of blood at 1100-1300 x g for approximately 10 minutes to separate the cells from the serum. Serum specimens may be stored refrigerated (2-8 °C) for up to 7 days. If greater than 7 days, serum must be kept frozen (-20 °C or colder). For long-term storage, the serum should be frozen (-20 °C or colder).

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Serum specimens may be stored refrigerated and shipped on gel ice-packs if they will be received at CDC within 7 days of collection. Specimens that will not be received at CDC within 7 days of collection should be kept frozen and sent with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday-Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 12
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Sender is responsible for shipping charges. International submitters must request CDC's import permit and include this with the Air Waybill.

Methodology	Enzyme-linked Immunosorbent Assay (ELISA)
Turnaround Time	2 Weeks
Interferences & Limitations	Sera collected from patients with less than 2 weeks or greater than 12 weeks of cough or from patients vaccinated with a pertussis-containing vaccine in the previous 6 months are not appropriate for this test. Sera should not be sent if they have incurred more than 5 freeze-thaw cycles. Sera with preservatives such as anti-coagulants will invalidate results. Hemolyzed and lipemic sera are considered suboptimal for this assay.
Additional Information	None
CDC Points of Contact	Lucia Pawloski (404) 639-4506 ecz6@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

Version 3.1

Test Order
Bordetella species Study
CDC-10167

Synonym(s) *Bordetella pertussis*, *B. parapertussis*, *B. holmesii*, *B. bronchiseptica*, whooping cough, pertussis

CDC Pre-Approval Needed **Pam Cassidy**
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Supplemental Information Required **Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of cough, recent antibiotic history and pertussis-containing vaccine status.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing For isolation and/or PCR: Nasopharyngeal swabs or nasopharyngeal aspirates; calcium alginate and cotton swabs are not acceptable.
For isolate confirmation: Pure culture isolates or cryopreserved isolates.
For PCR only: Extracted DNA.

Minimum Volume Required 0.5 mL nasopharyngeal aspirates; 0.2 mL DNA; 0.5 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Swabs for culture and PCR: Nasopharyngeal swabs should be polyester, rayon or nylon. Swabs should be placed in tubes of Regan-Lowe transport medium and kept refrigerated at 4 °C until shipment.

Nasopharyngeal aspirates for culture and PCR: Nasopharyngeal aspirates should be in leak-proof plastic tubes. Aspirates should be kept refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, aspirates should be kept frozen at -20 °C.

Swabs for PCR only: Nasopharyngeal swabs should be polyester, rayon or nylon. Swabs should be placed in dry, sterile tubes. Swabs in universal transport medium are also acceptable. All swabs should be kept refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, swabs should be kept frozen at -20 °C.

Isolates: Isolates can be frozen at -70 °C in cryopreservation medium or kept refrigerated at 4 °C on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (*B. parapertussis*, *B. holmesii*, or *B. bronchiseptica* only) slants.

DNA: DNA extracted from nasopharyngeal specimens should be in leak-proof plastic tubes. DNA should be kept frozen at -20 °C.

Transport Medium	<p>Regan-Lowe transport medium is recommended for specimens for culture. Amies Charcoal transports are acceptable, but may decrease the probability of isolation. Specimens in Regan-Lowe can be tested by both culture and PCR.</p> <p>Isolates can be frozen at -70 °C in cryopreservation medium; for best results a fresh subculture on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (<i>B. parapertussis</i>, <i>B. holmesii</i>, or <i>B. bronchiseptica</i> only) slant should be sent.</p> <p>Dry swabs in sterile tubes are preferred for PCR; if only one swab is collected for both culture and PCR, the swabs should be sent in Regan-Lowe transport as described previously.</p>
Specimen Labeling	<p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>For best results, specimens should be shipped within 24-48 hours of collection. Specimens refrigerated (isolates on slants, nasopharyngeal swabs in transports, nasopharyngeal aspirates) should be shipped overnight on gel ice-packs. Specimens frozen (cryopreserved isolates, nasopharyngeal aspirates and swabs, and extracted DNA) should be shipped overnight on dry ice.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 12 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p> <p>Sender is responsible for shipping charges. International submitters must request CDC's import permit and include this with the Air Waybill.</p>
Methodology	<p>Culture, Multi-target Polymerase Chain Reaction (PCR), Whole Genome Sequencing, Pulsed-Field Gel Electrophoresis, Multi-Locus Sequence Typing, Antibiotic Susceptibility, Antigen Testing</p>
Turnaround Time	
Interferences & Limitations	<p>Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Bordetella</i> spp. Patients coughing more than two weeks will likely not be culture positive. Specimens collected from patients with more than 4 weeks of cough are not appropriate for culture or PCR. Specimens should not be tested if they have incurred more than 2 freeze-thaw cycles.</p>
Additional Information	<p>None</p>

CDC Points of Contact Pam Cassidy
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Version 2.0

Test Order
Bordetella spp. Identification (not *B. pertussis/parapertussis*)
 CDC-10143

Synonym(s)	<i>Bordetella</i> Identification
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Borrelia burgdorferi (Lyme Disease) Serology
 CDC-10298

Synonym(s) Lyme Disease, Borreliosis

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
- Prior antibiotic treatment (type of antibiotic and date administered)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Upon collection and serum separation, serum specimens should be held at 2-8 °C. Serum samples can be stored at 2-8 °C for up to 14 days and shipped on gel ice packs. If testing is delayed longer than 14 days, serum samples may be frozen (-20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If serum can be shipped to CDC within 14 days of sample collection, serum samples should be kept refrigerated and shipped on gel ice packs. If serum specimens are frozen, they should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 Bacterial Diagnostic and Reference Laboratory
 3156 Rampart Road
 Fort Collins, CO 80521
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Enzyme immunoassay (EIA), Western blot; Standard two-tier testing (STTT),
Modified two-tier testing (MTTT)

Turnaround Time 3 Weeks

Interferences & Limitations

Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 2.1

Test Order
Borrelia Culture and Identification
 CDC-10299

Synonym(s) Lyme Disease, Borreliosis, Relapsing fever

CDC Pre-Approval Needed **Jeannine Petersen**
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- **Test order name (one per submission form)**
- **Patient full name, sex, birth date**
- **Date of onset (of symptoms)**
- **Specimen collected date**
- **Specimen source (type)**
- **Submitting agency address, contact name, phone number and email address for each submitter**
- **Brief clinical summary (include signs, symptoms, and underlying illnesses if known)**
- **Prior antibiotic treatment (type of antibiotic and date administered)**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Whole blood (citrate-treated blood is preferred, but EDTA-treated and heparin-treated blood are acceptable). Contact the POC for approval prior to sending other specimen types, such as skin biopsy (erythema migrans rash).

Minimum Volume Required 0.5 mL (whole blood). Contact the CDC POC for minimum volume required for other sample types.

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate (2-8°C) all specimens promptly after collection. For whole blood, citrate-treated samples are preferred, but heparin-treated and EDTA-treated samples are acceptable. For any other sample types, contact POC prior to collection for specific requirements. Do not freeze samples.

Transport Medium Contact the CDC POC for appropriate guidance on transport medium for skin biopsy specimens.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimens refrigerated on gel ice packs. Avoid freezing specimens.
CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Culture, Microscopy Confirmation

Turnaround Time 8 Weeks

Interferences & Limitations

Samples should be collected pretreatment as antibiotic treatment will reduce the sensitivity and minimize growth potential of culture.

Avoid freezing specimens as this will reduce bacterial viability.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.8

Test Order
Borrelia hermsii (Tick-borne Relapsing Fever) Serology
 CDC-10399

Synonym(s) Borreliosis, soft tick relapsing fever

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
- Prior antibiotic treatment (type of antibiotic and date administered)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Upon collection and serum separation, serum specimens should be held at 2-8 °C. Serum samples can be stored at 2-8 °C for up to 14 days and shipped on gel ice packs. If testing is delayed longer than 14 days, serum samples may be frozen (-20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If serum can be shipped to CDC within 14 days of sample collection, serum samples should be kept refrigerated and shipped on gel ice packs. If serum specimens are frozen, they should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	EIA (enzyme immunoassay), Western Blot
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Turnaround Time	3 Weeks
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Interferences & Limitations	Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.
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Additional Information	This test is not intended for <i>Borrelia miyamotoi</i> (<i>Borrelia miyamotoi</i> disease, hard tick relapsing fever) serology.
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CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
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Version	2.9
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Test Order
Borrelia Molecular Detection - Relapsing Fever
 CDC-10532

Synonym(s)	Relapsing fever, Tickborne relapsing fever, <i>Borrelia miyamotoi</i> disease, Louse-borne relapsing fever, <i>Borrelia hermsii</i> , <i>Borrelia turicatae</i> , <i>Borrelia miyamotoi</i> , <i>Borrelia recurrentis</i>
CDC Pre-Approval Needed	None
Supplemental Information Required	Required information on the CDC 50.34 Specimen Submission Form: <ul style="list-style-type: none"> • Test order name (one per submission form) • Patient full name, sex, birth date • Date of onset (of symptoms) • Specimen collected date • Specimen source (type) • Submitting agency address, contact name, phone number and email address for each submitter • Brief clinical summary (include signs, symptoms, and underlying illnesses if known) • Prior antibiotic treatment (type of antibiotic and date administered)
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated whole blood is preferred; acute serum or plasma (collected while patient is symptomatic) is also acceptable.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8 °C) prior to transport.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship specimens refrigerated on gel ice packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment may reduce sensitivity by decreasing the amount of bacterial DNA present in specimens. Detection in serum or plasma is less sensitive than detection in EDTA-treated whole blood.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	1.3

Test Order
Borrelia Special Study
 CDC-10300

Synonym(s)	
CDC Pre-Approval Needed	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Supplemental Information Required	Required information on the CDC 50.34 Specimen Submission Form: <ul style="list-style-type: none"> • Test order name (one per submission form) • Patient full name, sex, birth date • Date of onset (of symptoms) • Specimen collected date • Specimen source (type) • Submitting agency address, contact name, phone number and email address for each submitter • Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 2.2

Test Order

Botulism Laboratory Confirmation

CDC-10132

Synonym(s)	Botulinum toxin, Clostridium botulinum
CDC Pre-Approval Needed	None
Supplemental Information Required	<p>For clinical samples, provide patient name, date of birth, history of present illness, and treatment history, including date of BabyBIG or BAT administration.</p> <p>Complete one CDC Specimen Submission Form (50.34) per specimen and include in shipment. Include the following information within the CDC 50.34 Specimen Submission Form: point of contact name, phone number and email address for State Department of Health and Hospital.</p>
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Contact CDC POC prior to specimen submission for specimen acceptance, collection, storage and preservation requirements.
Minimum Volume Required	<p>Adult patients: 5 mL serum, 10 g of stool.</p> <p>Infant patients: 10 g of stool.</p> <p>Note: Smaller quantities of stool (up to 0.5 - 1 g) may be tested; if needed, enema can be obtained with sterile non-bacteriostatic water. Minimum volume for serum is 1 mL.</p>
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Serum samples must be collected before antitoxin treatment. If enema is needed, use sterile non-bacteriostatic water.</p> <p>Foods should be left in their original containers or placed in sterile unbreakable containers. Empty containers with remnants of foods can also be recovered and submitted for testing.</p> <p>Refrigerate all specimens promptly after collection. Maintain specimen refrigerated (2-8°C) until shipment. Ship to CDC within 2 days of collection.</p> <p>Note: serum samples can be shipped within 20 days of collection date.</p>
Transport Medium	Submit cultures of suspected botulinum neurotoxin producing species of <i>Clostridium</i> in Chopped Meat Glucose Starch broth or Chopped Meat Glucose broth
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated (refrigerated or frozen cold packs). Package must have proper labeling for biological hazards: UN3373 biological substance, Category B.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 26
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Mouse Bioassay, Mass Spectrometry (MS), Polymerase Chain Reaction (PCR)
Turnaround Time	12 Weeks
Interferences & Limitations	Incorrect storage and/or spoilage of food may affect results.
Additional Information	CDC pre-approval is not needed; however, hospitals must obtain approval from their state health department prior to submitting specimens to CDC. Turnaround Time: Preliminary results may be available within 48 hours of specimen receipt.
CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov

Version 2.2

Test Order
Botulism Special Study
CDC-10133

Synonym(s) Botulinum toxin, Clostridium botulinum

CDC Pre-Approval Needed **Carolina Luquez**
(404) 639-0896
fry6@cdc.gov
Janet Dykes
(404) 639-3625
jkd1@cdc.gov

Supplemental Information Required **If specimen contains botulinum neurotoxin and/or botulinum neurotoxin producing species of Clostridium, the transfer must be approved by APHIS/CDC Federal Select Agents Program.**

Complete one CDC Specimen Submission Form (50.34) per specimen and include in shipment. Include the following information within the CDC 50.34 Specimen Submission Form: point of contact name, phone number and email address for State Department of Health and Hospital.

Supplemental Form **Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).**
https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Serum, stool, isolates

Minimum Volume Required 5 mL (serum), 10 g (stool)

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate all specimens promptly after collection. Maintain specimen refrigerated (2-8 °C) until shipment.

Transport Medium For isolates: Chopped Meat Glucose Starch

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. All submitted specimens should include two unique identifies. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

Shipping Instructions which Include Ship refrigerated specimens (2-8 °C) with cold packs.
Specimen Handling Requirements

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 26

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Mouse Bioassay, Mass Spectrometry (MS), Polymerase Chain Reaction (PCR), Whole Genome Sequencing
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Turnaround Time	24 Weeks
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Interferences & Limitations	To be determined
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Additional Information	None
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CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov
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Version 2.0

Test Order

Brucella species Identification, Genotyping and Antimicrobial Susceptibility Testing (AST) CDC-10207

Synonym(s) Brucellosis, Brucella

CDC Pre-Approval Needed None

Supplemental Information Required Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents please consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).

Supplemental Form Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).
https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Suspected or presumptive *Brucella* Isolates

Minimum Volume Required Not applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolates should be kept at room temperature (15-25°C) prior to shipping

Transport Medium Agar slants preferred for shipping isolates.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Isolates should be shipped at room temperature with room-temperature cold packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR), Biochemicals, Phage Suseptability, Broth Micro Dilution

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information Due to the slow growing nature of Brucella spp, Brucella culture can take up to 30 days.

Antimicrobial susceptibility testing (AST) for test order CDC-10207 'Brucella species ID, genotyping and AST' will only be performed upon special request. Please consult with the CDC POC for the AST request prior to sample submission.

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Rebekah Tiller
(404) 639-4507
eto3@cdc.gov
Elke Saile
(404) 639-0716
csx2@cdc.gov
David Lonsway
(404) 639-2825
dul7@cdc.gov

Version 2.2

Test Order
***Brucella* species Molecular Detection**
CDC-10208

Synonym(s)	<i>Brucella</i> PCR
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood and serum. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin)
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens can be refrigerated (2-8°C) for up to 14 days post-collection and frozen (-20°C or lower) for up to 28 days and not exceed 3 freeze/thaw cycles.
Transport Medium	Transport medium not required.
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	The <i>Brucella</i> molecular detection test has not been cleared and approved by the FDA.

Additional Information None

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Rebekah Tiller
(404) 639-4507
eto3@cdc.gov
Elke Saile
(404) 639-0716
csx2@cdc.gov

Version 2.2

Test Order
Brucella species Serology
 CDC-10197

Synonym(s)	BMAT
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Paired serum samples are preferred (acute: during active stage of illness; convalescent: 2-4 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 14 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Brucella microagglutination test (BMAT)
Turnaround Time	2 Weeks

Interferences & Limitations Acute and convalescent sera are preferred for confirming diagnosis. Plasma is not an acceptable specimen. Hemolysis can interfere with testing. No serology test is available for *B. canis* or vaccine strain RB51. May have poor sensitivity for chronic or complicated brucellosis.

Additional Information None

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov

Version 1.5

Test Order
Brucella species Study
CDC-10209

Synonym(s)

CDC Pre-Approval Needed **Robyn Stodard**
(404) 639-2053
frd8@cdc.gov
Rebekah Tiller
(404) 639-4507
eto3@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Rebekah Tiller
(404) 639-4507
eto3@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Version 1.2

Test Order
Burkholderia mallei/pseudomallei Identification, Genotyping and AST
 CDC-10210

Synonym(s)	Glanders, Melioidosis
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form. For select agents, consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).
Supplemental Form	Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Suspected or presumptive <i>Burkholderia mallei/pseudomallei</i> isolates
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates should be kept at room temperature (15-25°C) prior to shipping
Transport Medium	Agar slants preferred for isolates
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Isolates should be shipped at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR), Biochemicals, Broth Micro Dilution, Multilocus sequence typing (MLST), Multiple-Locus Variable number tandem repeat Analysis (MLVA)

Turnaround Time 2 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information Turnaround time will vary depending on if an isolate is sent for identification or a specimen is sent for isolation. Identification of isolates generally is completed within 3 days while isolation from specimens and subsequent ID may take up to 10 days.

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov
David Lonsway
(404) 639-2825
dul7@cdc.gov

Version 2.2

Test Order
Burkholderia mallei/pseudomallei Molecular Detection
 CDC-10211

Synonym(s)	Glanders, Melioidosis
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	http://www.selectagents.gov/forms.html
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Whole blood and serum. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin)
Minimum Volume Required	250 µL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at 2-8°C for up to 14 days post-collection and 20°C or lower for up to 28 days and not to exceed 3 freeze/thaw cycles.
Transport Medium	Dependent on specimen type
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin).
Additional Information	For additional information please refer to the ASM sentinel laboratory guide: http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov

Version 1.3

Test Order
Burkholderia mallei/pseudomallei Study
CDC-10212

Synonym(s)

CDC Pre-Approval Needed **Mindy Elrod**
(404) 639-4055
wzg0@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov

Supplemental Information Required **Please provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form. For select agents please consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**

Supplemental Form **Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).**
https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state, and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information To be determined

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov

Version 2.1

Test Order
Burkholderia pseudomallei Serology
 CDC-10198

Synonym(s)	Melioidosis
CDC Pre-Approval Needed	None
Supplemental Information Required	Please provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Serum (acute: during active stage of illness; convalescent: 2 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 7 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Indirect Hemagglutination (IHA)
Turnaround Time	2 Weeks
Interferences & Limitations	Acute and convalescent are required.

Additional Information Turnaround time may be longer to account for testing of paired specimens.
Turnaround time may be shorter depending on risk and need.

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov

Version 2.2

Test Order
Burkholderia spp. Identification (not *B. mallei/pseudomallei*)
 CDC-10144

Synonym(s)	<i>Burkholderia</i> Identification
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Campylobacter and Helicobacter Study
CDC-10125

Synonym(s) *Campy, Helicobacter species*

CDC Pre-Approval Needed **Charlotte Lane**
(404) 718-4789
koe7@cdc.gov
Rachael Aubert
(404) 639-3816
vrl7@cdc.gov

Supplemental Information Required **Refer to study protocol for specific requirements.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Refer to study protocol for specific requirements.

Minimum Volume Required Refer to study protocol for specific requirements.

Collection, Storage, and Preservation of Specimen Prior to Shipping Refer to study protocol for specific requirements.

Transport Medium Refer to study protocol for specific requirements.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship isolates overnight on gel ice-packs and ensure that the specimen tube does not come into direct contact with the gel ice-pack to prevent freezing. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Tuesday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 18
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Refer to study protocol for specific requirements.

Turnaround Time

Interferences & Limitations Specimens that are not shipped overnight or are exposed to temperatures above or below refrigeration temperatures (2-8 °C) may be at risk for reduced/lost viability of the specimen.

Frozen specimens (less than or equal to -70 °C) should be shipped with sufficient dry ice to maintain frozen state. Thawed specimens may be at risk for reduced/lost viability.

Additional Information None

CDC Points of Contact Charlotte Lane
(404) 718-4789
koe7@cdc.gov
Rachael Aubert
(404) 639-3816
vrl7@cdc.gov

Version 1.4

Test Order
***Campylobacter* species Serology**
CDC-10455

Synonym(s) Enteric serology, *Campy* serology

CDC Pre-Approval Needed **Rachael Aubert**
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Specimen Submission Form: date of specimen collection, date of illness onset and clinical diagnosis (e.g. Guillain-Barre or Accute Flaccid Paralysis). Also indicate if patient has undergone plasmapheresis or received immunoglobulin.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Preferred specimen type is paired patient serum collected during acute (within 1 week of symptom onset) and convalescent (at least 4 weeks post symptom onset) stages of illness.

Serum is preferred, but plasma is acceptable. Do not pool specimens. Include a CDC 50.34 Specimen Submission Form for each specimen submitted.

Minimum Volume Required 0.1 mL required, more preferred if available

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum can be stored refrigerated (2-8 °C) for up to one month, or frozen (less than or equal to -20 °C). Avoid repeat freeze/thaw cycles.

Transport Medium Serum or plasma should be transferred to clean sterile tube for storage and shipment.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Serum can be shipped in a leak-proof container on gel ice-packs, frozen specimens should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
CDC Point of Contact
Centers for Disease Control and Prevention
RDSB/STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
CDC Point of Contact's Telephone Number

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Enzyme-Linked Immunoassay (ELISA)
Turnaround Time	20 Weeks
Interferences & Limitations	Specimen should be stored and shipped either refrigerated (2-8 °C) or frozen (below -20 °C), as repeat freeze/thaw cycles can lower test sensitivity. Hemolysis present in serum specimens has not shown to interfere with this test, but should be avoided if possible.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. When submitting multiple specimens for one patient, include a separate CDC 50.34 Specimen Submission Form for each specimen submitted.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Zuzana Kucerova (404) 718-4143 zik0@cdc.gov

Version 2.1

Test Order

Campylobacter, Helicobacter, and Related Organisms Identification

CDC-10126

Synonym(s) *Campy, Helicobacter* species

CDC Pre-Approval Needed None

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number. Provide any previous laboratory results or suspect identifications in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code requested if available.**

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates, Sequence Data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolate preparation includes the following:
Solid agar transport media slants (HIA or chocolate agar, or Wang's transport semisolid media) should be inoculated with fresh bacterial growth and incubated in a microaerobic environment for 18-24 hours prior to shipment.

Semisolid or liquid transport media should be inoculated by harvesting fresh bacterial growth from an agar plate using a swab and placing the swab into the transport medium (semisolid Cary Blair or Amies) and shipped immediately. Isolates should be prepared for shipment and shipped within 4 hours of preparation. Short term storage (i.e., more than 24 hours) of isolates under any condition (e.g., room temperature or 15-25°C, refrigerated or 2-8°C, or any temperature higher than -70°C) is not recommended as it has the potential to lose viability.

Prepared isolates can also be stored long-term frozen at -70 °C or lower (i.e., more than one month)

Transport Medium Preferred solid agar transport media includes Heart Infusion agar (HIA), Wang's medium, Blood agar, Columbia agar, or Chocolate agar. Screw cap tubes are preferred.

Preferred semisolid or liquid transport media includes Modified Cary Blair, or Amies Transport medium (with or without charcoal).

Specimen Labeling Test subject to CLIA regulation requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship isolates overnight on gel ice-packs and ensure that the specimen tube does not come into direct contact with the gel ice-pack to prevent freezing. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Tuesday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 18
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic Identification, Genetic Identification
Turnaround Time	13 Weeks
Interferences & Limitations	<p>Specimens that are not shipped overnight or are exposed to temperatures above or below refrigeration temperatures (2-8 °C) may be at risk for reduced/lost viability of the specimen.</p> <p>Frozen specimens (less than or equal to -70 °C) should be shipped with sufficient dry ice to maintain frozen state. Thawed specimens may be at risk for reduced/lost viability.</p>
Additional Information	<p>The original isolate should be retained by the submitter for the duration of testing at CDC.</p> <p>Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.</p>
CDC Points of Contact	Charlotte Lane (404) 718-4789 koe7@cdc.gov Patricia Fields (404) 639-1748 pif1@cdc.gov

Version 2.3

Test Order

Campylobacter, Helicobacter, and Related Organisms Identification and Subtyping CDC-10127

Synonym(s)	<i>Campy, Helicobacter</i> species
CDC Pre-Approval Needed	None
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code requested if available.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of <i>Campylobacter, Helicobacter</i> ; Sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Isolate preparation includes the following: Solid agar transport media slants (HIA or chocolate agar, or Wang's transport semisolid media) should be inoculated with fresh bacterial growth and incubated in a microaerobic environment for 18-24 hours prior to shipment.</p> <p>Semisolid or liquid transport media should be inoculated by harvesting fresh bacterial growth from an agar plate using a swab and placing the swab into the transport medium (semisolid Cary Blair or Amies) and shipped immediately. Isolates should be prepared for shipment and shipped within 4 hours of preparation. Short term storage (i.e., more than 24 hours) of isolates under any condition (e.g., room temperature or 15-25°C, refrigerated or 2-8°C, or any temperature higher than -70°C) is not recommended as it has the potential to lose viability.</p> <p>Prepared isolates can also be stored long-term frozen at -70 °C or lower (i.e., more than one month)</p>
Transport Medium	<p>Preferred solid agar transport media includes Heart Infusion agar (HIA), Wang's medium, Blood agar, Columbia agar, or Chocolate agar. Screw cap tubes are preferred.</p> <p>Preferred semisolid or liquid transport media includes Modified Cary Blair, or Amies Transport medium (with or without charcoal).</p>

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship isolates overnight on gel ice-packs and ensure that the specimen tube does not come into direct contact with the gel ice-pack to prevent freezing. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Tuesday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 18
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Antimicrobial Susceptibility Testing (AST), Whole Genome Sequencing (WGS), Penner serotyping

Turnaround Time 13 Weeks

Interferences & Limitations Specimens that are not shipped overnight or are exposed to temperatures above or below refrigeration temperatures (2-8 °C) may be at risk for reduced/lost viability of the specimen.

Frozen specimens (less than or equal to -70 °C) should be shipped with sufficient dry ice to maintain frozen state. Thawed specimens may be at risk for reduced/lost viability.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Charlotte Lane
(404) 718-4789
koe7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Version 3.3

Test Order
Cell Culture of Tissues for Infectious Agent Isolation
CDC-10560

Synonym(s) Microbiology, cell culture, tissue culture, autopsy, biopsy, pathology

CDC Pre-Approval Needed **Infectious Diseases Pathology Mailbox**
(404) 639-3132
pathology@cdc.gov
Hannah Bullock
(404) 718-6434
ocr3@cdc.gov

Supplemental Information Required **Please include the following information with each submission:**

Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:

- **Test order code**
- **Test order name**
- **Patient full name**
- **Patient birth date**
- **Date of death (if applicable)**
- **Patient ID (e.g., medical record number or autopsy number)**
- **Specimen ID (e.g., surgical pathology accession number)**
- **State public health laboratory (PHL) point of contact**
- **Original submitter contact information**

One electronically completed copy of the CDC 50.34 Specimen Submission Form per case is sufficient, unless specimens are being submitted from multiple specimen collection dates in one package.

Requested additional information:

- **A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information**
 - **A copy of: (a) the autopsy report (preliminary or final), or (b) surgical pathology report**
 - **Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)**
 - **Relevant clinical, gross pathology, or microscopic pathology images, as available**
 - **A key listing the tissues submitted for evaluation**
-

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing	Frozen (un-fixed) biopsy, autopsy, or necropsy tissues from any organ or site are acceptable. However, tissue specimens should be submitted from the site(s) of the patient's disease process. If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process. Tissue specimens submitted for infectious agent isolation must be fresh and not in formalin. The tissues must be kept on ice and be frozen as quickly as possible after removal from the body. Specimens suspected of infection with Category A pathogens (https://emergency.cdc.gov/agent/agentlist-category.asp) will not be accepted.
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Freeze specimens (-20°C or lower) immediately and ship within 24 to 48 hours of collection. Do not add any media to specimens. If specimens must be stored for more than 48 hours, freeze immediately at -70°C or lower and ship within 4 weeks of collection.
Transport Medium	No transport media necessary.
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, contact IDPB (pathology@cdc.gov) immediately. Ship tissue specimens frozen on dry ice in leak proof plastic containers. Do not ship specimens in glass containers. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship for overnight delivery.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	Microbiology (cell culture), Microbiology (cell culture)
Turnaround Time	8 Weeks
Interferences & Limitations	Clinical treatment with antivirals, antibiotics, and antiparasitics may minimize growth potential of cultures. Long term refrigeration may minimize growth potential of cultures.

Additional Information CDC Pre-Approval Needed:

- Contact Pre-approval POC
- Infectious Diseases Pathology Branch Mailbox

More specific guidelines regarding tissue sampling and submission can be found on the IDPB website: <http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html>

Turnaround Time is case-dependent:

- Human surgical biopsy cases it is 6-8 weeks
- Complex cases, routine human autopsy cases, and animal cases it is 12 weeks.

CDC Points of Contact Infectious Diseases Pathology Mailbox

(404) 639-3132

pathology@cdc.gov

Hannah Bullock

(404) 718-6434

ocr3@cdc.gov

Roosecelis Martines

(404) 639-3886

xgn7@cdc.gov

Version 1.1

Test Order
Chagas Disease Molecular Detection
CDC-10475

Synonym(s) *Trypanosoma cruzi*; American trypanosomiasis, parasite

CDC Pre-Approval Needed **Susan Montgomery**
(404) 718-4731
zqu6@cdc.gov
Theresa Benedict
(404) 718-4124
tg5@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 2.2 mL (pediatric 0.2 mL)

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens shall be stored in leak-proof containers.

Blood, CSF and unpreserved tissue can be stored refrigerated (2-8°C) when specimens will be received by CDC within 7 days of collection. CSF and unpreserved heart tissue can be frozen (-20 °C or lower) when specimens will be received at CDC after 7 days from day of collection.

Specimens not meeting these conditions will not be accepted for testing and a new specimen will be required.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent.

EDTA whole blood, refrigerated tissue, and CSF shall be shipped refrigerated with refrigerated or frozen cold packs. Frozen tissue and CSF shall be shipped frozen with dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 52
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Real-time Polymerase Chain Reaction (PCR)
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Turnaround Time	2 Weeks
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Interferences & Limitations	Formalin-fixed specimens are not suitable for this test order. Please see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov regarding testing of formalin-fixed specimens.
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Additional Information	This assay is used in clinically indicated situations such as acute or congenital infections, post-transplant from a donor with confirmed <i>T. cruzi</i> infection, or risk of reactivation due to immunocompromise in patients with chronic Chagas disease. Serological testing is the preferred method to diagnose chronic infection in patients.
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CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov
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Version 1.9

Test Order
Chagas Disease Serology
CDC-10458

Synonym(s)	<i>Trypanosoma cruzi</i> ; American trypanosomiasis, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Indirect Fluorescent Antibody Assay, EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
Sue Montgomery
(404) 718-4731
zqu6@cdc.gov

Version 1.8

Test Order
***Chlamydia pneumoniae* Molecular Detection**
CDC-10152

Synonym(s)	<i>C. pneumoniae</i> , <i>Chlamydophila pneumoniae</i> , Atypical pneumonia, Community acquired pneumonia, CAP, <i>Chlamydia</i> , <i>Chlamydophila</i>
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum
Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Specimens should be refrigerated (2–8°C) after collection and frozen (-20°C or lower) within 96 hours of collection.
Transport Medium	Viral transport medium (VTM) for NP and OP swabs
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Multiplex Real-time Polymerase Chain Reaction (PCR)

Turnaround Time 7 Days

Interferences & Limitations Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.

Additional Information All specimens are tested using test order Atypical Bacterial Pneumonia Agents (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Legionella* species) Molecular Detection (CDC-10157) or *Chlamydia* Species (Respiratory) Molecular Detection (CDC-10525). Specimens in which *M. pneumoniae* is detected will also be tested using test order *Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping (CDC-10513).

CDC Points of Contact Maureen Diaz
(404) 639-4534
mdiaz1@cdc.gov
Jonas Winchell
(404) 639-4921
Jwinchell@cdc.gov

Version 2.4

Test Order
***Chlamydia psittaci* Molecular Detection**
CDC-10153

Synonym(s) *C. psittaci*, *Chlamydophila psittaci*, Atypical pneumonia, Community acquired pneumonia, CAP, *Chlamydia*, *Chlamydophila*, Parrot fever, Psittacosis

CDC Pre-Approval Needed **Jonas Winchell**
(404) 639-4921
Jwinchell@cdc.gov
Maureen Diaz
(404) 639-4534
mdiaz1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.

Minimum Volume Required 0.4 mL preferred, 0.2 mL minimum

Collection, Storage, and Preservation of Specimen Prior to Shipping Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Specimens should be refrigerated (2–8°C) after collection and frozen (-20°C or lower) within 96 hours of collection.

Transport Medium Viral transport medium (VTM) for NP and OP swabs

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	Laboratory test results may also include results for Chlamydia pneumoniae by Chlamydia Species (Respiratory) Molecular Detection (see test order CDC-10525).
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov

Version 3.5

Test Order
Chlamydia Species (Respiratory) Molecular Detection
CDC-10525

Synonym(s) *C. pneumoniae*, *Chlamydophila pneumoniae*, *C. psittaci*, *Chlamydophila psittaci*, Atypical pneumonia, Community acquired pneumonia, CAP, *Chlamydia*, *Chlamydophila*, Parrot fever, Psittacosis

CDC Pre-Approval Needed **Jonas Winchell**
(404) 639-4921
jwinchell@cdc.gov
Maureen Diaz
(404) 639-4534
mdiaz1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.

Minimum Volume Required 0.4 mL preferred, 0.2 mL minimum

Collection, Storage, and Preservation of Specimen Prior to Shipping For nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inhibit some molecular assays (See "Interferences & Limitations"). Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral or universal transport media (VTM, UTM). Tissue should be frozen promptly upon collection. All other specimens should be refrigerated at 4 °C if shipped within 72 hours of collection; otherwise specimens should be frozen at -20 °C.

Transport Medium Viral transport medium (VTM) for NP and OP swabs

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	None
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 jwinchell@cdc.gov

Version 1.3

Test Order

Chlamydia trachomatis / *Neisseria gonorrhoeae* - Molecular Detection Nucleic Acid Amplification Tests (NAATs) CDC-10192

Synonym(s) *Chlamydia*, *Gonorrhea*, *NAATs*, *Neisseria gonorrhoeae*, *Chlamydia trachomatis*

CDC Pre-Approval Needed **Brian Raphael**
(404) 639-4292
elx9@cdc.gov
Evelyn Nash
(404) 718-5037
lmq5@cdc.gov

Supplemental Information Required **Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form:**

- **Specimen Collection Date**
- **Material Submitted (i.e. urine or swab)**
- **Specimen Source Site (i.e. urethra, cervix, vagina, throat, oropharynx, rectum, or urine)**
- **Transport Medium: (e.g. name of Aptima Collection Kit used)**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Pharyngeal, vaginal, and rectal swabs collected in Aptima Multitest Collection Kits, urethral and cervical swabs collected in Aptima Unisex Collection Kits, or urine collected in Aptima Urine Collection Kits.

Minimum Volume Required For Aptima urine specimen transport tube, transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.

Collection, Storage, and Preservation of Specimen Prior to Shipping

- 1) Urogenital Swab Specimens: After collection, transport and store the swab in the swab specimen transport tube at 2-30°C. If longer storage is needed, freeze at -20 to -70°C for up to 12 months after collection.
- 2) Extragenital (throat and rectal) Swab Specimens: After collection, transport and store the swab in the swab specimen transport tube between 4-30°C or -20°C to -70°C for up to 60 days.
- 3) Urine Specimens: Urine samples in primary container must be transferred into the Aptima urine specimen transport tube within 24 hours of collection and stored at 2-30°C. If longer storage is needed, freeze Aptima urine transport tubes at -20°C to -70°C for up to 116 days after collection.

Transport Medium Specimens should be transported in Aptima Collection Kits according to package insert.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Aptima swabs must be transported in the provided swab specimen transport medium and tube. Refer to package instructions for shipment temperature.

Urine specimens in the Aptima urine specimen transport tube should be transported and stored at room temperature or refrigerated until tested. Urine samples in primary collection container must be frozen and transported on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state, and federal regulations.

Methodology	Nucleic Acid Amplification Tests (NAATs), Nucleic Acid Amplification Test (NAAT) using Aptima Combo 2 Assay
Turnaround Time	3 Weeks
Interferences & Limitations	Therapeutic failure or success cannot be determined with the Aptima Combo 2 Assay since nucleic acid may persist following appropriate antimicrobial therapy. Results from the Aptima Combo 2 Assay should be interpreted in conjunction with other laboratory and clinical data available to clinician. Refer to package insert for other assay limitations.
Additional Information	None
CDC Points of Contact	Brian Raphael (404) 639-4292 elx9@cdc.gov Evelyn Nash (404) 718-5037 lmq5@cdc.gov Monica Morris (404) 639-2733 vul8@cdc.gov

Version	3.3
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Test Order

Chlamydia trachomatis Lymphogranuloma venereum (LGV) Molecular Detection CDC-10523

Synonym(s) Lymphogranuloma venereum (LGV), *Chlamydia trachomatis* (CT) serovar L

CDC Pre-Approval Needed **Brian Raphael**
(404) 639-4292
elx9@cdc.gov
Samantha Katz
(404) 639-3710
goy3@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Aptima Combo 2®-tested *Chlamydia trachomatis*-positive rectal swabs in
for Testing Aptima Multitest specimen collection tube

Minimum Volume Required 0.4 mL

Collection, Storage, and Preservation After testing with the Aptima Combo 2®, *Chlamydia trachomatis* (CT)-positive
of Specimen Prior to Shipping specimens should be stored frozen at -70°C or lower for up to 60 days after
collection.

Transport Medium Aptima Multitest swab transport medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Shipping Instructions which Include Refrigerated specimens should be shipped on gel ice-packs. Frozen specimens
Specimen Handling Requirements should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Nucleic Acid Amplification Tests (NAATs), Real-Time Multiplex Polymerase Chain
Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations No significant interferences or limitations are currently known

Additional Information None

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Samantha Katz
(404) 639-3710
goy3@cdc.gov

Version 3.3

Test Order
***Clostridium perfringens* Detection - Foodborne Outbreak**
CDC-10111

Synonym(s) *C. perfringens*, CPE

CDC Pre-Approval Needed **Haley Martin**
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Supplemental Information Required **Only specimens from foodborne outbreaks accepted. Consult with CDC POC before sending samples. Include a CDC 50.34 Specimen Submission Form with each sample. For human specimens (including derived isolates), provide the following information: date of onset, fatal, specimen collected date, material submitted, specimen source (type), and if applicable, transport medium/specimen preservative and any preliminary results available. For food or environmental samples (including derived isolates), provide the following information: specimen collected date, material submitted, specimen source (type), and if applicable, transport medium/specimen preservative and any preliminary results available.**

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Only stool specimens and implicated foods from foodborne outbreaks are acceptable; stool is the preferred sample type. Send raw (bulk) stools collected within 48 hours of illness onset from two or more individuals. If stools are in transport medium/specimen preservative, four or more specimens are required. If only one stool is available, send with implicated food. Food or stool stored longer than two weeks are not acceptable. Consult with CDC POC prior to sending specimens.

Minimum Volume Required 10 g (stool) and 25 g (food)

Collection, Storage, and Preservation of Specimen Prior to Shipping Collect stool while patient is symptomatic (within 48 hours after illness onset). Separate foods into individual containers or bags. Refrigerate samples promptly after collection and maintain at 2-8 °C. Ship samples within two weeks from collection date. Food or stool stored longer than two weeks are not acceptable. If samples cannot be shipped within 2 weeks, promptly freeze upon collection at <-20 °C, and ship frozen.

Transport Medium

Raw stool is preferred; the addition of transport medium (e.g. Cary-Blair Transport Medium, Enteric Transport Medium) is not needed. Ship isolates on anaerobic transport medium.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with ice packs and ship frozen specimens on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Toxin Detection (Stool only), Culture (Stool and Food), Polymerase Chain Reaction (Isolates)

Turnaround Time 13 Weeks

Interferences & Limitations Dilution of stool with transport media affects toxin detection. Incorrect storage and/or spoilage of food may affect results. Reduced toxin detection and/or culture occurs in food older than two weeks. Stools collected 48 hours after illness onset and/or after patient recovery are not suitable for testing, as they may not contain detectable toxin/organism.

Additional Information Direct toxin detection requires at least two raw stool specimens. If stool is placed in transport medium prior to shipment, at least four specimens are required for toxin testing. Toxin testing is not performed on food.

CDC Points of Contact Haley Martin
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Version 1.5

Test Order
***Corynebacterium diphtheriae* Study**
CDC-10172

Synonym(s) *Corynebacterium diphtheriae*, *C.ulcerans*, *C. pseudotuberculosis*, diphtheria

CDC Pre-Approval Needed **Pam Cassidy**
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Supplemental Information Required **Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of symptoms, specimen source, recent antibiotic history.**

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For isolation and/or PCR: Throat, nasal and wound swabs, pseudo-membrane, and sputum.
 For isolate confirmation: Pure culture isolates or cryopreserved isolates.
 For PCR only: Extracted DNA.

Minimum Volume Required 0.1 mL DNA; 0.2 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Throat, nasal, or wound swabs should be placed in tubes of transport medium and kept refrigerated at 4 °C until shipment. Sputum should be placed in a leak-proof plastic tube and refrigerated at 4 °C until shipment. Pseudo-membrane should be placed in a leak-proof plastic container with physiological saline and kept refrigerated at 4 °C until shipment. Pseudo-membrane in formalin is not acceptable. Isolates should be refrigerated at 4 °C on agar slants or frozen in cryopreservative and stored at -70 °C until shipment. DNA extracted from specimens should be placed in leak-proof plastic tubes and kept frozen at -20 °C until shipment.

Transport Medium Common transport media such as Amies or Stuart may be used for swabs. Isolates can be frozen at -70 °C in cryopreservation medium; for best results a 24-48 hour subculture on common agar slants such as blood, trypticase soy, or nutrient is recommended. Pieces of pseudo-membrane for culture and PCR must be in physiological saline; formalin is not acceptable.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements For best results, specimens should be shipped within 24-48 hours of collection. Specimens refrigerated (isolates on slants, swabs in transport media, pseudo-membrane in saline, sputum) should be shipped overnight on gel ice-packs. Specimens frozen (cryopreserved isolates, extracted DNA) should be shipped overnight on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 12
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Sender is responsible for shipping charges. International submitters must request CDC's import permit and include this with the Air Waybill.

Methodology	Culture, Multi-target Polymerase Chain Reaction (PCR), Whole Genome Sequencing, Multi-Locus Sequence Typing, Antibiotic Susceptibility
Turnaround Time	
Interferences & Limitations	PCR is not a confirmatory test for diphtheria toxin production. PCR detects the presence of the diphtheria toxin gene but does not show diphtheria toxin production. Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Corynebacterium</i> spp.
Additional Information	None
CDC Points of Contact	Pam Cassidy (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

Version 2.0

Test Order

Corynebacterium diphtheriae/ulcerans/pseudotuberculosis Detection, Identification, and Toxin Testing CDC-10168

Synonym(s) *Corynebacterium diphtheriae*, *C. ulcerans*, *C. pseudotuberculosis*, diphtheria

CDC Pre-Approval Needed None

Supplemental Information Required **Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of symptoms, specimen source, recent antibiotic history.**

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Contact CDC POC prior to specimen submission for specimen acceptance, collection, storage and preservation requirements.

Minimum Volume Required Not applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Throat, nasal, or wound swab for PCR only (no culture): collect from patient and immediately place in a dry, sterile tube. Freeze at (-20°C or lower) within 30 minutes of collection.

Throat, nasal, or wound swab for culture and PCR: collect from patient and immediately place in an Amies clear gel transport tube and store within 30 minutes of collection refrigerated (2-8°C) until shipment. Ship within 24-72 hours of collection.

Pseudomembrane or heart tissue for culture and PCR: collect from patient and place in physiological saline without formalin in a leak-proof plastic container and store within 30 minutes of collection refrigerated (2-8°C) until shipment. Ship within 24-48 hours of collection.

Pure culture isolate for confirmation by culture and/or PCR: inoculate on 5% sheep blood solid agar slant or plate, chocolate solid agar slant or plate, or trypticase soy (TSA) solid agar slant or plate and incubate in an aerobic atmosphere at 35-37°C until growth is observed (typically 24 h). After growth, store slant or plate refrigerated (2-8°C) until shipped. Ship within 24-48 hours after growth is present.

Alternatively, colony growth may be collected from a 5% sheep blood, chocolate, or trypticase soy (TSA) solid agar plate within 24 hours of plate inoculation using a swab and placed in a tube of Amies clear gel transport. The Amies clear gel transport should not be incubated; instead, store the inoculated transport tube refrigerated (2-8°C) until shipment. Ship within 24-48 hours of transport inoculation.

Transport Medium Throat, nasal, or wound swab for PCR only (no culture): Dry in sterile tube without transport medium.

Throat, nasal, or wound swab for culture and PCR: Amies clear gel transport medium.

Pseudomembrane or heart tissue for culture and PCR: Physiological saline without formalin.

Pure culture isolate for confirmation by culture and/or PCR: 5% sheep blood solid agar slant or plate, chocolate solid agar slant or plate, trypticase soy (TSA) solid agar slant or plate, or Amies clear gel transport.

Specimen Labeling Test subject to CLIA regulation and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.

Throat, nasal, or wound swab for culture and PCR:

- Ship refrigerated overnight with refrigerated or frozen cold packs within 24-72 hours of collection.

Pseudomembrane or heart tissue for culture and PCR:

- Ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours of collection.

Throat, nasal, or wound swab for PCR only (no culture):

- Ship frozen overnight with dry ice within 1 week of collection. Once frozen, do not allow swab to thaw.

Pure culture isolate for confirmation by culture and/or PCR:

- Ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours after growth is present.
- Pure culture isolate in Amies clear gel transport: ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours of transport media inoculation.

Note: Submitting lab should keep a subculture of isolate until test results are received if isolate needs to be resubmitted due to nonviability.

Ship To:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 12

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Culture, Multi-target Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations PCR is not a confirmatory test for diphtheria toxin production. PCR detects the presence of the diphtheria toxin gene but does not show diphtheria toxin production. Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with *Corynebacterium* spp.

Additional Information None

CDC Points of Contact Pam Cassidy
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Version 2.3

Test Order
Corynebacterium species Identification (not *C. diphtheriae*)
 CDC-10136

Synonym(s)	Coryneform gram-positive rods
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Coxiella burnetii Molecular Detection
 CDC-10304

Synonym(s) Q fever

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute whole blood (taken within 14 days of illness onset or while symptomatic): EDTA-treated, or ACD A treated.
 Acute serum: Serum separator tube, or cryo-tubes. Vascularized tissue biopsies, including skin biopsy specimens from the site of rash or eschar. Swab specimen of eschar, using a dry, sterile cotton swab (include eschar scab when available). Samples must be collected before or within 72 hours of initiation of a tetracycline-class antibiotic, e.g., doxycycline (within 48 hours is preferred), or, if occurring outside of this established time frame, patients must be symptomatic at the time of collection.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For swab, place in sterile specimen container without any medium.

Transport Medium For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline. For swab, place in sterile specimen container without any medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Samples in saline buffer have decreased sensitivity and are subject to rejection. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with nucleic acid extraction.

Additional Information Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.

The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Molecular detection of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Ehrlichia, Anaplasma, and Orientia may be performed. Results are reported directly to SPHLs.

Additional RZB specimen and shipping information can be found at the following address:

<https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 2.0

Test Order
Coxiella burnetii Serology
 CDC-10305

Synonym(s) Q fever

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Ehrlichia, Anaplasma, and Orientia may be performed. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov

Test Order
Coxiella Special Study
CDC-10306

Synonym(s) Q fever

CDC Pre-Approval Needed **Marah Condit**
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Supplemental Information **To be determined**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing As determined during pre-approval consultation.

Minimum Volume Required As determined during pre-approval consultation.

Collection, Storage, and Preservation of Specimen Prior to Shipping As determined during pre-approval consultation.

Transport Medium As determined during pre-approval consultation.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Molecular detection, serology, culture, other

Turnaround Time

Interferences & Limitations As determined during pre-approval consultation.

Additional Information As determined during pre-approval consultation.

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 1.9

Test Order
Crimean-Congo Hemorrhagic Fever Testing
CDC-10302

Synonym(s) CCHF

CDC Pre-Approval Needed Trevor Shoemaker
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VSPB Specimen Submission Form.
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing For molecular and/or serology testing the accepted specimen types are whole blood (EDTA) or serum. CDC POC contact is required prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Cryptosporidium Special Study
CDC-10491

Synonym(s)

CDC Pre-Approval Needed Dawn Roellig
(404) 718-4134
iyd4@cdc.gov
Colleen Lysen
(404) 639-4654
vqy1@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From None

Acceptable Sample / Specimen Type for Testing Stools must be collected in a non-formalin based fixative, preservative, or storage medium. For additional information about acceptable preservatives, contact the CDC POC.

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship fixed/preserved specimens at room temperature. Ship unpreserved specimens on wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if stored frozen.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Dawn Roellig
(404) 718-4134
iyd4@cdc.gov
Colleen Lysen
(404) 639-4654
vqy1@cdc.gov

Version 1.6

Test Order
Cyclospora Molecular Detection
CDC-10477

Synonym(s) *Cyclospora cayetenensis*, parasite

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.5 g or 0.5mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens shall be stored in leak-proof containers.

Stool samples can be stored in PCR-compatible fixative (e.g. TotalFix, UniFix, EcoFix or modified PVA (Zn- or Cu-based)) at room temperature (15-25°C) for up to 7 days. Unpreserved stool specimens can be stored refrigerated (2-8°C) when specimens will be received at CDC within 7 days of collection. Unpreserved stool specimens can be frozen (-20 °C or lower) when specimens will be received at CDC more than 7 days after collection.

Specimens not meeting these conditions will not be accepted for testing and a new specimen will be required.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent. Stool in PCR-compatible fixative can be shipped at room temperature. Unpreserved specimens shall remain refrigerated with frozen cold packs. Frozen unpreserved specimens shall be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 52
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Real-time Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations

Stool specimens fixed in formalin-containing preservatives or low-viscosity polyvinyl-alcohol (LV-PVA) are not suitable for this test order.

Additional Information None

CDC Points of Contact Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
Theresa Benedict
(404) 718-4124
tgd5@cdc.gov

Version 2.6

Test Order
Cysticercosis Serology
CDC-10459

Synonym(s)	Neurocysticercosis, <i>Taenia solium</i> , cysitcercus, EITB, LLGP-EITB, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and CSF for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum and CSF can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera and CSF specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.6

Test Order
Cytomegalovirus (CMV) Detection
CDC-10263

Synonym(s) CMV

CDC Pre-Approval Needed **Shelia Dollard**
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Urine, saliva, or whole blood
for Testing

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of
of Specimen Prior to Shipping collection; otherwise specimen should be kept frozen at -20 °C. Whole blood
should be collected in EDTA or citrate tubes.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Ship specimens with cold packs or dry ice as an etiologic agent.
Specimen Handling Requirements
CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Shelia Dollard
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Version 1.3

Test Order
Cytomegalovirus (CMV) Serology
CDC-10264

Synonym(s) CMV

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum or plasma
for Testing

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of
of Specimen Prior to Shipping collection; otherwise specimen should be kept frozen at -20 °C.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Ship specimens with cold packs or dry ice as an etiologic agent.
Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by
Enzyme Immunoassay (EIA)

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Version 1.3

Test Order
Dengue Virus Detection and Serology
CDC-10307

Synonym(s) Dengue fever, severe dengue

CDC Pre-Approval Needed **Rafael Tosado**
(787) 706-3449
npp0@cdc.gov
Jorge L Munoz
(787) 706-2469
ckq2@cdc.gov

Supplemental Information Required **Provide the following information on the form: complete name, age, date of birth and sex of patient, home address, sample collection date, date of onset of symptoms, pregnancy status, complete name and mailing address of the provider (physician, laboratory, clinic, or hospital). Specimen identification must match the identification on the form. One form must be completed for each sample sent.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute serum, collected during the first 7 days of illness is suitable for molecular and serological tests, and convalescent serum, collected after the first 7 days of illness is suitable for serological tests. Other specimen types such as whole blood, plasma and cerebrospinal fluid may be acceptable upon consultation with the laboratory.

Minimum Volume Required 0.5 mL (1.0 mL preferred)

Collection, Storage, and Preservation of Specimen Prior to Shipping The blood should be collected in a red-top or tiger-top tube. After blood is allowed to clot, separate serum by centrifugation and keep refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, specimen should be kept frozen at -20 °C.

Citrate (collected in yellow top tubes) and heparin plasma (collected in green top tubes) can be tested by real-time polymerase chain reaction (RT-PCR). Refer to collection devices manufacturer instructions for more details.

If specimens can be shipped to the CDC Dengue Branch Lab within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on cold packs. If specimens must be held for more than 72 hours before shipping, they should be promptly frozen at -20 °C and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens should be shipped on dry ice and refrigerated specimens on frozen gel packs. Serum must remain frozen if specimens are to be held for more than 72 hours before shipping. If dry ice is not available for shipping, we recommend that the serum be stored refrigerated and shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Dengue Branch
1324 Calle Cañada
San Juan, P. R. 00920-3860
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the Laboratory POC providing information on the shipping company, shipped date, expected delivery date and package tracking number.

Methodology	Real-Time Polymerase Chain Reaction (RT-PCR), Enzyme Linked Immunosorbent Assay (ELISA)
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Turnaround Time	10 Days
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Interferences & Limitations	Dengue antibody detection (serological testing) can be affected by cross reactivity with other Flaviviruses, including recent vaccinations (dengue, yellow fever, Japanese encephalitis, tickborne encephalitis), and natural infections (Zika, St. Louis encephalitis, West Nile viruses).
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Serum with evidence of hemolysis or contaminated samples are not acceptable for serological testing. EDTA may cause interference with PCR testing and should be avoided.

Warming or freeze-thawing affects stability of viral nucleic acid and antibodies in serum reducing the sensitivity of molecular and serological testing.

The use of lavender/violet-top collection tubes with EDTA is not recommended for PCR testing. Convalescent serum samples from blood collected in Lavender/violet or green-top tubes should not be used for serological testing.

Additional Information To diagnose dengue infection, an acute serum sample obtained during the first 7 days of illness is required for molecular diagnosis by direct detection of the virus nucleic acid. The 4 dengue serotypes can be identified through real-time polymerase chain reaction (RT-PCR) testing.

If the acute sample is negative, a convalescent serum sample is required for case confirmation by serological testing. The convalescent serum should be collected after the first 7 days of illness. The case is confirmed by antibody seroconversion through the detection of dengue-specific Immunoglobulin M antibodies (IgM) in the convalescent serum. Informing the patient about the importance of returning for a second sample, and providing an appointment for a specific day and time, will increase the probability of obtaining the second sample. If the patient makes the first visit to the physician after the 7th day of illness, a serum sample collected then would be sufficient. In that case, the patient would not need to return for collection of a second sample.

Sample rejection criteria include:

1. Samples sent without the appropriate documentation (CDC form 50.34)
2. Specimen submission forms sent without a sample
3. Illegible or incomplete sample submission forms (especially lacking the date of onset of symptoms and/or the date of sample collection)
4. Samples delivered at suboptimal temperatures (over 25 °C)
5. Spilled samples or damaged samples containers
6. Samples received more than 90 days after the onset of symptoms.
7. Serum hemolysis would be a rejection criterion for convalescent samples only.

More information available at: <https://www.cdc.gov/dengue/index.html>

CDC Points of Contact Rafael Tosado
(787) 706-4339
npp0@cdc.gov
Jorge L Munoz
(787) 706-2469
ckq2@cdc.gov
Candimar Colon
(787) 706-2473
cqc1@cdc.gov

Version 2.1

Test Order
Ebola Hemorrhagic Fever Testing
CDC-10309

Synonym(s) None

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For molecular and/or serology testing the accepted specimen types are whole
for Testing blood (EDTA) or serum. CDC POC contact is required prior to sending any
specimens.

Animal specimens or human research specimens may be submitted with
approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Molecular specimens must be must be kept refrigerated (2-8°C) for up to 3 days,
of Specimen Prior to Shipping or frozen (-20°C or below) for up to 2 months. Serology specimens must be kept
must be kept refrigerated (2- 8°C) for up to 7 days, or frozen (-20°C or below) for
up to 2 months. See link to supplemental submission form for specific
information on various specimen types. Contact the CDC POC for approval prior
to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens.
Testing subject to CLIA regulations requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Echinococcosis Serology
CDC-10460

Synonym(s)	Hydatid Disease, <i>Echinococcus granulosus</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Immunoblot, Western Blot, Antibody detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.5

Test Order
Ehrlichia Molecular Detection
CDC-10499

Synonym(s) Human monocytic ehrlichiosis and HME

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- **Test order name (one per submission form)**
- **SPHL point of contact including phone number of the person responsible for sample submission and follow-up**
- **Patient full name, sex, birth date**
- **Date of onset (of symptoms)**
- **Specimen collected date**
- **Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)**
- **Therapeutic agent and dates (specific antibiotic therapy and initiation date)**
- **State of illness**
- **Brief clinical summary (include signs, symptoms, and underlying illnesses if known)**

Requested additional information:

- **Previous laboratory results (physical exam findings and pertinent laboratory values)**
- **Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)**
- **Exposure history (including animals and arthropods)**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute whole blood (taken within 14 days of illness onset or while symptomatic): EDTA-treated, or ACD A treated.
 Acute serum: Serum separator tube, or cryo-tubes. Vascularized tissue biopsies, including skin biopsy specimens from the site of rash or eschar. Swab specimen of eschar, using a dry, sterile cotton swab (include eschar scab when available). Samples must be collected before or within 72 hours of initiation of a tetracycline-class antibiotic, e.g., doxycycline (within 48 hours is preferred), or, if occurring outside of this established time frame, patients must be symptomatic at the time of collection.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For swab, place in sterile specimen container without any medium.

Transport Medium For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline. For swab, place in sterile specimen container without any medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Samples in saline buffer have decreased sensitivity and are subject to rejection. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with nucleic acid extraction.

Additional Information Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.

The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Molecular detection of other rickettsial disease organisms including Anaplasma, Rickettsia, Coxiella, and Orientia may be performed. Results are reported directly to SPHLs.

Additional RZB specimen and shipping information can be found at the following address:

<https://www.cdc.gov/nceid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 2.5

Test Order
Ehrlichia Serology
CDC-10311

Synonym(s) Human monocytic ehrlichiosis

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB / STATT Unit 78
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	<p>Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.</p> <p>The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Anaplasma, Coxiella, and Orientia may be performed. Results are reported directly to SPHLs.</p> <p>Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</p>
CDC Points of Contact	<p>Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov</p> <p>Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov</p>

Test Order
Ehrlichia Special Study
CDC-10498

Synonym(s)	Human monocytic ehrlichiosis and HME
CDC Pre-Approval Needed	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov
Supplemental Information Required	As determined during pre-approval consultation.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	As determined during pre-approval consultation.
Minimum Volume Required	As determined during pre-approval consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	As determined during pre-approval consultation.
Transport Medium	As determined during pre-approval consultation.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice. <p style="text-align: center;">CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p style="text-align: center;">Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p style="text-align: center;">All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	As determined during pre-approval consultation.
Additional Information	As determined during pre-approval consultation.

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 1.6

Test Order
Elizabethkingia species - Special Study
CDC-10514

Synonym(s) None

CDC Pre-Approval Needed **John McQuiston**
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 17
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.1

Test Order
Entamoeba histolytica/dispar Molecular Detection
CDC-10478

Synonym(s) Amebiasis, *Entameba histolytica*, *Entameba dispar*, parasite

CDC Pre-Approval Needed **Ibne Ali**
(404) 718-4157
xzn5@cdc.gov
Jennifer Cope
(404) 718-4878
bjt9@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **Not applicable**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Stool, liver aspirate
for Testing

Minimum Volume Required 0.5 g formed stool; 1.0 g preferred.
0.5 mL liquid stool or liver aspirate; 1.0 mL preferred.

Collection, Storage, and Preservation Stool or liver aspirate specimens should be collected in the absence of
of Specimen Prior to Shipping preservatives, and must be kept frozen (-20°C or lower) and shipped with dry-ice
within 60 days of collection.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday – Friday. Ship frozen stool or liver aspirate
specimens on dry ice within 7 days of collection.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations. Upon shipment, submitter should send an email to the CDC
POC providing shipping company, shipped date and package tracking number.

Methodology Real-Time PCR

Turnaround Time 21 Days

Interferences & Limitations Specimens fixed in formalin-containing preservatives or LV-PVA are not suitable
for molecular studies.

Additional Information None

CDC Points of Contact Ibne Ali
(404) 718-4157
xzn5@cdc.gov
Jennifer Cope
(404) 718-4878
bjt9@cdc.gov

Version 4.4

Test Order
Enteric Isolation - Primary Specimen
CDC-10106

Synonym(s) Enteric Pathogen Culture, Stool Culture

CDC Pre-Approval Needed **Haley Martin**
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing For FilmArray Gastrointestinal Panel testing, stool in Cary Blair transport medium is required. For surveillance only testing, acceptable specimen will be determined upon consultation.

Minimum Volume Required For FilmArray Gastrointestinal Panel testing, a minimum volume of 0.2 mL is required. For surveillance only testing, acceptable minimum volumes will be determined upon consultation.

Collection, Storage, and Preservation of Specimen Prior to Shipping For FilmArray Gastrointestinal Panel testing, specimens should be shipped as soon as possible but may be held at room temperature (15-25°C), refrigerated (2-8°C), or frozen (-20°C or lower) for up to 3 weeks prior to shipping. For surveillance only testing, acceptable storage and preservation conditions will be determined upon consultation.

Transport Medium For FilmArray Gastrointestinal Panel testing, Cary Blair transport medium is required. For surveillance only testing, transport medium requirements will be determined upon consultation.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For FilmArray Gastrointestinal Panel testing, specimens may be shipped at room temperature with room temperature cold packs, refrigerated with refrigerated or frozen cold packs, or frozen with dry ice. For surveillance only testing, specimen shipping conditions will be determined upon consultation.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 129
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Enrichment, Detection and Isolation, Phenotypic or Genetic Identification and Subtyping, including Syndromic PCR Panels, Serotyping, and Virulence Profiling
Turnaround Time	13 Weeks
Interferences & Limitations	Inferences and limitations will be discussed upon consultation.
Additional Information	Targeted organisms include: <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , Shiga toxin-producing <i>Escherichia coli</i> (STEC) and other diarrheagenic <i>Escherichia coli</i> , pathogenic <i>Enterobacteriaceae</i> , <i>Listeria</i> , <i>Vibrio</i> , <i>Cronobacter</i> , and related foodborne and waterborne pathogens.
CDC Points of Contact	Haley Martin (404) 639-1612 hww0@cdc.gov Nancy Strockbine (404) 639-4186 nas6@cdc.gov

Version 1.7

Test Order
Enteric Special Study
CDC-10512

Synonym(s) none

CDC Pre-Approval Needed **Andrew Huang**
(404) 639-1545
wwm8@cdc.gov
A Jo Williams Newkirk
(404) 639-1087
igy7@cdc.gov

Supplemental Information Required **Notify POCs before sending specimens and send study-specific datasheet.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Stool or pathogen isolate

Minimum Volume Required Stool: 4 mL unless lower volume preapproved; pathogen isolate: n/a

Collection, Storage, and Preservation of Specimen Prior to Shipping Stool specimens must be frozen at -70 °C or lower upon receipt by the submitting laboratory and held at that temperature until shipment to CDC

Transport Medium Stool: none or Cary Blair; Pathogen isolate: pathogen-appropriate agar in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Stool samples must be shipped on dry ice. Ship pathogen isolates at ambient temperature.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology

Turnaround Time

Interferences & Limitations n/a

Additional Information This test is for the submission of samples to participate in an enteric pathogen special study. No results of testing will be reported back to submitters.

CDC Points of Contact Andrew Huang
(404) 639-1545
wwm8@cdc.gov
A Jo Williams Newkirk
(404) 639-1087
igy7@cdc.gov

Version 1.2

Test Order

Enterovirus and Parechovirus Detection and Identification, including Enterovirus-D68 (EV-D68) CDC-10312

Synonym(s) Enterovirus (EV), coxsackieviruses (CVA) (CVB), Echovirus, Parechovirus, Enterovirus-D68 (EV-D68)

CDC Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Stool, cerebrospinal fluid (CSF), serum, nasopharyngeal swab (NP) in virus transport media (VTM), oropharyngeal swab (OP) in VTM, nasopharyngeal/oropharyngeal swab (NP/OP) in VTM, nasal swab (NS)

Minimum Volume Required Stool: 1 gram, 10 - 20 grams preferred
Cerebrospinal fluid (CSF): 0.15 mL, 0.5-2 mL preferred
Serum: 0.15 mL, 0.5 - 2 mL preferred
Respiratory swab specimens in virus transport media: 0.5 mL, 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample.

For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media.

For stool, CSF, respiratory wash specimen - collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Do not add transport medium.

For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes and centrifuge.

After collection, freeze (-20°C or lower) all specimens and ship to CDC within 1 month. If necessary, specimens may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing.

Transport Medium Viral transport medium (VTM) should be used with these specimen types: nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), nasal swabs (NS)

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 76
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular techniques
Turnaround Time	2 Weeks
Interferences & Limitations	Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.
Additional Information	Not Applicable
CDC Points of Contact	Picornavirus Laboratory

PicornaLab@cdc.gov
Shannon Rogers
(404) 639-2677
boo9@cdc.gov
Terry Fei Fan Ng
(404) 639-4880
ylz9@cdc.gov

Version 2.5

Test Order
Entomology Special Study
CDC-10494

Synonym(s) Insect

CDC Pre-Approval Needed **Gena Lawrence**
(404) 718-4315
geg7@cdc.gov
Alice Sutcliffe
(404) 718-4326
gok0@cdc.gov

Supplemental Information **To be determined**
Required

Supplemental Form **None**

Performed on Specimens From Animal

Acceptable Sample / Specimen Type Insects, insect DNA, and other types to be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 222
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology To be determined

Turnaround Time

Interferences & Limitations To be determined

Additional Information Turnaround time is to be determined based on the tests performed.

CDC Points of Contact Gena Lawrence
(404) 718-4315
geg7@cdc.gov
Alice Sutcliffe
(404) 718-4326
gok0@cc.gov

Version 1.1

Test Order
Epstein Barr Virus (EBV) Detection
CDC-10265

Synonym(s)	EBV
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL (saliva, cerebrospinal fluid (CSF), whole blood)
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours.</p> <p>Whole blood should be collected in anticoagulant blood collection tubes (EDTA). Refrigerate whole blood (2-8°C) within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower).</p> <p>All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.</p>
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information None

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 1.5

Test Order
Escherichia and *Shigella* Identification, Serotyping, and Virulence Profiling
 CDC-10114

Synonym(s) *Escherichia*, STEC, *Shigella*, *E. coli*, serotyping, virulence, profiling

CDC Pre-Approval Needed None

Supplemental Information

Required Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Escherichia* and *Shigella*; sequence data

Minimum Volume Required No minimum volume required.

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship at ambient temperature or frozen with dry ice. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 07
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling
Turnaround Time	13 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Devon Stoneburg (404) 639-2251 euo4@cdc.gov Haley Martin (404) 639-1612 hvw0@cdc.gov

Version 2.3

Test Order
***Escherichia* and *Shigella* Study**
CDC-10115

Synonym(s) *Escherichia*, STEC, *Shigella*, *E. coli*

CDC Pre-Approval Needed **Devon Stoneburg**
(404) 639-2251
euo4@cdc.gov
Haley Martin
(404) 639-1612
hvw0@cdc.gov

Supplemental Information Required **Refer to study protocol for specific requirements.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Refer to study protocol for specific requirements.

Minimum Volume Required Refer to study protocol for specific requirements.

Collection, Storage, and Preservation of Specimen Prior to Shipping Refer to study protocol for specific requirements.

Transport Medium Refer to study protocol for specific requirements.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship isolates as directed by study protocol.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 07
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Refer to study protocol for specific requirements

Turnaround Time

Interferences & Limitations Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.

Additional Information None

CDC Points of Contact Nancy Strockbine
(404) 639-4186
nas6@cdc.gov
Devon Stoneburg
(404) 639-2251
euo4@cdc.gov
Haley Martin
(404) 639-1612
hvw0@cdc.gov

Version 1.3

Test Order
Escherichia coli (STEC) Serology (not serotyping)
CDC-10452

Synonym(s) Enteric serology, Hemolytic Uremic Syndrome (HUS) serology

CDC Pre-Approval Needed **Rachael Aubert**
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Specimen Submission Form: date of specimen collection, date of illness onset and clinical diagnosis (e.g. HUS). Also indicate if patient has undergone plasmapheresis and include any preliminary laboratory results (e.g. culture or shiga toxin detection from stool).**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Preferred specimen type is paired patient serum collected during acute (within 1 week of symptom onset) and convalescent (at least 4 weeks post symptom onset) stages of illness. Serum is preferred, but plasma is acceptable. Do not pool specimens.

Minimum Volume Required 0.1 mL required, more preferred if available

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum can be stored refrigerated (2-8 °C) for up to one month, or frozen (below -20 °C). Avoid repeat freeze/thaw cycles.

Transport Medium Serum or plasma should be transferred to clean sterile tube for storage and shipment.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Serum can be shipped in a leak-proof container on gel ice-packs, frozen specimens should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Enzyme-Linked Immunoassay (ELISA)
Turnaround Time	20 Weeks
Interferences & Limitations	Specimen should be stored and shipped either refrigerated (2-8 °C) or frozen (below -20 °C), as repeat freeze/thaw cycles can lower test sensitivity. Hemolysis present in serum specimens has not shown to interfere with this test, but should be avoided if possible.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. When submitting multiple specimens for one patient, include a separate CDC 50.34 Specimen Submission Form for each specimen submitted.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Zuzana Kucerova (404) 718-4143 zik0@cdc.gov

Version 2.1

Test Order
***Escherichia coli* and *Shigella* Subtyping**
CDC-10116

Synonym(s) *Escherichia*, STEC, *Shigella*, *E. coli*, subtyping

CDC Pre-Approval Needed None

Supplemental Information

Required

Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates, Sequence Data

Minimum Volume Required No minimum volume required.

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship at ambient temperature or frozen with dry ice. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 07
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	20 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Devon Stoneburg (404) 639-2251 euo4@cdc.gov Haley Martin (404) 639-1612 hvw0@cdc.gov

Version 1.5

Test Order
Fascioliasis Serology
CDC-10505

Synonym(s)	Fascioliasis, <i>Fasciola hepatica</i> , liver fluke
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Sera can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) until shipment.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Immunoblot, Western blot, Antibody detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.2

Test Order
Filariasis Serology
CDC-10462

Synonym(s)	<i>Brugia malayi</i> , <i>Wuchereria bancrofti</i> ; Bancroftian filariasis, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.4

Test Order
Francisella tularensis Culture and Identification
CDC-10313

Synonym(s) Tularemia

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

For transfer of a select agent, a completed Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2) is required.

Supplemental Form

For transfer of a select agent: Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2)

<https://www.selectagents.gov/forms.html>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Lymph node aspirate, sputum, bronchial/tracheal wash, pleural fluid, whole blood (EDTA-treated, heparin-treated, or citrate-treated), blood culture bottle, ulcer, tissues (lymph node, lung, spleen, liver).

Minimum Volume Required Fluids: 1 mL
Tissues: 1 cm³

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate (2-8°C) all specimens to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Do not freeze non-tissue samples as this will reduce bacterial viability.

Transport Medium Transport respiratory specimens, aspirates and tissues in a sterile container. Original blood tubes and blood culture bottles are acceptable. If swabs are utilized for transport, Cary-Blair is recommended.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimens refrigerated on gel ice packs. Avoid freezing non-tissue specimens. Contact CDC POC for specific guidance on shipment of different specimen types.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Culture, Direct Fluorescent Antibody (DFA), Biochemical subtyping
Turnaround Time	3 Weeks
Interferences & Limitations	Antibiotic treatment will reduce the sensitivity of culture; samples should be collected pre-treatment.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 1.8

Test Order
Francisella tularensis Molecular Detection
CDC-10546

Synonym(s) Tularemia, Deerfly fever, rabbit fever

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
- Prior antibiotic treatment (type of antibiotic and date administered)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing EDTA-treated whole blood, pleural fluid or suspect isolate

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen refrigerated (2-8 °C) prior to transport.

Transport Medium Suspect *Francisella tularensis* cultures should be transported on chocolate or other cysteine containing agar.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship specimens refrigerated on gel ice packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase chain reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Prior antibiotic treatment may reduce sensitivity by decreasing the amount of bacterial DNA present in specimens.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.2

Test Order
Francisella tularensis Serology
CDC-10314

Synonym(s) Tularemia

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL (serum)

Collection, Storage, and Preservation of Specimen Prior to Shipping Upon collection and serum separation, serum specimens should be held at 2-8 °C. Serum samples can be stored at 2-8 °C for up to 14 days and shipped on gel ice packs. If testing is delayed longer than 14 days, serum samples may be frozen (-20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If serum can be shipped to CDC within 14 days of sample collection, serum samples should be kept refrigerated and shipped on gel ice packs. If serum specimens are frozen, they should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

Bacterial Diagnostic and Reference Laboratory

3156 Rampart Road

Fort Collins, CO 80521

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Microagglutination

Turnaround Time 2 Weeks

Interferences & Limitations

Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.8

Test Order
Francisella tularensis Special Study
 CDC-10315

Synonym(s)	
CDC Pre-Approval Needed	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Supplemental Information Required	Required information on the CDC 50.34 Specimen Submission Form: <ul style="list-style-type: none"> • Test order name (one per submission form) • Patient full name, sex, birth date • Date of onset (of symptoms) • Specimen collected date • Specimen source (type) • Submitting agency address, contact name, phone number and email address for each submitter • Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Culture, PCR, Direct fluorescent antibody testing
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 2.3

Test Order
Fungal Identification
CDC-10179

Synonym(s)	Fungal identification, mold identification, yeast identification
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure, viable culture isolate. Non-viable isolates will be rejected.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates can be refrigerated (2-8°C) or kept at an room temperature (15-25°C). Isolate should be maintained to ensure viability.
Transport Medium	Isolates should be on a suitable agar slant.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimen should be shipped at ambient temperature.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 40 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Phenotypic Testing, DNA sequencing, MALDI-ToF
Turnaround Time	6 Weeks
Interferences & Limitations	None
Additional Information	Turnaround Time: Turnaround time for yeast identification is 4 weeks or less and mold identification is 6 weeks or less.

CDC Points of Contact Elizabeth Berkow
(404) 639-2459
kuu4@cdc.gov
Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov

Version 1.4

Test Order

Fungal Serology - *Histoplasma*, *Blastomyces*, *Coccidioides*, *Paracoccidioides* CDC-10180

Synonym(s)	Fungal serology, fungal complement fixation, fungal immunodiffusion
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Serum. Plasma is not an acceptable specimen type and will be rejected.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, refrigerate serum (2-8°C) for no more than 48 hours, then store frozen (at -20°C or lower). Specimen must be received frozen within 42 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 37 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Complement Fixation, Immunodiffusion
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolysis and lipidemia may interfere with the test results.
Additional Information	Serum should be prepared as soon as possible after drawing blood to prevent hemolysis. Request for the testing of antibodies to <i>Paracoccidioides</i> should be noted in the “Suspected Agent” field on the Specimen Submission Form.

CDC Points of Contact Elizabeth Berkow
(404) 639-2459
kuu4@cdc.gov
Mark Lindsley
(404) 639-4340
mil6@cdc.gov

Version 2.3

Test Order
Fungal Study
CDC-10181

Synonym(s) None

CDC Pre-Approval Needed **Elizabeth Berkow**
(404) 639-2459
kuu4@cdc.gov
Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type Contact your CDC POC.
for Testing

Minimum Volume Required Contact your CDC POC.

Collection, Storage, and Preservation Contact your CDC POC.
of Specimen Prior to Shipping

Transport Medium Contact your CDC POC.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 40
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Contact your CDC POC.

Turnaround Time

Interferences & Limitations To be determined

Additional Information For Fungal Studies not covered under CDC-10179 and CDC-10180.

CDC Points of Contact Elizabeth Berkow
(404) 639-2459
kuu4@cdc.gov
Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov

Version 1.4

Test Order
Gastroenteritis Virus Special Study
CDC-10316

Synonym(s)

CDC Pre-Approval Needed **Jan Vinje**
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday – Friday.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 186
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Jan Vinje
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Version 1.3

Test Order
Genital Ulcer Disease (Syphilis, Chancroid, Herpes) Molecular Detection
CDC-10174

Synonym(s) GUD, *T. pallidum*, *H. ducreyi*, HSV 1&2

CDC Pre-Approval Needed **Weiping Cao**
(404) 639-5443
jpgz9@cdc.gov
Allan Pillay
(404) 639-2140
apillay@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Anogenital lesion swabs
for Testing

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation Lesion swabs must be frozen (-20°C or lower) within 3 hours of collection; or
of Specimen Prior to Shipping stored at 2-8 °C for up to 48 hr and then frozen (-20°C or lower).

Ship specimens frozen on dry ice.

Transport Medium Commercial transport medium suitable for nucleic acid amplification test (NAAT):
Becton-Dickinson UVT, Hologic Aptima Multitest swab collection kit, Hologic
Aptima Unisex swab collection kit, and Remel Microtest M4RT.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Shipping Instructions which Include Frozen specimen should be shipped on dry ice, as an etiologic agent.
Specimen Handling Requirements

CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday-Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Real-Time Multiplex PCR

Turnaround Time 2 Weeks

Interferences & Limitations Specimen must remain frozen, multiple freeze-thaw cycles may reduce the sensitivity of PCR detection.

Additional Information None

CDC Points of Contact Weiping Cao
(404) 639-5443
jgz9@cdc.gov
Allan Pillay
(404) 639-2140
apillay@cdc.gov
Charles Thurlow
(404) 718-7388
oso4@cdc.gov
Kevin Pettus
(404) 639-4338
kbp9@cdc.gov

Version 2.6

Test Order
Gram Negative Bacillus (non-enteric/nonfermenter) Identification
CDC-10135

Synonym(s)	Gram-negative rod/bacillus
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order

Gram Positive Bacillus Identification

CDC-10137

Synonym(s)	Gram-positive rod identification, gram-positive bacillus identification
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay..

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order

Gram-negative Coccus (not *Gonococcus* or *meningococcus*), *Neisseria* species, and *Moraxella* species Identification CDC-10138

Synonym(s) *Neisseria* Identification, GNC

CDC Pre-Approval Needed None

Supplemental Information Required Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.

Supplemental Form None

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 17
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
***Haemophilus influenzae* Identification and Serotyping**
CDC-10221

Synonym(s) *H. influenzae* ID and Serotyping, Hi ID

CDC Pre-Approval Needed None

Supplemental Information Required **Two primary patient identifiers are required for this test order. Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing. For surveillance testing, please submit under *Haemophilus influenzae* Surveillance order (CDC-10222).**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Bacterial isolates (viable bacterial culture at room temperature or frozen stocks) and primary specimens [cerebrospinal fluid (CSF) and serum]. Other sterile site specimen types must be submitted under the CDC-10222 Test Order (*Haemophilus influenzae* Surveillance).

Minimum Volume Required 0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping.

When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates.

Cerebrospinal fluid (CSF) and serum should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.

Transport Medium When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF and serum) should be shipped on dry ice and received frozen.

Enclose CDC 50.34 Specimen Submission Form in shipment. Email the tracking number in advance, particularly if prioritized testing is requested.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 44
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (rt-PCR), Slide Agglutination Serotyping (SAST), Bacterial isolates will be characterized using real-time Polymerase Chain Reaction (rt-PCR) and slide agglutination serogrouping (SASG); primary specimens will be characterized using rt-PCR.
Turnaround Time	4 Weeks
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Test results provide or confirm serotype of <i>H. influenzae</i> .
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Henju Marjuki (404) 639-2803 vsd1@cdc.gov

Version 2.3

Test Order
Haemophilus influenzae Surveillance
 CDC-10222

Synonym(s) *H. influenzae* Surveillance, Hi study

CDC Pre-Approval Needed None

Supplemental Information Required Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form or on the surveillance submission form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing. If results are intended for diagnostic purposes, submit under *Haemophilus influenzae* Identification and Serogrouping test order (CDC-10221).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Bacterial isolates: viable bacterial culture at room temperature or frozen stocks
 Primary specimens: cerebrospinal fluid (CSF), serum, and other sterile site specimen types

Minimum Volume Required 0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping.

When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates.

Primary specimens (CSF, serum and other sterile site specimen types) should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.

Transport Medium When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. All submitted specimens should include two unique identifiers (state ID & accession number). The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF, serum and other sterile site specimen types) should be shipped on dry ice and received frozen.

If using a specimen inventory spreadsheet for submission, include a copy within the shipment and also email it to the CDC POCs prior to shipment.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 44
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (rt-PCR) and/or slide agglutination serotyping (SAST)
Turnaround Time	
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Additional microbiological and/or molecular testing can be completed as needed.
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Henju Marjuki (404) 639-2803 vsd1@cdc.gov

Version 2.7

Test Order
Haemophilus species (not *H. influenza*/*H. ducrey*) Identification
 CDC-10141

Synonym(s)	
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Biochemical analysis, Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Hantavirus Testing
CDC-10319

Synonym(s) Hanta, HPS, HFRS

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required **See Supplemental Form**

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For molecular and/or serology testing the accepted specimen types are whole blood (EDTA) or serum. CDC POC contact is required prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2- 8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order
Healthcare-Associated Infections (HAI) - Outbreak Strain Identification (ID) and
Typing
CDC-10162

Synonym(s) Healthcare Outbreak, Nosocomial Outbreak, Healthcare-Associated Infection (HAI) Outbreak, HAI Identification and Typing

CDC Pre-Approval Needed **Paige Gable**
(404) 718-5815
woz8@cdc.gov
Heather Moulton-Meissner
(404) 639-4864
ftw2@cdc.gov

Supplemental Information Required **For all submissions, contact the CDC POC for instructions on completing a Supplemental Line List. For pure culture isolate submittals, the CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the date the submitted culture was inoculated onto transport media. For environmental samples, the CDC 50.34 Specimen Submission Form or GFAT must include the date of collection.**

Supplemental Form **Contact the CDC POC regarding contents of the required Supplemental Line List.**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Acceptable samples include pure culture isolates and primary environmental specimen types (e.g. swabs, wipes, water and other fluids, medical devices, products), however, additional sample types may be accepted for testing upon consultation.

Minimum Volume Required Not applicable for pure culture isolates. Minimum volumes may be required for certain types of environmental samples. Please confirm volume requirements with the CDC POC before collecting samples.

Collection, Storage, and Preservation of Specimen Prior to Shipping Store all isolates at room temperature (15-25 °C). If isolates cannot be shipped within 24 hours, refrigerate only non-fastidious organisms (2-8 °C).

 Primary environmental specimens should be refrigerated (2-8 °C) within 4 hours. Products should be stored in accordance with manufacturer's instructions. Special storage and preservation requirements for anaerobic isolates available upon request.

Transport Medium Transport room temperature (15-25 °C) and refrigerated (2-8 °C) isolates on suitable agar slant (not an agar plate or broth culture media). Transport refrigerated (2-8 °C) environmental specimens in suitable buffers or media if necessary (e.g. swabs). Transport conditions for anaerobic isolates available upon request.

Specimen Labeling Research or surveillance specimens should be labeled with two unique specimen identifiers which correspond with the Supplemental Line Listing. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For pure culture isolates, ship overnight at room temperature within 24 hours after the 18-24 hour incubation of the culture being submitted with room-temperature cold packs. If shipment must be delayed, cultures can be shipped refrigerated within 48 hours of 18-24 hour incubation with refrigerated or frozen cold packs. Cultures frozen within 7 days of 18-24 hour incubation should be shipped on dry ice. For environmental samples please contact the CDC POC for shipping instructions.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 154
 1600 Clifton Road, NE
 Atlanta, GA 30329

[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Primary Processing of non-clinical specimens (e.g., culture and isolation, species identification, membrane filtration, sterility testing), Molecular Identification and Typing of non-clinical specimens (e.g., MALDI-ToF, 16S, Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS))
Turnaround Time	3 Weeks
Interferences & Limitations	Primary environmental samples should not be held at room temperature for >1 hour. Doing so may decrease recovery of microorganisms or otherwise adversely affect the results obtained from testing recovered organisms. Neutralization of chlorine residual in potable water is necessary during collection. Samples that arrive containing personally identifiable information under this test code will be rejected for testing.
Additional Information	<p>Contact the CDC POC for approval prior to submitting any specimen.</p> <p>If a Healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Prior epidemiologic consultation with CDC/DHQP Prevention and Response Branch [haioutbreak@cdc.gov] also required.</p> <p>Turnaround Time: 3 weeks; 8 weeks for Nontuberculous Mycobacteria (NTM) and Anaerobes.</p> <p>The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.</p>

CDC Points of Contact Paige Gable
(404) 718-5815
woz8@cdc.gov
Heather Moulton-Meissner
(404) 639-4864
ftw2@cdc.gov

Version 2.2

Test Order
Hendra Hemorrhagic Fever Testing
CDC-10324

Synonym(s)

CDC Pre-Approval Needed Trevor Shoemaker
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VSPB Specimen Submission Form.
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For serology testing, the accepted specimen types are whole blood (EDTA) or serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	ELISA, Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Hepatitis A NAT and Genotyping
CDC-10530

Synonym(s) HAV, HAV NAT

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum, EDTA-treated plasma (purple top), or stool
for Testing

Minimum Volume Required 500 µL; 1 mL preferred

Collection, Storage, and Preservation Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated
of Specimen Prior to Shipping at 4 °C if shipped in less than 72 hours of collection.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 90
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Qualitative real time PCR and genotyping by sequencing

Turnaround Time 4 Weeks

Interferences & Limitations Hemolyzed specimen are not acceptable.

Avoid sending whole blood.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

Testing results may not be reported back to submitters.

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 1.0

Test Order
Hepatitis A Serology
CDC-10325

Synonym(s) HAV, Hepatitis A virus

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type
for Testing Serum, EDTA-treated plasma (purple-top)

Minimum Volume Required 1 mL; 2 mL preferred

Collection, Storage, and Preservation
of Specimen Prior to Shipping After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2-8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C. Frozen specimens should undergo no more than one freeze-thaw cycle.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include
Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 90
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Total antibody to Hepatitis A virus (Total anti-HAV) by Chemiluminiscence Immunoassay, Immunoglobulin M (IgM) antibody to hepatitis A virus (anti-HAV) by Chemiluminiscence Immunoassay, Immunoglobulin G (IgG) antibody to hepatitis A virus by Chemiluminiscence Immunoassay, Hepatitis A virus (HAV) Ribonucleic Acid (RNA) by Real-Time quantitative reverse transcriptase polymerase chain reaction (qRT-PCR), HAV Genotyping

Turnaround Time 3 Weeks

Interferences & Limitations Hemolyzed specimen are not accepted

Additional Information Some of the test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 2.1

Test Order
Hepatitis B Genotyping
CDC-10529

Synonym(s)	HBV
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum or EDTA-treated plasma (purple top)
Minimum Volume Required	0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Hepatitis B genotyping through sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolyzed specimen are not acceptable. Avoid sending whole blood.
Additional Information	None

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 1.0

Test Order
Hepatitis B Serology and Quantitative PCR
CDC-10326

Synonym(s)	HBV, Hepatitis B virus
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, EDTA-treated plasma (purple-top) NOTE: For Quantitative anti-HBs test - Serum only
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2-8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C. Frozen specimens should undergo no more than one freeze-thaw cycle.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Hepatitis B surface antigen (HBsAg) by Chemiluminescence Immunoassay, Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) by Chemiluminescence Immunoassay, Total hepatitis B core antibody (anti-HBc) by Chemiluminescence Immunoassay, Hepatitis B surface antibodies (anti-HBs) by Chemiluminescence Immunoassay, Hepatitis B e-antigen (HBeAg) by Chemiluminescence Immunoassay, Hepatitis B virus (HBV) Deoxyribonucleic Acid (DNA) by Real-Time Polymerase Chain Reaction (PCR), Quantitative antibody to hepatitis B surface gene (quantitative anti-HBs)
Turnaround Time	10 Days

Interferences & Limitations Hemolyzed specimen are not acceptable.

Avoid sending whole blood.

Additional Information None

CDC Points of Contact Amanda Poe
(404) 639-0723
DVHLabTesting@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 2.1

Test Order
Hepatitis C Serology, Quantitative PCR, and Genotyping
CDC-10327

Synonym(s)	HCV, Hepatitis C virus
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, EDTA Plasma
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored refrigerated (2–8°C) for up to 48 hours prior to shipping. Specimens stored beyond these time points must be frozen at or below -20 °C and received at CDC less than 7 days post collection. Frozen specimens should undergo no more than one freeze-thaw cycle.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All samples should be shipped frozen on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	Anti-HCV by Chemiluminescence, HCV RNA by Real Time qRT-PCR, HCV Genotyping
Turnaround Time	5 Days
Interferences & Limitations	Hemolyzed specimen are not accepted
Additional Information	NAT based assays and genotyping may take up to 3 weeks for turn around time

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 2.2

Test Order
Hepatitis D Serology, NAT and Genotyping
CDC-10328

Synonym(s) HDV, Hepatitis D virus

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum, EDTA Plasma
for Testing

Minimum Volume Required 2 mL

Collection, Storage, and Preservation Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated
of Specimen Prior to Shipping at 4 °C if shipped in less than 72 hours of collection.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 90
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Total antibodies to hepatitis D virus (total anti-HDV), hepatitis D Ribonucleic acid testing (HDV NAT), hepatitis D genotyping

Turnaround Time 2 Weeks

Interferences & Limitations Hemolyzed specimen are not accepted

Additional Information The tests used have not been cleared and approved by the FDA. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 2.1

Test Order
Hepatitis E Serology, NAT and Genotyping
CDC-10329

Synonym(s)	HEV, Hepatitis E virus
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum and EDTA-treated plasma (purple-top): Serology, Nucleic Acid Testing and Genotyping Stool: Nucleic Acid Testing and Genotyping
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoglobulin M (IgM) antibody to hepatitis E virus (anti-HEV) by enzyme-linked immunosorbent assay (ELISA), Immunoglobulin G (IgG) Anti-HEV by ELISA, Hepatitis E Virus (HEV) Ribonucleic Acid (RNA) by Real Time quantitative Real Time Polymerase Chain Reaction (qRT-PCR), HEV Genotyping
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed specimen are not accepted
Additional Information	The tests used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Amanda Poe
(404) 639-0723
anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Version 2.1

Test Order
Hepatitis Special Study
CDC-10331

Synonym(s)	None
CDC Pre-Approval Needed	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Saleem Kamili (404) 639-4431 sek6@cdc.gov
Supplemental Information Required	Contact the CDC POC for appropriate guidance/relevant information.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Serum, EDTA-treated plasma (purple-top), stool, or environmental
Minimum Volume Required	2 mL (or greater if environmental samples - water samples require a minimum of 10 mL)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens (serum, plasma, and stool) should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection. Room Temperature or -20 °C for environmental samples.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	4 Weeks
Interferences & Limitations	To be determined
Additional Information	To be determined

CDC Points of Contact Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov
Mike Purdy
(404) 639-2332
mup3@cdc.gov

Version 2.0

Test Order
Hepatitis Surveillance
CDC-10531

Synonym(s) Global Hepatitis Outbreak and Surveillance Technology (GHOST), Hepatitis A, Hepatitis B, and Hepatitis C outbreaks

CDC Pre-Approval Needed **Ryan Augstine**
(404) 718-5613
hepaoutbreaklab@cdc.gov
Amanda Poe
(404) 639-0723
anp0@cdc.gov

Supplemental Information **CDC 50.34 Specimen Submission Form**
Required

Indicate the following code for test criteria in the Patient History Section of CDC 50.34 Specimen Submission Form:

1 - Specimen from a case in a county that has yet reported a hepatitis A case in an at-risk population

2 - Specimen from a case patient who does not report any known risk factors or contact with at-risk populations (e.g., household or sexual contact, volunteering at a homeless shelter)

3 - Specimen from a case patient suspected to be associated with foodborne transmission

4 - Archived/stored specimen from a patient who has died and whose classification as an out-break related death requires nucleic acid testing beyond anti-HAV IgM-positivity

5 - Other patient specimens not meeting the above criteria that require nucleic acid testing or molecular characterization (to be discussed on a case-by-case basis).

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum or EDTA-treated plasma (purple top)

Minimum Volume Required 500 µL; 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 90
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Next Generation Amplicon Sequencing
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Turnaround Time	4 Weeks
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Interferences & Limitations	Hemolyzed specimen are not acceptable.
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Avoid sending whole blood.

Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
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Testing results may not be reported back to submitters.

CDC Points of Contact	Amanda Poe (404) 639-0723 anp0@cdc.gov Sumathi Ramachandran (404) 639-1403 dcq6@cdc.gov
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Version	1.0
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Test Order
Herpes Simplex Virus 1/2 Detection
CDC-10258

Synonym(s) Oral herpes, Genital herpes

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required Cerebrospinal fluid (CSF): 0.5 mL

Whole blood: 1 mL

Viral transport media (VTM) inoculated with swabs from vesicular or pustular fluid: 1 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping For the collection of skin lesion specimens, unroof the scab and place it directly into a breakage resistant tube. For swab collections of vesicular/pustular fluid from lesions, use a sterile needle to unroof the top of the vesicle. Use a sterile synthetic swab, e.g. polyester swab, to vigorously swab the base of the lesion, applying enough pressure to collect epithelial cells. Swabs may be placed directly into a storage tube. Swabs without VTM and skin lesion specimens should be kept dry, stored at room temperature (15-25°C), and shipped at room temperature within 1 week after collection.

Swabs can also be placed in viral transport media. Refrigerate (2-8°C) viral transport medium (VTM) inoculated with swabs from vesicular or pustular fluid. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower.

Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and stored in a leak proof container. CSF should be stored at -20°C or lower after collection but if needed, it can be stored at 2-8°C for no more than 72 hours. CSF specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. CSF can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Anticoagulant blood collection tubes (EDTA) should be used for the collection of whole blood. Refrigerate whole blood within 1 hour of collection. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower.

All viral transport medium inoculated with swabs from vesicular or pustular fluid, CSF, and whole blood specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Transport Medium	Viral transport medium (VTM) inoculated with swabs from vesicular or pustular fluid.
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Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
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Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Swabs from vesicular or pustular fluid without viral transport media and skin lesion samples should be shipped overnight at room temperature with room-temperature cold packs.

Cerebrospinal fluid (CSF), viral transport media inoculated with swabs from vesicular or pustular fluid and whole blood specimens should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	None
CDC Points of Contact	Sheila Dollard (404) 639-2178 sgd5@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

Version 2.5

Test Order
Herpes Simplex Virus 1/2 Serology
CDC-10259

Synonym(s) Oral herpes, Genital herpes

CDC Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum, plasma, or cerebrospinal fluid (CSF)

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen at -20°C.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship specimens with cold packs or dry ice as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology IgG antibody detected by Enzyme Immunoassay (EIA)

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have been cleared and approved by the FDA but the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Joseph Icenogle
(404) 639-4557
jci1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 2.4

Test Order
Herpesvirus Encephalitis Panel
CDC-10262

Synonym(s)

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sgd5@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours.

CSF should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) specimens should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR) for VZV, Polymerase Chain Reaction (PCR) for HSV1, Polymerase Chain Reaction (PCR) for HSV2, Polymerase Chain Reaction (PCR) for EBV, Polymerase Chain Reaction (PCR) for HHV6

Turnaround Time 7 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 2.3

Test Order
HIV Molecular Surveillance Study (International Only)
CDC-10332

Synonym(s)	HIV subtypes, HIV molecular epidemiology, HIV outbreak
CDC Pre-Approval Needed	Joshua DeVos (404) 639-5442 ext8@cdc.gov Joy Chang (404) 639-1589 ckc7@cdc.gov
Supplemental Information Required	Contact the CDC POCs to obtain the appropriate forms and supplemental information/materials to assist in completing the laboratory specific forms and packaging guidance for DBS.
Supplemental Form	Supplemental forms will be provided after pre-approval for specimen submission. Contact the CDC Point of Contacts for: 1) ILB-160-F08D Drug Resistance Requisition Form 2) CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma prepared from EDTA whole blood (centrifuged within 6 hours of collection). Dried blood spots (DBS) prepared from EDTA whole blood (venous whole blood preferred) on a 903 sample collection card or similar.
Minimum Volume Required	Plasma: 0.2 mL (0.5mL preferred) of EDTA plasma. DBS: 4 DBS of 100 µL (5 DBS preferred) in each 13mm printed circle on a blood collection card.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma: EDTA whole blood centrifuged within 6 hours of collection and aliquoted in 1.5 - 2.0 mL polypropylene tube with screw cap and O-ring. Freeze plasma aliquots at -70 °C or colder within 24 hours. DBS: Prepared DBS specimens must be labeled and dried thoroughly prior to packaging. To prevent cross-contamination, separate DBS cards with glassine paper and place in a gas-impermeable bags containing desiccant packs and humidity indicator. Humidity indicators must be visible inside bag without opening. Gently apply pressure to the partially sealed bag to expel the air before completely sealing. If humidity indicator card or dessicant packs must be changed, allow bags to equilibrate to ambient temperature before opening to avoid exposure of samples to humidity. Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.
Transport Medium	None

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Plasma: Pack plasma specimens per IATA guidelines and ship on dry ice. DBS: Prior to transport, check the dessicants and humidity indicator cards for presence of humidity. Change if necessary. Transport DBS specimens at ambient temperature (15 °-30 °C) if to be received within 14 days; otherwise ship DBS on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 97
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Identification of HIV-1 group M subtypes, determination of transmission clusters of genetically related viruses, phylogenetic analyses of circulating strains from suspected cases, Phylogenetic analysis might be performed in gag, pol, or env HIV-1 gene sequences

Turnaround Time 16 Weeks

Interferences & Limitations Testing will not be performed on the following specimens:

- Improperly labeled or unlabeled
- Discrepant or missing documentation
- Insufficient sample volume
- Evidence of leakage or contamination
- Use of any anticoagulant other than EDTA
- DBS prepared on FTA cards
- DBS shipped without dessicant or humidity indicators
- Transport time is greater than 14 days

Test sensitivity is reduced when specimen undergo multiple freeze thaw cycles.

Additional Information None

CDC Points of Contact Joshua DeVos
(404) 639-5442
ext8@cdc.gov
Joy Chang
(404) 639-1589
ckc7@cdc.gov

Version 1.4

Test Order
HIV Special Study
CDC-10278

Synonym(s)

CDC Pre-Approval Needed **Silvina Masciotra**
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jlj6@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 77
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov

Version 1.3

Test Order
HIV-1 Genotype Drug Resistance (International Only)
CDC-10335

Synonym(s) HIV drug resistance (DR), HIVDR, HIV susceptibility to antiretroviral drugs (ARV), PI, NRTI, NNRTI, INSTI

CDC Pre-Approval Needed **Joshua DeVos**
(404) 639-5442
ext8@cdc.gov
Joy Chang
(404) 639-1589
ckc7@cdc.gov

Supplemental Information Required **Contact the CDC POCs to obtain the appropriate forms and supplemental information/materials to assist in completing the laboratory specific forms and packaging guidance for DBS.**

Supplemental Form **Supplemental forms will be provided after pre-approval for specimen submission. Contact the CDC Point of Contacts for: 1) ILB-160-F08D Drug Resistance Requisition Form 2) CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Plasma prepared from EDTA whole blood (centrifuged within 6 hours of collection). Dried blood spots (DBS) prepared from EDTA whole blood (venous whole blood preferred) on a 903 sample collection card or similar.

Minimum Volume Required Plasma: 0.2 mL (0.5mL preferred) of EDTA plasma.
DBS: 4 DBS of 100 µL (5 DBS preferred) in each 13mm printed circle on a blood collection card.

Collection, Storage, and Preservation of Specimen Prior to Shipping Plasma: EDTA whole blood centrifuged within 6 hours of collection and aliquoted in 1.5 - 2.0 mL polypropylene tube with screw cap and O-ring. Freeze plasma aliquots at -70 °C or colder within 24 hours.

DBS: Prepared DBS specimens must be labeled and dried thoroughly prior to packaging. To prevent cross-contamination, separate DBS cards with glassine paper and place in a gas-impermeable bags containing desiccant packs and humidity indicator. Humidity indicators must be visible inside bag without opening. Gently apply pressure to the partially sealed bag to expel the air before completely sealing. If humidity indicator card or dessicant packs must be changed, allow bags to equilibrate to ambient temperature before opening to avoid exposure of samples to humidity.

Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.

Transport Medium None

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements

Plasma: Pack plasma specimens per IATA guidelines and ship on dry ice.

DBS: Prior to transport, check the dessicants and humidity indicator cards for presence of humidity. Change if necessary. Transport DBS specimens at ambient temperature if to be received within 14 days; otherwise ship DBS on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 97

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology

Identification of mutations within HIV-1 pol gene region by ribonucleic acid (RNA) extraction, polymerase chain reaction (PCR) amplification, deoxyribonucleic acid (DNA) sequencing, and Drug Resistance analysis

Turnaround Time

16 Weeks

Interferences & Limitations

Testing will not be performed on the following specimens:

- Improperly labeled or unlabeled
- Discrepant or missing documentation
- Insufficient sample volume
- Evidence of leakage or contamination
- Use of any anticoagulant other than EDTA
- DBS prepared on FTA cards
- DBS shipped without dessicant or humidity indicators
- Transport time is greater than 14 days

Test sensitivity is reduced when specimen undergo multiple freeze thaw cycles.

Additional Information

The genotyping assay may not detect minor viral species infecting a patient that constitute less than 20% of virus mixtures. Consultation with an expert in HIV drug resistance is encouraged to facilitate interpretation of susceptibility or resistance to antiretroviral drugs and to evaluate antiretroviral treatment options.

CDC Points of Contact Joshua DeVos
(404) 639-5442
ext8@cdc.gov
Joy Chang
(404) 639-1589
ckc7@cdc.gov

Version 1.3

Test Order
 HIV-1 Limiting Antigen Avidity Enzyme Immunoassay (International Only)
 CDC-10540

Synonym(s)	LAG
CDC Pre-Approval Needed	Ernest Yufenyuy 404-639-1548 yod0@cdc.gov Trudy Dobbs 404-639-3760 Tld3@cdc.gov
Supplemental Information Required	Supplemental forms will be provided upon Pre-Approval. Following fields are required: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested. All submitted specimens must include two unique specimen identifiers and collection date.
Supplemental Form	ILB-160-F08B HIV Serology Requisition Form
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma, Serum, Dried Blood Spots (DBS). DBS are made from fingerstick or venipuncture (EDTA) whole blood on Whatman 903 filter paper.
Minimum Volume Required	Plasma: 0.5 mL (2 mL preferred) Serum: 0.5 mL (2 mL preferred) Dried Blood Spots (DBS): 2 full blood spots (3 full blood spots preferred). DBS should be 13mm circles containing 75 µL of whole blood.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood should be processed into plasma or serum within 24 hours. For plasma whole blood collection, blood can be collected in EDTA anticoagulant tubes. Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at at -20°C or colder. Do not send specimens after more than 5 freeze-thaw cycles. Dried Blood Spots (DBS): DBS must be placed in a airtight zippered bag with 3-5 desiccant packs and 1 humidity indicator card once the blood spot is dried (no more than 24 hours after collection). Up to 10 cards, separated by glassine paper, can be included in 1 zippered bag. Bag may be stored at 15-30°C for up to 14 days after collection) if shipped within 14 days, or at 2-8°C for up to 2 months or at -20°C or colder.
Transport Medium	Plasma/ Serum: Specimens should be shipped in leak-proof plastic screw-cap vials. For shipments that are in transit for up to 7 days, ship on gel ice-packs. For shipments that are in transit for greater than 7 days, ship on dry ice. DBS: DBS cards should be stored in gas impermeable plastic bag with desiccant bags and humidity indicator card. For shipments that are in transit for up to 14 days, maintain at room temperature (15-35°C). For shipments that are in transit for greater than 14 days, ship on dry ice.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 100
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Limiting antigen avidity enzyme immunoassay
Turnaround Time	8 Weeks
Interferences & Limitations	Classification of individuals as recent seroconverters or long-term infections is based on average development of higher avidity HIV-antibodies calculated from data using a large number of people. As a result, differences among individuals in terms of maturation of HIV antibodies and the rates at which high avidity HIV-antibodies are made may exist. Moreover, while this assay is useful at the population level, its predictive value for individuals has not been determined (especially when levels are close to the cutoff). Therefore, the assay should not be used for individual assessment of recency of infection. Persons with diagnosis of AIDS or low CD4+ T cell counts (<200 cells per µl), recipients of anti-retroviral therapy, and known elite controllers should be excluded from the study as they appear to contribute to the misclassification of long-term infections.
Additional Information	Determination of HIV-1 incidence for surveillance purposes only. Specimen will be rejected for any of the following reasons: improperly labeled, unlabeled, discrepant documentation, no documentation, insufficient quantity, and/or evidence of contamination.
CDC Points of Contact	Ernest Yufenyuy 404-639-1548 yod0@cdc.gov Trudy Dobbs 404-639-3760 Tld3@cdc.gov

Version 1.1

Test Order
HIV-1 Nucleic Acid Amplification (Qualitative)
CDC-10275

Synonym(s) HIV-1 RNA qualitative, HIV NAAT

CDC Pre-Approval Needed None

Supplemental Information

Required Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum or EDTA-treated plasma

Minimum Volume Required 2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Whole blood can be stored at 2°C to 30°C (do not freeze whole blood) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used.

Separated plasma may be stored at 2°C to 8°C for up to 3 days or at ≤ -20°C for up to 60 days.

For up to 24 hours after specimen collection, serum tubes containing centrifuged serum may be stored at 2°C to 30°C. After 24 hours, serum may be stored in the serum tube at 2°C to 8°C for up to 3 days. Separated serum may be stored at 2°C to 8°C for up to 3 days, or at -20°C (as per the package insert) for up to 60 days.

Specimen should not have incurred more than 2 freeze-thaw cycles.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship separated plasma or serum stored at 2-8 °C on cold packs. Ship frozen serum or plasma specimens on dry-ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 77
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Nucleic acid amplification
Turnaround Time	3 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Minimize storage at 18°C to 30°C in order to preserve HIV-1 RNA.
Additional Information	If testing results are inconclusive, additional plasma or serum may be required for subsequent testing.
CDC Points of Contact	Silvina Masciotra (404) 639-1004 svm6@cdc.gov Jeffrey Johnson (404) 639-4976 jjj6@cdc.gov M Leanne Ward 404-639-3265 mrw0@cdc.gov

Version 3.3

Test Order
HIV-1 PCR (International Only) Qualitative
CDC-10336

Synonym(s) HIV, EID, PMTCT, Early infant diagnostic, DNA

CDC Pre-Approval Needed **Clement Zeh**
(404) 553-7264
cbz2@cdc.gov
Guoqing Zhang
(404) 718-4268
uwz2@cdc.gov

Supplemental Information Required **Supplemental forms will be provided upon Pre-Approval:**
- Following fields are required to be filled: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested.
- All submitted specimens must include two unique specimen IDs and collection date.

Supplemental Form **ILB-160-F08E Viral Load-EID Requisition Form. Contact CDC POC to request form.**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Dried Blood Spots (DBS)

Minimum Volume Required At least 3 saturated 13mm circles (preferably 5) containing 70¹/₄L of whole blood including capillary blood obtained by finger/toe/heel stick which is dropped directly onto the DBS card.

Collection, Storage, and Preservation of Specimen Prior to Shipping The appropriate anticoagulant for DBS whole blood collection is EDTA.
Dried blood spots should be kept at an ambient temperature (15 °-35 °C) for storage and shipment if testing is performed within 14 days or frozen at -70 °C if testing is not performed within 14 days.

Transport Medium None

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g. patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact CDC POC prior to submission.

Dried blood spots should be transported in a gas impermeable bag with desiccant and humidity indicator card.

For shipments that are in transit for up to 14 days, maintain at ambient temperature (15-35 °C) and shipments that are in transit for greater than 14 days, maintain temperature at -20 °C or colder with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 96
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Qualitative Polymerase Chain Reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Do not use heparin as an anticoagulant. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.
Additional Information	Contact CDC POC for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing. NOTE: If a specific testing platform is required, please contact CDC POC.
CDC Points of Contact	Clement Zeh (404) 553-7264 cbz2@cdc.gov Guoqing Zhang (404) 718-4268 uwz2@cdc.gov

Test Order
HIV-1 PCR (International Only) Quantitative Viral Load
CDC-10337

Synonym(s) HIV, VL, RNA

CDC Pre-Approval Needed **Clement Zeh**
(404) 553-7264
cbz2@cdc.gov
Guoqing Zhang
(404) 718-4268
uwz2@cdc.gov

Supplemental Information Required **Supplemental forms will be provided upon Pre-Approval:**
- Following fields are required to be filled: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested.
- All submitted specimens must include two unique specimen IDs and collection date.

Supplemental Form **ILB-160-F08E Viral Load-EID Requisition Form. Contact CDC POC to request form.**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Plasma or dried blood spots (DBS)

Minimum Volume Required Plasma: 1.1mL plasma (3mL ideally)

DBS: At least 3 saturated 13mm circles (preferably 5) containing 70 $\hat{1}$ /₄L of whole blood including capillary blood obtained by venipuncture or finger/toe/heel stick which is dropped directly onto the DBS card

Collection, Storage, and Preservation of Specimen Prior to Shipping The appropriate anticoagulant for whole blood collection is EDTA.

Fresh whole blood may be held at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours. After centrifugation, plasma may be stored at 15-30 °C for up to 24 hours and at 2-8 °C for up to 5 days. Plasma may be frozen at -70 °C or colder. Freeze-thaw cycles should be avoided and should not exceed 3 cycles.

Dried blood spots should be kept at an ambient temperature (15 °-35 °C) for storage and shipment if testing is performed within 14 days or frozen at -70 °C if testing is not performed within 14 days.

Transport Medium None

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g. patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Plasma: Refer to Plasma Shipment information on page 4 of International Laboratory Branch Test Directory or contact CDC POC prior to submission. Plasma specimens should be submitted in 1.5-2.0 mL polypropylene tubes, screw cap with O-ring. To maintain temperature of -20 °C or colder, plasma specimens should be shipped on dry ice.

DBS: Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact CDC POC prior to submission. DBS should be shipped in gas impermeable bags with desiccant and humidity indicator cards. For shipments that are in transit for up to 14 days, maintain at ambient temperature (15-35 °C) and shipments that are in transit for greater than 14 days, maintain temperature at -20 °C or colder with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 96
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Quantitative Polymerase Chain Reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Do not use heparin as an anticoagulant. Do not use specimens after more than 5 freeze-thaw cycles for the Roche assays and 3 freeze-thaw cycles for the Abbott m2000 assay. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	Contact CDC POC for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing.
NOTE: If a specific testing platform is required, please contact CDC POC.	

CDC Points of Contact Clement Zeh
(404) 553-7264
cbz2@cdc.gov
Guoqing Zhang
(404) 718-4268
uwz2@cdc.gov

Version 1.6

Test Order
HIV-1 Rapid Recency Assay
CDC-10541

Synonym(s) Recent Infection, Rapid Point-of-Care Assay, Immunoassay, Lateral Flow, Incidence, International only

CDC Pre-Approval Needed **Ernest Yufenyuy**
404-639-1548
yod0@cdc.gov
Trudy Dobbs
404-639-3760
Tld3@cdc.gov

Supplemental Information Required **Supplemental forms will be provided upon Pre-Approval. Following fields are required: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested. All submitted specimens must include two unique specimen identifiers and collection date.**

Supplemental Form ILB-160-F08B HIV Serology Requisition Form

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Plasma, Serum

Minimum Volume Required Plasma: 0.5 mL (2 mL preferred) Serum: 0.5 mL (2 mL preferred)

Collection, Storage, and Preservation of Specimen Prior to Shipping

Whole blood should be processed into plasma or serum within 24 hours. Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at -20°C or colder.

For plasma whole blood collection, blood can be collected in EDTA anticoagulant tubes.

Transport Medium Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at -20°C or colder.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 100
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Lateral flow rapid test
Turnaround Time	8 Weeks
Interferences & Limitations	Determination of HIV-1 incidence for surveillance purposes only. Persons with diagnosis of AIDS or low CD4+ T cell counts (<200 cells per µl), recipients of anti-retroviral therapy, and known elite controllers should be excluded from the study populations to reduce the likelihood of misclassification of recency of infection. The Rapid Test for Recent Infection (RTRI) does not distinguish between HIV-1 and HIV-2. HIV-2 positive specimens should be excluded from recency analysis.
Additional Information	Determination of HIV-1 incidence for surveillance purposes only. Specimen will be rejected for any of the following reasons: improperly labeled, unlabeled, discrepant documentation, no documentation, insufficient quantity, and/or evidence of contamination.
CDC Points of Contact	Ernest Yufenyuy 404-639-1548 yod0@cdc.gov Trudy Dobbs 404-639-3760 Tld3@cdc.gov

Version 1.1

Test Order

HIV-1 Western Blot

CDC-10557

Synonym(s)	HIV-1 serology, HIV-1 antibodies
CDC Pre-Approval Needed	None
Supplemental Information Required	Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum or EDTA-treated plasma
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood can be stored at 2°C to 30°C (do not freeze whole blood) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Separated plasma or serum may be stored at 2-8°C for up to 5 days or ≤ -20°C for long-term storage. Specimen should not have incurred more than 2 freeze-thaw cycles.
Transport Medium	Transport medium is not required
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship separated plasma or serum stored at 2-8 °C on cold packs. Ship frozen serum or plasma specimens on dry-ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	The HIV-1/2 antigen/antibody combination immunoassay, if reactive, is followed by the HIV-1 Western Blot and the HIV-1/2 differentiation supplemental assay.
Turnaround Time	3 Weeks
Interferences & Limitations	Extensive hemolysis may affect test performance. Minimize storage at 18°C to 30°C to preserve p24 antigen reactivity.
Additional Information	Additional plasma or serum may be required for subsequent testing if results were inconclusive.

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov
M Leanne Ward
(404) 639-3265
mrw0@cdc.gov

Version 1.0

Test Order
HIV-1/2 Antibody (International Only) Rapid Test
CDC-10339

Synonym(s) HIV, RT

CDC Pre-Approval Needed Ernest Yufenyuy
(404) 639-1548
yod0@cdc.gov
Keisha Jackson
(404) 639-2547
iqz5@cdc.gov

Supplemental Information Required Specimens must be accompanied with complete requisition form(s).
CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Plasma and serum

Minimum Volume Required Plasma and serum 0.5 mL (2.0 mL recommended)

Collection, Storage, and Preservation of Specimen Prior to Shipping Plasma: The appropriate anticoagulant for whole blood collection is EDTA.
If testing is to be performed within 7 days keep specimen refrigerated at 2-8 °C.
If testing is to be performed after 7 days, keep specimen frozen at -20 °C or colder.

Transport Medium Specimen should be transported in a plastic screw-cap vial

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 100
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Immuno-chromatography

Turnaround Time 13 Weeks

Interferences & Limitations Do not use specimens after more than 5 freeze-thaw cycles. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.

Additional Information Turn around times are dependent on batch specimen:
Batch with less than 200 specimens - within 50 days
Batch with 200-600 - within 70 days
Batch with greater than 600 specimens - within 90 days

CDC Points of Contact Ernest Yufenyuy
(404) 639-1548
yod0@cdc.gov
Keisha Jackson
(404) 639-2547
iqz5@cdc.gov

Version 1.3

Test Order
HIV-1/2 Laboratory Algorithm
CDC-10272

Synonym(s) CDC/APHL HIV Diagnostic Algorithm, HIV Serology Testing with reflex to NAT

CDC Pre-Approval Needed None

Supplemental Information

Required Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum or EDTA-treated plasma.

Minimum Volume Required 2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Whole blood can be stored at 2°C to 30°C (do not freeze whole blood) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used.

Separated plasma may be stored at 2°C to 8°C for up to 3 days or at ≤ -20°C for up to 60 days.

For up to 24 hours after specimen collection, serum tubes containing centrifuged serum may be stored at 2°C to 30°C. After 24 hours, serum may be stored in the serum tube at 2°C to 8°C for up to 3 days. Separated serum may be stored at 2°C to 8°C for up to 3 days, or at -20°C (as per the package insert) for up to 60 days.

Specimen should not have incurred more than 2 freeze-thaw cycles.

Transport Medium Not applicable

Specimen Labeling Testing is subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship separated plasma or serum stored at 2-8 °C on cold packs. Ship frozen serum or plasma specimens on dry-ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 77
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology The HIV-1/2 antigen/antibody immunoassay is followed by an HIV-1/2 differentiation supplemental assay, which may be followed by an HIV-1 RNA amplification (qualitative - CDC-10275).

Turnaround Time 3 Weeks

Interferences & Limitations Extensive hemolysis may affect test performance. Do not exceed 48 hours storage at 18°C to 30°C to preserve p24 antigen reactivity.

Additional Information Additional whole blood EDTA tube may be required for additional testing for CDC testing that yielded inconclusive results.

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov
M Leanne Ward
404-639-3265
mrw0@cdc.gov

Version 3.3

Test Order
HIV-1/2 Serology Diagnostic Algorithm (International Only)
CDC-10338

Synonym(s)	HIV, EIA, WB, ELISA
CDC Pre-Approval Needed	Ernest Yufenyuy (404) 639-1548 yod0@cdc.gov Keisha Jackson (404) 639-2547 iqz5@cdc.gov
Supplemental Information Required	Specimens must be accompanied with complete requisition form(s). Plasma or serum: CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form Dried Blood Spots: Requisition Form
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma, serum and dried blood spots
Minimum Volume Required	Plasma or serum: 0.5 mL (2.0 mL recommended). Dried Blood Spots: 4 saturated paper circles (13 mm filter) (5 recommended) containing 75 µL of whole blood.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma and Dried Blood Spots (DBS): Prepare from EDTA whole blood. Plasma and Serum storage: Store and ship plasma and serum specimens at -20 °C or colder. Dried Blood Spot storage: Separate individual dried blood spot specimen cards using glassine paper and package them into gas impermeable bags with desiccants and humidity indicator card. Store and ship dried blood spots at -20 °C or colder. Contact CDC POC for DBS filter paper card requirements. For shipping, organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID. For shipping, organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID.
Transport Medium	Transport plasma and/or serum in plastic screw-cap vial with O-ring. Dried blood spots should be in gas impermeable plastic bag with desiccant and humidity indicator card and packaged separately.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID prior to shipping.

For serum and plasma shipments that are in transit for up to 7 days, maintain refrigerated temperature. If the serum and plasma shipments are in transit for greater than 7 days, maintain frozen temperature with dry ice.

For DBS shipments that are in transit for up to 14 days, maintain at refrigerated temperature. If the DBS shipments that are in transit for greater than 14 days, maintain frozen temperatures with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 100
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Enzyme Immunoassay, Immunochromatography (Supplemental/Confirmatory Assay), Enzyme-linked Immunosorbent Blot Technique (Western Blot)

Turnaround Time 23 Weeks

Interferences & Limitations Do not use plasma and serum after more than 5 freeze-thaw cycles. Plasma or serum will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.

Dried blood spots will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.

Additional Information Positive results are confirmed by the Supplemental Assay and/or Western Blot. Western Blot with an EIA-positivity has combined specificity of greater than 99.9%.

Testing for EIA, Supplemental Assay and Western Blot is performed in batches and the turnaround times are the following:

- Batch with less than 200 specimens - within 8 weeks
- Batch with 200-600 - within 11 weeks
- Batch with 600 - 1,000 specimens - within 13 weeks
- Batch with greater than 1,000 specimens - within 23 weeks

Contact CDC POC for batches greater than 2,000 specimens.

CDC Points of Contact Ernest Yufenyuy
(404) 639-1548
yod0@cdc.gov
Keisha Jackson
(404) 639-2547
iqz5@cdc.gov

Version 2.1

Test Order
HIV-2 Western Blot
CDC-10273

Synonym(s)	HIV-2 serology, HIV-2 antibodies
CDC Pre-Approval Needed	None
Supplemental Information Required	Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum or EDTA-treated plasma
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood can be stored at 2°C to 30°C (do not freeze whole blood) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Separated plasma or serum may be stored at 2-8°C for up to 5 days or ≤ -20°C for long-term storage. Specimen should not have incurred more than 2 freeze-thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship separated plasma or serum stored at 2-8 °C on cold packs. Ship frozen serum or plasma specimens on dry-ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	The HIV-1/2 antigen/antibody combination immunoassay, if reactive, is followed by the HIV-2 Western Blot and the HIV-1/2 differentiation supplemental assay.
Turnaround Time	3 Weeks
Interferences & Limitations	Extensive hemolysis may affect test performance. Do not exceed 48 hours storage at 18°C to 30°C to preserve p24 antigen reactivity.

Additional Information If testing results are inconclusive, additional plasma or serum may be required for subsequent testing.

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov
M Leanne Ward
(404) 639-3265
mrw0@cdc.gov

Version 4.2

Test Order

Human Herpesvirus 6 Detection and Subtyping

CDC-10266

Synonym(s)	HHV6
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours.</p> <p>Whole blood should be collected in anticoagulant blood collection tubes (EDTA). Refrigerate (2-8°C) whole blood within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower).</p> <p>All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.</p>
Transport Medium	Not applicable.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information None

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 2.3

Test Order
Human Herpesvirus 6 Serology
CDC-10497

Synonym(s) HHV6

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Supplemental Information
Required **None**

Supplemental Form
None

Performed on Specimens From Human

Acceptable Sample / Specimen Type
for Testing Serum and plasma

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation
of Specimen Prior to Shipping Serum or plasma samples may be stored at 4 °C for up to one week and can be shipped overnight on cold packs in well-sealed O-ring vials. If more than a week, store at -20 °C and can be shipped overnight on dry ice in well-sealed O-ring vials.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include
Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Enzyme Linked Immunosorbent Assay (ELISA)

Turnaround Time 7 Days

Interferences & Limitations False positive results may be obtained if samples are excessively lipemic or contaminated by bacteria. False negative results may be obtained if samples are not properly stored after collection.

Additional Information HHV-6 antibody detection method (HHV-6 ELISA) used to detect HHV-6 IgG specific antibodies in human serum or plasma.

The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Version 2.3

Test Order
Human Herpesvirus 7 Detection
CDC-10267

Synonym(s) HHV7

CDC Pre-Approval Needed None

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours.

Whole blood should be collected in anticoagulant blood collection tubes (EDTA or citrate). Refrigerate (2-8°C) whole blood within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower).

All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Transport Medium Not applicable.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information None

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 2.3

Test Order
Human Herpesvirus 8 Detection
CDC-10268

Synonym(s) Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Whole blood or saliva
for Testing

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of
of Specimen Prior to Shipping collection; otherwise specimen should be kept frozen at -20 °C. Whole blood
should be collected in EDTA or citrate tubes.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Ship specimens with cold packs or dry ice as an etiologic agent.
Specimen Handling Requirements
CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Version 2.1

Test Order
Human Herpesvirus 8 Serology
CDC-10269

Synonym(s) Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum and plasma
for Testing

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum or plasma samples may be stored at 4 °C for up to one week and can be shipped overnight on cold packs in well-sealed O-ring vials. If more than a week, store at -20 °C and can be shipped overnight on dry ice in well-sealed O-ring vials.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship specimens with cold packs or dry ice as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 80

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology IgG antibody detected by Immunofluorescence Antibody Assay (IFA)

Turnaround Time 7 Days

Interferences & Limitations None

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Joseph Icenogle
(404) 639-4557
jci1@cdc.gov

Version 2.1

Test Order

Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Testing and Sequence Analysis CDC-10533

Synonym(s) HIV-1

CDC Pre-Approval Needed **Bill Switzer**
(404) 639-0219
bis3@cdc.gov
Hongwei Jia
(404) 639-0233
hbj8@cdc.gov

Supplemental Information Required **A separate form for additional information will be provided after the test request is approved.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum, plasma or whole blood

Minimum Volume Required 1 mL plasma or serum; 10 mL whole blood

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen stability is affected by elevated temperature. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping. Plasma and serum specimens may be stored an additional five days at 2 °C to 8 °C following centrifugation. Plasma and serum specimens may be stored at less than or equal to -20 °C for up to 6 months; however, storage at these temperatures for longer periods has not been fully evaluated.

Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Plasma can be collected using plasma preparation tubes (PPT) or EDTA or ACD. Serum can be collected in serum tubes. Follow sample tube manufacturer's instructions. Shipping of specimens the same day of collection is preferred.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Shipping Instructions which Include Specimen Handling Requirements Ship unprocessed whole blood specimens overnight for next morning delivery at ambient temperature. Shipping of whole blood specimens overnight on wet ice packs is acceptable during periods of high environmental temperatures. If serum or plasma is collected, these specimens should be shipped frozen overnight on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 227
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Nucleic acid (DNA and RNA) amplification and sequence analysis
Turnaround Time	3 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	For RNA testing, separate the plasma or serum by centrifugation and transfer serum or plasma to a polypropylene screw-cap tube with an O-ring for shipment. Freeze (-70 °C is optimal, -20 °C acceptable) sera/plasma as soon as possible after separation (min volume of 1mL of plasma/sera is required, 5 mLs is optimal).
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Hongwei Jia (404) 639-0233 hbj8@cdc.gov

Version 1.0

Test Order
Human Papillomavirus (HPV) Special Study
CDC-10131

Synonym(s)

CDC Pre-Approval Needed **Elizabeth Unger**
(404) 639-3533
eru0@cdc.gov
Gitika Panicker
(404) 639-2269
dhv1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 178
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology To be determined

Turnaround Time

Interferences & Limitations To be determined

Additional Information HPV testing is for surveillance/research studies and needs to be arranged with CDC POC. Assays include a variety of HPV typing and HPV serology platforms.

CDC Points of Contact Elizabeth Unger
(404) 639-3533
eru0@cdc.gov
Gitika Panicker
(404) 639-2269
dhv1@cdc.gov
Troy Querec
(404)639-2864
hep0@cdc.gov

Version 2.0

Test Order
Influenza Antiviral Resistance Detection in Clinical Specimens
CDC-10423

Synonym(s)	Flu, Influenza Drug resistance, Neuraminidase inhibitor, Influenza Resistance testing
CDC Pre-Approval Needed	None
Supplemental Information Required	Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password). Please be sure to include patient's name and date of birth on the CDC 50.34 Specimen Submission form.
Supplemental Form	Influenza Specimen Submission Form. https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Must type/subtype prior to submission. Nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), dual nasopharyngeal/throat swabs (NPS/TS), bronchoalveolar lavage (BAL), bronchial wash (BW), tracheal aspirate (TA).
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens collected shall be promptly transported to the laboratory within 2 hours and frozen at -20 °C or lower. Ship specimens to CDC within 7 days.
Transport Medium	Swabs should be placed in viral transport media. Other specimens can be shipped as collected.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Prior to shipping, notify CDC Influenza Division (fluantiviral@cdc.gov). Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship frozen specimens on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 199 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Pyrosequencing
Turnaround Time	3 Days

Interferences & Limitations Specimens with Ct values above 29 are not recommended for submission or genetic variance can affect test results.

Additional Information Turnaround time may be greater than 3 days during holidays. Testing is not performed on the weekends or on federal holidays. Questions can be directed to fluantiviral@cdc.gov.

CDC Points of Contact Larisa Gubareva
(404) 639-3204
LGubareva@cdc.gov
Juan De La Cruz
(404) 639-0159
JADeLaCruz@cdc.gov

Version 2.2

Test Order

Influenza Molecular Detection in Clinical Specimens

CDC-10421

Synonym(s)	Influenza Real Time PCR, Influenza Diagnostics, Flu
CDC Pre-Approval Needed	None
Supplemental Information Required	Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password). Please be sure to include patient's name and date of birth on the CDC 50.34 Specimen Submission form.
Supplemental Form	Influenza Specimen Submission Form. https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue)
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron [®] , and an aluminum or plastic shaft. Clinical specimens should be transported to the laboratory within less than or equal to 2 hours. Specimens that are to be shipped to CDC should be stored frozen (-20°C or lower) until shipped. May be held for up to 7 days prior to shipping.
Transport Medium	Respiratory specimens must be in viral transport medium (VTM).
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship frozen specimens on dry ice. Urgent specimens can be shipped any time with prior approval from the laboratory. Prior to shipping, notify CDC Influenza Division that you are sending a specimen. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 198 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Real Time PCR, Genetic Sequence Identification, Real-Time Reverse Transcription
- Polymerase Chain Reaction (rRT-PCR), Genetic Sequence Identification Influenza
A (H3)

Turnaround Time 7 Days

Interferences & Limitations Low virus numbers or co-infections can affect test results. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended because it can cause a false-negative result.

Additional Information Specimens requiring additional testing and specimens submitted for surveillance studies will take longer than seven days for results.

CDC Points of Contact Kai-Hui Wu
(404) 639-4508
ckq8@cdc.gov
John Barnes
(404) 639-2434
fzq9@cdc.gov

Version 2.1

Test Order
Influenza Molecular Surveillance
CDC-10545

Synonym(s)	Flu Panels
CDC Pre-Approval Needed	None
Supplemental Information Required	Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password)
Supplemental Form	Influenza Specimen Submission Form. https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Virus isolates, RNA, respiratory clinical specimens (i.e. nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, lower respiratory tract specimens), and others upon consultation with the laboratory.
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron [®] , and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended because it can cause a false-negative result. Clinical specimens should be placed at 4 °C and transported to the laboratory promptly. Specimens received cold that are to be shipped within 48 hours should be stored refrigerated (2 °-8 °C); otherwise specimens should be frozen at or below -70 °C until shipped.
Transport Medium	Swabs must be in viral transport medium
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship extracted RNA and frozen specimens on dry ice. Refrigerated specimens should be shipped on cold packs. Urgent specimens can be shipped any time with prior approval from the laboratory. Prior to shipping, notify CDC Influenza Division that you are sending specimens. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB / STATT Unit 198
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (CDC rRT-PCR Influenza Panels)
Turnaround Time	
Interferences & Limitations	Low virus numbers or co-infections can affect test results.
Additional Information	If there is a need for a report, please contact lab POC to coordinate.
CDC Points of Contact	Kai Wu (404) 639-4508 ckq8@cdc.gov John Barnes (404) 639-2434 fza9@cdc.gov

Version 1.0

Test Order
Influenza Serology
CDC-10424

Synonym(s) Influenza Hemagglutination inhibition assay, Influenza microneutralization assay

CDC Pre-Approval Needed **Min Levine**
(404) 639-3504
mwl2@cdc.gov
Terrence Tumpey
(404) 639-5444
tft9@cdc.gov

Supplemental Information Required **Supplemental form will be supplied upon consultation with laboratory**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Paired Serum; Acute (less than 7 days post symptoms onset) and convalescent (at least 14 days after acute serum collection)

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Should be collected and immediately frozen. Specifics around storage and preservation are supplied on the supplemental form and upon consultation with laboratory.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 82s
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Hemagglutination inhibition assay, Microneutralization assay

Turnaround Time 6 Weeks

Interferences & Limitations Whole blood cannot be used for testing. Lipemic or hemolyzed sera will affect test results.

Additional Information None

CDC Points of Contact Min Levine
(404) 639-3504
mwl2@cdc.gov
Terrence Tumpey
(404) 639-5444
tft9@cdc.gov

Version 1.4

Test Order
Influenza Special Study
CDC-10425

Synonym(s)

CDC Pre-Approval Needed **David Wentworth**
(404) 639-3387
gll9@cdc.gov
Rebecca Kondor
(404) 639-1371
dqy5@cdc.gov

Supplemental Information Required **Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password)**

Supplemental Form **Influenza Specimen Submission Form.**
https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.
ATTN: Angie Foust

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 198
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact John Steel
(404) 718-7843
pdx1@cdc.gov
Larisa Gubareva
(404) 639-3204
lqg3@cdc.gov
Rebecca Kondor
(404) 639-1371
dqy5@cdc.gov

Version 1.6

Test Order
Influenza Surveillance
CDC-10422

Synonym(s)	Flu, Influenza Antigen Characterization
CDC Pre-Approval Needed	None
Supplemental Information Required	Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password)
Supplemental Form	Influenza Specimen Submission Form. https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Respiratory specimens (nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, dual nasopharyngeal/throat swabs, bronchoalveolar lavage, sputum, tracheal aspirate, etc.), virus cultures, and others upon consultation with the laboratory.
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron [®] , and an aluminum or plastic shaft. Ensure that, when transporting human respiratory specimens, all applicable regulations for the transport of etiologic agents are met. Specimens received cold should be stored refrigerated (2-8 °C) for up to 72 hours before processing. Store any residual specimens at or below -70 °C. Although optimal performance is met when testing fresh specimens within 72 hours of collection, performance has been demonstrated with frozen specimens. If testing of a fresh specimen is not possible within 72 hours storage at 2-8 °C, the specimen may be frozen at or below -70 °C and tested at a later time. Specimens received frozen should be stored at or below -70 °C until processing. Store any residual specimens at or below -70 °C.
Transport Medium	Swabs must be in viral transport medium
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship extracted RNA and frozen specimen on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Urgent specimen can be shipped any time with prior approval from the laboratory. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 200
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Hemagglutination Inhibition (HI) test, Virus Culture
Turnaround Time	4 Weeks
Interferences & Limitations	Low virus numbers or co-infections can affect test results. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended because it can cause a false-negative result.
Additional Information	Turn around time may take up to a month if the virus needs to be cultured. Turn around time for isolates may be less than 1 month.
CDC Points of Contact	Wendy Sessions (404) 639-3211 gra6@cdc.gov David Wentworth (404) 639-3387 gll9@cdc.gov

Version 1.4

Test Order

International Infection Control Program (IICP) Special Studies (International Only) CDC-10558

Synonym(s) International Infection Control Program (IICP), Antimicrobial Resistance in Communities and Hospitals (ARCH), Global Action in Healthcare Network (GAIHN), Global Antimicrobial Laboratory & Response Network (GARLRN); Healthcare Associated Infections (HAI)

CDC Pre-Approval Needed **Gillian McAllister**
(404) 639-2283
HAISeq@cdc.gov
Alison Halpin
(404) 639-1776
vif0@cdc.gov

Supplemental Information Required **Contact the CDC POC for pre-approval to send specimens to CDC for testing, to obtain appropriate forms for submission, and to obtain information/materials to assist with the submission process.**

Supplemental Form **The following supplemental forms will be provided after pre-approval for submission: Study-Specific Requisition Form(s) and CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease.**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates: Pure Cultural Isolates of Antimicrobial Resistant Bacteria.
DNA: Extracted Nucleic Acid in Elution Buffer

Minimum Volume Required For isolates: No minimum volume.

For DNA extract: Minimum volume of 50 µL; recommended volume 500 µL. Recommended concentration is 10 ng/µL (20 ng/µL if quantifying with Nanodrop).

Collection, Storage, and Preservation of Specimen Prior to Shipping For isolates: Non-fastidious isolates should be refrigerated (2-8 °C). For all fastidious organisms store at room temperature (15-25 °C).

For DNA: Extracts should be frozen (-15 to -25 °C) within one week post-extraction and protected from repeated freeze thaws. For long-term storage, extractions should be kept frozen (-70°C to -80°C).

Transport Medium For Isolates: Transport refrigerated (2-8 °C) specimens on suitable agar medium. Transport frozen (-25 °C to -15 °C) specimens in TSB plus glycerol.

For DNA: Transport frozen (-80 °C to -15 °C) in elution buffer, with sufficient dry ice for shipping times.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship frozen specimens on sufficient dry ice for shipping times, room temperature specimens at room temperature and refrigerated specimens on ice packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 154
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Amplification and next generation sequencing, phenotypic testing, Disk Diffusion, E-test, Molecular Detection of Antimicrobial Resistance Markers, Broth Microdilution (BMD), Antimicrobial Susceptibility Testing (AST)
Turnaround Time	52 Weeks
Interferences & Limitations	The ability to generate sequences relies primarily on nucleic acid quantity and specimen quality.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Amelia Bhatnagar (404) 639-4786 wmt7@cdc.gov Alison Halpin (404) 639-1776 vif0@cdc.gov Gillian McAllister (404) 639-2283 HAISeq@cdc.gov

Version 1.1

Test Order
Junin Hemorrhagic Fever Testing
CDC-10340

Synonym(s) Argentine Hemorrhagic Fever, AHF, *arenavirus*

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For serology testing, the accepted specimen types are whole blood (EDTA) or
for Testing serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or
of Specimen Prior to Shipping below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70 1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	ELISA, Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Kyasanur Forest Disease Testing
CDC-10341

Synonym(s) KFD

CDC Pre-Approval Needed Trevor Shoemaker
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VSPB Specimen Submission Form.
<https://www.cdc.gov/nceid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For serology testing, the accepted specimen types are whole blood (EDTA) or serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Molecular testing specimens must be placed in plastic screw capped vials, frozen to -70 °C, and sent on dry ice. Serology testing specimens must be kept cold (at or below 4 °C) and shipped with a cold pack, or on dry ice in a plastic tube. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	ELISA
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order
Laguna Hemorrhagic Fever Testing
CDC-10342

Synonym(s) HPS, hanta

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For serology testing, the accepted specimen types are whole blood (EDTA) or
for Testing serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or
of Specimen Prior to Shipping below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	ELISA, Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Lassa Fever Testing
CDC-10343

Synonym(s) *Arenavirus*

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required **See Supplemental Form**

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/nceid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For molecular and/or serology testing the accepted specimen types are whole blood (EDTA) or serum. CDC POC contact is required prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Molecular specimens must be kept refrigerated (2-8°C) for up to 3 days, or frozen (-20°C or below) for up to 2 months. Serology specimens must be kept refrigerated (2- 8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order

Legionella species Detection and Identification from Clinical Specimens or Isolates CDC-10159

Synonym(s) *Legionella pneumophila*, *L. pneumophila*, *Legionella*, Legionnaires' disease, LD, Legionellosis, Pontiac fever

CDC Pre-Approval Needed

legionellalab@cdc.gov (Primary)
Melisa Willby
(404) 639-5479
mwillby@cdc.gov

Supplemental Information None
Required

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing For culture: sputum, fresh lung tissue, bronchial lavage (BAL), bronchial washings, tracheal aspirate, endotracheal tube washes
For molecular characterization: presumptive *Legionella* isolates, sputum, fresh lung tissue, bronchial lavage (BAL), bronchial washings
For urinary antigen testing: urine

Minimum Volume Required 0.2 mL required but 0.5 mL preferred.

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours.

Transport Medium Buffered charcoal yeast extract (BCYE) slants (preferred) or plates for isolates.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen on dry ice (next day delivery). Isolates should be shipped refrigerated with refrigerated or frozen cold packs (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 33
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Culture, Serogrouping, Sequencing, Real-time Polymerase Chain Reaction (PCR), Urinary Antigen Test (UAT)., Specimens and isolates: culture, sequencing, real-time polymerase chain reaction (PCR)

Urine: urinary antigen testing (UAT)

Turnaround Time 4 Weeks

Interferences & Limitations Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping.

Additional Information Pre-approval needed for urinary antigen testing.

CDC Points of Contact legionellalab@cdc.gov (Primary Contact)
404-639-5479
legionellalab@cdc.gov
Melisa Willby
404-639-5479
ghx9@cdc.gov
Jonas Winchell
(404)639-4921
jwinchell@cdc.gov

Version 4.4

Test Order

Legionella species Detection and Identification from Environmental Samples and Isolates

CDC-10160

Synonym(s) *Legionella pneumophila*, *L. pneumophila*, *Legionella*, Legionnaires' disease, LD, Legionellosis, Pontiac fever

CDC Pre-Approval Needed legionellalab@cdc.gov (Primary)

Jonas Winchell
(404) 639-4921
jwinchell@cdc.gov

Supplemental Information Required **None**

Supplemental Form **None**

Performed on Specimens From Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Samples from associated environmental sources and other associated sources and their derived isolates. Consult with CDC POC prior to sending samples.

Minimum Volume Required Consult POC for minimum volume required.

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast Extract (BCYE)] and stored refrigerated at 2-8°C.

Transport Medium Buffered Charcoal Yeast Extract (BCYE) or equivalent slants for isolates

Specimen Labeling Other

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Refrigerated specimens should be shipped on gel ice-packs. Frozen specimens should be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 33
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations

Methodology Culture, Sequencing, Real-time Polymerase Chain Reaction (PCR)

Turnaround Time 4 Weeks

Interferences & Limitations Samples that are not collected, stored, or transported at specified conditions may be rejected by the laboratory

Additional Information None

CDC Points of Contact legionellalab@cdc.gov (Primary Contact)
404-639-5479
legionellalab@cdc.gov
Melisa Willby
404-639-5479
ghx9@cdc.gov
Jonas Winchell (Emergency)
(404)639-4921
jwinchell@cdc.gov

Version 4.4

Test Order
Leishmania species Identification
CDC-10238

Synonym(s) Parasite

CDC Pre-Approval Needed **Leishmania Mailbox**
(404) 718-4175
leishmania@cdc.gov
Sarah Sapp
(404) 718-5227
xyz6@cdc.gov

Supplemental Information **Not Applicable**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Tissue specimens should be placed in a sterile buffered medium (e.g., buffered saline, RPMI, Eagle's growth, Schneider's, Tobie's, etc), kept refrigerated (2-8°C), and promptly sent to CDC by same- or next-day courier for weekday delivery. Tissue stored beyond 7 days should be frozen at or below -20°C for up to 30 days. Blood and bone marrow specimens must be kept refrigerated (2-8°C) and shipped within 7 days of collection.

Transport Medium Unpreserved tissue specimens should be transported in a sterile buffered medium (e.g., buffered saline, RPMI, Eagle's growth, Schneider's, Tobie's, etc). EDTA-treated (purple top) whole blood and bone marrow do not require transport medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent. Samples stored refrigerated are to be shipped in insulated shipping containers with frozen cold packs. Frozen samples shall be shipped frozen on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 52
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Conventional and Real-time Polymerase Chain Reaction (PCR) and Sanger sequencing

Turnaround Time 2 Weeks

Interferences & Limitations

Formalin-fixed specimens are not suitable for this test order. Please see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov regarding testing of formalin-fixed specimens.

Additional Information Please contact leishmania@cdc.gov for pre-approval first before contacting the secondary POC

CDC Points of Contact Sarah Sapp
(404) 718-5227
leishmania@cdc.gov
Yvonne Qvarnstrom
(404) 718-2120
leishmania@cdc.gov

Version 4.8

Test Order
Leishmaniasis Serology
CDC-10463

Synonym(s)	Leishmaniasis Serology, Visceral leishmaniasis, Kala azar; <i>Leishmania donovoni</i> , <i>Leishmania infantum</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 3 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Antibody detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested. Please contact Leishmania POC.

CDC Points of Contact Leishmania Mailbox
(404) 718-4175
leishmania@cdc.gov
Katie Bowden
404-718-4100
wzi1@cdc.gov

Version 4.7

Test Order
Leptospira species Identification and Genotyping
 CDC-10199

Synonym(s)	Leptospirosis
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Cultured isolates in appropriate media (see transport medium) or appropriate media (see transport medium) inoculated with clinical specimen (whole blood, tissue, or urine)
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Culture should be stored between 20-30 °C.
Transport Medium	Isolates need to be shipped on Ellinghausen-McCullough-Johnson-Harris (EMJH) semisolid media.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>Cultures should be shipped at room temperature.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state, and federal regulations.</p>
Methodology	Pulsed field gel electrophoresis (PFGE), Polymerase Chain Reaction (PCR), Microscopy, 16S-rRNA sequencing, Whole Genome Sequencing (WGS)
Turnaround Time	24 Weeks
Interferences & Limitations	None
Additional Information	Turnaround time varies but may take a maximum of 6 months due to slow growth of <i>Leptospira</i> .

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Version 2.2

Test Order
Leptospira species Molecular Detection
CDC-10200

Synonym(s) Leptospirosis, PCR

CDC Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Whole blood, serum, urine, cerebral spinal fluid (CSF)

Minimum Volume Required 0.25 mL (CSF, serum, and whole blood) and 2 mL (urine)

Collection, Storage, and Preservation of Specimen Prior to Shipping Blood, serum, or CSF: refrigerated (2-8°C) for up to 14 days post- collection and frozen (-20°C or lower) for up to 28 days. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin).

Urine: refrigerated (2-8°C) for up to 3 days post-collection and frozen (-20°C or lower) for up to 28 days.

All specimens cannot to exceed 3 freeze/thaw cycles

Transport Medium Transport medium is not required.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Heparin may cause interference with the molecular tests and should be avoided.

Additional Information None

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Version 1.7

Test Order
Leptospira species Serology
CDC-10201

Synonym(s)	Leptospirosis serology, MAT, microagglutination test
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Paired serum samples is preferred (acute: during active stage of illness; convalescent: 2-4 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 7 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Microagglutination test (MAT)
Turnaround Time	2 Weeks
Interferences & Limitations	Plasma is not an acceptable specimen. Hemolysis can interfere with testing.
Additional Information	None

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Version 1.5

Test Order
Leptospira species Study
CDC-10202

Synonym(s)

CDC Pre-Approval Needed **Renee Galloway**
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 91
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Zoonoses and Select Agent Labo (ZSAL)
(404) 639-1711
ZSAL@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Version 1.2

Test Order
Listeria Identification
CDC-10128

Synonym(s)	<i>Listeria</i>
CDC Pre-Approval Needed	None
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of <i>Listeria</i> ; sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	If isolates are shipped at room temperature or on ice packs, inoculate on nutrient agar or non-selective similar agar (trypticase soy agar, brain heart infusion agar, chocolate agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 20 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification
Turnaround Time	13 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Christine Lee
(404) 498-2295
pfx6@cdc.gov

Version 1.3

Test Order
Listeria monocytogenes Identification and Subtyping
 CDC-10129

Synonym(s) *Listeria* Typing

CDC Pre-Approval Needed None

Supplemental Information Required Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Listeria monocytogenes*; sequence data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium If isolates are shipped at room temperature or on ice packs, inoculate on nutrient agar or non-selective similar agar (trypticase soy agar, brain heart infusion agar, chocolate agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 20
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Genetic Identification and Subtyping

Turnaround Time 13 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Christine Lee
(404) 498-2295
pfx6@cdc.gov

Version 1.4

Test Order
Listeria Study
CDC-10130

Synonym(s)

CDC Pre-Approval Needed Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Christine Lee
(404) 498-2295
pfx6@cdc.gov

Supplemental Information Required Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates, Sequence Data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 20
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Refer to study protocol for specific requirements.

Turnaround Time

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information Refer to study protocol for specific requirements.

CDC Points of Contact Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Christine Lee
(404) 498-2295
pfx6@cdc.gov

Version 2.2

Test Order
LRN Biothreat Multi-Agent Screening - Environmental
CDC-10430

Synonym(s)	Screening for <i>Bacillus anthracis</i> , <i>Brucella spp.</i> , <i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> , <i>Francisella tularensis</i> , <i>Yersinia pestis</i> , Orthopoxvirus, and ricin toxin.
CDC Pre-Approval Needed	Jennifer Thomas (404) 639-4259 fsu8@cdc.gov Nazia Kamal (404) 639-4733 ird7@cdc.gov
Supplemental Information Required	Please contact Dr. Jennifer Thomas at (404) 639-4259 or fsu8@cdc.gov, for the required supplemental form and packaging and shipping requirements.
Supplemental Form	None
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Bulk sampling of visible materials (e.g., powders, liquids, etc.) and/or sampling from contaminated surfaces (e.g., with polyester swabs).
Minimum Volume Required	Dependent on Specimen Type
Collection, Storage, and Preservation of Specimen Prior to Shipping	Dry swabs or powders can be stored and shipped at room temperature. Liquid samples should be held and shipped at 4 °C.
Transport Medium	None
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. If weekend delivery is necessary, please contact laboratory upon shipment. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 49A 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real Time PCR, Culture Isolation, Time-Resolved Fluorescence
Turnaround Time	7 Days
Interferences & Limitations	Dependent on sample type
Additional Information	Turnaround time is dependent on test and sample type.

CDC Points of Contact Jennifer Thomas
(404) 639-4259
fsu8@cdc.gov
Nazia Kamal
(404) 639-4733
ird7@cdc.gov

Version 3.3

Test Order
Lymphocytic Choriomeningitis (LCM) Testing
CDC-10345

Synonym(s) LCM, *Arenavirus*

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/nceid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For molecular and/or serology testing the accepted specimen types are whole
for Testing blood (EDTA), serum, or cerebral spinal fluid (CSF). CDC POC contact is required
prior to sending any specimens.

Animal specimens or human research specimens may be submitted with
approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Molecular specimens must be kept refrigerated (2-8°C) for up to 3 days,
of Specimen Prior to Shipping or frozen (-20°C or below) for up to 2 months. Serology specimens must be kept
must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for
up to 2 months. See link to supplemental submission form for specific
information on various specimen types. Contact the CDC POC for approval prior
to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens.
Testing subject to CLIA regulations requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order
Machupo Hemorrhagic Fever Testing
CDC-10347

Synonym(s) Bolivian Hemorrhagic Fever, BHF, *Arenavirus*

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For serology testing, the accepted specimen types are whole blood (EDTA) or
for Testing serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or
of Specimen Prior to Shipping below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order

Malaria Drug Resistance Surveillance

CDC-10235

Synonym(s)	Malaria Drug Resistance typing, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	Please provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: The patient's travel and treatment history, if available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood collected in EDTA tubes
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store collected specimen refrigerated at 4 °C until shipped to CDC, preferably within 7 days of collection.
Transport Medium	Transport medium not applicable.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	<p>Ship specimen at ambient temperature.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 221 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Polymerase Chain Reaction (PCR), DNA Sequencing, In-vitro culture
Turnaround Time	26 Weeks
Interferences & Limitations	No signs of interference or limitations are currently known.

Additional Information Please use (770) 488-7788 and/or nciddpdmalaria@cdc.gov as your first option for requesting testing or additional information for Malaria diagnostic testing.

The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient. Please contact us if the results are required sooner than the proposed turnaround time.

CDC Points of Contact Christina Carlson
(404) 718-7923
okq1@cdc.gov
Edlin Talundzic
(404) 718-4403
etalundzic@cdc.gov
Dragan Ljolje
(404) 718-1480
dljolje@cdc.gov
Venkatachalam Udhayakumar
(404) 718-4418
vxu0@cdc.gov

Version 5.2

Test Order
Malaria Molecular Identification
CDC-10480

Synonym(s)	<i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	Submit the blood smear slides with the whole blood, each with their own 50.34. Microscopy examination of blood smears is mandatory prior to performing molecular detection.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Storage conditions before shipment: Specimens should be stored in leak-proof containers and kept refrigerated (2-8°C) until shipment within 7 days of collection. Specimens not meeting these conditions will not be accepted for testing, and a new specimen will be required.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping conditions: All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent and shall remain refrigerated with refrigerated or frozen cold packs and received at CDC within 7 days of collection.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Conventional and Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Provide country of travel on specimen submission form. For questions about submitting specimens email dpx@cdc.gov . For malaria diagnostic options and related clinical questions call the Malaria Hotline: (770) 488-7788.

CDC Points of Contact Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
Theresa Benedict
(404) 718-4124
tgd5@cdc.gov

Version 4.2

Test Order
Malaria Serology
CDC-10464

Synonym(s) *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium malariae*, parasite

CDC Pre-Approval Needed **Malaria Hotline**
(770) 488-7788
ncicdpdmalaria@cdc.gov
Francisca Abanyie
(404) 718-4775
why6@cdc.gov

Supplemental Information **CDC 50.34 Specimen Submission Form must include travel history**
Required (REQUIRED) and other relevant risk factors; clinical symptoms, treatment
and relevant lab results.

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 57
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Indirect Fluorescent Antibody Assay, Antibody Detection

Turnaround Time 3 Weeks

Interferences & Limitations Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin

Additional Information Please use (770) 488-7788 and/or nciddpdmalaria@cdc.gov as your first option for requesting testing or additional information for Malaria diagnostic testing.

Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.7

Test Order
Malaria: Morphologic Identification
CDC-10520

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Thick and/or thin blood films (stained or unstained) (Preferred), EDTA-treated whole blood
Minimum Volume Required	N/A
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stained and unstained blood films may be air-dried or fixed and stored at room temperature (15-25°C) prior to submission. Whole blood must be collected in unexpired, EDTA-treated vacutainer tubes and refrigerated at 2-8°C prior to shipment. Whole blood must be received no more than 3 days post collection to be acceptable for morphologic analysis.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>Shipping is specimen specific and available on consultation.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	Provide country of travel on specimen submission form. For questions about submitting specimens please email dpdx@cdc.gov. For malaria diagnostic options and related clinical questions call the Malaria Hotline: (770) 488-7788.

CDC Points of Contact DPDx
(404) 718-4120
dpdx@cdc.gov
Sarah Sapp
(404) 718-5227
xyz6@cdc.gov

Version 3.3

Test Order
Marburg Hemorrhagic Fever Testing
CDC-10349

Synonym(s)

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For molecular and/or serology testing the accepted specimen types are whole blood (EDTA) or serum. CDC POC contact is required prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Measles Avidity
CDC-10248

Synonym(s) Rubeola

CDC Pre-Approval Needed **Sara Mercader**
(404) 639-4568
sjm7@cdc.gov
Stephen Crooke
(404) 718-4003
qjf9@cdc.gov

Supplemental Information Required **CDC 50.34 Specimen Submission Form. Provide the following information: date of birth, date of onset, date of specimen collection, date(s) of MMR vaccination, clinical symptoms, and travel history. Provide any preliminary results available.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum.
Samples must be measles IgG positive for testing. IgG status will be confirmed by additional testing at CDC.

The following conditions may result in the specimen being rejected for testing:

- Specimen is measles IgG negative.
 - Specimen is not frozen upon receipt at CDC.
 - Specimen is hemolyzed, lipemic, or bacterially contaminated.
-

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal.

Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for avidity testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 2 weeks prior to shipping.

Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Measles IgG avidity

Turnaround Time 4 Weeks

Interferences & Limitations

Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with measles vaccine. If obtained, intermediate avidity results are not interpretable.

Additional Information The measles avidity assay is a specialized tool that may help with confirmation of suspect cases with RT-PCR-negative results or with questionable IgM results (false positive or false negative results are suspected). However, avidity results cannot rule out cases. Avidity testing can also help in vaccine failure classification.

For additional information, see: <https://www.cdc.gov/measles/lab-tools/serology.html> and <https://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html>

CDC Points of Contact Sara Mercader
(404) 639-4568
sjm7@cdc.gov
Stephen Crooke
(404) 718-4003
qjf9@cdc.gov

Version 1.7

Test Order
Measles Detection
CDC-10543

Synonym(s)	Rubeola
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, throat swabs, urine
Minimum Volume Required	50 mL urine 0.2 mL (nasopharyngeal swabs, throat swabs); 2 mL preferred (nasopharyngeal swabs, throat swabs)
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Detection of measles RNA is most successful when samples are collected on the first day of rash through the 3 days following onset of rash. Detection of measles RNA by RT-PCR may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected. RT-PCR has the greatest diagnostic sensitivity when samples are collected at first contact with a suspected case.</p> <p>Nasopharyngeal swabs and throat swabs: Commercial swab products designed for the collection of throat specimens or flocked polyester fiber swabs are preferred. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Throat and nasopharyngeal swab specimens should be stored at 2-8°C immediately after collection and should preferably be frozen at -70°C or lower within 1 hour after collection. If laboratories do not have immediate access to a freezer and storage at -70°C or lower is not feasible within 1 hour of collection, these specimens may be stored for up to 72 hours at 2-8°C before freezing. Freezing at -20°C or lower is acceptable if the laboratory is unable to freeze at -70°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen either at -70°C or -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 5 days of being frozen at -70°C or -20°C or lower.</p> <p>Urine: 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens should arrive at CDC within 5 days of specimen collection. Urine cannot be frozen.</p>
Transport Medium	For nasopharyngeal swabs and throat swabs: Standard viral transport medium (VTM). Transport medium is not required for urine.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Reverse transcription real-time PCR (RT-qPCR) , real-time reverse-transcription polymerase chain reaction (RT-PCR) assay

Turnaround Time 7 Days

Interferences & Limitations Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in RT-PCR. Non-Flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently. A negative result should not be used to rule out measles infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB).

Additional Information For additional information regarding laboratory testing, please see the laboratory testing section in the measles surveillance manual: <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html>. For information about molecular diagnostics, see the CDC Measles Webpage: <https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics>

CDC Points of Contact Paul Rota
404-639-4181
par1@cdc.gov
Bettina Bankamp
404-639-1242
bfb9@cdc.gov

Version 1.2

Test Order
Measles Genotyping
CDC-10240

Synonym(s)	Rubeola
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, nasal swabs, throat swabs, urine, and viral isolates
Minimum Volume Required	50 mL for urine, 0.2 mL (preferred 2 mL) for all other specimen types
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>For nasopharyngeal swabs, nasal swabs, and throat swabs: Commercial swab products designed for the collection of throat specimens or flocked polyester fiber swabs are preferred. Swabs should be placed in 2 mL of standard viral transport medium (VTM) . Allow the swab to remain in VTM for at least 1 hour at 4 °C. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab can be broken off and left in the tube or discarded. Following collection, samples should be maintained at 4 °C and shipped on cold packs (4 °C) within 24 hours. If there is a delay in shipment, the sample is best preserved by freezing at -70 °C. Frozen samples should be shipped on dry ice.</p> <p>For urine: A minimum volume of 50 mL of urine should be collected in a sterile container and then processed by centrifuging at 2500 x g for 15 minutes at 4 °C. The sediment should be resuspended in 2 mL of VTM. Store urine sediment in VTM at 4 °C and, if possible, ship on cold packs within 24 hours. The best method for preserving measles virus in processed (centrifuged) urine is to freeze the sample at -70 °C and ship on dry ice.</p> <p>For isolates: An aliquot should be frozen at -70 °C and shipped on dry ice.</p>
Transport Medium	Standard viral transport medium (VTM). As a substitute to VTM, cell culture medium (minimal essential medium or Hanks' balanced salt solution) or other sterile isotonic solution (e.g. phosphate buffered saline) can be used. The presence of protein, for example 1% bovine albumin, 0.5% gelatin, or 2% serum, stabilizes the virus and can be added to the cell culture medium.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Reverse transcription PCR (RT-PCR), genotyping by nucleic acid sequencing, viral culture
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Turnaround Time	7 Days
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Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity.
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Commercial products designed for the collection of throat specimens or a flocculated polyester fiber swab can be used. Synthetic swabs are preferred over cotton swabs, which may contain substances that are inhibitory to enzymes used in RT-PCR. Flocculated synthetic swabs appear to be absorbent and elute samples more efficiently.

Samples without a source of protein in the medium will lose 90%-99% infectivity within 2 hours at 4 °C.

Additional Information	For additional information regarding laboratory testing, please see the measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html in the laboratory testing section
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For information about molecular diagnostics, see the CDC Measles Webpage: <https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics>

CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Bettina Bankamp (404) 639-1242 bfb9@cdc.gov
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Test Order
Measles Neutralization Antibody (Not for Immune Status)
CDC-10250

Synonym(s)	Rubeola, PRN test, Plaque-reduction neutralization
CDC Pre-Approval Needed	Carole Hickman (404) 639-3339 cjh3@cdc.gov Sun Sowers (404) 639-1360 sib9@cdc.gov
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: date of birth, date of onset, date of specimen collection, date(s) of MMR vaccination, clinical symptoms and travel history. Provide any preliminary results available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate serum promptly after collection. If serum specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on gel ice-packs. Freezing should be avoided if possible. If specimens must be held for >72 hours, they should be frozen at -20 °C and shipped on dry ice.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Neutralization assay - quantitative serological assay
Turnaround Time	4 Weeks
Interferences & Limitations	There are no known interferences and limitations.

Additional Information For additional information related to specialized serologic testing at CDC, see <https://www.cdc.gov/measles/lab-tools/serology.html>.

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Version 1.2

Test Order
Measles Serology
CDC-10244

Synonym(s) Rubeola

CDC Pre-Approval Needed None

Supplemental Information Required **Provide the following information on CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination (if known) and travel history. Provide any preliminary results available.**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum.
The following conditions may result in the specimen being rejected for testing:

- Specimen is hemolyzed, lipemic, or bacterially contaminated.
- Specimen is not frozen upon receipt at CDC.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal.

Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 2 weeks prior to shipping.

Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as a medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA
Turnaround Time	7 Days
Interferences & Limitations	IgM positive may not occur until 4 days post-rash onset
Additional Information	IgM and IgG assays are qualitative assays. Include vaccination history, age, date of onset and sample collection.

CDC Points of Contact Stephen Crooke
(404) 718-4003
qjf9@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Version 2.2

Test Order
Measles Special Study
CDC-10251

Synonym(s) Rubeola

CDC Pre-Approval Needed **Stephen Crooke**
(404) 718-4003
qjf9@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum
for Testing

Minimum Volume Required 0.3 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate serum promptly after collection. If serum specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on gel ice-packs. Freezing should be avoided if possible. If specimens must be held for >72 hours, they should be frozen at -20 °C and shipped on dry ice.

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA, or plaque reduction neutralization assay or IgG avidity

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Stephen Crooke
(404) 418-4003
qjf9@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Version 1.5

Test Order
Measles Vaccine Virus Detection
CDC-10528

Synonym(s) Rubeola

CDC Pre-Approval Needed **Paul Rota**
(404) 639-4181
par1@cdc.gov
Bettina Bankamp
(404) 639-1242
bfb9@cdc.gov

Supplemental Information Required **A CDC 50.34 Specimen Submission Form for each individual specimen.**
Please include date of vaccination and date of rash onset.

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Nasopharyngeal swabs, throat swabs, urine

Minimum Volume Required 50 mL urine
0.2 mL (nasopharyngeal swabs, throat swabs); 2 mL preferred (nasopharyngeal swabs, throat swabs)

Collection, Storage, and Preservation of Specimen Prior to Shipping Detection of measles RNA is most successful when samples are collected on the first day of rash through the 3 days following onset of rash. Detection of measles RNA by RT-PCR may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected. RT-PCR has the greatest diagnostic sensitivity when samples are collected at first contact with a suspected case.

Nasopharyngeal swabs and throat swabs: Commercial swab products designed for the collection of throat specimens or flocked polyester fiber swabs are preferred. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Throat and nasopharyngeal swab specimens should be stored at 2-8°C immediately after collection and should preferably be frozen at -70°C or lower within 1 hour after collection. If laboratories do not have immediate access to a freezer and storage at -70°C or lower is not feasible within 1 hour of collection, these specimens may be stored for up to 72 hours at 2-8°C before freezing. Freezing at -20°C or lower is acceptable if the laboratory is unable to freeze at -70°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen either at -70°C or -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 5 days of being frozen at -70°C or -20°C or lower.

Urine: 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens should arrive at CDC within 5 days of specimen collection. Urine cannot be frozen.

Transport Medium	For nasopharyngeal swabs and throat swabs: Standard viral transport medium (VTM). Transport medium is not required for urine.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	Reverse transcription real-time PCR, real-time reverse-transcription polymerase chain reaction (RT-PCR) assay
Turnaround Time	7 Days
Interferences & Limitations	<p>Specimens must remain frozen; warming or freeze thawing reduces sensitivity.</p> <p>Commercial products designed for the collection of throat specimens or a flocked polyester fiber swab can be used. Synthetic swabs are preferred over cotton swabs, which may contain substances that are inhibitory to enzymes used in RT-PCR. Flocked synthetic swabs appear to be absorbent and elute samples more efficiently.</p> <p>A negative result should not be used to rule out measles infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB).</p>
Additional Information	<p>This assay specifically detects measles vaccine strains and must be performed in parallel with the existing Measles Detection and Genotyping (CDC-10240). It should only be performed on specimens collected from patients that have potentially been exposed to wild-type virus OR may have a suspect vaccine reaction due to a recently administered vaccination (i.e., within 21 days of measles containing vaccine). Vaccination history is required.</p> <p>For additional information, please see the measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html and the CDC measles webpage for information about molecular diagnostics https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics</p>

CDC Points of Contact Paul Rota
(404) 639-4181
par1@cdc.gov
Bettina Bankamp
(404) 639-1242
bfb9@cdc.gov

Version 2.2

Test Order
MERS-CoV Molecular Detection
CDC-10488

Synonym(s) MERS-CoV PCR, Middle East Respiratory Syndrome Coronavirus PCR

CDC Pre-Approval Needed **Everardo Vega**
(404) 639-2396
evega@cdc.gov
Hannah Kirking
(404) 718-8345
hrj7@cdc.gov

Supplemental Information Required **See Supplemental Form**

Supplemental Form <http://www.cdc.gov/coronavirus/mers/downloads/MERS-investigation-short-form.pdf>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate or freeze tubes after specimens are placed in them. If specimens will be examined within 48 hours after collection, they can be refrigerated. If specimens must be held longer than 48 hours, freeze them as soon as possible after collection. Although storage in an ultra-low freezer (-70 °C) is preferable, storage in a home-type freezer (if properly set at -20 °C) is acceptable for short periods.

<http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html> _ _
<http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html>

Transport Medium Swabs may be shipped in commercial viral transport media

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 84
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

See the following link for additional shipping information:
<http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html>

Methodology	Polymerase Chain Reaction (PCR), Sequencing
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Turnaround Time	2 Weeks
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Interferences & Limitations	Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of MERS-CoV specimens are NOT recommended at this time. However, if done, these activities must be performed in a BSL-3 facility using BSL-3 work practices.
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Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocked swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.

Additional Information	http://www.cdc.gov/coronavirus/mers/index.html , http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html , http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html
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CDC Points of Contact	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov
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Version 2.4

Test Order
Microsporidia Molecular Identification
CDC-10481

Synonym(s)	<i>Anncaliia</i> , <i>Encephalitozoon cuniculi</i> , <i>Encephalitozoon hellem</i> , <i>Encephalitozoon intestinalis</i> , <i>Septata intestinalis</i> , <i>Tubulinosema</i> , <i>Enterocytozoon bieneusi</i> , <i>Nosema</i> , <i>Pleistophora</i> , <i>Trachipleistophora</i> , <i>Vittaforma corneae</i> , <i>Nosema corneum</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 g (stool) or 1 mL (urine) or 25 mg (tissue)
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Specimens shall be stored in leak-proof container and kept:</p> <p>Stool samples in PCR-compatible fixative, i.e. TotalFix, UniFix, EcoFix or modified PVA (Zn- or Cu-based) can be kept at room temperature (about 15-25°C) for up to 7 days. Unpreserved stool specimens can be stored refrigerated when specimens will be received at CDC within 7 days of collection. Store unpreserved specimens frozen at or below -20 °C when specimens will be received at CDC after more than 7 days after collection.</p> <p>Tissue, aspirates, BAL, CSF, eye fluid, and urine can be refrigerated at 2-8°C when specimens will be received by CDC within 7 days of collection. Tissue, aspirates, BAL, CSF, eye fluid, and urine can be frozen at or below -20°C, when specimens will be received by CDC at more than 7 days from day of collection.</p> <p>Specimens not meeting these conditions will not be accepted for testing, and a new specimen will be required.</p>
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping conditions: All specimens shall be shipped to CDC by same- or next-day courier as an etiologic agent:
a. refrigerated specimens: shall remain refrigerated with refrigerated or frozen cold packs, and received at CDC within 7 days of collection
b. frozen specimens: shall remain frozen (with dry ice) until received at CDC
c. preserved/fixed stool specimens: shall be shipped at room temperature with room-temperature cold packs and received at CDC within 7 days of collection.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 52
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Conventional Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations

Stool specimens fixed in formalin-containing preservatives or low viscosity polyvinyl-alcohol (LV-PVA) are not suitable for this test order. For testing of formalin-fixed paraffin embedded (FFPE) tissue, see Test Order #CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.

Additional Information None

CDC Points of Contact Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
Theresa Benedict
(404) 718-4124
tgd5@cdc.gov

Version 2.6

Test Order
***Moraxella* species Identification**
CDC-10140

Synonym(s)	<i>Moraxella</i> , GNDC
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
MPIR - Study
CDC-10428

Synonym(s) Anthrax TNA

CDC Pre-Approval Needed **Jarad Schiffer**
(404) 639-0894
aku3@cdc.gov
Han Li
(404) 639-1306
hbl1@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type Paired acute and convalescent sera
for Testing

Minimum Volume Required 200 $\frac{1}{4}$ L

Collection, Storage, and Preservation Serum should be separated from whole blood and kept at -80 °C
of Specimen Prior to Shipping

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition, as well as the date of collection.

Shipping Instructions which Include Ship paired sera together and all frozen specimen should be shipped on dry ice.
Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Contact laboratory prior to shipment.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit MPIR
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Cell Based Serological Assay

Turnaround Time 2 Weeks

Interferences & Limitations Prefer non-hemolyzed specimen and non-lipemic specimen. If they are hemolyzed or lipemic, the specimen will not be tested. Plasma specimen are not accepted. Do not store or send specimen in tubes with preservatives or cell growth inhibitors.

Additional Information Ensure submitter information is included on the test requisition form.

CDC Points of Contact Jarad Schiffer
(404) 639-0894
aku3@cdc.gov
Rita Desai
(404) 639-3887
rwd7@cdc.gov
Han Li
(404) 639-1306
hbl1@cdc.gov

Version 2.1

Test Order
Multipathogen Respiratory Panel (Molecular Detection)
CDC-10526

Synonym(s)	TaqMan [®] Array Card, TAC, Community acquired pneumonia, CAP, respiratory pathogens
CDC Pre-Approval Needed	Jonas Winchell (404) 639-4921 jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Combined upper respiratory swabs (Nasopharyngeal (NP) and Oropharyngeal (OP)), aspirates, or sputum are the preferred specimen types. Bronchoalveolar lavage (BAL), lung tissue, cerebrospinal fluid (CSF), pure culture isolates, and purified nucleic acid are also acceptable. Other specimen types may be acceptable upon consultation with POC.
Minimum Volume Required	0.2 mL (viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF)); 0.4 mL preferred 0.1 mL (purified nucleic acid)
Collection, Storage, and Preservation of Specimen Prior to Shipping	For nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inhibit some molecular assays (See "Interferences & Limitations"). Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral or universal transport media (VTM, UTM). Tissue should be frozen promptly upon collection. All other specimens should be refrigerated at 4 °C if shipped within 72 hours of collection; otherwise specimens should be frozen at -20 °C.
Transport Medium	Viral transport medium (VTM) or Universal transport medium (UTM)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Refrigerated specimens should be shipped on gel ice-packs. Frozen specimens
Specimen Handling Requirements should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (PCR) microfluidic array
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	The intended use of this test is for investigation of unexplained respiratory disease outbreaks. Visit www.cdc.gov/urdo for additional information or contact URDOutbreaks@cdc.gov . The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 jwinchell@cdc.gov

Version 2.0

Test Order
Mumps Detection
CDC-10544

Synonym(s)	
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Buccal swabs
Minimum Volume Required	0.2 mL (buccal swabs); 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Collect buccal swabs as soon as mumps disease is suspected. RT-PCR has the greatest diagnostic sensitivity when samples are collected within 3 days of symptom onset. The buccal swabs specimens are obtained by massaging the parotid gland area for 30 seconds prior to swabbing the area around Stensen's duct.</p> <p>A commercial product designed for the collection of throat specimens or a flocced polyester fiber swab can be used. Buccal swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube.</p> <p>Specimens should be stored 2-8°C immediately after collection and should preferably be frozen at -70°C or lower within 1 hour after collection. If laboratories do not have immediate access to a freezer and storage at -70°C or lower is not feasible within 1 hour of collection, specimens may be stored for up to 72 hours at 2-8°C before freezing. Freezing at -20°C or lower is acceptable if the laboratory is unable to freeze at -70°C or lower. Prior to being shipped to CDC, specimens should be frozen either at -70°C or -20°C or lower and shipped overnight to CDC on dry ice. Specimens should arrive at CDC within 5 days of being frozen at -70°C or -20°C or lower.</p>
Transport Medium	Buccal swabs: Standard viral transport medium (VTM).
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Reverse transcription real-time PCR (RTq-PCR) , real-time reverse-transcription polymerase chain reaction (RT-PCR) assay

Turnaround Time 7 Days

Interferences & Limitations Specimens must remain frozen; warming or freeze thawing reduces sensitivity.

Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in RT-PCR. Non-Flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently.

A negative result should not be used to rule out mumps infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB).

Additional Information For additional information, please see the CDC mumps webpages:
<https://www.cdc.gov/mumps/lab/index.html>

CDC Points of Contact Paul Rota
404-639-4181
par1@cdc.gov
Bettina Bankamp
404-639-1242
bfb9@cdc.gov

Version 1.2

Test Order
Mumps Genotyping
CDC-10241

Synonym(s)	
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Buccal swabs, buccal smears, oral swabs, nasal swabs, throat swabs, urine, cerebrospinal fluid (CSF) and viral isolates
Minimum Volume Required	50 mL for urine, 0.2 mL (preferred 2.0 mL) for all other specimen types
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Swabs and smears should be placed in 2 mL of standard viral transport medium (VTM). Allow the swab to remain in VTM for at least 1 hour at 4 °C. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab can be broken off and left in the tube or discarded.</p> <p>For swabs, buccal smears and CSF: Following collection, samples should be maintained at 4 °C and shipped on cold packs (4 °C) within 24 hours. If there is a delay in shipment, the sample is best preserved by freezing at -70 °C. Frozen samples should be shipped on dry ice.</p> <p>For urine: A minimum volume of 50 mL of urine should be collected in a sterile container and then processed by centrifuging at 2500 x g for 15 minutes at 4 °C. The sediment should be resuspended in 2 mL of VTM. Store urine sediment in VTM at 4 °C and, if possible, ship on cold packs within 24 hours. The best method for preserving measles virus in processed (centrifuged) urine is to freeze the sample at -70 °C and ship on dry ice.</p> <p>For isolates: An aliquot should be frozen at -70 °C and shipped on dry ice.</p>
Transport Medium	Standard viral transport medium (VTM). As a substitute, cell culture medium (minimal essential medium or Hanks' balanced salt solution) or other sterile isotonic solution (e.g. phosphate buffered saline) can be used. The presence of protein, for example 1% bovine albumin, 0.5% gelatin, or 2% serum, stabilizes the virus. Samples without a source of protein in the medium will lose 90%-99% infectivity within 2 hours at 4 °C.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Reverse transcription real-time PCR (RTq-PCR), reverse transcription PCR (RT-PCR), genotyping by nucleic acid sequencing, viral culture
Turnaround Time	7 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Commercial products designed for the collection of throat specimens or a flocculated polyester fiber swab can be used. Synthetic swabs are preferred over cotton swabs, which may contain substances that are inhibitory to enzymes used in RT-PCR. Flocculated synthetic swabs appear to be absorbent and elute samples more efficiently. Samples without a source of protein in the medium will lose 90%-99% infectivity within 2 hours at 4 °C.
Additional Information	For additional information, please see the CDC mumps webpages https://www.cdc.gov/mumps/lab/index.html
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Bettina Bankamp (404) 639-1242 bfb9@cdc.gov

Version 3.1

Test Order
Mumps Neutralization Antibody (Not for Immune Status)
CDC-10351

Synonym(s)	PRN test, Plaque-reduction neutralization
CDC Pre-Approval Needed	Sun Sowers (404) 639-1360 sib9@cdc.gov Carole Hickman (404) 639-3339 cjh3@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Paired serum specimens: Acute-phase serum sample (collected as soon as possible upon suspicion of mumps disease) and a second serum sample (collected 5-10 days after symptom onset)
Minimum Volume Required	0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate serum promptly after collection. If serum specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on gel ice-packs. Freezing should be avoided if possible. If specimens must be held for >72 hours, they should be frozen at -20 °C and shipped on dry ice.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Neutralization assay - quantitative serological assay
Turnaround Time	4 Weeks
Interferences & Limitations	There are no known interferences and limitations.

Additional Information For additional information related to specimen collection, storage and shipment, see <https://www.cdc.gov/mumps/lab/specimen-collect.html>.

CDC Points of Contact Sun Sowers
(404) 639-1360
sib9@cdc.gov
Carole Hickman
(404) 639-3339
cjh3@cdc.gov

Version 1.2

Test Order

Mumps Serology

CDC-10245

Synonym(s)	
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum. The following conditions may result in the specimen being rejected for testing: <ul style="list-style-type: none"> • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>If it has been >3 days after symptom onset, blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower).</p> <p>Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal.</p> <p>If the serum sample collected >3 days after parotitis onset is IgM negative, and the case has a negative (or not done) result for RT-PCR, and there is a strong suspicion of mumps a second serum sample collected greater than 5 days after symptom onset is recommended because, in some cases, the IgM response is not detectable until 5 days after symptom onset.</p> <p>Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 2 weeks prior to shipping.</p> <p>Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.</p>
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	CDC IgM Capture, Commercial indirect IgG
Turnaround Time	7 Days
Interferences & Limitations	Rheumatoid factor, Parainfluenza viruses 1, 2, and 3, Epstein-Barr virus, adenovirus, and Human Herpes Virus 6 have all been noted to interfere with mumps serologic assays.
Additional Information	IgM and IgG assays are qualitative assays Please include vaccination history, age, date of onset and sample collection
CDC Points of Contact	Sun Sowers (404) 639-1360 sib9@cdc.gov Stephen Crooke (404) 718-4003 qjf9@cdc.gov

Version 1.6

Test Order
Mumps Special Study
CDC-10252

Synonym(s)	
CDC Pre-Approval Needed	Stephen Crooke (404) 718-4003 qjf9@cdc.gov Sun Sowers (404) 639-1360 sib9@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate serum promptly after collection. If serum specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on gel ice-packs. Freezing should be avoided if possible. If specimens must be held for >72 hours, they should be frozen at -20 °C and shipped on dry ice.
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA, IgG immunoassay or plaque reduction neutralization assay
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined

CDC Points of Contact Stephen Crooke
(404) 718-4003
qjf9@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Version 1.5

Test Order
***Mycobacterium* TB Complex (International Only) Identification and Drug Susceptibility Testing**
CDC-10352

Synonym(s) Culture, DST, AST, MTB, MDR TB

CDC Pre-Approval Needed **Patricia Hall**
(404) 718-1440
igg5@cdc.gov
Kyle DeGruy
(404) 639-0875
gsz4@cdc.gov

Supplemental Information Required **Contact the CDC POCs 1) for approval to send isolates to CDC for testing, 2) to obtain appropriate forms for submission and 3) to obtain information/materials to assist with the submission process.**

Supplemental Form **The following supplemental forms will be provided after pre-approval for isolate submission: ILB-160-F08C TB Requisition Form and CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of human disease.**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Pure isolates of suspected *Mycobacterium tuberculosis* complex (MTBC)

Minimum Volume Required 0.3 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Store MTBC isolates with or without glycerol in sterile 2.0 mL screw cap cryovials with O-rings. Isolates should be stored at -60 °C to -70 °C until shipped to preserve the viability of MTBC.

Transport Medium Middlebrook 7H9 or *Mycobacterial Growth Indicator Tube* (MGIT) liquid media

Specimen Labeling Research or surveillance isolates may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Store specimens at -60 °C to -70 °C until packed for shipping. Ship specimens in triple packaging and on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 99
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology MGIT 960 SIRE and PZA Drug Susceptibility Testing, GenoType MTBDRplus, GenoType MTBDRsl, GenoType CM, Immunochromatographic Assay, Xpert MTB/RIF, Xpert MTB/RIF Ultra

Turnaround Time 22 Weeks

Interferences & Limitations Testing will not be performed on nonviable, contaminated or mixed isolates.

Additional Information 22 weeks turnaround time for batches with less than 100 isolates. Contact CDC POC for batches greater than 100 isolates. Isolates may be rejected if improperly labeled, missing or discrepant documentation, insufficient volume for testing or leaking containers.

CDC Points of Contact Patricia Hall
(404) 718-1440
igg5@cdc.gov
Kyle DeGruy
(404) 639-0875
gsz4@cdc.gov
Zilma Rey
(404) 639-2345
yxr0@cdc.gov
Mariela Scarbrough
(404) 639-1389
hqz4@cdc.gov

Version 1.4

Test Order
***Mycobacterium* TB Complex - Drug Susceptibility Testing**
CDC-10185

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate or original specimen), the specimen source (type), specimen collection date, and transport medium/specimen preservative (isolates only).
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure <i>Mycobacterium tuberculosis</i> complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Agar proportion, Pyrazinamide (PZA) by MGIT 960
Turnaround Time	6 Weeks

Interferences & Limitations Some isolates of MTB (<5% of submitted isolates) do not grow on the media used for testing. Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated; submitting laboratory may submit a pure culture if clinically needed.

Additional Information On average, TAT times range from 35 to 60 calendar days. Delays may occur due to holidays and unexpected events (e.g., closure of CDC).

CDC Points of Contact TB Lab
(404) 639-2455
TBLab@cdc.gov
Atanaska Marinova Petkova
(404) 639-1285
lxy8@cdc.gov

Version 2.2

Test Order
***Mycobacterium* TB Complex - Identification**
CDC-10187

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate), the specimen source (type), specimen collection date, and transport medium/specimen preservative.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure <i>Mycobacterium tuberculosis</i> complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Genetic based testing
Turnaround Time	4 Weeks
Interferences & Limitations	None

Additional Information None

CDC Points of Contact TB Lab
(404) 639-2455
TBLab@cdc.gov
Atanaska Marinova Petkova
(404) 718-5254
lxy8@cdc.gov

Version 2.2

Test Order
***Mycobacterium* TB Complex - Identification and Drug Susceptibility Testing**
CDC-10188

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate), the specimen source (type), specimen collection date, and transport medium/specimen preservative.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure <i>Mycobacterium tuberculosis</i> complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Genetic based testing, Pyrazinamide (PZA) by MGIT 960, Agar Proportion
Turnaround Time	6 Weeks

Interferences & Limitations Some isolates of MTB (<5% of submitted isolates) do not grow on the media used for susceptibility testing. Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated; submitting laboratory may submit a pure culture if clinically needed.

Additional Information On average, TAT times range from 35 to 60 calendar days. Delays may occur due to holidays and unexpected events (e.g., closure of CDC).

CDC Points of Contact TB Lab
(404) 639-2455
TBLab@cdc.gov
Atanaska Marinova Petkova
(404) 718-5254
lxy8@cdc.gov

Version 2.2

Test Order

Mycobacterium TB Complex - Identification and Pyrazinamide Susceptibility Testing CDC-10190

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate), the specimen source (type), specimen collection date, and transport medium/specimen preservative.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure <i>Mycobacterium tuberculosis</i> complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Pyrazinamide (PZA) by MGIT 960, Genetic based testing
Turnaround Time	4 Weeks

Interferences & Limitations Contaminated samples (i.e., not a pure culture of MTB) for PZA by MGIT 960 are reported as contaminated and additional submission of pure culture may be clinically needed.

Additional Information None

CDC Points of Contact TB Lab
(404) 639-2455
TBLab@cdc.gov
Atanaska Marinova Petkova
(404) 718-5254
lxy8@cdc.gov

Version 2.2

Test Order

Mycobacterium TB Complex - Molecular Detection of Drug Resistance (MDDR) CDC-10186

Synonym(s) MTB DST, TB, Tuberculosis, MTBC

CDC Pre-Approval Needed **TB Lab**
(404) 639-2455
TBLab@cdc.gov
Atanaska Petkova
(404) 718-5254
lxy8@cdc.gov

Supplemental Information Required **Pre-approval is required for this test using the Molecular Detection of Drug Resistance Request Form.**

Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate, original specimen, or DNA), the specimen source (type), specimen collection date, and transport medium/specimen preservative (isolates only).

Supplemental Form

Molecular Detection of Drug Resistance Request Form (CDC-002-00220)
<http://www.cdc.gov/tb/topic/laboratory/MDDRsubmissionform.pdf>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Nucleic Acid Amplification Test positive (NAAT+) sediment; Pure *Mycobacterium tuberculosis* complex isolate(s) on solid medium or in broth medium; Mixed cultures known to contain MTBC; MTBC NAAT+ DNA from fixed tissues, forwarded for MDDR testing by the CDC Infectious Diseases Pathology Branch. Only one sample per patient should be submitted; however, testing of duplicate samples will be considered on a case-by-case basis; contact the CDC POC for approval prior to sending.

Minimum Volume Required Sediment: 0.5 mL, 1 mL is preferred
Liquid medium: 0.5 mL, 1 mL is preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Sediments: Store refrigerated (2-8°C) up to 30 days post collection or frozen (-20°C or lower) up to 60 days post collection

MTBC Isolates in solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection

MTBC Isolates in liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection

Transport Medium Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit sediment in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A).

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 29
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Targeted DNA Sequencing (Pyrosequencing or Sanger sequencing based on submission criteria provided by submitter), Agar Proportion DST, MGIT 960 Pyrazinamide (PZA) also performed for sediments and isolates
Turnaround Time	3 Days
Interferences & Limitations	Results are reported for the sample as received. Samples with low numbers of MTBC may not amplify; Heteroresistance may not be detected; the results of MDDR assay should not be used to rule out the presence of MTBC in a sample.
Additional Information	On average, TAT ranges from 1-6 calendar days. Delays may occur due to holidays and unexpected events (e.g., closure of CDC).
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov Atanaska Marinova Petkova (404) 718-5254 lxy8@cdc.gov

Version 2.4

Test Order
***Mycobacterium* TB Complex - Pyrazinamide Susceptibility Testing**
CDC-10189

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate), the specimen source (type), specimen collection date, and transport medium/specimen preservative.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure <i>Mycobacterium tuberculosis</i> complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 120 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-65°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 50 mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact]Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Pyrazinamide (PZA) by MGIT 960
Turnaround Time	4 Weeks

Interferences & Limitations Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated and additional submission of pure culture may be clinically needed. Submitting laboratory may submit a pure culture if clinically needed.

Additional Information None

CDC Points of Contact TB Lab
(404) 639-2455
TBLab@cdc.gov
Atanaska Marinova Petkova
(404) 718-5254
lxy8@cdc.gov

Version 2.2

Test Order
Mycobacterium TB Complex - Special Study
CDC-10191

Synonym(s) MTB DST, TB, Tuberculosis, MTBC

CDC Pre-Approval Needed **TB Lab**
(404) 639-2455
TBLab@cdc.gov
Atanaska Petkova
(404) 718-5254
bem1@cdc.gov

Supplemental Information Required **Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (isolate), the specimen source (type), specimen collection date, and transport medium/specimen preservative.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 29
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov Atanaska Marinova Petkova (404) 718-5254 lxy8@cdc.gov

Version 1.3

Test Order
***Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping**
CDC-10513

Synonym(s)	<i>M. pneumoniae</i> , <i>Mycoplasma</i> , Atypical pneumonia, Walking pneumonia, Community acquired pneumonia, CAP, macrolide, macrolide resistance, antimicrobial resistance, AMR
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum
Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Specimens should be refrigerated (2–8°C) after collection and frozen (-20°C or lower) within 96 hours of collection.
Transport Medium	Viral transport medium (VTM) for NP and OP swabs
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (PCR) with high-resolution melt (HRM)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	All specimens will be tested using test order Atypical Bacterial Pneumonia Agents (<i>Chlamydia pneumoniae</i> , <i>Mycoplasma pneumoniae</i> , <i>Legionella</i> species) Molecular Detection (CDC-10157) to confirm the presence of <i>M. pneumoniae</i> .
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov

Version 1.3

Test Order
***Mycoplasma pneumoniae* Molecular Detection**
CDC-10155

Synonym(s) *M. pneumoniae*, *Mycoplasma*, Atypical pneumonia, Community acquired pneumonia, CAP, Walking pneumonia

CDC Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.

Minimum Volume Required 0.2 mL; 0.4 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs, if available. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Specimens should be refrigerated (2–8°C) after collection and frozen (-20°C or lower) within 96 hours of collection.

Transport Medium Viral transport medium (VTM) for NP and OP swabs

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery).

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 23
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Multiplex Real-time Polymerase Chain Reaction (PCR)

Turnaround Time 7 Days

Interferences & Limitations Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs with wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.

Additional Information All specimens are tested using test order Atypical Bacterial Pneumonia Agents (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Legionella* species) Molecular Detection (CDC-10157). Specimens in which *M. pneumoniae* is detected will be subjected to *Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping (CDC-10513).

CDC Points of Contact Maureen Diaz
(404) 639-4534
mdiaz1@cdc.gov
Jonas Winchell
(404) 639-4921
Jwinchell@cdc.gov

Version 2.4

Test Order
***Naegleria* Molecular Detection**
CDC-10482

Synonym(s) Free-living amoeba, parasite, primary amoebic meningoencephalitis, PAM, brain-eating amoeba

CDC Pre-Approval Needed **Jennifer Cope**
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Supplemental Information Required **Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpx@cdc.gov for more information about submitting images.**

Supplemental Form **Not needed.**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For *Naegleria fowleri* molecular detection, CSF is the preferred specimen type. We also accept fresh or frozen brain tissue for *N. fowleri* molecular detection.

Minimum Volume Required 0.2 mL (CSF); 1 mL preferred.
0.1 g tissue (brain); 0.2 g preferred.

Collection, Storage, and Preservation of Specimen Prior to Shipping CSF (preferred) or brain tissue (in 0.5x PBS) should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower; in the absence of PBS buffer) for up to 60 days.

Transport Medium Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen at room temperature, not on dry ice, as an etiologic agent, unless the specimen has been previously frozen. Frozen specimens may be shipped in cold with ice-packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred over the formalin-fixed specimens.
Additional Information	None
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov

Version 2.5

Test Order
NARMS Susceptibility Testing
CDC-10107

Synonym(s)	National Antimicrobial Resistance Monitoring System, NARMS surveillance, AST
CDC Pre-Approval Needed	None
Supplemental Information Required	Submitter must be a NARMS participating laboratory. Specimens accepted according to current National Antimicrobial Resistance Monitoring System (NARMS) sampling scheme. NARMS log sheet or entry into NARMS web interface.
Supplemental Form	NARMS logsheet https://wwwn.cdc.gov/NARMS/UserLogin.aspx
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Isolates. Specimens accepted according to NARMS guidelines.
Minimum Volume Required	Minimum volume for microbial isolates is not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 127 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Broth Microdilution Antimicrobial Susceptibility (AST), E-Test Susceptibility Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	The turn around time depends on the nature of subtyping performed. Results are typically reported directly to the surveillance databases.

CDC Points of Contact Jean Whichard
(404) 639-2000
zyr3@cdc.gov
Jason Foster
(404) 639-4948
gux8@cdc.gov
Hayat Caidi
(404) 639-0766
foi0@cdc.gov

Version 1.2

Test Order
Neisseria gonorrhoeae Susceptibility Testing
 CDC-10102

Synonym(s) *Neisseria gonorrhoeae* Antimicrobial Susceptibility Testing (AST), Gonorrhea (GC) Susceptibility

CDC Pre-Approval Needed **Brian Raphael**
(404) 639-4292
elx9@cdc.gov
Cau Pham
(404) 718-5642
whi4@cdc.gov

Supplemental Information Required **Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: Document the specimen source (type): blood, urethral swab, urine, throat (oropharyngeal) swab, oral swab, rectal swab, or swab. Document the specimen source site: urethra, throat, oropharynx, rectum, vagina, or cervix.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Viable frozen culture with confirmed identification of *N. gonorrhoeae* by biochemical assay (i.e. API™ NH and RapID™ NH), immunologic assay (i.e. Phadebact), molecular assays (16s rDNA) or matrix-assisted laser-desorption/ionization time-of-flight (MALDI-TOF).

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Bacterial cultures should be grown on a non-selective medium (Chocolate II or GC base + 1% growth supplements) and incubated for 16-18 hours at 35-37°C in a 4-6% CO₂-enriched atmosphere. Cultures should be resuspended (at concentration of ≥4 McFarland) in transport medium and immediately frozen at <-70°C or below. Isolates may be stored up to 6 months prior to shipment to CDC.

Transport Medium Bacterial culture should be resuspended in trypticase soy broth (TSB) with 15-20% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimen should be shipped on dry ice, as an etiologic agent.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Agar Plate Dilution, E-test
Turnaround Time	4 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known
Additional Information	Not Applicable
CDC Points of Contact	Brian Raphael (404) 639-4292 elx9@cdc.gov Cau Pham (404) 718-5642 whi4@cdc.gov

Version 3.1

Test Order
Neisseria meningitidis Identification and Serogrouping
 CDC-10219

Synonym(s) *N. meningitidis* ID and Serogrouping, Nm ID

CDC Pre-Approval Needed None

Supplemental Information Required **Two primary patient identifiers are required for this test order. Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing. For surveillance testing, please submit under the *Neisseria meningitidis* Surveillance test order (CDC-10220).**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Bacterial isolates (viable bacterial culture at room temperature or frozen stocks) and primary specimens [cerebrospinal fluid (CSF) and serum]. Other sterile site specimen types must be submitted under the CDC-10220 Test Order (*Neisseria Meningitidis* Surveillance).

Minimum Volume Required 0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping.

When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates.

Cerebrospinal fluid (CSF) and serum should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.

Transport Medium When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF and serum) should be shipped on dry ice and received frozen.

Enclose CDC 50.34 Specimen Submission Form in shipment. Email the tracking number in advance, particularly if prioritized testing is requested.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 10
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (rt-PCR), Slide Agglutination Serogrouping (SASG), Bacterial isolates will be characterized using real-time Polymerase Chain Reaction (rt-PCR) and slide agglutination serogrouping (SASG); primary specimens will be characterized using rt-PCR.
Turnaround Time	4 Weeks
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Test results provide or confirm serogroup of <i>N. meningitidis</i> .
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Henju Marjuki (404) 639-2803 vsd1@cdc.gov

Version 2.3

Test Order
Neisseria meningitidis Surveillance
 CDC-10220

Synonym(s) *N. meningitidis* surveillance, Nm study

CDC Pre-Approval Needed None

Supplemental Information Required Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form or on the surveillance submission form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing. If results are intended for diagnostic purposes, submit under *Neisseria meningitidis* Identification and Serogrouping test order CDC-10219.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Bacterial isolates (viable bacterial culture at room temperature or frozen stocks) and primary specimens [cerebrospinal fluid (CSF), serum and other sterile site specimen types].

Minimum Volume Required 0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping.

When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates.

Primary specimens (CSF, serum and other sterile site specimen types) should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.

Transport Medium When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF, serum and other sterile site specimen types) should be shipped on dry ice and received frozen.

If using a specimen inventory spreadsheet for submission, include a copy within the shipment and also email it to the CDC POCs prior to shipment.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 10
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Whole genome sequencing (WGS), real-time polymerase chain reaction (rt-PCR), and/or slide agglutination serogrouping.
Turnaround Time	
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result. For molecular typing methods, primary specimens with low bacterial DNA load may not be acceptable for testing.
Additional Information	Additional microbiological and/or molecular testing can be completed as needed.
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Henju Marjuki (404) 639-2803 vsd1@cdc.gov

Version 2.6

Test Order
***Neisseria* species (not GC or *meningococcus*) Identification**
CDC-10139

Synonym(s)	Gram-negative coccus (not GC or meningococcus) identification, <i>Neisseria</i> species identification
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Nipah Virus Testing
CDC-10354

Synonym(s)

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required **See Supplemental Form**

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For molecular and/or serology testing the accepted specimen types are whole blood (EDTA) or serum. CDC POC contact is required prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), serology, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order
Nocardia species Identification
 CDC-10150

Synonym(s)	Beaded branching gram-positive rod, aerobic actinomycetes
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Keep refrigerated (2- 8°C) for up to 7 days if isolate cannot be shipped within 72 hours. For fastidious organisms store at room temperature (15-25°C) for up to 24 hours.
Transport Medium	Not Applicable
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Nocardia species Identification and Antimicrobial Susceptibility Testing
 CDC-10151

Synonym(s)	
CDC Pre-Approval Needed	None
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.
Transport Medium	Not applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.

Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.2

Test Order
Nontuberculous Mycobacteria (NTM) - Identification (ID)
CDC-10225

Synonym(s) *Nontuberculous (Non-TB) Mycobacteria (NTM), Nontuberculous Mycobacteria (NTM), Mycobacterium, Mycobacteria Identification*

CDC Pre-Approval Needed None

Supplemental Information Required **All submittals must include the State Public Health Department contact information and previous testing results demonstrating that the isolate is pure and is not a part of the Mycobacterium tuberculosis complex (MTC) on either the CDC Form 50.34 Specimen Submission Form or GFAT.**

For isolates from wounds or surgical sites, document that nontuberculosis mycobacteria (NTM) was abundant on primary culture (3+ to 4+) or was the only organism isolated.

For isolates from sputum, document that NTM was from two or more sputum cultures, collected on different days; was the only mycobacterial species present and that there was abundant growth on primary culture.

For pure culture isolate submittals, document the date the submitted culture inoculated onto transport media.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Pure cultural isolates of NTMs demonstrated to not be part of the Mycobacterium tuberculosis complex (MTC) from the following sources: Sterile sites (e.g. Whole blood, cerebral spinal fluid (CSF), other body fluids); Abscess, exudate or skin lesion; Wounds or surgical sites (see Supplemental Information); Bronchoalveolar lavage (BAL)/bronchial wash; Sputum (see Supplemental Information); Gastric lavage (pediatric).

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping For pure culture isolates (or inoculated transport media) store at room temperature (15-25 °C). Keep refrigerated (2-8 °C) if sample cannot be shipped within 48 hours of inoculation to transport media.

Transport Medium For pure culture isolates, Lowenstein-Jensen agar, Middlebrook 7H10/7H11 agar or Middlebrook 7H9 broth. NOTE: The Mycobacteria Growth Indicator tube (MGIT) is not an acceptable transport media.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For pure culture isolates or inoculated media, ship overnight at room temperature with room-temperature cold packs. If shipment must be delayed, samples can be shipped refrigerated with refrigerated or frozen cold packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 13
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	16S ribosomal ribonucleic acid (rRNA) and rpoB gene sequencing, matrix assisted laser desorption ionization-time of flight (MALDI-TOF), additional phenotypic testing, 16S ribosomal ribonucleic acid (16S rRNA) gene and β subunit of bacterial RNA polymerase (rpoB) sequencing, matrix assisted laser desorption ionization-time of flight (MALDI-TOF), additional phenotypic testing
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Turnaround Time	4 Weeks
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Interferences & Limitations	No significant interferences or limitations are currently known.
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Additional Information	If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Isolates require specific documentation depending on the site of collection as outlined in Supplemental Information Needed. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
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CDC Points of Contact	David Lonsway (404) 639-2825 dul7@cdc.gov Nadege Toney (404) 639-1282 ngc6@cdc.gov
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Version 2.2

Test Order
Norovirus Genotyping
CDC-10356

Synonym(s) Norovirus

CDC Pre-Approval Needed **Jan Vinje**
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type stool, vomitus, environmental swab
for Testing

Minimum Volume Required 0.25 g or 0.25 mL

Collection, Storage, and Preservation Specimen must be stored at 2 °-8 °C
of Specimen Prior to Shipping

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Refrigerated specimen should be shipped on cold packs.
Specimen Handling Requirements

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 186
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR), Sequencing

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Jan Vinje
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Version 1.3

Test Order
Norovirus Molecular Detection and Genotyping
CDC-10358

Synonym(s) Norovirus

CDC Pre-Approval Needed **Jan Vinje**
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type stool, vomitus, environmental swab
for Testing

Minimum Volume Required 0.25 g or 0.25 mL

Collection, Storage, and Preservation Specimen must be stored at 2 °-8 °C
of Specimen Prior to Shipping

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Refrigerated specimen should be shipped on cold packs.
Specimen Handling Requirements

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 186

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR), Sequencing

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Jan Vinje
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Version 1.3

Test Order
***Orientia* Molecular Detection**
CDC-10359

Synonym(s) Scrub typhus

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute whole blood (taken within 14 days of illness onset or while symptomatic): EDTA-treated, or ACD A treated.
 Acute serum: Serum separator tube, or cryo-tubes. Vascularized tissue biopsies, including skin biopsy specimens from the site of rash or eschar. Swab specimen of eschar, using a dry, sterile cotton swab (include eschar scab when available). Samples must be collected before or within 72 hours of initiation of a tetracycline-class antibiotic, e.g., doxycycline (within 48 hours is preferred), or, if occurring outside of this established time frame, patients must be symptomatic at the time of collection.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For swab, place in sterile specimen container without any medium.

Transport Medium For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline. For swab, place in sterile specimen container without any medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Samples in saline buffer have decreased sensitivity and are subject to rejection. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with nucleic acid extraction.

Additional Information Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.

The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Molecular detection of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Anaplasma, Coxiella, and Ehrlichia may be performed. Results are reported directly to SPHLs.

Additional RZB specimen and shipping information can be found at the following address:

<https://www.cdc.gov/nceid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 2.0

Test Order
Orientia Serology
 CDC-10360

Synonym(s) Scrub typhus

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB / STATT Unit 78
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	<p>Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.</p> <p>The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia spotted fever group, Rickettsia typhus group, Anaplasma, Coxiella, and Ehrlichia may be performed. Results are reported directly to SPHLs.</p> <p>Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</p>
CDC Points of Contact	<p>Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov</p> <p>Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov</p>

Test Order
Orientia Special Study
CDC-10500

Synonym(s) Scrub typhus

CDC Pre-Approval Needed **Marah Condit**
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Supplemental Information Required **As determined during pre-approval consultation.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing As determined during pre-approval consultation.

Minimum Volume Required As determined during pre-approval consultation.

Collection, Storage, and Preservation of Specimen Prior to Shipping As determined during pre-approval consultation.

Transport Medium As determined during pre-approval consultation.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Molecular detection, serology, culture, other

Turnaround Time

Interferences & Limitations As determined during pre-approval consultation.

Additional Information As determined during pre-approval consultation.

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 1.6

Test Order
Paragonimiasis Serology
CDC-10465

Synonym(s)	<i>Paragonimus westermani</i> ; <i>Paragonimus kellicotti</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.5

Test Order
Parasite - Special Study
CDC-10237

Synonym(s)

CDC Pre-Approval Needed **Katie Bowden**
(404) 718-4100
wzi1@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required To be determined

Collection, Storage, and Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 57
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Katie Bowden
(404) 718-4100
wzi1@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 1.5

Test Order
Parasites: Morphologic Identification
CDC-10234

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite, ova and parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	Supplemental form not needed
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool specimens (must be preserved), blood, and tissue. Consult the laboratory regarding submission of additional specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific and available on consultation
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>Shipping is specimen specific and available on consultation.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None

CDC Points of Contact DPDx
(404) 718-4120
dpdx@cdc.gov
Sarah Sapp
(404) 718-5227
xyz6@cdc.gov

Version 2.4

Test Order
Pathologic Evaluation of Fixed Tissues for Possible Infectious Etiologies
CDC-10365

Synonym(s) Autopsy, necropsy, biopsy, formalin-fixed tissues, formalin-fixed paraffin-embedded (FFPE), pathology, paraffin blocks, histopathology, immunohistochemistry, polymerase chain reaction (PCR)

CDC Pre-Approval Needed **Infectious Diseases Pathology Mailbox**
(404) 639-3132
pathology@cdc.gov
Sarah Reagan Steiner
(404) 639-2811
sor1@cdc.gov

Supplemental Information Required **Please include the following information with each submission:**

Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:

- Test order code
- Test order name
- Patient full name
- Patient birth date
- Date of death (if applicable)
- Patient ID (e.g., medical record number or autopsy number)
- Specimen ID (e.g., surgical pathology accession number)
- State public health laboratory (PHL) point of contact
- Original submitter contact information
- Comments (bottom of page 2): If unstained slides are submitted, the date that unstained slides were created should be provided here.

One electronically completed copy of the CDC 50.34 Specimen Submission Form per case is sufficient, unless specimens are being submitted from multiple specimen collection dates in one package.

Requested additional information:

- A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information
 - A copy of: (a) the autopsy report (preliminary or final), or (b) surgical pathology report
 - Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)
 - Relevant clinical, gross pathology, or microscopic pathology images, as available
 - If paraffin-embedded tissue blocks or unstained slides are submitted, a block key listing the tissues in each paraffin-embedded tissue block.
-

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Biopsy tissues and autopsy tissues from any organ or site are acceptable; however, tissue specimens should be submitted from the site(s) of the patient's disease process.

If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process.

Formalin-fixed paraffin-embedded tissue (FFPE) tissue blocks: Preferred specimen type for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories. Not acceptable if > 10 years of age.

- Biopsy and autopsy tissue specimens: Only acceptable if embedded within 2 weeks after being placed in formalin.

Formalin-fixed wet tissues:

- For biopsy tissue specimens: NOT acceptable for testing
- For autopsy tissue specimens: Only acceptable if the duration of formalin-fixation has been within 2 weeks, or if tissues have been transferred to 70% ethanol within 2 weeks after initial placement in formalin.

Unstained paraffinized tissue slides:

- Acceptable for histopathology, histochemistry (special stains), immunohistochemistry. Only acceptable if created within 10 days prior to submission of specimens to CDC - not acceptable for PCR testing and sequencing or nucleic extraction for transfer to other CDC laboratories

Formalin-fixed paraffin-embedded (FFPE) tissue scrolls: - NOT acceptable for testing

For more information, reference the Additional Information field.

Minimum Volume Required	Not Applicable
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Collection, Storage, and Preservation of Specimen Prior to Shipping

Formalin-fixed paraffin-embedded (FFPE) tissue blocks:
• Process within 2 weeks of formalin-fixation of tissues
• Store at room temperature (15-25°C)

Autopsy specific, formalin-fixed wet tissue:

- The volume of 10% neutral buffered formalin used to fix tissues should be 10 times the volume of tissue
- Place thinly-sliced tissue in 10% neutral buffered formalin for 7 days.
- For brain tissue, place thinly-sliced tissue in 10% neutral buffered formalin for 2 weeks or longer until fully fixed.

After fixation, if not paraffin-embedded, tissues should be transferred to 70% ethanol for long-term storage and stored at room temperature (15-25°C). Unstained paraffinized tissue slides should be stored at room temperature (15-25°C).

Transport Medium	If formalin-fixed wet tissues are submitted, transport medium can include 10% neutral buffered formalin or 70% ethanol.
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Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Paraffin-embedded tissue blocks should be shipped refrigerated with refrigerated or frozen cold packs during hot summer months to prevent them from melting.

Formalin-fixed wet tissue that is currently in formalin or has been transferred to 70% ethanol:

- Should be shipped in leak proof containers at room temperature with room-temperature cold packs.
- The maximum volume of formalin per primary specimen container cannot exceed 30 mL (excess formalin should be discarded prior to shipping).
- The maximum net volume of formalin per shipping package cannot exceed 1 L.
- If the specimen is in 70% ethanol, discard most of the ethanol prior to shipping.
- Leakproof containers should be placed in double Ziploc style bags and add sufficient absorbent material to the outer bag to absorb any potential leaks. Ship for overnight delivery.

Ship To:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 109

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Histopathology (H&E-stained sections), Histochemistry (special stains), Immunohistochemistry (IHC), Polymerase Chain Reaction (PCR) and Sequencing, Electron Microscopy (EM), Tissue Culture, Nucleic Acid Extraction for transfer to other CDC Laboratories, Histopathology (hematoxylin and eosin (H&E)-stained sections), histochemistry (special stains), immunohistochemistry (IHC), polymerase chain reaction (PCR) and sequencing, nucleic acid extraction for transfer to other CDC Laboratories

Turnaround Time 8 Weeks

Interferences & Limitations Decalcification may interfere with some PCR assays.

Paraffin-embedded cell blocks from body fluids (e.g., pleural, pericardial fluid) and aspirates (e.g., bone marrow) may be acceptable in select circumstances but assay sensitivity may be reduced; immunohistochemical, PCR and sequencing assays have been optimized for performance on FFPE tissue samples.

Freezing of formalin-fixed wet tissue can result in distorted histopathology and freezing artifacts (formation of interstitial and intracytoplasmic vacuoles resulting from ice-crystal formation). Specimens should not be frozen; specimens should be kept at room temperature (15-25°C).

Additional Information CDC Pre-Approval Needed:

- Contact Infectious Diseases Pathology Branch Mailbox and pre-approval POC

Acceptable Sample/ Specimen Type for Testing:

- More specific guidelines regarding syndrome and pathogen specific tissue sampling and submission can be found on the IDPB website:
<http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html>
- In the setting of potentially scant paraffin-embedded tissue block samples, submission of original stained slides (e.g., H&E, Gram) may be requested.
- For autopsy tissues demonstrating decomposition, consultation with POC is required to determine acceptable specimen type(s) on a case-by-case basis.

Turnaround Time is case-dependent:

- Human surgical biopsy cases it is 6-8 weeks
- Complex cases, routine human autopsy cases, and animal cases it is 12 weeks.

The course of testing will be determined by the clinical history, the histopathology observed, and the availability of specimens.

CDC Points of Contact Infectious Diseases Pathology Branch Mailbox
(404) 639-3132
pathology@cdc.gov
Sarah Reagan Steiner
(404) 639-2811
sor1@cdc.gov
Jana M Ritter
(404) 639-1611
vtr0@cdc.gov
Roosecelis B Martines
(404) 639-3886
xgn7@cdc.gov

Version 3.4

Test Order
Picornavirus Detection and Identification (not Hepatitis A, not Rhinovirus)
CDC-10374

Synonym(s)	Theier's murine encephalomyelitis virus (TMEV), Saffold virus (SAFV), Cosavirus (COSV) (Dekavirus), Salivirus (SALV) (Klassevirus), Kobuvirus, Aichi virus, Encephalomyocarditis virus (EMCV), Vilyuisk virus
CDC Pre-Approval Needed	Terry Fei Fan Ng (404) 639-4880 ylz9@cdc.gov Shannon Rogers (404) 639-2677 boo9@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool, cerebrospinal fluid (CSF), serum, nasopharyngeal swab (NP) in virus transport media (VTM), oropharyngeal swab (OP) in VTM, nasopharyngeal/oropharyngeal swab (NP/OP) in VTM, nasal swab (NS)
Minimum Volume Required	Stool: 1 gram, 10 - 20 grams preferred Cerebrospinal fluid (CSF): 0.15 mL, 0.5-2 mL preferred Serum: 0.15 mL, 0.5 - 2 mL preferred Respiratory swab specimens in virus transport media: 0.5 mL, 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample. For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media. For stool, CSF, and respiratory wash specimen - collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Do not add transport medium. For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes and centrifuge. After collection, freeze (-20°C or lower) all specimens and ship to CDC within 1 month. If necessary, specimens may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing.
Transport Medium	Viral transport medium (VTM) should be used with these specimen types: Respiratory swab specimens, including nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), nasal swabs (NS)

Specimen Labeling Research or surveillance specimens may be labeled with unique identifiers according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 76
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Molecular techniques

Turnaround Time

Interferences & Limitations Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.

Additional Information Not Applicable

CDC Points of Contact Shannon Rogers
(404) 639-2677
boo9@cdc.gov
Terry Fei Fan Ng
(404) 639-4880
ylz9@cdc.gov

Version 1.5

Test Order
Picornavirus Special Study
CDC-10375

Synonym(s)

CDC Pre-Approval Needed **Shannon Rogers**
(404) 639-2677
boo9@cdc.gov
Terry Fei Fan Ng
(404) 639-4880
ylz9@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Stool, cerebrospinal fluid (CSF), serum, nasopharyngeal swab (NP) in VTM, oropharyngeal swab (OP) in VTM, nasopharyngeal/oropharyngeal swab (NP/OP) in VTM

Minimum Volume Required Stool: 1 gram, 10 - 20 grams preferred
Cerebrospinal fluid (CSF): 0.15 mL, 0.5-2 ml preferred,
Serum: 0.15 mL, 0.5-2 ml preferred
Respiratory swab specimens in VTM: 0.5 mL; 1 ml preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample.

For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media.

For stool, CSF, respiratory wash specimen - collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Do not add transport medium.

For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes and centrifuge.

After collection, freeze (-20°C or lower) all specimens and ship to CDC within 1 month. If necessary, specimens may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing.

Transport Medium Viral transport medium (VTM) should be used with these specimen types: nasopharyngeal swab (NP), oropharyngeal swab (OP), nasopharyngeal/oropharyngeal swab (NP/OP)

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 76
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Contact the CDC POC for appropriate guidance/relevant information., Reverse Transcriptase Polymerase Chain Reaction (RT-PCR); virus isolation for stool

Turnaround Time 2 Weeks

Interferences & Limitations Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.

Additional Information Not Applicable

CDC Points of Contact Picornavirus Laboratory

AFMLab@cdc.gov
Shannon Rogers
(404) 639-2677
boo9@cdc.gov
Terry Fei Fan Ng
(404) 639-4880
ylz9@cdc.gov

Version 1.5

Test Order
Polio Direct Detection and Titration
CDC-10549

Synonym(s) Polio special study, CCID50

CDC Pre-Approval Needed None

Supplemental Information
Required

Supplemental Form

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Performed on stool. Contact POC for further guidance and information.

Minimum Volume Required 1 gram (stool); 2-3 grams preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Stool should be collected into a sterile container and stored refrigerated (2-8°C) for no more than 48 hours before being processed. Once processed, stools should be frozen (-20°C or lower) until shipped frozen on dry ice.

Transport Medium Specimens should be shipped frozen on dry ice. Stool: No transport medium needed.

Specimen Labeling Research or surveillance specimens may be labeled with unique identifiers according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen on dry ice.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB / STATT Unit 225
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Molecular biology; Cell culture, Polymerase chain reaction (PCR); virus titration assay; cell culture

Turnaround Time 2 Weeks

Interferences & Limitations

Additional Information For clinical trials, please submit under test order CDC-10549. For surveillance, please submit under test order CDC-10376.

CDC Points of Contact Jennifer Anstadt
(404) 718-1362
yrq1@cdc.gov
Cara Burns
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Version 1.1

Test Order
Polio Isolation and Genotyping
CDC-10376

Synonym(s)	PV, polio virus, Polio sequencing, AFP, acute flaccid paralysis
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool, cell culture isolate, Fast Technology for Analysis of nucleic acids (FTA) cards, wastewater
Minimum Volume Required	Tissue culture isolate: 0.5 mL Stool: 1 gram; 10 - 20 grams preferred Wastewater: 500mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimens refrigerated (2-8 °C) or frozen (-20 °C or lower). For stool, do not add transport medium. Wastewater should be stored refrigerated (2-8 °C) upon collection and stored frozen (-20 °C or lower) prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled with unique identifiers according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. FTA cards should be shipped at ambient temperatures and should include humidity indicator cards and desiccant pouches. When shipping ambient specimens, no temperature-maintaining materials (e.g., cold packs) are required. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Molecular techniques, Cell culture
Turnaround Time	3 Weeks
Interferences & Limitations	None

Additional Information If case investigation form is readily available, please submit with specimen

CDC Points of Contact Cara Burns
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Version 1.3

Test Order
Polio Serology
CDC-10377

Synonym(s) Neutralization assay, NT, MNT

CDC Pre-Approval Needed **Bernardo Mainou**
(404) 718-3261
qlk6@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum
for Testing

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Sera need to be collected from clotted whole blood or through serum separated tubes (SST). Samples must be refrigerated (2-8°C) after collection for short-term storage, not to exceed 24 hours and frozen (-20°C or lower) until shipment without exceeding 1 month. Document conditions in which sample was maintained (e.g., temperature and time) on CDC 50.34 Specimen Submission Form in the comments section.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. Refrigerated specimens should be shipped with refrigerated or frozen cold packs.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 225
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Neutralization assay
Turnaround Time	4 Weeks
Interferences & Limitations	Red blood cell hemolysis will adversely affect test results
Additional Information	None
CDC Points of Contact	Bernardo Mainou (404) 718-3261 qlk6@cdc.gov Nicholas Wiese (404) 639-2650 kue6@cdc.gov

Version 1.6

Test Order
Polio Special Study
CDC-10378

Synonym(s) None

CDC Pre-Approval Needed **Cara Burns**
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type Stool, cell culture isolate
for Testing

Minimum Volume Required Tissue culture isolate: 0.5 mL. Stool: 1 gram; 10 - 20 grams preferred

Collection, Storage, and Preservation Keep specimens refrigerated (2-8 °C) or frozen (-20 °C or lower). For stool, do not
of Specimen Prior to Shipping add transport medium.

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled with unique identifiers
according to protocol. Labels should not include personally identifiable
information. The results reported should NOT be used for diagnosis, treatment,
assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday – Friday. Frozen specimens should be shipped on
dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 76
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Contact the CDC POC for appropriate guidance/relevant information., Cell
Culture, PCR, drug susceptibility testing, or genetic sequencing

Turnaround Time

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information Not Applicable

CDC Points of Contact Cara Burns
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Version 1.3

Test Order
Poxvirus Molecular Detection
CDC-10515

Synonym(s) *Monkeypox virus, Variola virus, Vaccinia virus, smallpox, sore mouth*

CDC Pre-Approval Needed **Poxvirus Inquiry Line**
(404) 639-4129
poxvirus@cdc.gov
Whitni Davidson
(404) 639-2933
wdavidson@cdc.gov

Supplemental Information Required **Consultation is required prior to specimen submission. A brief written clinical summary with pertinent medical information (e.g. rash onset date, rash type, symptoms, smallpox vaccination date if relevant) and exposure history should be included. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.**

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Lesion material is required for persons with an active lesion or rash. Lesion material includes lesion fluid, lesion roof, lesion tissue, or crust. Specimen collection encompasses biopsy (non-formalin fixed), scrapings, touch prep or smear slides, or swab(s). Original specimen material is preferred but viral culture can also be tested.

Minimum Volume Required 0.5 mL (viral culture, viral transport media)

Collection, Storage, and Preservation of Specimen Prior to Shipping Sample each lesion separately with a sterile nylon, polyester, or Dacron swabs with a plastic, wood, or thin aluminum shaft. Do not use other types of swabs. Place in an individual collection tube (i.e., one tube per lesion sampled). Write site of collection on each specimen.

Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection. Store refrigerated samples for up to 7 days and frozen samples for up to 1 month. Refrigerated samples should be sent within 5 days of collection, frozen samples should be shipped within 21 days of collection.

Transport Medium Transport media should not be added to specimens; however, swabs stored in viral transport, M4, or universal transport media or tissue stored in saline will be tested. Specimens stored in molecular transport media will not be tested.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition form.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship specimen(s) refrigerated on cold packs, unless frozen, then ship on dry ice.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 47
1600 Clifton Road NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Real-time polymerase chain reaction
Turnaround Time	5 Days
Interferences & Limitations	Cotton swabs and swabs in media designed for bacterial preservation and/or transport may cause PCR inhibition and should not be used. Use of viral transport media dilutes DNA quantities. Specimens with insufficient human DNA will be resulted as inconclusive.
Additional Information	Submitters should contact the Poxvirus Inquiry Line by telephone prior to using email and/or contacting the second POC. Diagnostic real-time polymerase chain reaction can detect the following poxviruses: variola, monkeypox, vaccinia, orf, pseudocowpox, and bovine papular stomatitis virus. Research real-time polymerase chain reaction can detect the viruses listed above plus cowpox, sealpox, molluscum contagiosum, and tanapox virus.
CDC Points of Contact	Poxvirus Inquiry Line (404) 639-4129 poxvirus@cdc.gov Whitni Davidson (404) 639-2933 wdavidson@cdc.gov

Version 1.3

Test Order
Poxvirus Serology
CDC-10516

Synonym(s) Orthopoxvirus serology

CDC Pre-Approval Needed **Poxvirus Inquiry Line**
(404) 639-4129
poxvirus@cdc.gov
Whitni Davidson
(404) 639-2933
wdavidson@cdc.gov

Supplemental Information Required **Consultation is required prior to specimen submission. A brief written clinical summary with pertinent medical information (e.g. rash onset date, rash type, symptoms, smallpox vaccination date if relevant) and exposure history should be included. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL; 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Use blood collection tubes containing a clot activator and/or gel for serum separation. Separate and aliquot serum prior to storage and transport. Refrigerate (2-8 °C) or freeze (-20 °C or lower) specimens within an hour after collection. Store refrigerated samples for up to 7 days and frozen samples for up to 60 days. Refrigerated samples must be received at CDC within 7 days, frozen samples must be received at CDC within 60 days.

Transport Medium No transport media is required.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship specimen(s) refrigerated on cold packs, unless frozen, then ship on dry ice.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 47
1600 Clifton Road NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Enzyme-linked immunosorbent assay (ELISA)
Turnaround Time	14 Days
Interferences & Limitations	Blood collection in tubes with either heparin and/or ethylenediaminetetraacetic acid (EDTA) may interfere with results. Detection of immunoglobulin M and G antibodies is dependent upon the number of days the specimen was collected post-symptom onset. A previous history of smallpox vaccination or orthopoxvirus exposure may affect result interpretation.
Additional Information	Submitters should contact the Poxvirus Inquiry Line by telephone prior to using email and/or contacting the second POC. ELISA will detect an antibody response in persons infected with an orthopoxvirus (e.g. variola, monkeypox, vaccinia, or cowpox virus). Test results apply to the sample as received.
CDC Points of Contact	Poxvirus Inquiry Line (404) 639-4129 poxvirus@cdc.gov Whitni Davidson (404) 639-2933 wdavidson@cdc.gov

Version 1.4

Test Order
Puumala Hemorrhagic Fever Testing
CDC-10391

Synonym(s) Hanta, HFRS, Nephropathia epidemica

CDC Pre-Approval Needed **Trevor Shoemaker**
(470) 312-0094
spather@cdc.gov
John Klana
(404) 639-0114
irc4@cdc.gov

Supplemental Information **See Supplemental Form**
Required

Supplemental Form **VSPB Specimen Submission Form.**
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type For serology testing, the accepted specimen types are whole blood (EDTA) or
for Testing serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or
of Specimen Prior to Shipping below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	ELISA, Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 3.1

Test Order
Rabies Antemortem Human Testing
CDC-10392

Synonym(s) Human Rabies Rule Out Testing

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information Required **Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form (for each specimen) and Possible Human Rabies - "Patient Information (CDC Form 55.30 (E)) before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussions during initial phone consultation is not a suitable alternative to a written record. Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted.**

Supplemental Form **Possible Human Rabies - "Patient Information (CDC Form 55.30 (E))**
<http://www.cdc.gov/rabies/pdf/rorform.pdf>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Four samples listed below are required to provide an antemortem rule out of rabies. A rule out cannot be provided if all samples are not submitted: serum, CSF, nuchal (skin) biopsy, and saliva.

Minimum Volume Required 0.5 mL (Serum, CSF, saliva, greater than 1 ml preferred).
Nuchal skin biopsy must be a full punch (5-6 millimeters) contain at minimum 10 hair follicles.

Collection, Storage, and Preservation of Specimen Prior to Shipping Saliva should be collected prior to mouth cleansing using a sterile eyedropper pipette. Collect saliva sterile container that can be sealed securely. If the saliva is difficult to obtain, please collect an oral swab from the patient prior to mouth cleansing.

A nuchal (skin) biopsy should be a full punch of skin 5 to 6 mm in diameter collected from the posterior region of the neck at the hairline. The biopsy specimen should contain a minimum of 10 hair follicles and be of sufficient depth to include the cutaneous nerves at the base of the follicle. Place the biopsy specimen in sterile container.

Serum and cerebral spinal fluid (CSF) should also be collected. Do not send whole blood.

No preservatives or additional fluids should be added to any specimen type.

Samples can be stored refrigerated (2-8°C) for up to 72 hours after collection and frozen (-20°C or lower) for up to 5 days. Samples should be shipped within 5 days.

Samples collected before rabies was suspected can be stored frozen (-20°C or lower) and sent if within 1 month of collection date.

Please see the supplemental link for specific specimen storage and preservation. <https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html>

Transport Medium No samples should be put in a transport medium

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC 50.34 Specimen Submission Form is required for each of the four samples (serum, CSF, skin biopsy, and saliva). Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. Frozen specimens (serum, CSF, skin biopsy, and saliva) should be shipped on dry ice (preferred). If dry ice is not available, refrigerated specimens may be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Direct Fluorescent Antibody Test (DFA) (Nuchal (skin) biopsy), Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) on Nuchal (skin) biopsy, RT-PCR on Saliva, IgG and IgM by Indirect Fluorescent Antibody Test (IFA) on Serum and CSF, Viral Neutralizing Antibodies by Rapid Fluorescent Focus Inhibition Test (RFFIT) on Serum and CSF

Turnaround Time 7 Days

Interferences & Limitations Saliva and Nuchal (skin) biopsy specimens must remain frozen; warming or freeze thawing reduces sensitivity. Saliva and CSF specimen should be free of blood because blood may interfere with test results due to the inhibitors present in blood.

Additional Information Do not ship specimens without prior consultation and approval. Submitters should contact the Rabies Duty Officer by telephone prior to using email and/or contacting the second CDC POC.

Critical specimens will take less than 3 days to determine results; if testing needs to be repeated, results may take up to 7 days.

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Version 1.6

Test Order
Rabies Antibody Titer (Animal)
CDC-10395

Synonym(s) Rabies vaccination status

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James A. Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Animal

Acceptable Sample / Specimen Type Serum
for Testing

Minimum Volume Required 0.5 to 1.0 mL

Collection, Storage, and Preservation Specimen can be kept refrigerated at 4 °C but prefer frozen at -20 °C
of Specimen Prior to Shipping

Transport Medium Do not use transport media

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Frozen and refrigerated specimens should be shipped on cold packs.
Specimen Handling Requirements

Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Rapid Fluorescent Focus Inhibition Test (RFFIT)

Turnaround Time 4 Weeks

Interferences & Limitations Hemolyzed samples interfere with test results.

Additional Information If the test needs to be repeated results may take up to an additional 7 days. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC.

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Version 2.0

Test Order
Rabies Antibody Titer (Human)
CDC-10393

Synonym(s) Serology, Immunization status, Rabies titer

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information **Supplemental Form not required**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum
for Testing

Minimum Volume Required 0.5 mL; 1 mL preferred

Collection, Storage, and Preservation Samples can be stored refrigerated (2-8°C) for up to 7 days after collection or
of Specimen Prior to Shipping frozen (-20°C or lower) for up to 1 month. Samples should be shipped within 7
days for refrigerated samples and 1 month for frozen samples. Please see the
supplemental link for specific specimen storage and preservation.
<https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html>

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Shipping Instructions which Include Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the
Specimen Handling Requirements CDC Point of Contact with the tracking number of package. Frozen and
refrigerated specimens should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Rapid Fluorescent Focus Inhibition Test (RFFIT)

Turnaround Time 10 Days

Interferences & Limitations Hemolyzed samples interfere with test results

Additional Information Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If the test needs to be repeated results may take up to an additional 7 days.

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Version 2.1

Test Order
Rabies Confirmatory Testing (Animal)
CDC-10394

Synonym(s) Rabies Direct Fluorescent Antibody Test (DFA), Rabies Confirmatory DFA, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), LN 34 Real-time Assay

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information Required **Consultation is required prior to specimen submission. Submitter must submit a CDC 50.34 Specimen Submission Form for each specimen before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, initial phone consultation is not a suitable alternative to a written record.**

Supplemental Form **None**

Performed on Specimens From Animal

Acceptable Sample / Specimen Type for Testing Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required.

Collection, Storage, and Preservation of Specimen Prior to Shipping Stored at -80 °C and should be kept on dry ice

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship all specimens overnight and provide the CDC Point of Contact with the package tracking number. Frozen specimens should be shipped on dry ice.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Direct Fluorescent Antibody Test (DFA), Direct Rapid Immunohistochemistry test (DRIT), Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Virus Isolation, Antigenic Typing, Sequence Analysis
Turnaround Time	3 Days
Interferences & Limitations	Decomposition of tissues will interfere or limit testing results due to denaturation of viral protein and degradation of nucleic acids.
Additional Information	Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. May take longer than 3 days if repeat testing and additional procedures are required to rule-out rabies. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Duty Officers (404) 639-1050 Rabies@cdc.gov Lillian Orciari (404) 639-1065 Lorciari@cdc.gov James Ellison (404) 639-2693 JEllison@cdc.gov

Version 2.0

Test Order
Rabies Field Surveillance
CDC-10517

Synonym(s) Rabies Field Studies (Domestic and International)

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-2693
Rabies@cdc.gov
James A. Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Serum and (cerebrospinal fluid) CSF. Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required. 0.5 to 1.0 mL for serum and CSF. Other volumes may be considered upon consultation with Rabies Duty Officer.

Collection, Storage, and Preservation of Specimen Prior to Shipping Stored at -80 °C and should be kept on dry ice

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens should be shipped on dry ice.

Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular detection, Serology, Culture, Immunohistochemistry (IHC),, Other
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Turnaround Time	4 Weeks
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Interferences & Limitations	Test is limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
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Additional Information	This test is for the submission of samples to participate in a rabies surveillance. No results of testing will be reported back to submitters. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
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CDC Points of Contact	Rabies Duty Officer (404) 639-1050 Rabies@cdc.gov James A. Ellison (404) 639-2693 JEllison@cdc.gov
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Version 1.1

Test Order

Rabies Postmortem Human Testing

CDC-10396

Synonym(s) Rabies Direct Fluorescent Antibody Test (DFA), Direct Fluorescent Antibody Test, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), LN 34 Real-time Assay, Immunohistochemistry Test, Rabies IHC

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James A. Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information Required **Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form (for each specimen) and Possible Human Rabies - "Patient Information (CDC Form 55.30 (E)) before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussions during initial phone consultation is not a suitable alternative to a written record. Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted.**

Supplemental Form **Possible Human Rabies - "Patient Information (CDC Form 55.30 (E))**
<http://www.cdc.gov/rabies/pdf/rorform.pdf>

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Fresh-frozen brain tissues: full cross section of brain stem and representative aliquots of cerebellum (vermis, right and left lateral lobes). Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Fresh-frozen brain tissues: full cross section of brain stem and representative aliquots of cerebellum (vermis, right and left lateral lobes).

Collection, Storage, and Preservation of Specimen Prior to Shipping Unfixed tissue should be stored at -80 °C

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens should be shipped on dry ice.

Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	DFA for rabies virus antigen, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Direct Rapid Immunohistochemistry test (DRIT), Virus Isolation, Sequence Analysis, Antigenic Typing, Immunohistochemistry (IHC)
Turnaround Time	7 Days
Interferences & Limitations	Tests are limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
Additional Information	If fresh frozen brain tissues (preferred) are unavailable, then formalin-fixed tissues may be tested by immunohistochemistry (IHC) tests if approved by the Rabies Duty Officer. Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing. Please submit processed and paraffin embedded tissue blocks and unstained slides (5 per block) from the required tissues full cross section of the brain stem and representative aliquots of cerebellum, (vermis, right and left lobes) rather than tissues in 10% percent buffered formalin. Ship tissue blocks and unstained slides at ambient temperature, and do not freeze. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC.

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact	Rabies Duty Officer (404) 639-1050 Rabies@cdc.gov Lillian Orciari (404) 639-1065 Lorciari@cdc.gov James Ellison (404) 639-2693 JEllison@cdc.gov
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Test Order
Rabies Special Study
CDC-10501

Synonym(s) None

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Serum and (cerebrospinal fluid) CSF. Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required. 0.5 to 1.0 mL for serum and CSF. Other volumes may be considered upon consultation with Rabies Duty Officer.

Collection, Storage, and Preservation of Specimen Prior to Shipping Stored at -80C and should be kept on dry ice.

Transport Medium To be determined upon consultation with Rabies Duty Officer

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 89
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Direct Fluorescent Antibody Test (DFA) for rabies virus antigen, Direct Rapid Immunohistochemistry test (DRIT), Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Virus Isolation, Antigenic Typing, Sequence Analysis
Turnaround Time	6 Weeks
Interferences & Limitations	Test is limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
Additional Information	Do not ship specimens without prior consultation and approval. Critical specimens will take less than 3 days to turn around. If testing needs to be repeated results may take up to 12 weeks. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC.
CDC Points of Contact	James Ellison (404) 639-2693 JEllison@cdc.gov Subbian Satheshkumar Panayampalli (404) 639-1594 xdv3@cdc.gov

Version 1.2

Test Order
Rabies Virus Genetic Typing
CDC-10397

Synonym(s) Rabies Antigenic Typing, Rabies Monoclonal Antibody Typing, Rabies MAB Typing, Rabies RT-PCR, Rabies Sequence Analysis, Rabies Variant Typing

CDC Pre-Approval Needed **Rabies Duty Officer**
(404) 639-1050
Rabies@cdc.gov
James A. Ellison
(404) 639-2693
JEllison@cdc.gov

Supplemental Information Required **Please provide the county of origin of the animal in the CDC 50.34 Specimen Submission Form -æEpidemiological Data Section, in Other, specify box -.**

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Fresh-frozen brain tissues: full cross section of brain stem and cerebellum (vermis, right and left lateral lobes) preferred, or a viral isolate. Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Full cross section of brainstem is required.

Collection, Storage, and Preservation of Specimen Prior to Shipping Stored at -80 °C and should be kept on dry ice

Transport Medium Not Applicable

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC 50.34 Specimen Submission Form is required for each specimen. Ship all specimens overnight, delivery (before 10:30 AM) and provide the CDC Point of Contact with the tracking number of package. Frozen specimens should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

RDSB/STATT Unit 89

1600 Clifton Road, NE

Atlanta, GA 30329

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Antigenic Typing, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Sequencing

Turnaround Time 12 Weeks

Interferences & Limitations Decomposition of tissues will interfere or limit testing results due to denaturation of viral protein and degradation of nucleic acids.

Additional Information Samples for genetic typing may be a single sample, part of a large study or part of annual samples from a state for typing. The amount of testing required will depend on the reason for the testing and tests range from antigenic typing to whole genome sequencing and comparison with regional samples. Urgent samples for typing or molecular epidemiology are tested rapidly.

The test(s) used have not been cleared and approved by the FDA, the performance characteristics have established by CDC Rabies Laboratory. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC.

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov
Yu Li
(404) 639-2185
yuli@cdc.gov
Lillian Orciari
(404) 639-1065
lorciari@cdc.gov

Version 1.3

Test Order
Respiratory Panel (SARS-2, Influenza A/B)
CDC-10542

Synonym(s)	SARS-2 and Influenza A/B Respiratory Virus, COVID-19, coronavirus, SARS-CoV-2
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Upper or lower respiratory tract specimens, see CDC interim guidance: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Respiratory specimens stored for longer than 72 hours should be stored frozen at $\leq -70^{\circ}\text{C}$. All specimens submitted to CDC for testing should be shipped on dry ice overnight. Liquid specimen aliquots should be in properly labeled, leak-proof, unbreakable screw cap vials.
Transport Medium	Respiratory specimens should be collected and placed into appropriate transport media, such as viral transport media (VTM) or sterile saline.
Specimen Labeling	This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition. Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 66 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	3 Days

Interferences & Limitations Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests.

Additional Information None

CDC Points of Contact Jennifer Folster
(404) 639-3668
apz5@cdc.gov
John Barnes
(404) 639-2434
fzq9@cdc.gov
SARS2 FluAB Mailbox

CDCSARS2FluAB@cdc.gov

Version 1.2

Test Order
Respiratory Virus (Non-Influenza) Special Study
CDC-10400

Synonym(s)

CDC Pre-Approval Needed **Everardo Vega**
(404) 639-2396
evega@cdc.gov
Hannah Kirking
(404) 718-8345
hrj7@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 84
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Version 2.4

Test Order
Respiratory Virus Molecular Detection (Non-Influenza)
CDC-10401

Synonym(s) Non-influenza Respiratory Virus

CDC Pre-Approval Needed **Everardo Vega**
(404) 639-2396
evega@cdc.gov
Hannah Kirking
(404) 718-8345
hrj7@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping All specimens should be collected and processed in a manner that prevents cross-contamination between specimens, including changing gloves between specimens. Liquid specimens should be aliquoted into properly labeled, leak-proof, unbreakable screw cap vials.

All specimens should be refrigerated (2-8°C) promptly after collection. Specimens should be frozen (-20°C or lower) within 72 hours of collection then shipped on dry ice.

Transport Medium Swabs may be shipped in commercial viral transport media

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 84
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocked swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.

Additional Information None

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Version 2.5

Test Order
Rickettsia Molecular Detection
 CDC-10402

Synonym(s) Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group rickettsiosis, typhus group rickettsiosis

CDC Pre-Approval Needed None

**Supplemental Information
 Required**

Required information on the CDC 50.34 Specimen Submission Form:

- **Test order name (one per submission form)**
- **SPHL point of contact including phone number of the person responsible for sample submission and follow-up**
- **Patient full name, sex, birth date**
- **Date of onset (of symptoms)**
- **Specimen collected date**
- **Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)**
- **Therapeutic agent and dates (specific antibiotic therapy and initiation date**
- **State of illness**
- **Brief clinical summary (include signs, symptoms, and underlying illnesses if known)**

Requested additional information:

- **Previous laboratory results (physical exam findings and pertinent laboratory values)**
- **Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)**
- **Exposure history (including animals and arthropods)**

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute whole blood (taken within 14 days of illness onset or while symptomatic): EDTA-treated, or ACD A treated.
 Acute serum: Serum separator tube, or cryo-tubes. Vascularized tissue biopsies, including skin biopsy specimens from the site of rash or eschar. Swab specimen of eschar, using a dry, sterile cotton swab (include eschar scab when available). Samples must be collected before or within 72 hours of initiation of a tetracycline-class antibiotic, e.g., doxycycline (within 48 hours is preferred), or, if occurring outside of this established time frame, patients must be symptomatic at the time of collection.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For swab, place in sterile specimen container without any medium.

Transport Medium For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline. For swab, place in sterile specimen container without any medium.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Samples in saline buffer have decreased sensitivity and are subject to rejection. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with nucleic acid extraction.

Additional Information Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.

The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Molecular detection of other rickettsial disease organisms including Anaplasma, Coxiella, Orientia, and Ehrlichia may be performed. Results are reported directly to SPHLs.

Additional RZB specimen and shipping information can be found at the following address:

<https://www.cdc.gov/nceid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 2.1

Test Order
Rickettsia Serology Spotted Fever Group (RMSF) Serology
 CDC-10403

Synonym(s) Spotted fever group rickettsiosis, Rocky Mountain spotted fever (RMSF)

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB / STATT Unit 78
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	<p>Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially.</p> <p>The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia typhus group, Anaplasma, Coxiella, Orientia, and Ehrlichia may be performed. Results are reported directly to SPHLs.</p> <p>Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</p>
CDC Points of Contact	<p>Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov</p> <p>Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov</p>

Test Order
Rickettsia Serology Typhus Group Serology
 CDC-10404

Synonym(s) Typhus group rickettsiosis, including epidemic typhus and murine typhus

CDC Pre-Approval Needed None

Supplemental Information

Required

Required information on the CDC 50.34 Specimen Submission Form:

- Test order name (one per submission form)
- SPHL point of contact including phone number of the person responsible for sample submission and follow-up
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type, e.g., serum, whole blood, swab, tissue, etc.)
- Therapeutic agent and dates (specific antibiotic therapy and initiation date)
- State of illness
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Requested additional information:

- Previous laboratory results (physical exam findings and pertinent laboratory values)
- Travel history (within 4 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)
- Exposure history (including animals and arthropods)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature (2-8°C) up to 7 days after draw. If storing over 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped refrigerated on cold packs. If previously frozen, then keep specimen frozen, and ship on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. An antibody response may not be detected in the acute phase of illness; therefore, acute and convalescent serum samples are needed for diagnosis. Results from unpaired single sample titers may be indicative of a previous exposure. Single acute samples are directed towards molecular testing or subject to rejection.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Serological testing of other rickettsial disease organisms including Rickettsia spotted fever group, Anaplasma, Coxiella, Orientia, and Ehrlichia may be performed. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iww7@cdc.gov

Test Order
***Rickettsia* Special Study**
CDC-10405

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group rickettsiosis, typhus group rickettsiosis
CDC Pre-Approval Needed	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov
Supplemental Information Required	As determined during pre-approval consultation.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	As determined during pre-approval consultation.
Minimum Volume Required	As determined during pre-approval consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	As determined during pre-approval consultation.
Transport Medium	As determined during pre-approval consultation.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice. <p style="text-align: center;">CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.</p> <p style="text-align: center;">Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p style="text-align: center;">All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	As determined during pre-approval consultation.

Additional Information As determined during pre-approval consultation.

CDC Points of Contact Yan Zeng
(404) 639-5177
RZBrefdxlab@cdc.gov
Arlyn N Gleaton
(404) 639-4904
iww7@cdc.gov

Version 2.0

Test Order
Rift Valley Fever (RVF) Testing
CDC-10406

Synonym(s) RVF

CDC Pre-Approval Needed Trevor Shoemaker
(470) 312-0094
spather@cdc.gov
John Klena
(404) 639-0114
irc4@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VSPB Specimen Submission Form.
<https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html>

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing For serology testing, the accepted specimen types are whole blood (EDTA) or serum. Contact the CDC POC for approval prior to sending any specimens.

Animal specimens or human research specimens may be submitted with approval from CDC POC.

Minimum Volume Required 4 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.

Transport Medium Not Applicable

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order

Rotavirus Detection

CDC-10408

Synonym(s)	Rotavirus Antigen EIA, Rotavirus Antigen ELISA
CDC Pre-Approval Needed	None
Supplemental Information Required	Contact laboratory for supplemental forms
Supplemental Form	None
Performed on Specimens From	None
Acceptable Sample / Specimen Type for Testing	Solid stool, liquid stool and rectal swabs.
Minimum Volume Required	0.25 g or 0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stool specimens should be collected as soon after onset of symptoms as possible. Peak viral counts are reported to occur on days 3-5 after onset of symptoms. Samples collected eight days or more after onset of symptoms may not contain enough rotavirus antigen to produce a positive reaction. Do not collect specimens in containers having media, preservatives, animal serum or detergent, as any of these may interfere with the Premier Rotaclone assay. Diluted samples may be stored at 2-8°C for three days without interference with the assay performance. For long term storage of undiluted specimens, -20°C or colder is recommended. Repeated freezing and thawing of samples is not recommended and may cause erroneous results. Do not store in self-defrosting freezers.
Transport Medium	Do not send specimen in bacterial or viral transport medium or a fixative
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Include a hardcopy list of specimens with your shipment.</p> <p>Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 187 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.</p>
Methodology	Enzyme immunoassay (EIA)
Turnaround Time	14 Days
Interferences & Limitations	None

Additional Information Not Applicable

CDC Points of Contact Mike Bowen
(404) 639-4922
mkb6@cdc.gov
Amy Hopkins
(404) 639-1295
iwb3@cdc.gov

Version 2.6

Test Order
Rotavirus Genotyping
CDC-10409

Synonym(s)	Rotavirus Real Time RT-PCR, Rotavirus RT-PCR, Rotavirus Sequencing
CDC Pre-Approval Needed	None
Supplemental Information Required	Contact laboratory for supplemental forms.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Human stool
Minimum Volume Required	0.5 g or 0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen should be kept either frozen at -20 °C or colder or refrigerated at 4 °C. Specimen tubes or cups must be packed inside of a leak proof secondary container. The secondary container needs to be packed inside an approved class B specimen shipping container (i.e. Fisher scientific cat# 22-130-431).
Transport Medium	Contact laboratory about testing a stool specimen in Cary-Blair or viral transport media. Do not send the specimen in a fixative solution.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Include a hardcopy list of specimens with your shipment. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 187 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	RT-PCR, Sequencing
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	Contact laboratory for instructions to recover a limited sample from diaper material

CDC Points of Contact Mike Bowen
(404) 639-4922
mkb6@cdc.gov
Amy Hopkins
(404) 639-1295
iwk3@cdc.gov

Version 1.6

Test Order
Rubella Detection
CDC-10242

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs are preferred specimen types. Other acceptable specimen types include: throat swabs and urine.
Minimum Volume Required	Urine: 1 mL, not to exceed 50 mL. Throat and nasopharyngeal swabs: 1-3 mL of viral transport medium.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat and nasopharyngeal swabs: detection is most successful when samples are collected the first day of rash through 3 days following rash onset. Detection may be successful as late as 7 days post rash onset. Samples collected from suspected congenital rubella syndrome (CRS) cases, the collection window is from birth to 3 months of age for nasopharyngeal swab, throat swab, and urine specimens. Throat and nasopharyngeal swabs should be stored immediately in 1-3 mL of viral transport medium and should not be allowed to dry out. Synthetic swabs are recommended. Throat and nasopharyngeal swab specimens should be stored refrigerated (2-8°C) immediately after collection and should preferably be frozen (-20°C or lower) within 1 hour after collection. If laboratories do not have immediate access to a freezer and storage frozen (-20°C or lower) is not feasible within 1 hour of collection, these specimens may be stored for up to 72 hours refrigerated (2-8°C) before freezing. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen (-20°C or lower) and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 5 days of being frozen (-20°C or lower). Urine: Urine should be collected in a sterile, leakproof container. Urine specimens should be stored at refrigerated (2-8°C) immediately after collection and shipped to CDC overnight on cold packs. Urine specimens should arrive at CDC within 5 days of specimen collection. Urine cannot be frozen.
Transport Medium	Viral transport medium (VTM) for nasopharyngeal or throat swabs. Swabs should be immersed in 1-3 mL of viral transport medium. Transport medium is not required for urine.
Specimen Labeling	Test is subject to CLIA regulations and requires two patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as a medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swabs specimens should be shipped on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Laboratory developed real-time reverse-transcription polymerase chain reaction (RT-PCR) assay
Turnaround Time	10 Days
Interferences & Limitations	A negative result should not be used to rule out rubella infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB)
Additional Information	For additional information on rubella RNA detection, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the RNA Detection section.
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov

Version 3.2

Test Order
Rubella Genotyping
CDC-10550

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide any preliminary results available.
Supplemental Form	
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Throat swab, nasopharyngeal aspirate or swab are preferred sample types. Urine. Consult the Point of Contact for the following specimen types: Cataracts, lens aspirate, oral fluid, cerebrospinal fluid (CSF), dried blood spots, serum, isolates and tissue samples.
Minimum Volume Required	The volume of nasopharyngeal samples should be at least 1 mL. Urine volume should be at least 1 mL and should not exceed 50 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Detection is most successful when samples are collected the first day of rash through 3 days following rash onset. Detection may be successful as late as 7 to 10 days post rash onset. For urine samples, centrifuge at 1500 rpm for 10 minutes at 4 °C. Re-suspend the sediment in 2-3 mL of sterile transport media or tissue culture medium. Specimens can be kept refrigerated at 4 °C if shipped less than 72 hours after collection; otherwise specimen should be frozen at -70 °C. For samples collected from suspected CRS cases, the collection window is extended from birth to 3 months after birth for nasopharyngeal and urine samples and up to one year for cataracts.
Transport Medium	Viral transport medium for swabs and cataracts. Swabs should be immersed in 1-3 mL of viral transport medium. Cell culture medium for isolates.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be removed from centrifugation tube and transferred to a sterile plastic vial prior to shipment. Non-frozen specimens should be shipped with gel ice-packs; frozen specimens should be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Laboratory developed RT-PCR assays for genotyping and Sanger nucleic acid sequencing
Turnaround Time	2 Weeks
Interferences & Limitations	The genotyping assays have not cleared or approved by the FDA. The performance characteristics have not been fully established by VVPDB. The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patients medical record. These results should not be used for diagnosis, treatment, or assessment of patient health or management.
Additional Information	For additional information on rubella genotyping assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the RNA Detection and Genetic Analysis sections. For additional detail on sample collection, storage, and shipment, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 idn1@cdc.gov

Version 1.2

Test Order

Rubella Serology

CDC-10246

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	<p>Serum separated from whole blood by centrifugation.</p> <p>The following conditions may result in the specimen being rejected for testing:</p> <ul style="list-style-type: none"> • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.1 mL; 0.5-1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Optimum time-point for collection is 5 days after onset of symptoms (fever and rash). For suspected congenital rubella syndrome (CRS), collect sample as soon after birth as possible. If paired sera are to be collected, the second sample should be collected 14 to 21 days after the acute specimen was collected.</p> <p>Collect blood into a serum separation tube (serum-separation tube (STT), red-top, or tiger top. Do not add anticoagulants or preservatives. Do not freeze whole blood prior to separating serum. Aseptically transfer serum to a sterile tube after centrifugation and prior to shipping, preferably into a tube that has an externally threaded cap with an o-ring seal. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. Refrigerate serum (2-8°C) within 8 hours of collection and store for up to 48 hours. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). Serum specimens can be stored frozen (-20°C or lower) prior to shipping for a maximum of two months. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.</p>
Transport Medium	Not applicable
Specimen Labeling	Test is subject to CLIA regulations and requires two patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as a medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All serum specimens should be frozen prior to shipping to CDC and should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by EIA
Turnaround Time	10 Days
Interferences & Limitations	If a serum collected less than 5 days after onset is negative, a second sample is necessary to confirm/rule out rubella.
Additional Information	For additional information on serology assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the serology section. For additional details on sample collection, storage, and transport, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov

Version 2.3

Test Order
Rubella Serology (IgM and IgG) and Avidity
CDC-10249

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum separated from whole blood by centrifugation The following conditions may result in the specimen being rejected for testing: <ul style="list-style-type: none"> • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.1 mL; 0.5-1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Optimum time-point for collection is 5 days after onset of symptoms (fever and rash). For suspected congenital rubella syndrome (CRS), collect sample as soon after birth as possible. If paired sera are to be collected, the second sample should be collected 14 to 21 days after the acute specimen was collected. Collect blood into a serum separation tube (serum-separation tube (STT), red-top, or tiger top. Do not add anticoagulants or preservatives. Do not freeze whole blood prior to separating serum. Aseptically transfer serum to a sterile tube after centrifugation and prior to shipping, preferably into a tube that has an externally threaded cap with an o-ring seal. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. Refrigerate serum (2-8°C) within 8 hours of collection and store for up to 48 hours. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). Serum specimens can be stored frozen (-20°C or lower) prior to shipping for a maximum of two months. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Test is subject to CLIA regulations and requires two patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as a medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All serum specimens should be frozen prior to shipping to CDC and should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 81
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by EIA, IgG avidity is determined by a laboratory-developed assay using EIA
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Turnaround Time	10 Days
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Interferences & Limitations	If a serum collected less than 5 days after onset is negative, a second sample is necessary to confirm/rule out rubella. The rubella IgG avidity assay has not been cleared or approved by the FDA. The performance characteristics have been established by the Viral Vaccine Preventable Diseases Branch.
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Additional Information	For additional information on serology assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the serology section. For additional details on sample collection, storage, and transport, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html .
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CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov
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Version 2.3

Test Order
Salmonella Identification and Serotyping
CDC-10110

Synonym(s)	<i>Salmonella</i> Typing
CDC Pre-Approval Needed	None
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide any available specimen information. Provide any preliminary results including serotype and PNUSA Number in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of <i>Salmonella</i> , sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 27 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping
Turnaround Time	13 Weeks

Interferences & Limitations Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Susan Van Duyne
(404) 639-0186
mdv9@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Version 1.7

Test Order
Salmonella serotype Typhi (only) Serology
CDC-10453

Synonym(s) Enteric serology, Typhi serology

CDC Pre-Approval Needed **Rachael Aubert**
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Submission Form: date of specimen collection and date of illness onset or if patient is a suspect chronic carrier. Also indicate if patient received or is currently on antibiotics.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Preferred specimen type is paired patient serum collected during acute (within 1 week of symptom onset) and convalescent (at least 4 weeks post symptom onset) stages of illness.

Plasma is not acceptable for this test. Do not pool specimens. Include a CDC 50.34 Specimen Submission Form for each specimen submitted.

Minimum Volume Required 0.2 mL required, more preferred if available

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum can be stored refrigerated (2-8 °C) for up to one month, or frozen (below -20 °C). Avoid repeat freeze/thaw cycles.

Transport Medium Serum should be transferred to clean sterile tube for storage and shipment.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Serum can be shipped in a leak-proof container on gel ice-packs, frozen specimens should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Various methods depending on consultation include Indirect Hemagglutination, Enzyme-Linked Immunoassay (ELISA)
Turnaround Time	20 Weeks
Interferences & Limitations	Specimen should be stored and shipped either refrigerated (2-8 °C) or frozen (below -20 °C), as repeat freeze/thaw cycles can lower test sensitivity. Hemolysis present in serum specimens can interfere with this test.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. When submitting multiple specimens for one patient, include a separate CDC 50.34 Specimen Submission Form for each specimen submitted.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Zuzana Kucerova (404) 718-4143 zik0@cdc.gov

Version 2.1

Test Order
Salmonella Study
CDC-10109

Synonym(s)

CDC Pre-Approval Needed **Susan Van Duyne**
(404) 639-0186
mdv9@cdc.gov
Ana Lauer
(404) 639-2117
ybp6@cdc.gov

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide any available specimen information. Provide any preliminary results including serotype and PNUSA Number in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. Include any relevant testing worksheets with the submission as well. For submissions of data_sequence, the specimen identifier should be the PNUSA number.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing As directed by study protocol

Minimum Volume Required Minimum volume for microbial isolates is not applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 27
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Refer to study protocol for specific requirements

Turnaround Time

Interferences & Limitations Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.

Additional Information Refer to study protocol for specific requirements.

CDC Points of Contact Susan Van Duyne
(404) 639-0186
mdv9@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Version 2.1

Test Order
Salmonella Subtyping
CDC-10108

Synonym(s)	<i>Salmonella</i> Typing
CDC Pre-Approval Needed	None
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide any available specimen information. Provide any preliminary results including serotype and PNUSA Number in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	As directed by study protocol
Minimum Volume Required	Minimum volume for microbial isolates is not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 27 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	20 Weeks

Interferences & Limitations Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Susan Van Duyne
(404) 639-0186
mdv9@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Version 1.4

Test Order
SARS-CoV-2 Surveillance Sequencing
CDC-10551

Synonym(s) next generation sequencing, coronavirus, COVID, SARS2

CDC Pre-Approval Needed **Suxiang Tong**
404-639-1372
sot1@cdc.gov
Krista Queen
404-639-2287
wyz0@cdc.gov

Supplemental Information Required **Please do not include any PII in the sample submission. Previous real-time PCR results are required. Contact CDC POCs for submission form.**

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Upper or lower respiratory tract specimens, see CDC interim guidance: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Swabs must be shipped in viral transport media. Contact lab regarding acceptable alternatives.

Transport Medium Specimens should be promptly frozen at -70°C and shipped on dry ice. Liquid specimen aliquots should be into properly labeled, leak-proof, unbreakable screw cap vials. Samples should be collected and processed in a manner that prevents cross-contamination between specimens, including changing gloves between specimens.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Please e-mail SARSseq@cdc.gov to notify the CDC POC of the shipment.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 66
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Next generation sequencing on various platforms

Turnaround Time 4 Weeks

Interferences & Limitations The ability to generate whole genome sequences relies primarily on specimen quality and the viral load.

Additional Information None

CDC Points of Contact Suxiang Tong
404-639-1372
sot1@cdc.gov
Krista Queen
404-639-2287
wyz0@cdc.gov

SARSseq@cdc.gov

Version 2.0

Test Order
Schistosomiasis Serology
CDC-10466

Synonym(s)	<i>Schistosoma mansoni</i> , <i>Schistosoma haematobium</i> , <i>Schistosoma japonicum</i> ; Bilharzia, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include travel history (REQUIRED) and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	FAST-ELISA, Immunoblot, Western Blot, MAMA, HAMA, JAMA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.5

Test Order
Shiga Toxin-producing *E. coli* Isolation from Enrichment Broth
CDC-10105

Synonym(s) *Escherichia*, STEC, *E. coli*, enrichment broth

CDC Pre-Approval Needed **Haley Martin**
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Submit only broths that are positive for Shiga toxins (Stx1/Stx2) or the genes encoding these toxins and produce growth on subculture. Consult with CDC POC before sending other specimen types or fecal specimens in enrichment broth that are Stx+/stx+ but no growth of STEC on subculture.

Minimum Volume Required 5 mL (broth)

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate specimen at 2-8 °C.

Transport Medium Gram Negative Broth (GN), MacConkey Broth, MacConkey Sorbitol Broth, or similar enrichment broth

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship with ice-packs. Shiga toxin-positive broths should be shipped as Category A Infectious Substances.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 7
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Isolation, Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling
Turnaround Time	20 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	A final report will be issued for broths that are not confirmed as positive by PCR for STEC or from broths that are confirmed as positive by PCR but from which an STEC isolate can not be obtained. Identification, serotyping, and virulence profiling will be performed on recovered STEC isolates, and a final report will be issued when all testing is complete. Consult with Dr. Nancy Strockbine if a preliminary report is needed.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Haley Martin (404) 639-1612 hvw0@cdc.gov Devon Stoneburg (404) 639-2251 euo4@cdc.gov

Version 2.1

Test Order

Simian Immunodeficiency Virus (SIV) and SIV/Human Immunodeficiency Virus (SHIV) Recombinant Virus Testing CDC-10534

Synonym(s) SIV, SHIV (SIV/HIV recombinants)

CDC Pre-Approval Needed **Bill Switzer**
(404) 639-0219
bis3@cdc.gov
Hao Zheng
(404) 639-2421
hxz2@cdc.gov

Supplemental Information Required **All submitted specimens should be accompanied by a completed and printed CDC 50.34 Specimen Submission Form.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) purple top tubes.

Minimum Volume Required 10 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Whole blood should not be frozen but can be stored at room temperature (15-25°C) for up to 6 hours or refrigerated (2-8°C) for up to 24 hours prior to shipping.

Specimen stability is affected by elevated temperature.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Shipping of specimens the same day of collection is preferred. Ship unprocessed whole blood specimens overnight for next morning delivery at ambient temperature. Shipping of specimens overnight on wet ice packs is acceptable during periods of high environmental temperatures.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 227
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology real-time Polymerase Chain Reaction (PCR)

Turnaround Time 3 Weeks

Interferences & Limitations Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.

Additional Information None

CDC Points of Contact Bill Switzer
(404) 639-0219
bis3@cdc.gov
HaoQiang Zheng
(404) 639-2421
hxz2@cdc.gov

Version 1.3

Test Order
Special Bacteriology Pathogen Study
CDC-10147

Synonym(s)	
CDC Pre-Approval Needed	John McQuiston (404) 639-0270 zje8@cdc.gov Melissa Bell (404) 639-1348 jqv7@cdc.gov
Supplemental Information Required	Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined after consultation with point of contact listed below.
Minimum Volume Required	To be determined after consultation with point of contact listed below.
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined after consultation with point of contact listed below.
Transport Medium	To be determined after consultation with point of contact listed below.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship at room temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state, and federal regulations.
Methodology	To be determined after consultation with point of contact listed below.
Turnaround Time	
Interferences & Limitations	To be determined after consultation with point of contact listed below.
Additional Information	To be determined after consultation with point of contact listed below.

CDC Points of Contact John McQuiston
(404) 639-0270
zje8@cdc.gov
Melissa Bell
(404) 639-1348
jqv7@cdc.gov

Version 2.1

Test Order
Staphylococcal Toxic Shock Syndrome Toxin - Identification (ID)
CDC-10426

Synonym(s) Staph Toxin, Toxic Shock Syndrome (TSS), Panton-Valentine leukocidin (PVL), Toxic Shock Syndrome Toxin-1 (TSST-1)

CDC Pre-Approval Needed **David Lonsway**
(404) 639-2825
dul7@cdc.gov
Davina Campbell
(404) 639-4185
xew9@cdc.gov

Supplemental Information Required **For all submittals, the CDC 50.34 Specimen Submission Form must include the State Public Health Department contact information and the date the submitted culture was inoculated onto transport media.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Staphylococcus spp.*

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Pure culture isolates: store at room temperature (15-25°C) and ship within 24 hours after the 18-24 hour incubation of the culture being submitted, or store at refrigerated temperature (2-8°C) and ship within 48 hours. Alternatively, freeze culture within 7 days after 18-24 hour incubation and store frozen (-20°C or lower) until shipped.

Transport Medium Pure culture isolates room temperature or refrigerated: trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Frozen submissions: trypticase soy broth (TSB) plus 15% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Pure culture isolates: ship overnight at room temperature within 24 hours after the 18-24 hour incubation of the culture being submitted with room-temperature cold packs. If shipment must be delayed, cultures can be shipped refrigerated within 48 hours of 18-24 hour incubation with refrigerated or frozen cold packs. Cultures frozen within 7 days of 18-24 hour incubation should be shipped on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 13
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a Healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
CDC Points of Contact	David Lonsway (404) 639-2825 dul7@cdc.gov Davina Campbell (404) 639-4185 xew9@cdc.gov

Version 3.1

Test Order
Staphylococcus and Micrococcus - Identification (ID)
 CDC-10226

Synonym(s)	<i>Staph</i> , <i>Micrococcus</i> , <i>Kocuria</i> Identification
CDC Pre-Approval Needed	None
Supplemental Information Required	For all submittals, the CDC 50.34 Specimen Submission Form must include the State Public Health Department contact information and the date the submitted culture was inoculated onto transport media.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of suspected <i>Staphylococcus spp.</i> , <i>Micrococcus spp.</i> , <i>Kocuria spp.</i> and other aerobic, catalase-positive, Gram-positive cocci species
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure culture isolates: store at room temperature (15-25°C) and ship within 24 hours after the 18-24 hour incubation of the culture being submitted, or store at refrigerated temperature (2-8°C) and ship within 48 hours. Alternatively, freeze culture within 7 days after 18-24 hour incubation and store frozen (-20°C or lower) until shipped.
Transport Medium	Pure culture isolates room temperature or refrigerated: trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Frozen submissions: trypticase soy broth (TSB) plus 15% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Pure culture isolates: ship overnight at room temperature within 24 hours after the 18-24 hour incubation of the culture being submitted with room-temperature cold packs. If shipment must be delayed, cultures can be shipped refrigerated within 48 hours of 18-24 hour incubation with refrigerated or frozen cold packs. Cultures frozen within 7 days of 18-24 hour incubation should be shipped on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	16S ribosomal ribonucleic acid (rRNA) gene sequencing, matrix assisted laser desorption ionization-time of flight (MALDI-TOF), additional phenotypic testing

Turnaround Time 4 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information If a Healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.

CDC Points of Contact David Lonsway
(404) 639-2825
dul7@cdc.gov
Davina Campbell
(404) 639-4185
xew9@cdc.gov

Version 2.1

Test Order
***Staphylococcus aureus* Detection - Foodborne Outbreak**
CDC-10113

Synonym(s) *S. aureus*, Staphylococcal enterotoxins, SEs

CDC Pre-Approval Needed **Haley Martin**
(404) 639-1612
hvw0@cdc.gov
Nancy Strockbine
(404) 639-4186
nas6@cdc.gov

Supplemental Information Required **Only specimens from foodborne outbreaks accepted. Consult with CDC POC before sending samples. Include a CDC 50.34 Specimen Submission Form with each sample. For food or environmental samples (including derived isolates), provide the following information: specimen collected date, material submitted, specimen source (type), and if applicable, transport medium/specimen preservative and any preliminary results available. For human specimens (including derived isolates), provide the following information: date of onset, fatal, specimen collected date, material submitted, specimen source (type), and if applicable, transport medium/specimen preservative and any preliminary results available.**

Supplemental Form **None**

Performed on Specimens From Human and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing

Only implicated food (preferred sample type), vomitus and stool specimens (collected within 48 hours of illness onset), and their derived isolates are acceptable. Consult with CDC POC prior to sending specimens.

Minimum Volume Required 25 g (food) and 10 g (stool, vomitus)

Collection, Storage, and Preservation of Specimen Prior to Shipping

Collect stool and vomitus while patient is symptomatic (within 48 hours after illness onset). Separate foods into individual containers or bags. Refrigerate samples promptly after collection and maintain at 2-8 °C. Ship samples within two weeks from collection date. Food or stool stored longer than two weeks are not acceptable. If samples cannot be shipped within 2 weeks, promptly freeze upon collection at <-20 °C and ship frozen.

Transport Medium

Transport medium not applicable with food. Ship stool raw or in transport medium (e.g. Cary-Blair, Enteric Transport Medium). Ship isolates on non-selective agar.

Specimen Labeling

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with ice packs and ship frozen specimens on dry ice.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB / STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Toxin Detection (Food only), Culture (Food, Vomitus and Stool), Polymerase Chain Reaction (Isolates)
Turnaround Time	13 Weeks
Interferences & Limitations	Incorrect storage and/or spoilage of food may affect results. Reduced toxin detection and/or culture occurs in food older than two weeks. Stools collected 48 hours after illness onset and/or after patient recovery are not suitable for testing as they may not contain detectable organism.
Additional Information	Direct toxin detection requires food (toxin testing is not performed on stool). The test methods(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Haley Martin (404) 639-1612 hvw0@cdc.gov Nancy Strockbine (404) 639-4186 nas6@cdc.gov

Version 1.5

Test Order
***Streptococcus* (Beta Hemolytic Strep) Typing**
CDC-10216

Synonym(s) GAS typing, GBS typing, other beta hemolytic strep, Group A Strep, Group B Strep

CDC Pre-Approval Needed **Lesley McGee**
(404) 639-0455
lmcgee@cdc.gov
Sopio Chochua
(404) 639-4401
schochua@cdc.gov

Supplemental Information Required **See supplemental form: Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form**

Supplemental Form **Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. <https://www.cdc.gov/streplab/testing-request/index.html>**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure bacterial isolates; for other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Pure bacterial isolates (Beta-hemolytic *Streptococcus*) should be stored on an agar medium (e.g. blood or chocolate) or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media) and kept refrigerated (2-8°C) if shipped in less than 72 hours of collection; otherwise specimens should be frozen (-20°C or lower). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Transport Medium Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. There results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Sopio Chochua (404) 639-4401 schochua@cdc.gov

Version 1.4

Test Order
***Streptococcus* (Catalase-Negative, Gram-Positive Coccus) Identification**
CDC-10213

Synonym(s) *Streptococci, viridans streptococci, Enterococcus, Abiotrophia, Aerococcus, Alloiococcus, Dolosicoccus, Dolosigranulum, Facklamia, Gemella, Globicatella, Granulicatella, Helcococcus, Ignavigranulum, Lactococcus, Leuconostoc, Pediococcus, Tetragenococcus, Globiticatella, Vagococcus, and Weissella*

CDC Pre-Approval Needed **Lesley McGee**
(404) 639-0455
lmcgee@cdc.gov
Patricia Shewmaker
(404) 639-4826
PSHEWMAKER@cdc.gov

Supplemental Information Required **Complete the Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. Fill in all fields applicable to your isolate and provide any preliminary test results available.**

Supplemental Form **Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. <https://www.cdc.gov/streplab/testing-request/index.html>**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates that are catalase negative, Gram positive cocci.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Pure bacterial isolates stored on an agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media and kept refrigerated (2-8°C) if shipped in less than 72 hours of collection; otherwise isolates should be frozen (-20°C or lower).

Transport Medium Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media).

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. There results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on frozen gel packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking.

Methodology	Phenotypic Biochemical and Serological Testing, Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Patricia Shewmaker (404) 639-4826 PSHEWMAKER@cdc.gov

Version 2.2

Test Order
Streptococcus ABCs Surveillance Study
CDC-10218

Synonym(s)

CDC Pre-Approval Needed **Lesley McGee**
(404) 639-0455
LMCGEE@cdc.gov
Sopio Chochua
(404) 639-4401
schochua@cdc.gov

Supplemental Information Required **See supplemental form: ACTIVE BACTERIAL CORE SURVEILLANCE (ABCS) CASE REPORT**

Supplemental Form **ACTIVE BACTERIAL CORE SURVEILLANCE (ABCS) CASE REPORT.**
<https://www.cdc.gov/abcs/methodology/data-collect-forms.html>

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Sterile site pure isolates of Group A *Streptococcus* (GAS), Group B *Streptococcus* (GBS) and *S. pneumoniae* that meet the ABCs inclusion criteria

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping For isolates, store on blood or chocolate agar, in transport media or as a frozen glycerol stock; additional details and directions will be provided upon consultation.

Transport Medium The transport media is the same as the storage media.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. There results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on frozen gel packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21-ABC
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Phenotypic Biochemical and Serological Testing, Molecular Testing

Turnaround Time 8 Weeks

Interferences & Limitations No significant interferences or limitations are currently known.

Additional Information See Active Bacterial Core surveillance (ABCs) website.
<https://www.cdc.gov/abcs/index.html>

CDC Points of Contact Lesley McGee
(404) 639-0455
LMCGEE@cdc.gov
Sopio Chochua
(404) 639-4401
schochua@cdc.gov

Version 2.1

Test Order

Streptococcus Identification and Antimicrobial Susceptibility Testing

CDC-10214

Synonym(s)	Streptococci, viridans streptococci, <i>Streptococcus pneumoniae</i> , <i>Streptococcus pyogenes</i> , <i>Streptococcus agalactiae</i> , AST, Sensitivity, MIC testing
CDC Pre-Approval Needed	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Patricia Shewmaker (404) 639-4826 PSHEWMAKER@cdc.gov
Supplemental Information Required	Complete the Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. Fill in all fields applicable to your isolate and provide any preliminary test results available.
Supplemental Form	Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of Genus <i>Streptococcus</i> .
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates stored on an appropriate agar medium (e.g. blood or chocolate), transport media, or frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media. Specimens can be kept refrigerated at 2-8 °C if shipped in less than 72 hours of collection; otherwise specimen should be frozen at or below -70 °C. Fastidious bacteria should be stored at room temperature (15 °C (59 °F) and 25 °C (77 °F)) and shipped within 24 hours or shipped frozen at or below -70 °C and shipped on dry ice in a 15% to 20% glycerol containing growth media. For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media).
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. There results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking.

Methodology	Phenotypic Biochemical and Serological Testing, Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
	Please include senders test results and presumed identificaiton.
CDC Points of Contact	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Patricia Shewmaker (404) 639-4826 PSHEWMAKER@cdc.gov

Version 3.2

Test Order
***Streptococcus pneumoniae* Typing**
CDC-10215

Synonym(s) Pneumococcus Serotyping

CDC Pre-Approval Needed **Lesley McGee**
(404) 639-0455
lmcgee@cdc.gov
Sopio Chochua
(404) 639-4401
schochua@cdc.gov

Supplemental Information Required **Supplemental form required for pre-approval: *Streptococcus pneumoniae* Testing Request Form. If you have questions, contact the CDC POC.**

Supplemental Form ***Streptococcus pneumoniae* Testing Request Form.**
<https://www.cdc.gov/streplab/testing-request/index.html>

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure *Streptococcus pneumoniae* bacterial isolates; contact the CDC POC for approval prior to sending other specimen types.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Pure *S. pneumoniae* isolates should be stored on an agar medium (e.g. blood or chocolate) or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media) and kept refrigerated (2-8°C) if shipped in less than 72 hours of collection; otherwise specimens should be frozen (-20°C or lower). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Transport Medium Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Specimen Labeling This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. There results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Sopio Chochua (404) 639-4401 schochua@cdc.gov

Version 1.5

Test Order
Streptococcus Study
CDC-10217

Synonym(s)	
CDC Pre-Approval Needed	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Sopio Chochua (404) 639-4401 schochua@cdc.gov
Supplemental Information Required	See supplemental form: Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form
Supplemental Form	Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure bacterial isolates; for other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates (Genus Streptococcus) should be stored on an agar medium (e.g. blood or chocolate) or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media) and kept refrigerated (2-8°C) if shipped in less than 72 hours of collection; otherwise specimens should be frozen (-20°C or lower). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 21
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Lesley McGee (404) 639-0455 lmcgee@cdc.gov Sopio Chochua (404) 639-4401 schochua@cdc.gov

Version 2.2

Test Order
Strongyloidiasis Serology
CDC-10467

Synonym(s)	Strongyloidiasis, <i>Strongyloides stercoralis</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.4

Test Order
Syphilis Serology
CDC-10173

Synonym(s) Treponemal and non-treponemal

CDC Pre-Approval Needed **Yetunde Fakile**
(404) 639-3784
yfakile@cdc.gov
Weiping Cao
(404) 639-5443
jgz9@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum, cerebrospinal fluid (CSF)
for Testing

Minimum Volume Required 1 mL (for serum), 0.5 mL (for CSF)

Collection, Storage, and Preservation Serum specimens can be stored refrigerated (2-8°C) for up to 48 hours after
of Specimen Prior to Shipping collection; after 48 hours, specimens must be frozen (-20°C or lower) until testing.

CSF specimens can be stored refrigerated (2-8°C) for up to 5 days after collection;
after 5 days, specimens must be frozen (-20°C or lower) until testing.

Transport Medium None

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g.,
patient first and last name, date of birth, unique patient identifier from time of
collection, such as medical record number) on the specimen container and on the
test requisition.

Shipping Instructions which Include Frozen specimen should be shipped on dry ice and refrigerated specimen should
Specimen Handling Requirements be shipped on cold packs, as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make
sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 24
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology CSF-VDRL, Serum-RPR, TPPA, Trep-Sure, Serum-VDRL (upon request)

Turnaround Time 3 Weeks

Interferences & Limitations Avoid freeze-thaw cycles as this can affect test results. Hyperlipemia, hemolytic, or contaminated samples can affect test results

Additional Information None

CDC Points of Contact Yetunde Fakile
(404) 639-3784
yfakile@cdc.gov
Weiping Cao
(404) 639-5443
jgz9@cdc.gov
Kevin Pettus
(404) 639-4338
kbp9@cdc.gov

Version 2.5

Test Order
Tick Borne Encephalitis (TBE) Testing
CDC-10415

Synonym(s)	
CDC Pre-Approval Needed	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klana (404) 639-0114 irc4@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	VSPB Specimen Submission Form. https://www.cdc.gov/ncezid/dhcpp/vspb/specimens.html
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	<p>For serology testing, the accepted specimen types are whole blood (EDTA) or serum. Contact the CDC POC for approval prior to sending any specimens.</p> <p>Animal specimens or human research specimens may be submitted with approval from CDC POC.</p>
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens must be kept refrigerated (2-8°C) for up to 7 days, or frozen (-20°C or below) for up to 2 months. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.
Transport Medium	Not Applicable
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 70
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Molecular Typing, Polymerase Chain Reaction (PCR), Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov John Klena (404) 639-0114 irc4@cdc.gov

Version 2.2

Test Order

Toxocariasis Serology

CDC-10468

Synonym(s)	Larva migrans, Toxocariasis, <i>Toxocara canis</i> , <i>Toxocara cati</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera or vitreous fluid specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 4.6

Test Order

Transmission Electron Microscopy (EM) Evaluation for Possible Infectious Etiologies CDC-10559

Synonym(s) Transmission electron microscopy (TEM), electron microscopy (EM), thin section, negative stain, autopsy, necropsy, biopsy, glutaraldehyde-fixed tissues, paraformaldehyde-fixed tissues, pathology

CDC Pre-Approval Needed **Infectious Diseases Pathology Mailbox**
(404) 639-3132
pathology@cdc.gov
Hannah Bullock
(404) 718-6434
ocr3@cdc.gov

Supplemental Information Required **Please include the following information with each submission:**

Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:

- Test order code
- Test order name
- Patient full name
- Patient birth date
- Date of death (if applicable)
- Patient ID (e.g., medical record number or autopsy number)
- Specimen ID (e.g., surgical pathology accession number)
- State public health laboratory (PHL) point of contact
- Original submitter contact information

One electronically completed copy of the CDC 50.34 Specimen Submission Form per case is sufficient, unless specimens are being submitted from multiple specimen collection dates in one package.

Requested additional information:

- A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information
 - A copy of: (a) the autopsy report (preliminary or final), or (b) surgical pathology report
 - Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)
 - Relevant clinical, gross pathology, or microscopic pathology images, as available
 - A key listing the tissues submitted for evaluation
-

Supplemental Form **None**

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing	<p>Glutaraldehyde-fixed biopsy, autopsy, or necropsy tissues from any organ or site are acceptable. However, tissue specimens should be submitted from the site(s) of the patient's disease process.</p> <p>Thin section EM: glutaraldehyde-fixed wet tissues, epoxy-embedded tissues, and ultrathin sections from epoxy-embedded tissues are acceptable.</p> <p>Negative stain EM: paraformaldehyde-fixed cell culture supernatants and body fluids (e.g., cerebral spinal fluid, saliva, urine, stool samples, and crusts to be evaluated for rash illness) are acceptable.</p> <p>Specimens may be rejected if specimen integrity is found to be compromised.</p>
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Wet tissue specimens:</p> <ul style="list-style-type: none"> • Gross in at approximately 1-3 mm³ and fix in phosphate-buffered 2-4% glutaraldehyde (2.5% preferred). • After fixation (preferably the next day but less than 2 weeks), tissues should be transferred to a container filled to the top with 0.1M phosphate buffer. • Store refrigerated (2-8°C); do not freeze. <p>Epoxy-embedded tissues:</p> <ul style="list-style-type: none"> • store at room temperature (15-25°C). <p>Specimens for negative stain analysis (cell culture supernatants and body fluids):</p> <ul style="list-style-type: none"> • Fix in phosphate-buffered 5% paraformaldehyde (preferred) at a 1:1 specimen to fixative ratio for a final concentration of 2.5% paraformaldehyde. • Store refrigerated (2-8°C); do not freeze. <p>Ship to CDC within 3 weeks of collection.</p>
Transport Medium	<p>Glutaraldehyde-fixed tissues: hold in 0.1M phosphate buffer.</p> <p>Epoxy embedded tissues: no transport medium required.</p> <p>Specimens for negative stain analysis (cell culture supernatants and body fluids): hold in phosphate-buffered 2.5% paraformaldehyde.</p>
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov).
 Glutaraldehyde-fixed tissues can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze. Epoxy-embedded tissues can be shipped at room temperature with room-temperature cold packs. Specimens for negative stain analysis (cell culture supernatants and body fluids) can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 109
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Electron Microscopy (EM), Electron Microscopy (EM)
Turnaround Time	8 Weeks
Interferences & Limitations	Prolonged glutaraldehyde fixation (greater than 2 weeks) may result in decreased morphological appearance. When indicated, 0.5-micron sections from the epoxy-embedded blocks (prepared after trimming or ultra-thin sectioning) will be reviewed by the pathologist to ensure that appropriate areas have been selected.
Additional Information	<p>CDC Pre-Approval Needed:</p> <ul style="list-style-type: none"> • Contact Pre-approval POC • Infectious Diseases Pathology Branch Mailbox <p>More specific guidelines regarding tissue sampling and submission can be found on the IDPB website: http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html</p> <p>Turnaround Time is case-dependent:</p> <ul style="list-style-type: none"> • Human surgical biopsy cases it is 6-8 weeks • Complex cases, routine human autopsy cases, and animal cases it is 12 weeks.
CDC Points of Contact	<p>Infectious Diseases Pathology Mailbox (404) 639-3132 pathology@cdc.gov Hannah Bullock (404) 718-6434 ocr3@cdc.gov Roosecelis Martines (404) 639-3886 xgn7@cdc.gov</p>

Test Order
Treponema pallidum Molecular Detection Study
 CDC-10176

Synonym(s)	Syphilis
CDC Pre-Approval Needed	Allan Pillay (404) 639-2140 apillay@cdc.gov Weiping Cao (404) 639-5443 jgz9@cdc.gov
Supplemental Information Required	Specimen type and specimen source must be filled on the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Swab of an ulcer, skin lesion, or mucous patch; whole blood collected in an EDTA tube (purple top); body fluids (cerebrospinal fluid (CSF), ocular fluid, amniotic fluid); frozen unfixed tissue; formalin-fixed paraffin-embedded (FFPE) tissue; lymph node aspirate; swab of nasal discharge (congenital cases); cord blood in EDTA tube (purple top).
Minimum Volume Required	0.5 mL whole blood (1 mL preferred) 1 mL cord blood (2-3 mL preferred) 0.2 mL cerebrospinal fluid (CSF) (1-2 mL preferred) 50 µL ocular fluid 0.5 mL amniotic fluid (1-3 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Lesion swabs must be frozen (-20°C or lower) within 3 hours of collection; or stored at 2-8°C for up to 48 hr and then frozen (-20°C or lower). Whole blood or cord blood in EDTA tube (purple top), body fluids, unfixed biopsy tissue, lymph node aspirate, and nasal discharge (congenital cases) must be frozen (-20°C or lower) within 3 hours of collection. FFPE tissue should be stored at room temperature (15-25°C). FFPE tissue must be shipped at room temperature. The other specimen types must be shipped frozen on dry ice.
Transport Medium	Lesion swabs should be transported on commercial transport medium suitable for nucleic acid amplification test (NAAT): Becton-Dickinson UVT, Hologic Aptima Multitest swab collection kit, Hologic Aptima Unisex swab collection kit, and Remel Microtest M4RT.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice, refrigerated specimen should be shipped on cold packs and FFPE can be shipped at room temperature, as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	PCR
Turnaround Time	
Interferences & Limitations	None
Additional Information	Only residual specimens collected for other routine diagnostics testing should be submitted. Specimens collected under this test order will be used for test validation or surveillance purposes. This test is not FDA-cleared or approved, or conducted under CLIA regulations. The results cannot be used for diagnosis, treatment, or assessment of patient health or management. A key agreement, which prevents personal identifying information from being shared with CDC, must be signed prior to submission of specimens.
CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov Weiping Cao (404) 639-5443 jgz9@cdc.gov Charles Thurlow (404) 718-7388 oso4@cdc.gov Kendra Vilfort (404) 718-8025 qmg5@cdc.gov
Version	3.2

Test Order
Treponema pallidum Molecular Typing Study
 CDC-10177

Synonym(s)	<i>Treponema pallidum</i> Genotyping, <i>Treponema pallidum</i> Strain Typing, Syphilis Typing
CDC Pre-Approval Needed	Allan Pillay (404) 639-2140 apillay@cdc.gov Weiping Cao (404) 639-5443 jgz9@cdc.gov
Supplemental Information Required	Specimen type and specimen source must be filled on the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Swab of an ulcer, skin lesion, or mucous patch; whole blood collected in an EDTA tube (purple top); body fluids (cerebrospinal fluid (CSF), ocular fluid, amniotic fluid); frozen unfixed tissue; lymph node aspirate; swab of nasal discharge (congenital cases); cord blood in EDTA tube (purple top).
Minimum Volume Required	0.5 mL whole blood (1 mL preferred) 1 mL cord blood (2-3 mL preferred) 0.2 mL cerebrospinal fluid (CSF) (1-2 mL preferred) 50 µL ocular fluid 0.5 mL amniotic fluid (1-3 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Lesion swabs must be frozen (-20°C or lower) within 3 hours of collection; or stored at 2-8°C for up to 48 hr and then frozen (-20°C or lower). Whole blood or cord blood in EDTA tube (purple top), body fluids, unfixed biopsy tissue, lymph node aspirate, and nasal discharge (congenital cases) must be frozen (-20°C or lower) within 3 hours of collection. Ship specimens frozen on dry ice.
Transport Medium	Lesion swabs should be transported on commercial transport medium suitable for nucleic acid amplification test (NAAT): Becton-Dickinson UVT, Hologic Aptima Multitest swab collection kit, Hologic Aptima Unisex swab collection kit, and Remel Microtest M4RT.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimen should be shipped on dry ice, refrigerated specimen should be shipped on cold packs and FFPE can be shipped at room temperature, as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 31
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	PCR, Sequencing, RFLP
Turnaround Time	
Interferences & Limitations	None
Additional Information	Only residual specimens collected for other routine diagnostics testing should be submitted. Specimens collected under this test order will be used for test validation or surveillance purposes. This test is not FDA-cleared or approved, or conducted under CLIA regulations. The results cannot be used for diagnosis, treatment, or assessment of patient health or management. A key agreement, which prevents personal identifying information from being shared with CDC, must be signed prior to submission of specimens.
CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov Weiping Cao (404) 639-5443 jgz9@cdc.gov Kendra Vilfort (404) 718-8025 qmg5@cdc.gov Charles Thurlow (404) 718-7388 oso4@cdc.gov
Version	3.2

Test Order
Trichinellosis Serology
CDC-10470

Synonym(s)	Trichinosis, <i>Trichinella spiralis</i> , parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 3 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted.</p> <p>Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact’s Telephone Number]</p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.

CDC Points of Contact Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Version 2.5

Test Order
Trichomonas Susceptibility
CDC-10239

Synonym(s)	<i>Trichomonas</i> , trich, parasite
CDC Pre-Approval Needed	None
Supplemental Information Required	A supplemental form is required. Please call the CDC POC to request a testing kit that will include the supplemental form and an InPouch TV culture media device for specimen submission. Alternatively, send mailing address and phone number to the CDC POC to request a kit. Please include the metronidazole treatment history and the supplemental form with the specimen.
Supplemental Form	Provided with the collection kit
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be sent to CDC on the same day as they are collected from the patient. Do not collect and send specimens on a Friday or the day before a federal holiday. Specimens received more than 2 days after collection will be rejected. Do not refrigerate or freeze the specimen.
Transport Medium	InPouch TV (Commercial product). See Supplemental Information Required for instructions how to obtain a testing kit prior to specimen collection.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ensure the InPouch is properly closed and place it in the mailing container that they arrived in. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Antimicrobial susceptibility
Turnaround Time	7 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	CDC does not pay for shipment of the organism.

CDC Points of Contact Parasitic Inquiries
(404) 718-4745
parasites@cdc.gov
Evan Secor
(404) 718-4141
was4@cdc.gov
Pete Augustini
(678) 860-6128
pfa9@cdc.gov

Version 2.5

Test Order
***Trypanosoma cruzi* Molecular Detection - Insects**
CDC-10493

Synonym(s)	Chagas, American Trypanosomiasis, trypanosome, parasite, triatomine, kissing bug, <i>T. cruzi</i>
CDC Pre-Approval Needed	None
Supplemental Information Required	Provide detailed information of the human exposure to the insect and where the insect was found (kitchen, bed, porch, etc.) in the Comments field of the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Triatomine insect
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store specimen dry or in 70% ethanol at ambient temperature.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Insects should be shipped in a crush-proof container in a box or shipping tube. Padded envelopes are not acceptable. Ship at ambient temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 222 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Conventional Polymerase Chain Reaction (PCR) and Sanger sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	None

CDC Points of Contact Gena Lawrence
(404) 718-4315
geg7@cdc.gov
Alice Sutcliffe
(404) 718-4326
gok0@cdc.gov

Version 2.0

Test Order
Varicella Zoster Virus (VZV) Avidity
CDC-10256

Synonym(s) Chicken pox, shingles

CDC Pre-Approval Needed **Joseph Icenogle**
(404) 639-4557
jci1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Supplemental Information
Required **None**

Supplemental Form
None

Performed on Specimens From Human

Acceptable Sample / Specimen Type Serum or plasma
for Testing

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of
of Specimen Prior to Shipping collection; otherwise specimen should be kept frozen at -20 °C.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Ship specimens with cold packs or dry ice as an etiologic agent.
Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology IgG avidity

Turnaround Time 7 Days

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Joseph Icenogle
(404) 639-4557
jci1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Version 1.6

Test Order
Varicella Zoster Virus (VZV) Genotyping (Clade Type)
CDC-10257

Synonym(s) Chicken pox, shingles

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Supplemental Information
Required **None**

Supplemental Form
None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Skin lesions, scab, saliva, cerebrospinal fluid (CSF), urine, biopsy/autopsy samples (disseminated infection), whole blood

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Skin lesion samples and scabs should be kept dry. Saliva, cerebrospinal fluid (CSF), urine, or whole blood can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection; otherwise these specimens should be kept frozen at -20 °C. Whole blood should be collected in EDTA or citrate tubes.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase Chain Reaction (PCR), DNA sequencing

Turnaround Time 2 Weeks

Interferences & Limitations There are no known interferences and limitations.

Additional Information The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Version 1.8

Test Order
Varicella Zoster Virus (VZV) Intrathecal Antibody Detection
CDC-10496

Synonym(s) Chicken pox, shingles

CDC Pre-Approval Needed **Sheila Dollard**
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Supplemental Information
Required **None**

Supplemental Form
None

Performed on Specimens From Human

Acceptable Sample / Specimen Type Paired serum sample and cerebrospinal fluid (CSF) (both samples are required)
for Testing

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of
of Specimen Prior to Shipping collection; otherwise specimen should be kept frozen at -20 °C. If stored at 4 °C,
it can be overnighted on cold packs in well-sealed O-ring vials; if frozen, it can be
overnighted on dry ice in well-sealed O-ring vials.

Transport Medium Transport medium is not required.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels
should not include personally identifiable information. The results reported
should NOT be used for diagnosis, treatment, assessment of health or
management of the individual patient.

Shipping Instructions which Include CDC does not accept routine shipments on weekends or holidays. Please make
Specimen Handling Requirements sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and
federal regulations.

Methodology Glycoprotein (gp) Enzyme Linked Immunosorbent Assay (ELISA)

Turnaround Time 7 Days

Interferences & Limitations At least one of the specificity controls must be both positive in serum and negative in the cerebrospinal fluid (CSF); if all three specificity controls are negative in both serum and CSF, interpretation is not possible (If specimen volume allows, additional specificity controls could be attempted, e.g., for anti-cytomegalovirus (CMV) antibody).

Additional Information gpELISA VZV antibody detection method used to determine presence of specific antibody in both CSF and serum. Herpes simplex virus 1 (HSV-1), 2 (HSV-2), and human herpesvirus 6 (HHV-6) antibody measurements are performed as specificity controls on both samples. A ratio of 1:10 CSF to serum VZV antibody (Ab) is regarded as positive if and only if at least one of the specificity controls is both Ab positive in serum and negative in CSF.

The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact Sheila Dollard
(404) 639-2178
sdollard@cdc.gov
Suganthi Suppiah
(404) 718-3461
ssuppiah@cdc.gov

Version 1.6

Test Order
Varicella Zoster Virus (VZV) Serology
CDC-10255

Synonym(s)	Chicken pox, shingles
CDC Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL (serum, plasma, cerebrospinal fluid (CSF))
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Collect whole venous peripheral blood in serum separator vacutainer tube. Allow specimen to fully clot by standing at room temperature (15-25°C) for at least 30 minutes. After the clot has formed, tube can be centrifuged at approximately 1100 - 1300 x g for 10 minutes. The clot will have passed to the bottom of the tube, leaving the serum on top of the separator plug. The serum can then be aliquoted into an o-ring seal freezing tube using a pipette.</p> <p>For plasma collection, use an anticoagulant venous vacutainer tube, e.g. EDTA. To ensure mixing of the anticoagulant with the whole blood, invert the tube several times immediately after collection. Centrifuge at 800 – 1000 x g for 10 minutes. Remove the plasma and aliquot into an o-ring seal freezing tube using a pipette.</p> <p>Serum and plasma should be refrigerated (2-8°C) within 1 hour of collection. If stored for longer than 48 hours, specimens should be frozen (-20°C or lower).</p> <p>Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and placed in a leak proof container. CSF should be frozen (-20°C or lower) after collection but, if needed, it can be stored at 2-8°C for no more than 72 hours. CSF specimens submitted for testing at CDC should be stored frozen at -20°C for a maximum of 1 week prior to shipping.</p> <p>All specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped within 1 week on dry ice overnight.</p>
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum, plasma, and cerebrospinal fluid (CSF) specimens should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by Enzyme Immunoassay (EIA)
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Turnaround Time	7 Days
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Interferences & Limitations	There are no known interferences and limitations.
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Additional Information	None
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CDC Points of Contact	Sheila Dollard (404) 639-2178 sgd5@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov
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Version 2.3

Test Order
Varicella Zoster Virus Detection (Wild-type vs. Vaccine)
CDC-10254

Synonym(s) Chicken pox, shingles

CDC Pre-Approval Needed None

Supplemental Information
Required None

Supplemental Form
None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing This test order is currently not accepting any specimens until further notice.

Minimum Volume Required Cerebral spinal fluid: 0.5 mL, 1 mL preferred

Whole blood: 0.5 - 1 mL

Viral transport media inoculated with swabs from vesicular or pustular fluid: 0.5 - 1 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping For the collection of skin lesion specimens, unroof the scab and place it directly into a breakage resistant tube. For swab collections of vesicular/pustular fluid from lesions, use a sterile needle to unroof the top of the vesicle. Use a sterile synthetic swab, e.g. polyester swab, to vigorously swab the base of the lesion, applying enough pressure to collect epithelial cells. Swabs may be placed directly into a storage tube. Swabs without VTM, skin lesion samples, and scabs should be kept dry and shipped at room temperature (15-25°C) within one week after collection.

Swabs can also be placed in viral transport media. Refrigerate (2-8°C) viral transport medium (VTM) inoculated with swabs from vesicular or pustular fluid. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower.

Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and stored in a leakproof container. CSF should be stored at -20°C or lower after collection but if needed, it can be stored at 2-8°C for no more than 72 hours. CSF specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. CSF can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Anticoagulant blood collection tubes (EDTA) should be used for the collection of whole blood. Fresh biopsy/autopsy specimens can be collecting by cutting a small piece of tissue (approximately 0.25 g) from the leading edge that is suspected of disseminated infection and place it in a sterile storage container containing saline. Refrigerate whole blood and fresh tissue biopsy/autopsy specimens stored in saline at 2-8°C within 1 hour of collection. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower.

CSF, viral transport media inoculated with swabs from vesicular or pustular fluid, whole blood, and fresh tissue biopsy/autopsy specimens stored in saline submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.

Transport Medium	Swabs inoculated with vesicular or pustular fluid should be placed in viral transport media. Fresh tissue biopsy/autopsy samples should be placed in sterile saline.
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Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
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Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Swabs without viral transport media (VTM), skin lesion samples and scabs should be shipped overnight at room temperature with room-temperature cold packs. Cerebrospinal fluid (CSF), viral transport media inoculated with swabs from vesicular or pustular fluid, whole blood and fresh tissue biopsy/autopsy specimens stored in saline should be shipped frozen on dry ice overnight.

Ship To:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 80
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact’s Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	For submission of fixed tissues for testing, submitters should contact Infectious Diseases Pathology Branch at pathology@cdc.gov for guidance on submission process.
CDC Points of Contact	Sheila Dollard (404) 639-2178 sgd5@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

Version 3.3

Test Order
***Vibrio cholerae* Identification and Subtyping**
CDC-10119

Synonym(s)	Cholera
CDC Pre-Approval Needed	None
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of <i>Vibrio cholerae</i> ; sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	If isolates are shipped at room temperature, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 08 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	13 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 3.2

Test Order
Vibrio cholerae Serology
CDC-10454

Synonym(s) Enteric serology

CDC Pre-Approval Needed **Rachael Aubert**
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Supplemental Information Required **Provide the following information on the CDC 50.34 Specimen Submission Form: date of specimen collection and date of illness onset. Also indicate if patient received or is currently on antibiotics.**

Supplemental Form **None**

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Preferred specimen type is paired patient serum collected during acute (within 1 week of symptom onset) and convalescent (at least 4 weeks post symptom onset) stages of illness.

Serum is preferred, but plasma is acceptable. Do not pool specimens. Include a CDC 50.34 Specimen Submission Form for each specimen submitted.

Minimum Volume Required 0.1 mL required, more preferred if available

Collection, Storage, and Preservation of Specimen Prior to Shipping Serum can be stored refrigerated (2-8 °C) for up to one month, or frozen (below -20 °C). Avoid repeat freeze/thaw cycles.

Transport Medium Serum or plasma should be transferred to clean sterile tube for storage and shipment.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Serum can be shipped in a leak-proof container on gel ice-packs, frozen specimens should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 129
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Various methods depending on consultation may include Enzyme-Linked Immunoassay (ELISA); Bacteriacidal Immunoassay
Turnaround Time	20 Weeks
Interferences & Limitations	Specimen should be stored and shipped either refrigerated (2-8 °C) or frozen (below -20 °C), as repeat freeze/thaw cycles can lower test sensitivity. Hemolysis present in serum specimens may interfere with this test depending on the methodology used.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. When submitting multiple specimens for one patient, include a separate CDC 50.34 Specimen Submission Form for each specimen submitted.
CDC Points of Contact	Rachael Aubert (404) 639-3816 vrl7@cdc.gov Patricia Fields (404) 639-1748 pif1@cdc.gov

Version 2.0

Test Order
Vibrio Subtyping
CDC-10122

Synonym(s)

CDC Pre-Approval Needed None

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 08
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Genetic Subtyping, Antimicrobial Susceptibility Testing (AST)

Turnaround Time 10 Weeks

Interferences & Limitations *Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2-8 °C) may lose viability.

Additional Information Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 1.3

Test Order
Vibrio, Aeromonas, and Related Organisms Identification
 CDC-10120

Synonym(s) *Vibrionaceae, Grimontia, Photobacterium*

CDC Pre-Approval Needed None

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.**

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Vibrio, Aeromonas* and related species; sequence data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium If isolates are shipped at room temperature, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 RDSB/STATT Unit 08
 1600 Clifton Road, NE
 Atlanta, GA 30329
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Phenotypic or Genetic Identification

Turnaround Time 13 Weeks

Interferences & Limitations *Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2-8 °C) may lose viability.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 1.4

Test Order
Vibrio, Aeromonas, and Related Organisms Study
CDC-10121

Synonym(s) *Vibrionaceae, Grimontia, Photobacterium*

CDC Pre-Approval Needed **Christine Lee**
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Isolates, Sequence Data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 08
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Refer to study protocol for specific requirements

Turnaround Time

Interferences & Limitations *Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2-8 °C) may lose viability.

Additional Information Refer to study protocol for specific requirements.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 2.2

Test Order
Waterborne Parasite Special Study
CDC-10527

Synonym(s) None

CDC Pre-Approval Needed **Dawn Roellig**
(404) 718-4134
iyd4@cdc.gov
Jennifer Murphy
(404) 718-4155
iod7@cdc.gov

Supplemental Information **None**
Required

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type To be determined
for Testing

Minimum Volume Required To be determined

Collection, Storage, and Preservation To be determined
of Specimen Prior to Shipping

Transport Medium To be determined

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Ship fixed/preserved specimens at room temperature. Ship unpreserved
Specimen Handling Requirements specimens on wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if
stored frozen.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology To be determined

Turnaround Time 3 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Dawn Roellig
(404) 718-4134
iyd4@cdc.gov
Jennifer Murphy
(404) 718-4155
iod7@cdc.gov

Version 1.1

Test Order
Yersinia (non-*Y. pestis*) and Other *Enterobacterales* Special Study
 CDC-10555

Synonym(s)	None
CDC Pre-Approval Needed	Christine Lee (404) 498-2295 pxf6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov
Supplemental Information Required	Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates, Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	Ship isolates on nutrient agar or similar non-selective agar (trypticase soy agar, heart infusion agar, etc.)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 16 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Yersinia serotyping and biotyping, Phenotypic or Genetic Subtyping
Turnaround Time	10 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information Turnaround times for special study isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 1.2

Test Order
***Yersinia* (non-*Y. pestis*) and Other *Enterobacterales* Subtyping**
CDC-10124

Synonym(s) *Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae, Yersiniaceae, Budvicia, Buttiauxella, Citrobacter, Cronobacter, Enterobacter, Erwinia, Hafnia, Klebsiella, Kluyvera, Morganella, Pantoea, Proteus, Providencia, Rahnella, Raoultella, Serratia, Yersinia, Yokenella*

CDC Pre-Approval Needed **Christine Lee**
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in 'Previous Laboratory Results' on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**

Supplemental Form **None**

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Yersinia* (non-*Y. pestis*) and *Enterobacterales*; Sequence Data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium If isolates are shipped at room temperature (15-25°C) or refrigerated (2-8°C), inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.). If isolates are shipped frozen (-20°C or lower), suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 16
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic or Genetic Subtyping, including Yersinia serotyping and biotyping
Turnaround Time	10 Weeks
Interferences & Limitations	Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Christine Lee (404) 498-2295 pfx6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov

Version 2.3

Test Order

Yersinia (non-*Y. pestis*) and Other *Enterobacterales* Identification CDC-10123

Synonym(s) *Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae, Yersiniaceae, Budvicia, Buttiauxella, Citrobacter, Cronobacter, Enterobacter, Erwinia, Hafnia, Klebsiella, Kluyvera, Morganella, Pantoea, Proteus, Providencia, Rahnella, Raoultella, Serratia, Yersinia, Yokenella*

CDC Pre-Approval Needed None

Supplemental Information Required **Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g data_sequence specimen type) the specimen identifier should be the PNUSA number.**

Supplemental Form None

Performed on Specimens From Human, Animal and Food/Environmental/Medical Devices/Biologics

Acceptable Sample / Specimen Type for Testing Pure culture isolates of *Yersinia* (non-*Y. pestis*) and *Enterobacterales*; Sequence Data

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.

Transport Medium If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
RDSB/STATT Unit 16
1600 Clifton Road, NE
Atlanta, GA 30329
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Phenotypic or Genetic Identification

Turnaround Time 13 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than -70 °C can result in genetic mutations and could affect results of subtyping tests.

Additional Information The original isolate should be retained by the submitter for the duration of testing at CDC.

Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.

CDC Points of Contact Christine Lee
(404) 498-2295
pfx6@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Version 2.3

Test Order
Yersinia pestis Culture and Identification
 CDC-10418

Synonym(s)	Plague
CDC Pre-Approval Needed	None
Supplemental Information Required	<p>Required information on the CDC 50.34 Specimen Submission Form:</p> <ul style="list-style-type: none"> • Test order name (one per submission form) • Patient full name, sex, birth date • Date of onset (of symptoms) • Specimen collected date • Specimen source (type) • Submitting agency address, contact name, phone number and email address for each submitter • Brief clinical summary (include signs, symptoms, and underlying illnesses if known) <p>For transfer of a select agent, a completed Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2) is required.</p>
Supplemental Form	<p>For transfer of a select agent: Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2)</p> <p>https://www.selectagents.gov/forms.html</p>
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Lymph node aspirate, sputum, bronchial/tracheal wash, pleural fluid, whole blood (EDTA-treated, heparin-treated, or citrate-treated), blood culture bottles, biopsy/autopsy tissues (sections of lymph node, lung, liver, spleen, bone marrow)
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate (2-8°C) all specimens to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Do not freeze non-tissue samples as this will reduce bacterial viability.
Transport Medium	Transport respiratory specimens, aspirates and tissues in a sterile container. Original blood tubes and blood culture bottles are acceptable. If swabs are utilized for transport, Cary-Blair is recommended.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Ship specimens refrigerated on gel ice packs. Avoid freezing specimens. Contact
Specimen Handling Requirements CDC POC for specific guidance on shipment of different specimen types.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Culture, Direct Fluorescent Antibody (DFA), Bacteriophage Lysis
Turnaround Time	3 Weeks
Interferences & Limitations	Antibiotic treatment will reduce the sensitivity of culture; samples should be collected pre-treatment.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 1.6

Test Order
***Yersinia pestis* Molecular Detection**
CDC-10547

Synonym(s) Bubonic plague, pneumonic plague, septicemic plague, Black Death

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
- Prior antibiotic treatment (type of antibiotic and date administered)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample / Specimen Type for Testing Lymph node aspirate or sputum are preferred; EDTA-treated whole blood and suspect isolates are also acceptable.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen refrigerated (2-8 °C) prior to transport.

Transport Medium Suspect *Yersinia pestis* cultures should be transport on TSA or blood agar slants.

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship specimens refrigerated on gel ice packs.

Ship To:
 [Insert CDC Point of Contact]
 Centers for Disease Control and Prevention
 Bacterial Diagnostic and Reference Laboratory
 3156 Rampart Rd
 Fort Collins, CO 80521
 [Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Polymerase chain reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Prior antibiotic treatment may reduce sensitivity by decreasing the amount of bacterial DNA present in specimens. Detection in EDTA-treated whole blood is less sensitive than detection in lymph node aspirate or sputum.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.1

Test Order
Yersinia pestis Serology
CDC-10419

Synonym(s) Plague

CDC Pre-Approval Needed None

Supplemental Information Required **Required information on the CDC 50.34 Specimen Submission Form:**

- Test order name (one per submission form)
- Patient full name, sex, birth date
- Date of onset (of symptoms)
- Specimen collected date
- Specimen source (type)
- Submitting agency address, contact name, phone number and email address for each submitter
- Brief clinical summary (include signs, symptoms, and underlying illnesses if known)

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample / Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL (serum)

Collection, Storage, and Preservation of Specimen Prior to Shipping Upon collection and serum separation, serum specimens should be held at 2-8 °C. Serum samples can be stored at 2-8 °C for up to 14 days and shipped on gel ice packs. If testing is delayed longer than 14 days, serum samples may be frozen (-20 °C) and shipped on dry ice.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If serum can be shipped to CDC within 14 days of sample collection, serum samples should be kept refrigerated and shipped on gel ice packs. If serum specimens are frozen, they should be shipped on dry ice.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:

[Insert CDC Point of Contact]

Centers for Disease Control and Prevention

Bacterial Diagnostic and Reference Laboratory

3156 Rampart Road

Fort Collins, CO 80521

[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology Passive Hemagglutination, Passive Hemagglutination Inhibition

Turnaround Time 2 Weeks

Interferences & Limitations

Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Version 1.6

Test Order
Yersinia pestis Special Study
 CDC-10420

Synonym(s)	
CDC Pre-Approval Needed	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Supplemental Information Required	Required information on the CDC 50.34 Specimen Submission Form: <ul style="list-style-type: none"> • Test order name (one per submission form) • Patient full name, sex, birth date • Date of onset (of symptoms) • Specimen collected date • Specimen source (type) • Submitting agency address, contact name, phone number and email address for each submitter • Brief clinical summary (include signs, symptoms, and underlying illnesses if known)
Supplemental Form	None
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	<p>This test order can accommodate diagnostic and non-diagnostic specimens. Testing subject to CLIA regulations requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.</p> <p>Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

Shipping Instructions which Include Specimen Handling Requirements CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday.

Ship to:
[Insert CDC Point of Contact]
Centers for Disease Control and Prevention
Bacterial Diagnostic and Reference Laboratory
3156 Rampart Road
Fort Collins, CO 80521
[Insert CDC Point of Contact's Telephone Number]

All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Culture, PCR, Direct fluorescent antibody testing
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

Version 2.3
