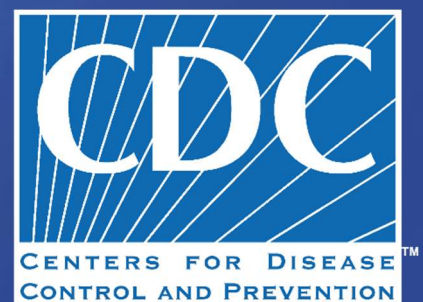


2019

CDC

INFECTIOUS DISEASES LABORATORY TEST DIRECTORY

February 2020, Version 10.2



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 February 24, 2020. 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

Pre-Approval Needed None

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 None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing For *Acanthamoeba* and *Balamuthia* molecular detection, tissue is the preferred specimen type; however, these amoebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For *Naegleria fowleri* molecular detection, CSF is the preferred specimen type. For suspected cases of *Acanthamoeba Keratitis (AK)*, we also accept deep corneal scraping, ocular fluid, and contact lens solution as specimen.

Minimum Volume Required 0.2 g tissue; 1 mL fluids

Collection, Storage, and Preservation of Specimen Prior to Shipping Storage and preservation is specimen specific

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/STAT 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

Test Order
Acanthamoeba Molecular Detection
CDC-10471

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 *Acanthamoeba* or *Balamuthia* detection, because a negative CSF test result does not completely rule out infections with these amoebae.

Additional Information None

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Test Order
Adenovirus Molecular Detection and Typing
CDC-10170

Synonym(s) None

Pre-Approval Needed Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov
Schneider, Eileen, (404) 639-5345, ees2@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 Upper or lower respiratory tract specimens, eye swabs, stool, serum, blood or plasma, pure culture isolate

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate all specimens promptly after collection. If 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, as this will reduce virus infectivity. Specimens for virus culture should not be frozen at -20° C. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted 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.

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/STAT 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), Sequencing

Turnaround Time 3 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

Test Order
Adenovirus Molecular Detection and Typing
CDC-10170

assays.

Additional Information None

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
Aerobic *Actinomyces* – Identification
CDC-10148

Synonym(s)	Nocardia, Streptomyces, Tsukamurella, Gordonia, Rhodococcus, Williamsia, Dietzia, Nocardiosis, Actinomadura, Pseudonocardia, Dermatophilus, Kroppenstedtia, and other related genera
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	Pure culture isolate on a suitable agar slant medium such as Lowenstein Jensen, trypticase soy agar (with, or without, sheep blood), heart infusion agar, Sabouraud dextrose agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
Transport Medium	Lowenstein Jensen, trypticase soy agar (with, or without, sheep blood), heart infusion agar, Sabouraud dextrose agar
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 identifiers. 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/STAT 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

Test Order
Aerobic *Actinomyces* – Identification
CDC-10148

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

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

Synonym(s)	Nocardia, Tsukamurella, Gordonia, Rhodococcus, Streptomyces, Actinomadura
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	Pure culture isolate on a suitable agar slant medium such as Lowenstein Jensen, trypticase soy agar (with, or without, sheep blood), heart infusion agar, Sabouraud dextrose agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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/STAT 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	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

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

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

Test Order

Alkhurma Hemorrhagic Fever Serology and Molecular Detection

CDC-10274

Synonym(s) AHFV

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Alkhurma Hemorrhagic Fever Serology and Molecular Detection
CDC-10274

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

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

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

Pre-Approval Needed None

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 None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Fresh, unfixed tissue and Paraffin-embedded and formalin-fixed tissue, cerebrospinal fluid (CSF), biopsy specimen, deep corneal scrapings, and ocular fluids

Minimum Volume Required 1 mL fluids; 0.2 g tissue

Collection, Storage, and Preservation of Specimen Prior to Shipping CSF and fresh, unfixed tissue should be kept at ambient temperatures. Paraffin-embedded and formalin-fixed tissue should be kept at room temperature. Send a few H&E-stained slides and a few (about 6) unstained slides for IHC test, or Paraffin-embedded tissue block.

Unfixed deep scraping and biopsy materials for identification of free-living amoeba are usually very small and may dry if they are not stored in proper fluid such as 0.5x PBS or "amoeba saline" (see composition in the 'Additional Information'). These specimens should be transported to the laboratory within 24 hours.

Transport Medium Care should be taken to pack glass slides securely, as they can be damaged in shipment if not packed in a crush-proof container. For deep scraping and biopsy materials please transport in amoeba saline solution, or in 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 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 24 hours of collection. Fresh, unfixed specimens (i.e., CSF and tissue), and formalin-fixed tissue specimens should be sent at ambient temperature by overnight priority mail. Please ship these specimens separately from other chilled or frozen samples being shipped. If specimen has been previously frozen, please send these specimens by overnight priority mail on ice-packs.

Please contact laboratory prior to shipping any specimen. 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/STAT Unit 53
1600 Clifton Road, NE
Atlanta, GA 30329

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

<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

Turnaround Time 7 Days

Interferences & Limitations For molecular detection, CSF is the preferred specimen type for *N. fowleri* only, and it is NOT the preferred specimen type for *Acanthamoeba* or *Balamuthia* detection. A negative CSF test result does not completely rule out infection with *Acanthamoeba* or *Balamuthia*. Fresh or frozen (unfixed) tissue specimens are preferred for *Balamuthia* or *Acanthamoeba* 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 Include the address of sender and physician contact information with the specimen.

For deep scraping and biopsy materials please provide the following information to the laboratorians: 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.

Ameba saline, 1X stock:
Sodium chloride (NaCl) 0.120g
Magnesium sulfate (MgSO₄.7HOH) 0.004 g
Sodium phosphate, dibasic (Na₂HPO₄) 0.142g
Potassium phosphate, monobasic (KH₂P O₄) 0.136g
Calcium chloride (CaCL₂.2HOH) 0.004g
Double distilled water to 1000.0 mL

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100

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

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

Pre-Approval Needed None

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 None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Sera (two specimen taken 2 weeks apart)

Minimum Volume Required 1 mL

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 (tiger top) tube (red/gray speckled top with gel in the tube). Please centrifuge the specimen, and if possible, send serum only. If using a plain red-top tube, you must separate the serum before shipping and send the serum only. Should be kept refrigerated or frozen.

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 Serum samples should be shipped refrigerated or frozen and packed with cold packs.

Please contact laboratory prior to shipping any specimen. 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/STAT 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*

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

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 you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100

Test Order
Ameba Special Study
CDC-10288

Synonym(s)	None
Pre-Approval Needed	Cope, Jennifer, (404) 718-4878, bjt9@cdc.gov Ali, Ibne, (404) 718-4157, xzn5@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	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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 53 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	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jennifer Cope (404) 718-4878
	If you are calling outside of regular business hours, please call the CDC

Test Order
Ameba Special Study
CDC-10288

bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Emergency Operations Center (EOC)
(770) 488-7100

Test Order

Anaerobic Bacteria Identification

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>
Pre-Approval Needed	None
Supplemental Information Required	For isolate submission, document the State Public Health Department contact information on 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	Pure culture isolates of anaerobic bacteria from clinically relevant sources
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates anaerobically at room temperature (15–25°C). Keep refrigerated (2–8°C) if isolate cannot be shipped within 24 hours. For fastidious organisms store at room temperature (15–25°C).
Transport Medium	Transport specimens in Chopped Meat Glucose broth or Thioglycollate broth at room temperature or refrigerated. Transport frozen specimens in Tryptic Soy Broth (TSB) 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	<p>Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on ice packs.</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/STAT 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.</p>
Methodology	16S ribosomal ribonucleic acid (rRNA) gene sequencing and additional phenotypic testing
Turnaround Time	4 Weeks
Interferences & Limitations	Specimens from respiratory, vaginal, and fecal sources are not acceptable.
Additional Information	<i>Clostridioides (Clostridium) difficile</i> outbreak strain typing should be requested using Test Order CDC-10229 Outbreak Strain Typing – <i>Clostridioides (Clostridium) difficile</i> .

Contact the CDC POC for approval prior to submitting any specimen type other

Test Order
Anaerobic Bacteria Identification
CDC-10227

than an isolate. If healthcare facility will be submitting samples directly to CDC they must receive prior approval from State Health Department.

CDC Points of Contact David Lonsway
(404) 639-2825
dul7@cdc.gov
Maria Karlsson
(404) 639-0698
fwt4@cdc.gov

Test Order
Anaplasma Molecular Detection
CDC-10290

Synonym(s) Human granulocytic anaplasmosis

Pre-Approval Needed None

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

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Specific antibiotic therapy, initiation date, and duration of treatment (e.g., drug name, dates of therapy)
- Specimen type (e.g., serum, whole blood, swab, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings (signs and symptoms, physical exam findings, and pertinent laboratory values)
- Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples taken within the first week of illness or while symptomatic, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; fresh tissue biopsy; swab (using a dry, sterile cotton swab); serum; collected before or within 48 hours of doxycycline administration.

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2–8°C) up to 7 days after draw. If storing over 7 days, freeze at less than or equal to –70°C and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.

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 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/STAT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329

Test Order
***Anaplasma* Molecular Detection**
CDC-10290

<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), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Anaplasma Serology
CDC-10292

Synonym(s) Human granulocytic anaplasmosis

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (taken within the first week of illness or while symptomatic)
- convalescent (2-4 weeks after initial sample)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

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/STAT 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.

Test Order
Anaplasma Serology
CDC-10292

Methodology Indirect immunofluorescence antibody assay (IFA)

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Anaplasma* Special Study**
CDC-10291

Synonym(s)	Human granulocytic anaplasmosis
Pre-Approval Needed	Condit, Marah, (404) 639-3423, RZBrefdxlab@cdc.gov Zeng, Yan, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177

Test Order
Anaplasma Special Study
CDC-10291

xcw9@cdc.gov

Test Order
Angiostrongylus cantonensis Molecular Detection
CDC-10472

Synonym(s) Angiostrongyliasis, Rat lungworm, parasite

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 Cerebrospinal fluid (CSF); tissue

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Store specimens refrigerated (e.g., 4°C or cold pack) or frozen (e.g., -20°C or 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 Ship specimen on wet ice (cold pack) 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/STAT 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 Formalin fixed specimens are not suitable for molecular studies

Additional Information None

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

Test Order

Antimicrobial Resistant Bacteria – Colonization Screening

CDC-10521

Synonym(s)	Point Prevalence Survey, Carbapenemase-Producing Organism (CPO) surveillance, processing of surveillance swabs, surveillance screening for Antimicrobial Resistant (AR) Bacteria
Pre-Approval Needed	Gilbert, Sarah, (404) 718-7550, hic3@cdc.gov Karlsson, Maria, (404) 639-0698, fwt4@cdc.gov
Supplemental Information Required	For isolate submission, document the State Public Health Department contact information on the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Rectal, Groin, Axilla, and Tracheal Aspirate swabs
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swabs in the transport tube can be stored at 2-8°C for up to 24 hours prior to shipping.
Transport Medium	Rectal swabs – Copan dual-swab, Cepheid catalog #900-0370; Groin, axilla, and tracheal aspirate swabs – Liquid Amies elution swab (Eswab)
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>Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on ice packs.</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/STAT 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.</p>
Methodology	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
Turnaround Time	3 Weeks
Interferences & Limitations	For Cepheid: Interfering substances: barium sulfate at >0.1% w/v, Pepto-Bismol at >0.01% w/v; or fecal fat 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

Test Order
Antimicrobial Resistant Bacteria – Colonization Screening
CDC-10521

the sample, one target may not be detected. However, it is unusual for carbapenemase-producing isolates to have more than one carbapenemase gene.

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] also required.

Turnaround Time: 5 days for Molecular Method; 3 weeks for Culture-Based Methods.

CDC Points of Contact Sarah Gilbert
(404) 718-7550
hic3@cdc.gov
Maria Karlsson
(404) 639-0698
fwt4@cdc.gov

Test Order

Antimicrobial Susceptibility Testing (AST) – Bacteria

CDC-10223

Synonym(s)	Antimicrobial Susceptibility Testing (AST), sensitivity, resistance, Minimum Inhibitory Concentration (MIC) testing
Pre-Approval Needed	None
Supplemental Information Required	Confirmation of unusual resistance is required before sending specimen for testing. Include documentation of specific antibacterial agent(s) of interest and provide previous results and testing method on the CDC 50.34 Specimen Submission Form or enclosed with the specimen. Unusual isolates on which the submitter cannot perform resistance testing will also be accepted. For isolate submission, document the State Health Department contact information on 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	Pure culture isolates of bacteria
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) if isolate cannot be shipped within 24 hours. For all fastidious organisms store at room temperature (15–25°C).
Transport Medium	Transport room temperature (15–25°C) or refrigerated (2–8°C) specimens on suitable agar medium. Transport frozen (–25°C to –15°C) specimens in TSB 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	<p>Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on ice packs.</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/STAT 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.</p>
Methodology	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

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

receive prior approval from the State Health Department.

CDC Points of Contact David Lonsway
(404) 639-2825
dul7@cdc.gov
Maria Karlsson
(404) 639-0698
fwt4@cdc.gov

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)
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 cm ³ , frozen as soon as possible (less than or equal to -20°C) and shipped on dry ice.
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. All submitted specimens should include two unique identifiers. 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>All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.</p> <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>

Test Order
Arbovirus Isolation and Identification
CDC-10281

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

ADBDiagnosics@cdc.gov

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)
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 cm ³ , 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	<p>All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.</p> <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	Reverse transcriptase (RT)-Polymerase Chain Reaction (PCR); real-time RT-PCR (rRT-PCR)

Test Order
Arbovirus Molecular Detection
CDC-10280

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

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)

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 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 Plaque reduction neutralization test (PRNT)

Turnaround Time 4 Weeks

Test Order
Arbovirus Neutralization Antibody
CDC-10283

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

ADBiagnostics@cdc.gov

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)
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	<p>All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC.</p> <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	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

Test Order
Arbovirus Serology
CDC-10282

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

ADBDiagnosics@cdc.gov

Test Order
Arbovirus Special Study
CDC-10284

Synonym(s)	Arbovirus
Pre-Approval Needed	Panella, Amanda, (970) 225-4237, ahf6@cdc.gov Velez, Jason, (970) 225-4262, jdv4@cdc.gov
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. All submitted specimens should include two unique identifiers. 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

Test Order
Arbovirus Special Study
CDC-10284

ahf6@cdc.gov
Jason Velez
(970) 225-4262
jdv4@cdc.gov

ADBiagnostics@cdc.gov

Test Order
***Arenavirus* (New World) Testing**
CDC-10293

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

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
***Arenavirus* (New World) Testing**
CDC-10293

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

Test Order
***Arenavirus* (Old World) Testing**
CDC-10294

Synonym(s) Old World *Arenavirus*

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
***Arenavirus* (Old World) Testing**
CDC-10294

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

Test Order

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

Synonym(s)	<i>C. pneumoniae</i> , <i>Chlamydophila pneumoniae</i> , <i>Chlamydia</i> , <i>Chlamydophila</i> , <i>M. pneumoniae</i> , <i>Mycoplasma</i> , <i>Legionella pneumophila</i> , <i>L. pneumophila</i> , <i>Legionella</i> , Atypical pneumonia, Community acquired pneumonia, CAP, Legionnaires' disease, LD, Legionellosis, Pontiac fever, Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swabs (Nasopharyngeal (NP) and Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM), 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	0.4 mL preferred, 0.2 mL minimum for viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF) 0.05 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. 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	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 identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23

Test Order

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

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 *Mycoplasma pneumoniae* is detected will also be tested using test order *Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping (CDC-10513). Specimens in which *Legionella* species is detected will also be tested using test order *Legionella* species Detection and Identification (CDC-10159) and/or *Legionella* 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

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

Synonym(s)	Babesiosis; <i>Babesia microti</i> ; <i>Babesia duncani</i> , parasite
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	Whole blood, blood smear slide
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect a 1–5 mL blood sample in Vacutainer® EDTA tubes prior to anti-parasitic therapy and store at 4°C. Blood smear slide may be shipped at room 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	Ship specimen on wet ice (cold pack) 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/STAT 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)
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

Test Order
Babesiosis Serology
CDC-10456

Synonym(s)	<i>Babesia microti</i> ; <i>Babesia duncani</i> ; <i>Babesia divergens</i> , babesiosis, parasite
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	Serum or plasma
Minimum Volume Required	0.5mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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

Test Order
Babesiosis Serology
CDC-10456

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
***Bacillus anthracis* Detection in Clinical Specimens**
CDC-10204

Synonym(s) Anthrax PCR

Pre-Approval Needed Bacterial Special Pathogens Branch (CDC), , (404) 639-1711, bzb@cdc.gov
Alternate Phone, , (404) 772-5131,

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 Serum, Plasma, Blood, Pleural fluid, Cerebrospinal fluid, Ascites fluid, Lesion swab, Lesion exudate, Rectal swab, Tissues from biopsy or autopsy.
Recommended sample type is dependent on clinical presentation. For more information, reference the Additional Information field.

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

Collection, Storage, and Preservation of Specimen Prior to Shipping Dependent on specimen type submitted. For more information, reference the Additional Information field.

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. All submitted specimens should include two unique identifiers. 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 Most samples can be sent on cold packs. Fresh tissue should be sent frozen on dry ice and fixed tissue can be sent 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/STAT 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. For more information, reference the Additional Information field.

Test Order
***Bacillus anthracis* Detection in Clinical Specimens**
CDC-10204

Methodology Culture, Polymerase Chain Reaction (PCR), Immunohistochemistry (IHC), Toxin detection

Turnaround Time 2 Weeks

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.

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 .

CDC Points of Contact Alex Hoffmaster
(404) 639-0852
amh9@cdc.gov
Chung Marston
(404) 639-4057
cdk5@cdc.gov

Test Order
***Bacillus anthracis* Genotyping and AST**
CDC-10203

Synonym(s)	Anthrax, Anthrax Gamma phage, Anthrax PCR, Anthrax typing
Pre-Approval Needed	Bacterial Special Pathogens Branch (CDC), , (404) 639-1711, bzb@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	<i>B. anthracis</i> 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 <i>Bacillus</i>
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. All submitted specimens should include two unique identifiers. 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/STAT 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	Genotyping (i.e., MLVA and genome sequence), Broth Microdilution, Rapid Antimicrobial Susceptibility Test (AST)
Turnaround Time	2 Weeks

Test Order
Bacillus anthracis Genotyping and AST
CDC-10203

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

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

CDC Points of Contact Chung Marston
(404) 639-4057
cdk5@cdc.gov
David Lonsway
(404) 639-2825
dul7@cdc.gov

Test Order
***Bacillus anthracis* Serology**
CDC-10196

Synonym(s)	Anthrax ELISA, Anthrax serology, Bacillus serology
Pre-Approval Needed	Bacterial Special Pathogens Branch (CDC), , (404) 639-1711, bzb@cdc.gov Alternate Phone, , (404) 772-5131,
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	Paired serum samples submitted at the same time are required, including an acute (7 days or less after symptom onset) and a convalescent-phase (14-35 days after symptom onset) specimen
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separate serum from clot, transfer sera to an appropriately labeled plastic freezing vial with a leak-proof screw caps, and store frozen at -20°C or colder.
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. All submitted specimens should include two unique identifiers. 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>Serum should be shipped frozen on dry ice. For more information, reference the Additional Information field.</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/STAT 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	Antibody detection by enzyme-linked immunosorbent assay (ELISA)
Turnaround Time	2 Weeks

Test Order
Bacillus anthracis Serology
CDC-10196

Interferences & Limitations Requires acute and convalescent serum for analysis.

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

Additional information on Shipping Instructions which Include Specimen Handling Requirements.

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

CDC Points of Contact Chung Marston
(404) 639-4057
cdk5@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Test Order
Bacillus anthracis Study
CDC-10205

Synonym(s)	None
Pre-Approval Needed	Hoffmaster, Alex, (404) 639-0852, amh9@cdc.gov Kolton, Cari, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Alex Hoffmaster (404) 639-0852 amh9@cdc.gov Cari Kolton (404) 639-2065

Test Order
Bacillus anthracis Study
CDC-10205

fts3@cdc.gov

Test Order
***Bacillus cereus* Detection – Foodborne Outbreak**
CDC-10104

Synonym(s) <i>B. cereus</i>	
Pre-Approval Needed	Luquez, Carolina, (404) 639-0896, fry6@cdc.gov Gomez, Gerry, (404) 639-0537, goe4@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), emesis and stool specimens (collected within 48 hours of illness onset), and their derived isolates are accepted. 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 emesis 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 accepted. 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. Send raw stool or stool with Cary-Blair or Enteric Transport Medium. Send pure culture isolates derived from food or stool on agar slants or broths.
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. 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 refrigerated specimens (2–8°C) with gel ice packs and, if already frozen, send frozen specimens (< -20°C) 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/STAT Unit 26 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
***Bacillus cereus* Detection – Foodborne Outbreak**
CDC-10104

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

Turnaround Time 12 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 method(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 Carolina Luquez
(404) 639-0896
fry6@cdc.gov
Gerry Gomez
(404) 639-0537
goe4@cdc.gov

Test Order
Bacillus cereus Genotyping
CDC-10206

Synonym(s) *Bacillus* MLST

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 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 identifiers. 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/STAT 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 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*.

Test Order
Bacillus cereus Genotyping
CDC-10206

CDC Points of Contact Alex Hoffmaster
(404) 639-0852
amh9@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov

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

Synonym(s)	Gram-positive bacilli
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	Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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/STAT 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.

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

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

Test Order
Bacterial Identification from Clinical Specimens (16S rRNA Polymerase Chain Reaction)
CDC-10146

Synonym(s)	None
Pre-Approval Needed	McQuiston, John, (404) 639-0270, zje8@cdc.gov Bell, Melissa, (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	Primary specimens with prior approval from a laboratory point of contact listed below
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
**Bacterial Identification from Clinical Specimens (16S rRNA Polymerase
Chain Reaction)**
CDC-10146

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

Test Order

Bacterial Identification of Unknown Isolate (Not Strict Anaerobe)

CDC-10145

Synonym(s)	Bacterial Identification
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	Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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.

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

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

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

Synonym(s)	Free-living amoeba, parasite
Pre-Approval Needed	None
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	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	For <i>Acanthamoeba</i> and <i>Balamuthia</i> molecular detection, tissue is the preferred specimen type; however, these amoebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For <i>Naegleria fowleri</i> molecular detection, CSF is the preferred specimen type.
Minimum Volume Required	0.2 g tissue; 1 mL fluids
Collection, Storage, and Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific
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/STAT 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 amoebae.

Test Order
Balamuthia Molecular Detection
CDC-10474

Additional Information None

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

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

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

Pre-Approval Needed None

Supplemental Information Required Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; clinical summary (signs and symptoms).

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

Test Order

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

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
***Bartonella* Special Study**
CDC-10297

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

Pre-Approval Needed Petersen, Jeannine, (970) 266-3524, nzp0@cdc.gov
Kingry, Luke, (970) 266-3567, vtx8@cdc.gov

Supplemental Information Required Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; clinical summary (signs and symptoms).

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. All submitted specimens should include two unique identifiers. 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

Test Order
Bartonella Special Study
CDC-10297

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
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
Baylisascariasis Serology
CDC-10457

Synonym(s)	Baylisascariasis, Raccoon roundworm, parasite
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	Serum or plasma; cerebrospinal fluid (CSF) only when paired with serum or plasma.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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

Test Order
Baylisascariasis Serology
CDC-10457

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Biodefense R&D Study
CDC-10487

Synonym(s)	Biodefense Research and Development Laboratory Study
Pre-Approval Needed	Weigel, Linda, (404) 639-1497, lew9@cdc.gov Sue, David, (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/STAT 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	Linda Weigel (404) 639-1497

Test Order
Biodefense R&D Study
CDC-10487

lew9@cdc.gov
David Sue
(404) 639-4027
btx6@cdc.gov

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

Synonym(s) BRAI, Recency assay

Pre-Approval Needed Johnson, Jeff, (404) 639-4976, jlj6@cdc.gov
Switzer, Bill, (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. All submitted specimens should include two unique identifiers. 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

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

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

Test Order
Biothreat Event
CDC-10432

Synonym(s) None

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

Supplemental Information Required To be determined

Supplemental Form None

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 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

Test Order

Blood Disorders Coagulation Study

CDC-10271

Synonym(s)	Coag
Pre-Approval Needed	Driggers, Jennifer, (404) 639-1269, jgq2@cdc.gov Boylan, Brian, (404) 718-4031, kio6@cdc.gov
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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 181 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	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jennifer Driggers (404) 639-1269

Test Order
Blood Disorders Coagulation Study
CDC-10271

jq2@cdc.gov
Brian Boylan
(404) 718-4031
kio6@cdc.gov

Test Order

Bordetella pertussis and Related Species Detection and Identification

CDC-10163

Synonym(s)	<i>Bordetella pertussis</i> , <i>B. parapertussis</i> , <i>B. holmesii</i> , <i>B. bronchiseptica</i> , whooping cough, pertussis
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	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 (<i>B. parapertussis</i> , <i>B. holmesii</i> , or <i>B. bronchiseptica</i> 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	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. 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. 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.
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

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

the test requisition.

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, 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.
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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/STAT 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)
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Turnaround Time	2 Weeks
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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.
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Additional Information	None
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CDC Points of Contact	Pam Cassidy (404) 639–1231 pxc1@cdc.gov Maria Tondella (404) 639–1239 mlt5@cdc.gov
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Test Order
***Bordetella pertussis* Serology**
CDC-10166

Synonym(s)	IgG against pertussis toxin, Pertussis ELISA, whooping cough
Pre-Approval Needed	Pawloski, Lucia, (404) 639-4506, ecz6@cdc.gov Tondella, Maria, (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, duration of cough, recent pertussis-containing vaccination status.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum from patients with 2-12 weeks of cough who have not been vaccinated with a pertussis-containing vaccine in the previous 6 months.
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	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	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/STAT 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

Test Order
Bordetella pertussis Serology
CDC-10166

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

Test Order
***Bordetella* species Study**
CDC-10167

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

Pre-Approval Needed Cassiday, Pam, (404) 639-1231, pxc1@cdc.gov
Tondella, Maria, (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 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.

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 (*B. parapertussis*, *B. holmesii*, or *B. bronchiseptica* only) slant should be sent.

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.

Specimen Labeling Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. All submitted specimens

Test Order
***Bordetella* species Study**
CDC-10167

should include two unique identifiers. 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, 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.

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/STAT 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, Pulsed-Field Gel Electrophoresis, Multi-Locus Sequence Typing, Antibiotic Susceptibility, Antigen Testing

Turnaround Time

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 *Bordetella* 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.

Additional Information None

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

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

Synonym(s)	<i>Bordetella</i> Identification
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	Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar, Regan-Lowe agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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.

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

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

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

Synonym(s)	Lyme Disease, Borreliosis
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; if available clinical summary (signs and symptoms) and antibiotic treatment (type of antibiotic and date of administration).
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	<p>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.</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 Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road 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	EIA (enzyme immunoassay), Western Blot
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed samples may interfere with test results
Additional Information	None

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

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

Test Order
***Borrelia* Culture and Identification**
CDC-10299

Synonym(s) Lyme Disease, Borreliosis, Relapsing fever

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

Supplemental Information Required Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; clinical summary (signs and symptoms); antibiotic treatment (type of antibiotic and date administered).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Whole blood, skin biopsy (Erythema Migrans Rash). Contact the POC for approval prior to sending other specimen types.

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. Whole blood may be collected in heparin, citrate or EDTA. For a skin biopsy, contact POC prior to collection for specific requirements. All specimens should be collected prior to antibiotic treatment.

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 Avoid freezing specimens as this will reduce bacteria viability.

Antibiotic treatment will minimize growth potential of culture.

Test Order
Borrelia Culture and Identification
CDC-10299

Additional Information None

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

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

Synonym(s)	Borreliosis, Recurrent fever, <i>Borrelia</i>
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; if available, clinical summary (signs and symptoms) and treatment information (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	<p>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.</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 Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road 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	EIA (enzyme immunoassay), Western Blot
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed samples may interfere with test results.
Additional Information	None

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

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

Test Order
***Borrelia* Molecular Detection – Relapsing Fever**
CDC-10532

Synonym(s) Relapsing fever, Tickborne relapsing fever, *Borrelia miyamotoi* disease, Louse-borne relapsing fever, *Borrelia hermsii*, *Borrelia turicatae*, *Borrelia miyamotoi*, *Borrelia recurrentis*

Pre-Approval Needed None

Supplemental Information Required Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; clinical summary (signs and symptoms).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Whole blood collected in EDTA tubes

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 Ship specimens refrigerated at 2–8°C on gel 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
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 Polymerase chain reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Prior antibiotic treatment may affect sensitivity.

Additional Information None

CDC Points of Contact Jeannine Peterson
(970) 266–3524

Test Order
Borrelia Molecular Detection – Relapsing Fever
CDC-10532

nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Test Order
***Borrelia* Special Study**
CDC-10300

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266-3524, nzp0@cdc.gov Dietrich, Elizabeth, (970) 494-6618, wul2@cdc.gov
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
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. All submitted specimens should include two unique identifiers. 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.</p> <p>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></p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
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.

Test Order
Borrelia Special Study
CDC-10300

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

Test Order
Botulism Laboratory Confirmation
CDC-10132

Synonym(s)	Botulinum toxin, Clostridium botulinum
Pre-Approval Needed	None
Supplemental Information Required	For clinical samples, provide patient name, date of birth, history of present illness, and treatment history, including date of BabyBIG or BAT administration. 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	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Foodborne botulism: serum (without anti-coagulant), stool, enema (with sterile non-bacteriostatic water), food. Although not ideal, gastric contents may also be submitted. Wound botulism: serum (without anti-coagulant), debrided tissue, swab from wounds, stool (only if foodborne is also suspected). Infant botulism: stool, enema (with sterile non-bacteriostatic water), rectal swabs. Potential sources (honey, opened formula, etc.) may also be submitted. We do not test unopened commercial products, except with permission from FDA/USDA.
Minimum Volume Required	Adult patients: 5 mL serum, 10 g of feces. Note: Smaller quantities may be tested, minimum volume for serum is 1 mL. Contact POC to discuss options. Infant patients: 10 g of feces. Note: Smaller quantities may be tested, contact POC to discuss options.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum samples must be collected before antitoxin treatment. If enema is needed, use sterile non-bacteriostatic water. 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. Refrigerate all specimens promptly after collection. Maintain specimen refrigerated (2–8°C) 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 the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship refrigerated (cold packs). Package must have proper labeling for biological hazards: UN3373 biological substance, Category B. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday.

Test Order
Botulism Laboratory Confirmation
CDC-10132

Ship to:
<Insert CDC Point of Contact>
Centers for Disease Control and Prevention
RDSB/STAT 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, submitted 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

Interferences & Limitations Incorrect storage and/or spoilage of food may affect results.

Additional Information Pre-approval is not needed. However, hospitals must obtain approval from their state health department prior to submitting specimens to CDC.

Turnaround Time: Final written reports are provided within 12 weeks.
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

Test Order
Botulism Special Study
CDC-10133

Synonym(s) Botulinum toxin, Clostridium botulinum

Pre-Approval Needed Luquez, Carolina, (404) 639-0896, fry6@cdc.gov
Dykes, Janet, (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 Specimen Handling Requirements Ship refrigerated specimens (2-8°C) with 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/STAT 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.

Test Order
Botulism Special Study
CDC-10133

Methodology Mouse Bioassay, Mass Spectrometry (MS), Polymerase Chain Reaction (PCR),
Whole Genome Sequencing

Turnaround Time 24 Weeks

Interferences & Limitations To be determined

Additional Information None

CDC Points of Contact Carolina Luquez
(404) 639-0896
fry6@cdc.gov
Janet Dykes
(404) 639-3625
jkd1@cdc.gov

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

Synonym(s)	Brucellosis, Brucella
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 <i>Brucella</i> isolates should be submitted for identification. Multiple specimen types may be submitted for <i>Brucella</i> culture including human whole blood, body fluids such as bone marrow, joint fluid, cerebrospinal fluid (CSF), breast milk, abscess fluid and tissue biopsies. Acceptable animal specimen types include fresh or frozen whole blood and tissue samples from lymph nodes, kidney, liver, and reproductive organs. Food products such as unpasteurized milk and cheese are suitable for <i>Brucella</i> culture.
Minimum Volume Required	A minimum volume of 1 mL of fresh blood or body fluid is required for culture. Tissue samples and biopsy material should be at least the size of a pea for adequate material for homogenization and culture.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood submitted for culture must be collected in a yellow top Sodium polyanethol sulfonate (SPS) blood collection tube, stored at 4°C and submitted within 24 hours of collection on ice packs. Tissues, biopsy material, body fluids should be stored at 4°C and submitted on ice packs within 48-72 hours of collection OR frozen at -20°C or lower and shipped on dry ice. Food products may be shipped on ice packs or dry ice dependent on their current holding temperature. Isolates should be kept at room temperature 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. All submitted specimens should include two unique identifiers. 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. Specimens should be shipped at 4°C or -20°C. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: <Insert CDC Point of Contact>

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

Centers for Disease Control and Prevention
RDSB/STAT 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	Rebekah Tiller (404) 639-4507 eto3@cdc.gov	Elke Saile (404) 639-0716 csx2@cdc.gov
	David Lonsway (404) 639-2825 dul7@cdc.gov	

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

Synonym(s) *Brucella* PCR

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 is the preferred specimen for *Brucella* molecular detection. Serum may also be tested.

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Blood submitted for molecular detection should be collected in a EDTA or Sodium Citrate blood collection tube, stored at 4°C and submitted within 5 days of collection on ice packs. Serum should be removed from the serum separator tube and placed in a sterile microcentrifuge tube, stored at 4°C and submitted within 5 days of collection on ice packs.

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. All submitted specimens should include two unique identifiers. 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 Specimens should be shipped on cold packs or 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/STAT 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 *Brucella* molecular detection test has not been cleared and approved by the

Test Order
Brucella species Molecular Detection
CDC-10208

FDA.

Additional Information

CDC Points of Contact Rebekah Tiller
 (404) 639-4507
 eto3@cdc.gov
 Elke Saile
 (404) 639-0716
 csx2@cdc.gov

Test Order
***Brucella* species Serology**
CDC-10197

Synonym(s) BMAT

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 Separate serum from clot, transfer sera to an appropriately labeled plastic freezing vial with a leak-proof screw caps, and store at 4°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. All submitted specimens should include two unique identifiers. 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 Refrigerate serum and ship on gel 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/STAT 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 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.

Test Order
Brucella species Serology
CDC-10197

Additional Information

CDC Points of Contact Robyn Stoddard
(404) 639-2053
frd8@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov

Test Order
***Brucella* species Study**
CDC-10209

Synonym(s)	None
Pre-Approval Needed	Stodard, Robyn, (404) 639-2053, frd8@cdc.gov Tiller, Rebekah, (404) 639-4507, eto3@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	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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Robyn Stoddard (404) 639-2053

Test Order
Brucella species Study
CDC-10209

frd8@cdc.gov
Rebekah Tiller
(404) 639-4507
eto3@cdc.gov

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

Synonym(s) Glanders, Melioidosis

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 Isolates, clinical specimens (blood, bone marrow, sputum or bronchoscopically obtained specimens, abscess material or wound swabs, and urine)

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolates can be kept at room temperature prior to shipping. Specimens can be kept at 4°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. All submitted specimens should include two unique identifiers. 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 Confirmed select agents need Form 2 approval by the Select Agent program prior to shipping. The Form 2 can be found at <http://www.selectagents.gov/forms.html>

Isolates should be shipped at room temperature. Specimens should be shipped at 4°C.

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/STAT 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

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

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 Mindy Elrod
(404) 639-4055
wzg0@cdc.gov
David Lonsway
(404) 639-2825
dul7@cdc.gov

Test Order
Burkholderia mallei/pseudomallei Molecular Detection
 CDC-10211

Synonym(s)	Glanders, Melioidosis
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	Blood, bone marrow, sputum or bronchoscopically obtained specimens, abscess material or wound swabs, urine, 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	No Specific Requirements
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	<p>Select agents that have been identified need form 2 approval prior to shipping. Form 2 can be found at http://www.selectagents.gov/forms.html</p> <p>Select agents must be shipped Monday through Wednesday to prevent weekend arrivals. Agar slants should be shipped at room temperature and specimens should be refrigerated.</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/STAT 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	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	Jay Gee (404) 639-4936

Test Order
Burkholderia mallei/pseudomallei Molecular Detection
CDC-10211

xzg4@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov

Test Order
Burkholderia mallei/pseudomallei Study
CDC-10212

Synonym(s)	None
Pre-Approval Needed	Elrod, Mindy, (404) 639-4055, wzg0@cdc.gov Gee, Jay, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Mindy Elrod (404) 639-4055 wzg0@cdc.gov Jay Gee

Test Order
Burkholderia mallei/pseudomallei Study
CDC-10212

(404) 639-4936
xzg4@cdc.gov

Test Order
***Burkholderia pseudomallei* Serology**
CDC-10198

Synonym(s)	Melioidosis
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	Store serum at 4°C before 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. All submitted specimens should include two unique identifiers. 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>Serum should be shipped at 4°C (e.g., frozen gel packs).</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/STAT 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.

Test Order
Burkholderia pseudomallei Serology
CDC-10198

CDC Points of Contact Alex Hoffmaster
(404) 639-0852
amh9@cdc.gov
Mindy Elrod
(404) 639-4055
wzg0@cdc.gov

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

Synonym(s) *Burkholderia* Identification

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 Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at 4°C if unable to ship immediately to preserve viability

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

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

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

Test Order
Campylobacter and *Helicobacter* Study
 CDC-10125

Synonym(s)	<i>Campy</i> , <i>Helicobacter</i> species
Pre-Approval Needed	Lane, Charlotte, (404) 718-4789, koe7@cdc.gov Aubert, Rachael, (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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Campylobacter and Helicobacter Study
CDC-10125

Additional Information None

CDC Points of Contact Charlotte Lane
(404) 718-4789
koe7@cdc.gov
Rachael Aubert
(404) 639-3816
vr17@cdc.gov

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

Synonym(s) Enteric serology, *Campy* serology

Pre-Approval Needed Aubert, Rachael, (404) 639-3816, vrl7@cdc.gov
Fields, Patricia, (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 Acute 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Campylobacter species Serology
CDC-10455

(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 Rachael Aubert
(404) 639-3816
vr17@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Test Order
Campylobacter, Helicobacter, and Related Organisms Identification
 CDC-10126

Synonym(s)	<i>Campy, Helicobacter</i> species
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	<p>Short term storage of specimens is not recommended as it reduces viability. Specimens should be prepared for shipment and shipped within 4 hours.</p> <p>All solid agar transport media should be inoculated with fresh bacterial growth and incubated microaerobically for 18–24 hours prior to shipment. Screw cap slant or stab tubes are preferred.</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 prior to shipment.</p> <p>Store isolates at less than or equal to –70°C for long-term storage.</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	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	<p>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.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Tuesday – Friday.</p> <p>Ship to: <Insert CDC Point of Contact></p>

Test Order
Campylobacter, Helicobacter, and Related Organisms Identification
CDC-10126

Centers for Disease Control and Prevention
RDSB/STAT 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 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 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
Rachael Aubert
(404) 639-3816
vrl7@cdc.gov

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

Synonym(s)	<i>Campy, Helicobacter</i> species
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	Isolates, Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Short term storage of specimens is not recommended as it reduces viability. Specimens should be prepared for shipment and shipped within 4 hours.</p> <p>All solid agar transport media should be inoculated with fresh bacterial growth and incubated microaerobically for 18–24 hours prior to shipment. Screw cap slant or stab tubes are preferred.</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 prior to shipment.</p> <p>Store isolates at less than or equal to –70°C for long-term storage.</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	<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. All submitted specimens should include two unique identifiers. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p>

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

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

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

Test Order

Chagas Disease Molecular Detection

CDC-10475

Synonym(s)	<i>Trypanosoma cruzi</i> ; American trypanosomiasis, parasite
Pre-Approval Needed	Montgomery, Susan, (404) 718-4731, zqu6@cdc.gov Benedict, Theresa, (404) 718-4124, tgd5@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Whole blood, tissue, cerebrospinal fluid (CSF)
Minimum Volume Required	2.2 mL (pediatric 0.2 mL)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect about 5 ml blood sample in Vacutainer® EDTA tubes prior to anti-parasitic therapy and store at 4°C
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	Ship specimen on wet ice (cold pack) 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/STAT Unit 52 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.
Methodology	Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
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.
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov

Test Order
Chagas Disease Molecular Detection
CDC-10475

Theresa Benedict
(404) 718-4124
tgd5@cdc.gov

Test Order
Chagas Disease Serology
CDC-10458

Synonym(s)	<i>Trypanosoma cruzi</i> ; American trypanosomiasis, parasite
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 or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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, 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

Test Order
Chagas Disease Serology
CDC-10458

igi2@cdc.gov
Sue Montgomery
(404) 718-4731
zqu6@cdc.gov

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>
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swabs (Nasopharyngeal (NP) and Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM), 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	0.4 mL preferred, 0.2 mL minimum for viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF) 0.05 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 many contain substances that inhibit some molecular assays. 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	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 identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329

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

<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

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

Synonym(s)	<i>C. psittaci</i> , <i>Chlamydophila psittaci</i> , Atypical pneumonia, Community acquired pneumonia, CAP, <i>Chlamydia</i> , <i>Chlamydophila</i> , Parrot fever, Psittacosis
Pre-Approval Needed	Winchell, Jonas, (404) 639-4921, jwinchell@cdc.gov Diaz, Maureen, (404) 639-4534, mdiaz1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swab or aspirate (Nasopharyngeal (NP) and/or Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM) 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 human specimen types may be acceptable upon consultation with POC. Consult POC for submission of acceptable animal specimen types.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum for viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF) 0.05 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 many contain substances that inhibit some molecular assays. 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	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 identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23

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

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

Test Order

Chlamydia Species (Respiratory) Molecular Detection

CDC-10525

Synonym(s)	<i>C. pneumoniae</i> , <i>Chlamydophila pneumoniae</i> , <i>C. psittaci</i> , <i>Chlamydophila psittaci</i> , Atypical pneumonia, Community acquired pneumonia, CAP, <i>Chlamydia</i> , <i>Chlamydophila</i> , Parrot fever, Psittacosis
Pre-Approval Needed	Winchell, Jonas, (404) 639-4921, jwinchell@cdc.gov Diaz, Maureen, (404) 639-4534, mdiaz1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swab or aspirate (Nasopharyngeal (NP) and/or Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM) 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 human specimen types may be acceptable upon consultation with POC. Consult POC for submission of acceptable animal specimen types.
Minimum Volume Required	0.2 mL minimum (viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF)); 0.4 mL preferred 0.05 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 many 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	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 identifiers. 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	Refrigerated specimens should be shipped 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

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

RDSB/STAT 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

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

Synonym(s)	Chlamydia, Gonorrhea, NAATs, <i>Neisseria gonorrhoeae</i> , <i>Chlamydia trachomatis</i>
Pre-Approval Needed	Raphael, Brian, (404) 639-4292, elx9@cdc.gov Katz, Samantha, (404) 639-3710, goy3@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	Oral pharynx swabs, cervical swabs, vaginal swabs, or rectal swabs collected on any suitable commercially available product, or urine
Minimum Volume Required	5 mL for urine in primary collection container. 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	Refer to the appropriate Aptima assay package insert for proper specimen storage conditions.
Transport Medium	Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium including transport media provided in Aptima Collection Kits.
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>Aptima swabs must be transported in the provided swab specimen transport medium and tube. Refer to package instructions for shipment temperature.</p> <p>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.</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/STAT Unit 31 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>

Test Order

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

Methodology Nucleic Acid Amplification Tests (NAATs)

Turnaround Time 2 Weeks

Interferences & Limitations Adhere to product insert instructions for swabs.

Additional Information None

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

Monica Morris
(404) 639-2733
vul8@cdc.gov

Test Order
***Chlamydia trachomatis* LGV Molecular Detection**
CDC-10523

Synonym(s)	Lymphogranuloma venereum, Chlamydia trachomatis (CT) Nucleic Acid Amplification Tests (NAATs)
Pre-Approval Needed	Raphael, Brian, (404) 639-4292, elx9@cdc.gov Kersh, Ellen, (404) 639-2728, egk6@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Probable LGV, Chlamydia trachomatis-positive oral pharynx swabs, cervical swabs, vaginal swabs, penile swabs, rectal swabs, and ulcer swabs collected on any commercially available product.
Minimum Volume Required	0.35 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	After swabbing area for specimen collection, remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents. Re-cap the swab specimen transport tube tightly. Transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed within 60 days of collection.
Transport Medium	Transport tube or cryotube containing Aptima 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 Specimen Handling Requirements	Refrigerated specimens should be shipped 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/STAT 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)
Turnaround Time	2 Weeks
Interferences & Limitations	Specimen collection instructions are specific for Aptima swab collection kits as this platform is commonly used in public health labs for <i>C. Trachomatis</i> diagnostics.

Test Order
Chlamydia trachomatis LGV Molecular Detection
CDC-10523

Additional Information None

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Ellen Kersh
(404) 639-2728
egk6@cdc.gov

Test Order
Chlamydia trachomatis, Genital – Study
CDC-10193

Synonym(s) Chlamydia, Chlamydia trachomatis (CT)

Pre-Approval Needed Raphael, Brian, (404) 639-4292, elx9@cdc.gov
Bowden, Katie, (404) 639-2661, wzil@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 Urine, oral pharynx swabs, cervical swabs, vaginal swabs, and rectal swabs collected on any commercially available product, or other specimen types upon consultation with laboratory.

Minimum Volume Required 5 mL for urine in primary collection container. 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 Refer to the appropriate Aptima assay package insert for proper specimen storage conditions. Specimens must be shipped in accordance with applicable national and international transportation regulations.

Transport Medium Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium including transport media provided in Aptima Collection Kits. For non-Aptima specimens, please contact the lab for further instructions.

Specimen Labeling This is not a CLIA regulated test. 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. 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 Specimens should be shipped frozen and transported on dry ice.
CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Thursday by overnight shipment.

Ship to:
<Insert CDC Point of Contact>
Centers for Disease Control and Prevention
RDSB/STAT 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 Polymerase chain reaction (PCR)

Turnaround Time 2 Weeks

Test Order
Chlamydia trachomatis, Genital – Study
CDC-10193

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

Additional Information To be determined

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Katie Bowden
(404) 639-2661
wzil@cdc.gov

Test Order
Clostridioides (Clostridium) difficile – Outbreak Strain Typing
 CDC-10229

Synonym(s)	<i>C. difficile</i> toxin, <i>C. difficile</i> , <i>C. difficile</i> characterization, <i>C. diff</i> , <i>Clostridioides (Clostridium) difficile</i> Strain Typing
Pre-Approval Needed	Gargis, Amy, (404) 639-8850, uvq0@cdc.gov Lutgring, Joseph, (404) 639-3821, yix4@cdc.gov
Supplemental Information Required	For isolate submission, document the State Public Health Department contact information on 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	Pure culture isolates. Other specimen types may be accepted with prior approval.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store anaerobically at room temperature (15–25 °C). Keep refrigerated (2–8 °C) if isolate cannot be shipped within 24 hours. Isolates may also be frozen for storage and shipment.
Transport Medium	Store anaerobically at room temperature (15–25 °C) or refrigerated (2–8 °C) in chopped meat broth media. Isolates may also be shipped frozen in skimmed milk plus glycerol mixture (each component is 10% by volume) or in Tryptic Soy Broth (TSB) plus 15% glycerol.
Specimen Labeling	Research or surveillance specimens should be labeled with the date of isolation and two unique specimen identifiers. Labels should not include personally identifiable information. All submitted specimens should include two unique identifiers. 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 frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on 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/STAT 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.
Methodology	Molecular ribotyping testing, additional phenotypic testing
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. Prior epidemiologic

Test Order
Clostridioides (Clostridium) difficile – Outbreak Strain Typing
CDC-10229

consultation with CDC/DHQP Prevention and Response Branch
[haioutbreak@cdc.gov] also required.

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 Amy Gargis
(404) 639-8850
uv90@cdc.gov
Joseph Lutgring
(404) 639-3821
yix4@cdc.gov

Test Order

Clostridium perfringens Detection – Foodborne Outbreak

CDC-10111

Synonym(s)	<i>C. perfringens</i> , CPE
Pre-Approval Needed	Luquez, Carolina, (404) 639-0896, fry6@cdc.gov Gomez, Gerry, (404) 639-0537, goe4@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 accepted; 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 accepted. 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 accepted. If samples cannot be shipped within 2 weeks, promptly freeze upon collection at <-20°C, and ship frozen.
Transport Medium	Raw stool is preferred, addition of transport medium is not needed. If stool is placed in transport medium (e.g., Cary-Blair Transport Medium, Enteric Transport Medium) prior to shipment, send four or more specimens for toxin testing. Send pure culture isolates derived from stool or food in anaerobic transport medium (e.g., chopped meat broth).
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. 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 refrigerated specimens (2–8°C) with gel ice packs and, if already frozen, send frozen specimens (< -20°C) 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

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

RDSB/STAT 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 Toxin Detection (Stool only), Culture (Stool and Food), Polymerase Chain Reaction (Isolates)

Turnaround Time 12 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 two or more stool specimens (toxin testing is not performed on food).

The test method(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 Carolina Luquez
(404) 639-0896
fry6@cdc.gov
Gerry Gomez
(404) 639-0537
goe4@cdc.gov

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

Synonym(s)	<i>Corynebacterium diphtheriae</i> , <i>C. ulcerans</i> , <i>C. pseudotuberculosis</i> , diphtheria
Pre-Approval Needed	Cassiday, Pam, (404) 639-1231, pxc1@cdc.gov Tondella, Maria, (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. All submitted specimens should include two unique identifiers. 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/STAT Unit 12 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
Corynebacterium diphtheriae Study
CDC-10172

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 *Corynebacterium* spp.

Additional Information None

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

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

Synonym(s)	<i>Corynebacterium diphtheriae</i> , <i>C. ulcerans</i> , <i>C. pseudotuberculosis</i> , diphtheria
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	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. For best results a 24-48 hour subculture on common agar slants such as blood, trypticase soy, or nutrient is recommended. 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. Cryopreservation medium for frozen isolates. Pieces of pseudo-membrane for culture and PCR must be in physiological saline; formalin is not acceptable.
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	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/STAT 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

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

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)

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

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

Synonym(s) Coryneform gram-positive rods

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 Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at 4°C if unable to ship immediately to preserve viability.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

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

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

Test Order
***Coxiella burnetii* Molecular Detection**
CDC-10304

Synonym(s) Q fever

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Specific antibiotic therapy, initiation date, and duration of treatment (e.g., drug name, dates of therapy)
- Specimen type (e.g., serum, whole blood, swab, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings (signs and symptoms, physical exam findings, and pertinent laboratory values)
- Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Samples (acute) taken within the first week of illness or while symptomatic, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; fresh tissue biopsy; swab (using a dry, sterile cotton swab); serum; collected before or within 48 hours of doxycycline administration

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2–8°C) up to 7 days after draw. If storing over 7 days, freeze at less than or equal to –70°C and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.

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 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/STAT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329

Test Order
***Coxiella burnetii* Molecular Detection**
CDC-10304

<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), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Coxiella burnetii Serology
CDC-10305

Synonym(s) Q fever

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (taken within the first week of illness or while symptomatic)
- convalescent (2-4 weeks after initial sample)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

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/STAT 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.

Test Order
Coxiella burnetii Serology
CDC-10305

Methodology Indirect immunofluorescence antibody assay (IFA)

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Coxiella* Special Study**
CDC-10306

Synonym(s)	Q fever
Pre-Approval Needed	Condit, Marah, (404) 639-3423, RZBrefdxlab@cdc.gov Zeng, Yan, (404) 639-5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
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. All submitted specimens should include two unique identifiers. 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/STAT 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	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177

Test Order
Coxiella Special Study
CDC-10306

xcw9@cdc.gov

Test Order

Crimean–Congo Hemorrhagic Fever Testing

CDC–10302

Synonym(s) CCHF

Pre-Approval Needed Shoemaker, Trevor, (470) 312–0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Crimean–Congo Hemorrhagic Fever Testing
CDC–10302

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

Test Order
Cryptosporidium Special Study
CDC-10491

Synonym(s) None

Pre-Approval Needed Roellig, Dawn M, (404) 718-4134, iyd4@cdc.gov
Xiao, Lihua, (404) 718-4161, lax0@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From None

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. All submitted specimens should include two unique identifiers. 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/STAT 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 Dawn M Roellig
(404) 718-4134
iyd4@cdc.gov
Lihua Xiao
(404) 718-4161
lax0@cdc.gov

Test Order
***Cyclospora* Molecular Detection**
CDC-10477

Synonym(s)	<i>Cyclospora cayetenensis</i> , parasite
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
Minimum Volume Required	0.5 g or 0.5mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stool collected in absence of preservatives (e.g., Carey-Blair) must be kept refrigerated (4°C) or frozen. Stool samples in a PCR-compatible fixative, e.g. TotalFix, UniFix, EcoFix and modified PVA (Zn- or Cu-based), can be kept at room temperature. Alternatively, stool specimens can be mixed in potassium dichromate 2.5% (1:1 dilution) or in absolute ethanol (1:1 dilution).
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>Ship fixed/preserved stool at room temperature. Ship unpreserved stool on wet ice (cold pack) if stored refrigerated or ship frozen (on dry ice) if stored frozen.</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/STAT 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	Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Stool specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict

Test Order
Cyclospora Molecular Detection
CDC-10477

(404) 718-4124
tgd5@cdc.gov

Test Order

Cysticercosis Serology

CDC-10459

Synonym(s)	Neurocysticercosis, <i>Taenia solium</i> , cysticercus, EITB, LLGP-EITB, parasite
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	Serum or plasma; cerebrospinal fluid (CSF) only when paired with serum or plasma.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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

Test Order
Cysticercosis Serology
CDC-10459

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Cytomegalovirus (CMV) Detection
CDC-10263

Synonym(s)	CMV
Pre-Approval Needed	Dollard, Shelia, (404) 639-2178, sgd5@cdc.gov Schmid, Scott, (404) 639-0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Urine, saliva, or whole blood
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. 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Cytomegalovirus (CMV) Detection
CDC-10263

Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Cytomegalovirus (CMV) Serology
CDC-10264

Synonym(s)	CMV
Pre-Approval Needed	Dollard, Sheila, (404) 639-2178, sgd5@cdc.gov Schmid, Scott, (404) 639-0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum or plasma
Minimum Volume Required	0.5 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Cytomegalovirus (CMV) Serology
CDC-10264

Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Dengue Virus Detection and Serology
CDC-10307

Synonym(s) Dengue fever, severe dengue

Pre-Approval Needed Tosado, Rafael, (787) 706-3449, npp0@cdc.gov
Munoz, Jorge L, (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

Test Order

Dengue Virus Detection and Serology

CDC-10307

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)

Turnaround Time 10 Days

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).

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.

Test Order
Dengue Virus Detection and Serology
CDC-10307

More information available at: <https://www.cdc.gov/dengue/index.html>

CDC Points of Contact Rafael Tosado
(787) 706-3449
npp0@cdc.gov
Jorge L Munoz
(787) 706-2469
ckq2@cdc.gov

Test Order
Detection of *Mycoplasma genitalium* Antimicrobial Resistance Markers
Study
CDC-10522

Synonym(s)	Mgen, Antimicrobial Resistance testing
Pre-Approval Needed	Raphael, Brian, (404) 639-4292, elx9@cdc.gov Bowden, Katie, (404) 639-2661, wzi1@cdc.gov
Supplemental Information Required	Yes. Please indicate the product or medium used for storage and/or transport.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Aptima tested, Mycoplasma genitalium-positive oral pharynx swabs, cervical swabs, vaginal swabs, urethral swabs, meatus swabs, and rectal swabs collected on any commercially available product, and urine.
Minimum Volume Required	5 mL (urine)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Adhere to product insert instructions for swabs
Transport Medium	Adhere to product insert instructions for swabs
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. 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 on dry ice if previously frozen, 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/STAT 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), Sanger sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	Adhere to product insert instructions for swabs
Additional Information	None
CDC Points of Contact	Brian Raphael (404) 639-4292 elx9@cdc.gov Katie Bowden

Test Order
Detection of *Mycoplasma genitalium* Antimicrobial Resistance Markers
Study
CDC-10522

(404) 639-2661
wzil@cdc.gov

Test Order

Ebola Hemorrhagic Fever Serology and Molecular Detection

CDC-10309

Synonym(s) None

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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 frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

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/STAT 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

Test Order
Ebola Hemorrhagic Fever Serology and Molecular Detection
CDC-10309

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

Test Order
Echinococcosis Serology
CDC-10460

Synonym(s)	Hydatid Disease, <i>Echinococcus granulosus</i> , parasite
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Specimens for serology testing should be collected, spun and transferred to leak proof tubes.</p> <p>Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –20°C or lower.</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>Ship specimen at room temperature or cold ice packs, not on dry ice, as an etiologic agent.</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/STAT 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

Test Order
Echinococcosis Serology
CDC-10460

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Ehrlichia Molecular Detection
CDC-10499

Synonym(s) Human monocytic ehrlichiosis and HME

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Specific antibiotic therapy, initiation date, and duration of treatment (e.g., drug name, dates of therapy)
- Specimen type (e.g., serum, whole blood, swab, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings (signs and symptoms, physical exam findings, and pertinent laboratory values)
- Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Samples (acute) taken within the first week of illness or while symptomatic, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; fresh tissue biopsy; swab (using a dry, sterile cotton swab); serum; collected before or within 48 hours of doxycycline administration

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C) upto 7 days after draw. If storing over 7 days, freeze at less than or equal to -70°C and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.

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 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/STAT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329

Test Order
Ehrlichia Molecular Detection
CDC-10499

<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), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Ehrlichia* Serology**
CDC-10311

Synonym(s) Human monocytic ehrlichiosis

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (taken within the first week of illness or while symptomatic)
- convalescent (2-4 weeks after initial sample)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

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/STAT 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.

Test Order
***Ehrlichia* Serology**
CDC-10311

Methodology Indirect immunofluorescence antibody assay (IFA)

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Ehrlichia Special Study
CDC-10498

Synonym(s)	Human monocytic ehrlichiosis and HME
Pre-Approval Needed	Condit, Marah, (404) 639-3423, RZBrefdxlab@cdc.gov Zeng, Yan, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177

Test Order
Ehrlichia Special Study
CDC-10498

xcw9@cdc.gov

Test Order
Elizabethkingia species – Special Study
CDC-10514

Synonym(s) None

Pre-Approval Needed McQuiston, John, (404) 639-0270, zje8@cdc.gov
Bell, Melissa, (404) 639-1348, jqv7@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 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
***Entamoeba histolytica*/ *dispar* Molecular Detection**
CDC-10478

Synonym(s)	Amebiasis, <i>Entameba histolytica</i> , <i>Entameba dispar</i> , parasite
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Stool, liver aspirate
Minimum Volume Required	0.5 g or 0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens collected in the absence of preservatives must be kept refrigerated (4° C) or frozen. Stool samples in a PCR-compatible fixative, e.g. TotalFix, UniFix, EcoFix and modified PVA (Zn- or Cu-based), can be kept at room temperature. Alternatively stool specimens can also be mixed in potassium dichromate 2.5% (1:1 dilution) or in absolute ethanol (1:1 dilution).
Transport Medium	If stool specimens are shipped in Cary Blair Transport Medium send these within 3 days of 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	<p>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.</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/STAT Unit 53 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	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

Test Order
Entamoeba histolytica/dispar Molecular Detection
CDC-10478

xzn5@cdc.gov
Jennifer Cope
(404) 718-4878
bjt9@cdc.gov

Test Order
Enteric Isolation – Primary Specimen
CDC-10106

Synonym(s)	Enteric Pathogen Culture, Stool Culture
Pre-Approval Needed	Martin, Haley, (404) 639-1612, hww0@cdc.gov Strockbine, Nancy, (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	Specimens that are acceptable will be determined upon consultation.
Minimum Volume Required	Minimum volume that is acceptable will be determined upon consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Storage and preservation are dependent upon consultation.
Transport Medium	Transport medium is dependent upon consultation.
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. All submitted specimens should include two unique identifiers. 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 specimens as directed by consultation.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 129 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	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.

Test Order
Enteric Isolation – Primary Specimen
CDC-10106

Additional Information Targeted organisms include: *Salmonella*, *Shigella*, *Campylobacter*, Shiga toxin-producing *Escherichia coli* (STEC) and other diarrheagenic *Escherichia coli*, pathogenic *Enterobacteriaceae*, *Listeria*, *Vibrio*, *Cronobacter*, and related foodborne and waterborne pathogens.

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

Test Order
Enteric Special Study
CDC-10512

Synonym(s)	none
Pre-Approval Needed	Huang, Andrew, (404) 639-1545, wwm8@cdc.gov Williams-Newkirk, AJo, (404) 639-1087, lgy7@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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Enteric Special Study
CDC-10512

A.Jo Williams-Newkirk
(404) 639-1087
lgy7@cdc.gov

Test Order
Enterovirus Detection and Identification
CDC-10312

Synonym(s)	Enterovirus (EV), coxsackieviruses (CVA) (CVB), Echovirus
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	Specimens include stool, serum, throat or nasal swab, cerebrospinal fluid (CSF), vesicle fluid or lesion, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs. Fresh or frozen tissues are preferred to Formalin fixed tissues, but will accept both.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Vesicle fluid, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs: 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. Place the swab immediately into a sterile viral containing 2 mL of viral transport media without antibiotics, if possible.</p> <p>Stool: Collect in a clean, dry, leak-proof container.</p> <p>Serum: For each serum specimen, 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.</p>
Transport Medium	Viral transport medium. If you do not have viral transport media, place the swab into a sterile vial without viral transport media. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. For NP/OP swabs, both swabs can be placed in the same vial, if desired.
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>Frozen specimen should be shipped on dry ice as an etiologic agent.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Include the full name, title, complete mailing address, email address, telephone, and fax number of the submitter. This will be the person to whom the final report will be mailed to.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 76 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</p>

Test Order
Enterovirus Detection and Identification
CDC-10312

federal regulations.

Methodology Molecular techniques

Turnaround Time 2 Weeks

Interferences & Limitations Collecting specimens during the first week of illness is ideal although the virus can be shed in stool for several weeks. A specimen set collected in the second week of illness should include a rectal swab or stool sample.

Additional Information Minimum volume for cell culture is 0.5–1 mL, for CSF is 60 uL, and for fresh frozen tissues is 2 mm².

Stool: Stool may be collected within 14 days of symptom onset. Collect 10–20 g of stool in a clean, dry, leak-proof container.

Serum: For each serum specimen, collect (adults and children > 6kg: 5 mL, children <6kg: 2 mL) of whole blood into a serum separator tube (marble or tiger top SST). A minimum of 1 mL of whole blood is needed for testing of pediatric patients. Allow to clot at room temperature for a minimum of 30 minutes and centrifuge.

CDC Points of Contact Alan Nix
(404) 639-1689
wbn0@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Enterovirus–D68 Detection
CDC–10524

Synonym(s)	EV–D68, EV–68
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	Respiratory specimens are acceptable; specifically throat or nasal swabs, or nasopharyngeal (NP)/oropharyngeal (OP) swabs or respiratory aspirates.
Minimum Volume Required	0.20 mL; prefer 0.5–1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	For nasal or throat swabs and nasopharyngeal (NP)/oropharyngeal (OP) swabs: 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. Place the swab immediately into a sterile viral containing 2mL of viral transport media without antibiotics, if possible. Freeze at -20°C as soon as possible.
Transport Medium	Viral transport medium. If you do not have viral transport media, place the swab into a sterile vial without viral transport media. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. For NP/OP swabs, both swabs can be placed in the same vial, if desired.
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 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/STAT 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 technique
Turnaround Time	2 Weeks
Interferences & Limitations	Collecting specimens during the first week of illness is ideal although the virus can be shed in the respiratory tract for up to 10 days.
Additional Information	None

Test Order
Enterovirus-D68 Detection
CDC-10524

CDC Points of Contact Allan Nix
(404) 639-1689
wbn0@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Entomology Special Study
CDC-10494

Synonym(s) Insect

Pre-Approval Needed Lawrence, Gena, (404) 718-4315, geg7@cdc.gov
Sutcliffe, Alice, (404) 718-4326, gok0@cdc.gov

Supplemental Information Required To be determined

Supplemental Form None

Performed on Specimens From Animal

Acceptable Sample/ Specimen Type for Testing Insects, insect DNA, and other types to be determined

Minimum Volume Required To be determined

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

Transport Medium Not Applicable

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. 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/STAT 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

Test Order
Epstein Barr Virus (EBV) Detection
CDC-10265

Synonym(s)	EBV
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Saliva, cerebrospinal fluid (CSF), or whole blood
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. Whole blood should be collected in EDTA or citrate tubes.
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>Ship specimens with cold packs or dry ice as an etiologic agent.</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/STAT 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	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

Test Order
***Escherichia* and *Shigella* Identification, Serotyping, and Virulence Profiling**
CDC-10114

Synonym(s)	<i>Escherichia</i> , STEC, <i>Shigella</i> , <i>E. coli</i> , serotyping, virulence, profiling
Pre-Approval Needed	Strockbine, Nancy, (404) 639-4186, nas6@cdc.gov Stoneburg, Devon, (404) 639-2251, euo4@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	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	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/STAT 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

Test Order
Escherichia and *Shigella* Identification, Serotyping, and Virulence
Profiling
CDC-10114

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	Haley Martin (404) 639-1612 hvw0@cdc.gov
Devon Stoneburg (404) 639-2251 euo4@cdc.gov	

Test Order
***Escherichia* and *Shigella* Study**
CDC-10115

Synonym(s)	<i>Escherichia</i> , STEC, <i>Shigella</i> , <i>E. coli</i>	
Pre-Approval Needed	Strockbine, Nancy, (404) 639-4186, nas6@cdc.gov Stoneburg, Devon, (404) 639-2251, euo4@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. All submitted specimens should include two unique identifiers. 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 isolates as directed by study protocol.</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/STAT Unit 07 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	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	Haley Martin (404) 639-1612

Test Order
Escherichia and *Shigella* Study
CDC-10115

Devon Stoneburg
(404) 639-2251
euo4@cdc.gov

hvw0@cdc.gov

Test Order
Escherichia coli (STEC) Serology (not serotyping)
 CDC-10452

Synonym(s)	Enteric serology, Hemolytic Uremic Syndrome (HUS) serology
Pre-Approval Needed	Aubert, Rachael, (404) 639-3816, vrl7@cdc.gov Fields, Patricia, (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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Escherichia coli (STEC) Serology (not serotyping)
CDC-10452

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 Rachael Aubert
(404) 639-3816
vr17@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Test Order
Escherichia coli and *Shigella* Subtyping
 CDC-10116

Synonym(s)	<i>Escherichia</i> , STEC, <i>Shigella</i> , <i>E. coli</i> , subtyping
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. All submitted specimens should include two unique identifiers. 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 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.</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/STAT Unit 07 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 or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	20 Weeks

Test Order
Escherichia coli and *Shigella* Subtyping
CDC-10116

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	Haley Martin (404) 639-1612 hvw0@cdc.gov
	Devon Stoneburg (404) 639-2251 euo4@cdc.gov	

Test Order

Fascioliasis Serology

CDC-10505

Synonym(s)	Fascioliasis, <i>Fasciola hepatica</i> , liver fluke
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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

Test Order
Fascioliasis Serology
CDC-10505

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Filariasis Serology
CDC-10462

Synonym(s)	<i>Brugia malayi</i> , <i>Wuchereria bancrofti</i> , Bancroftian filariasis, parasite
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 or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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	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

Test Order
Filariasis Serology
CDC-10462

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
***Francisella tularensis* Culture and Identification**
CDC-10313

Synonym(s)	Tularemia
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Human: lymph node aspirate, sputum, bronchia/tracheal wash, pleural fluid, whole blood, ulcer, tissues (lymph node, lung, spleen, liver). Animal: Necroscopy specimen (lymph node, lung, liver, spleen). Environmental Samples: Contact the POC for approval and guidance prior to sending other sample types.
Minimum Volume Required	Fluids: 1 mL Tissues: 1 cm ³
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate (2–8°C) all specimens containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at –70°C. Freezing of non-tissue samples should be avoided as this will reduce bacteria 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

Test Order
Francisella tularensis Culture and Identification
CDC-10313

collected pre-treatment.

Additional Information None

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
***Francisella tularensis* Serology**
CDC-10314

Synonym(s)	Tularemia
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
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	<p>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.</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 Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road 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	Microagglutination
Turnaround Time	2 Weeks
Interferences & Limitations	Hemolyzed samples interfere with test results.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266–3524

Test Order
Francisella tularensis Serology
CDC-10314

nzp0@cdc.gov
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
Francisella tularensis Special Study
CDC-10315

Synonym(s) None

Pre-Approval Needed Petersen, Jeannine, (970) 266-3524, nzp0@cdc.gov
Kingry, Luke, (970) 266-3567, vtx8@cdc.gov

Supplemental Information Required Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter; clinical summary (signs and symptoms).

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 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 identifiers. 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.

Test Order
Francisella tularensis Special Study
CDC-10315

Additional Information Contact the CDC POC for appropriate guidance/relevant information.

CDC Points of Contact Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
Fungal Identification
CDC-10179

Synonym(s) Fungal identification, mold identification, yeast identification

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 culture isolate

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Isolates can be refrigerated or kept at an ambient temperature.

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 Specimen should be shipped 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/STAT Unit 37
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 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

Test Order
Fungal Serology – *Histoplasma, Blastomyces, Coccidioides*
CDC-10180

Synonym(s)	Fungal serology, fungal complement fixation, fungal immunodiffusion
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; CSF. Plasma is not accepted.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be kept either refrigerated or frozen.
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	Refrigerated specimen should be shipped on cold packs. Frozen specimen 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/STAT Unit 37 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	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.
CDC Points of Contact	Elizabeth Berkow (404) 639-2459 kuu4@cdc.gov Shawn Lockhart (404) 639-2569 gyi2@cdc.gov

Test Order
Fungal Serology – *Paracoccidioides*
CDC-10184

Synonym(s) Fungal serology; fungal complement fixation; fungal immunodiffusion

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 accepted.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimens should be kept either refrigerated or frozen.

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 Refrigerated specimen should be shipped on cold packs. Frozen specimen 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/STAT Unit 37
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 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.

CDC Points of Contact Elizabeth Berkow
(404) 639-2459
kuu4@cdc.gov
Mark Lindsley
(404) 639-4340
mil6@cdc.gov

Test Order

Fungal Study

CDC-10181

Synonym(s)	None
Pre-Approval Needed	Berkow, Elizabeth, (404) 639-2459, kuu4@cdc.gov Lockhart, Shawn, (404) 639-2569, gyi2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Not Applicable
Minimum Volume Required	Not Applicable
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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	None
CDC Points of Contact	Elizabeth Berkow (404) 639-2459

Test Order
Fungal Study
CDC-10181

kuu4@cdc.gov
Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov

Test Order
Gastroenteritis Virus Special Study
CDC-10316

Synonym(s) None

Pre-Approval Needed Vinje, Jan, (404) 639-3721, ahx8@cdc.gov
Barclay, Leslie, (404) 639-1159, gvm3@cdc.gov

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 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. 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/STAT Unit 83
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 Jan Vinje
(404) 639-3721
ahx8@cdc.gov
Leslie Barclay
(404) 639-1159
gvm3@cdc.gov

Test Order

Genital Ulcer Disease (Syphilis, Chancroid, Herpes) Molecular Detection

CDC-10174

	Synonym(s) GUD, <i>T. pallidum</i> , <i>H. ducreyi</i> , HSV 1&2	
Pre-Approval Needed	Kersh, Ellen, (404) 639-2728, egk6@cdc.gov Pettus, Kevin, (404) 639-4338, kbp9@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Anogenital lesion swabs	
Minimum Volume Required	Not Applicable	
Collection, Storage, and Preservation of Specimen Prior to Shipping	Lesion swabs should be kept frozen at -20°C or colder.	
Transport Medium	Commercial transport medium suitable for Nucleic Acid Amplification Test (NAAT) including Hologic, Becton-Dickinson, Viral Transport Medium (VTM), and Universal Transport Medium (UTM)	
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>Frozen specimen should be shipped on dry ice, as an etiologic agent.</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/STAT Unit 31 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	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	Allan Pillay (404) 639-2140 aip7@cdc.gov Kevin Pettus (404) 639-4338	Munegowda Koralur (404) 639-1057 ncq9@cdc.gov Ellen Kersh (404) 639-2728

Test Order
Genital Ulcer Disease (Syphilis, Chancroid, Herpes) Molecular
Detection
CDC-10174

kbp9@cdc.gov

egk6@cdc.gov

Test Order

Gram Negative Bacillus (non-enteric/nonfermenter) Identification

CDC-10135

Synonym(s) Gram-negative rod/bacillus

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 Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen at 4°C if unable to ship immediately to preserve viability.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Gram Negative Bacillus (non-enteric/nonfermenter) Identification
CDC-10135

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

Test Order

Gram Positive Bacillus Identification

CDC-10137

	Synonym(s) Gram-positive rod identification, gram-positive bacillus identification
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	Pure culture isolate on a suitable agar slant medium such as trypticase soy agar (with, or without, sheep blood), heart infusion agar, or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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.

Test Order
Gram Positive Bacillus Identification
CDC-10137

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

Test Order

Gram-negative Coccus (not *Gonococcus* or *meningococcus*), *Neisseria* species, and *Moraxella* species Identification

CDC-10138

Synonym(s)	<i>Neisseria</i> Identification, GNC
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	Pure culture isolate on a suitable agar slant medium such as heart infusion agar or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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

Test Order

Gram-negative Coccus (not *Gonococcus* or *meningococcus*), *Neisseria* species, and *Moraxella* species Identification

CDC-10138

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

Test Order
Haemophilus ducreyi Molecular Detection Study
CDC-10511

Synonym(s) GUD

Pre-Approval Needed Kersh, Ellen, (404) 639-2728, egk6@cdc.gov
Pettus, Kevin, (404) 639-4338, kbp9@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Ulcer swabs, FFPE tissues or frozen tissues, and aspirates from ulcer or buboes

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping FFPE can be kept at room temperature and swabs and other specimens should be kept frozen

Transport Medium Nucleic Acid Amplification Test (NAAT) commercial transport medium, PBS, saline or TRIS buffer

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 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/STAT 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 2 Weeks

Interferences & Limitations none

Additional Information none

CDC Points of Contact Ellen Kersh
(404) 639-2728
egk6@cdc.gov
Kevin Pettus

Test Order
Haemophilus ducreyi Molecular Detection Study
CDC-10511

(404) 639-4338
kbp9@cdc.gov

Test Order
***Haemophilus influenzae* Identification and Serotyping**
CDC-10221

Synonym(s) *H. influenzae* ID and Serotyping, Hi ID

Pre-Approval Needed None

Supplemental Information Required If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.

Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in Previous Laboratory Results section on the CDC Specimen Submission (50.34) Form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate, frozen stock, primary specimen such as cerebrospinal fluid (CSF), whole blood, and serum. Consult with CDC POC prior to submission of other sterile site specimen types.

Minimum Volume Required 0.25 mL; 0.5 mL or more preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Primary specimens or stocks should be kept frozen. If submitting live cultures, slants should be incubated overnight at 37°C with 5% carbon dioxide to ensure viability of isolate, and then stored and shipped at ambient temperature.

Transport Medium Preferred medium includes frozen stocks or chocolate agar slants. When shipping 10 or more specimens, please submit frozen stocks only.

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.

If two primary patient identifiers are not available, the submitted specimens will not be tested under this test order. Please submit under Hi Surveillance test order CDC-10222; however, testing completed under CDC-10222 test order is not for diagnostic purposes and an official CLIA report will not be provided to submitter.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens and stocks should be shipped on dry ice. Agar slants (only for shipments of 10 or less isolates) should be shipped at ambient temperature. If applicable, aliquot specimen from glass bottles or vials into plastic prior to shipping.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Whenever possible, email the tracking number in advance (especially for suspected outbreak specimens or isolates).

Ship to:

<Insert CDC Point of Contact>

Centers for Disease Control and Prevention

RDSB/STAT 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

Test Order
***Haemophilus influenzae* Identification and Serotyping**
CDC-10221

federal regulations.

Methodology Real-time Polymerase Chain Reaction (rt-PCR), Slide Agglutination Serotyping (SAST)

Turnaround Time 4 Weeks

Interferences & Limitations Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.

Additional Information Test order results provide or confirm serotype for potential outbreak specimens or isolates. For research purposes only, additional microbiological and/or molecular testing can be completed as needed. Molecular characterization of *H. influenzae* isolates can be completed by whole genome sequencing with prior approval from CDC Bacterial Meningitis Laboratory POC.

CDC Points of Contact Melissa Whaley
(404) 639-3920
dbq3@cdc.gov
Caelin Potts
(404) 718-5532
lyi3@cdc.gov
Bacterial Meningitis Laboratory
(404) 639-1380

Test Order
Haemophilus influenzae Surveillance
CDC-10222

Synonym(s) Hi Surveillance, Hi study

Pre-Approval Needed None

Supplemental Information Required If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.

Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in Previous Laboratory Results section on the CDC Specimen Submission (50.34) Form or "tests used" column of surveillance submission form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate or frozen stock. If no viable isolate is available and bacterial DNA is detected, submit frozen primary specimens.

Minimum Volume Required No minimum volume required but 0.5 mL or more is preferred for clinical specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Primary specimens or stocks should be kept frozen. If submitting live cultures, slants should be incubated overnight at 37°C with 5% carbon dioxide to ensure viability of isolate, and then stored and shipped at ambient temperature.

Transport Medium Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.

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.

If results are intended for diagnostic purposes, submit with two primary patient identifiers and use Hi Identification and Serotyping test order CDC-10221.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens and stocks should be shipped on dry ice. Agar slants (only for shipments of 10 or less isolates) should be shipped at ambient temperature. If applicable, aliquot specimen from glass bottles or vials into plastic prior to shipping.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Enclose shipping spreadsheets or submission form(s) in all shipments. Please email spreadsheet prior to shipment.

Ship to:
<Insert CDC Point of Contact>
Centers for Disease Control and Prevention
RDSB/STAT 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.

Test Order
Haemophilus influenzae Surveillance
CDC-10222

Methodology Real-time Polymerase Chain Reaction (rt-PCR)

Turnaround Time

Interferences & Limitations Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.

Additional Information Additional microbiological and/or molecular testing completed as needed.

CDC Points of Contact	Melissa Whaley (404) 639-3920 dbq3@cdc.gov	Bacterial Meningitis Laboratory (404) 639-1380
	Caelin Potts (404) 718-5532 lyi3@cdc.gov	

Test Order
Haemophilus species (not *H. influenzae*/*H. ducrey*) Identification
 CDC-10141

Synonym(s)	None
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	Pure culture isolate on a suitable agar slant medium such as heart infusion agar or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order

Haemophilus species (not *H. influenza*/ *H. ducrey*) Identification

CDC-10141

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

Test Order
***Hantavirus* Testing**
CDC-10319

Synonym(s)	Hanta, HPS, HFRS
Pre-Approval Needed	Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.
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	<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. All submitted specimens should include two unique identifiers. 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>Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.</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/STAT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number></p>

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

Test Order
Hantavirus Testing
CDC-10319

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

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
Pre–Approval Needed	Gable, Paige, (404) 718–5815, woz8@cdc.gov Moulton–Meissner, Heather, (404) 639–4864, ftw2@cdc.gov
Supplemental Information Required	For isolate submission, include a Supplemental Line List. Document the test method that was used to identify the specimen in the "Previous Laboratory Results/Comments" section and provide the State Public Health Department contact information on the CDC 50.34 Specimen Submission Form.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Pure culture isolates and primary environmental specimen types (e.g. swabs, wipes, water and other fluids, medical devices, products). Other specimen types may be accepted with prior approval.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store all isolates at room temperature (15–25°C). Refrigerate only non–fastidious organisms (2–8°C) if isolates cannot be shipped within 24 hours. All primary environmental specimens should be refrigerated (2–8°C) within 4 hours. Products should be stored in accordance with manufacturer's instructions.
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).
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. All submitted specimens should include two unique identifiers. 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 frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on 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/STAT 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.
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))

Test Order
Healthcare–Associated Infections (HAI) – Outbreak Strain Identification
(ID) and Typing
CDC–10162

Turnaround Time 3 Weeks

Interferences & Limitations Holding environmental samples at room temperature >1 hour after collection may decrease recovery. Neutralization of chlorine residual in potable water is necessary during collection. Isolates and environmental specimens not maintained under specific selective pressure may lose mobile antibiotic resistance elements.

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] also required.

Turnaround Time: 3 weeks; 8 weeks for Nontuberculous Mycobacteria (NTM).

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 Paige Gable
(404) 718–5815
woz8@cdc.gov
Heather Moulton–Meissner
(404) 639–4864
ftw2@cdc.gov

Test Order
Helicobacter pylori Special Study
 CDC-10117

Synonym(s)	None	
Pre-Approval Needed	Simons-Petrusa, Brenna, (907) 729-3452, imd4@cdc.gov Morris, Julie, (907) 729-3445, zbf2@cdc.gov	
Supplemental Information Required	Please contact CDC POC initially to receive Cysteine Freeze Media for collection and transport, special intake forms and additional instructions for collection, storage and and transport of sample submission.	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Gastric biopsy or <i>H. pylori</i> bacterial isolate	
Minimum Volume Required	Biopsy bacterial isolate shall be placed in the provided Cysteine Freeze Transport Medium (1 mL). Please contact the CDC POC to receive instructions on the correct inoculation of this media.	
Collection, Storage, and Preservation of Specimen Prior to Shipping	Please contact CDC POC to receive instructions for sample or isolate collection and storage requirements.	
Transport Medium	Cysteine freeze media-provided by Arctic Investigations Program laboratory	
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	Please contact CDC POC to receive shipping instructions for sample submission. 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 Arctic Investigations Program Laboratory 4055 Tudor Centre Drive Anchorage, AK 99508 <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 and susceptibility testing for amoxicillin, tetracycline, clarithromycin and levofloxacin	
Turnaround Time	7 Weeks	
Interferences & Limitations	<i>H. pylori</i> is an extremely fragile organism. To ensure viability of the organism, only samples received in CDC POC-provided Cysteine Freeze Medium and stored under acceptable conditions will be accepted for testing.	
Additional Information	This testing is a special study with many variables. Therefore, it requires an initial consultation with CDC POC.	
CDC Points of Contact	Brenna Simons-Petrusa (907) 729-3452	Alisa Reasonover (907) 729-3448

Test Order
Helicobacter pylori Special Study
CDC-10117

imd4@cdc.gov
Julie Morris
(907) 729-3445
zbf2@cdc.gov

adr3@cdc.gov

Test Order

Hendra Hemorrhagic Fever Serology and Molecular Detection

CDC-10324

Synonym(s) None

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Hendra Hemorrhagic Fever Serology and Molecular Detection
CDC-10324

Methodology ELISA

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

Test Order
Hepatitis A NAT and Genotyping
CDC-10530

Synonym(s) HAV, HAV NAT

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), or stool

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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Hepatitis A NAT and Genotyping
CDC-10530

anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Test Order

Hepatitis A Serology

CDC-10325

Synonym(s)	HAV, Hepatitis A virus
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)
Minimum Volume Required	1 mL; 2 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	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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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.</p>
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

Test Order
Hepatitis A Serology
CDC-10325

Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Test Order
Hepatitis B Genotyping
CDC-10529

Synonym(s)	HBV
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. All submitted specimens should include two unique identifiers. 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>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/STAT 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.</p>
Methodology	Hepatitis B genotyping through sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	<p>Hemolyzed specimen are not acceptable.</p> <p>Avoid sending whole blood.</p>
Additional Information	None
CDC Points of Contact	Amanda Poe (404) 639-0723 anp0@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

Test Order
Hepatitis B Serology and Quantitative PCR
CDC-10326

Synonym(s)	HBV, Hepatitis B virus
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	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	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/STAT 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	
CDC Points of Contact	Amanda Poe (404) 639-0723

Test Order
Hepatitis B Serology and Quantitative PCR
CDC-10326

DVHLabTesting@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Test Order

Hepatitis C Serology, Quantitative PCR, and Genotyping CDC-10327

Synonym(s)	HCV, Hepatitis C virus
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	Specimens should be stored frozen
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>Frozen specimen should be shipped 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/STAT 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.</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

Test Order

Hepatitis D Serology, NAT and Genotyping

CDC-10328

Synonym(s)	HDV, Hepatitis D virus
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	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. All submitted specimens should include two unique identifiers. 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>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/STAT 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.</p>
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

Test Order

Hepatitis E Serology, NAT and Genotyping

CDC-10329

Synonym(s)	HEV, Hepatitis E virus
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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Hepatitis E Serology, NAT and Genotyping
CDC-10329

anp0@cdc.gov
Jan Drobeniuc
(404) 639-3790
DVHLabTesting@cdc.gov

Test Order
Hepatitis Special Study
CDC-10331

Synonym(s)	None	
Pre-Approval Needed	Drobeniuc, Jan, (404) 639-3790, jqd6@cdc.gov Kamili, Saleem, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Hepatitis Surveillance
CDC-10531

Synonym(s)	Global Hepatitis Outbreak and Surveillance Technology (GHOST), Hepatitis A, Hepatitis B, and Hepatitis C outbreaks
Pre-Approval Needed	Augstine, Ryan, (404) 718-5613, hepaoutbreaklab@cdc.gov Poe, Amanda, (404) 639-0723, anp0@cdc.gov
Supplemental Information Required	CDC 50.34 Specimen Submission Form 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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Hepatitis Surveillance
CDC-10531

Methodology Next Generation Amplicon 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
Sumathi Ramachandran
(404) 639-1403
dcq6@cdc.gov

Test Order
Herpes Simplex Virus 1/2 Detection
CDC-10258

Synonym(s) Oral herpes, Genital herpes

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Skin lesion, cerebrospinal fluid (CSF) or saliva

Minimum Volume Required 0.2 mL (CSF, saliva)

Collection, Storage, and Preservation of Specimen Prior to Shipping Skin lesion samples should be kept dry. Saliva can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise it should be kept frozen at -20°C.

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 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/STAT 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Test Order
Herpes Simplex Virus 1 / 2 Serology
CDC-10259

Synonym(s)	Oral herpes, Genital herpes
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	Skin lesion samples should be kept dry. Saliva can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise it 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. All submitted specimens should include two unique identifiers. 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/STAT 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	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford

Test Order
Herpes Simplex Virus 1 / 2 Serology
CDC-10259

(404) 639-2192
kjr7@cdc.gov

Test Order
Herpesvirus Encephalitis Panel
CDC-10262

Synonym(s)	None
Pre-Approval Needed	Schmid, Scott, (404) 639-0066, dss1@cdc.gov Radford, Kay, (404) 639-2192, kjr7@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Cerebrospinal fluid (CSF), saliva, whole blood, or skin lesions
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Skin lesion samples should be kept dry. Cerebrospinal fluid (CSF), saliva, 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	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 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/STAT 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	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192

Test Order
Herpesvirus Encephalitis Panel
CDC-10262

kjr7@cdc.gov

Test Order

HIV Molecular Surveillance Study (International Only)

CDC-10332

Synonym(s)	HIV subtypes, HIV molecular epidemiology, HIV outbreak
Pre-Approval Needed	DeVos, Joshua, (404) 639-5442, ext8@cdc.gov Chang, Joy, (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	<p>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.</p> <p>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.</p> <p>Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.</p>
Transport Medium	None
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. All submitted specimens should include two unique identifiers. 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>Plasma: Pack plasma specimens per IATA guidelines and ship on dry ice.</p> <p>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</p>

Test Order
HIV Molecular Surveillance Study (International Only)
CDC-10332

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/STAT 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

Test Order
HIV Special Study
CDC-10278

Synonym(s)	None
Pre-Approval Needed	Masciotra, Silvina, (404) 639-1004, svm6@cdc.gov Johnson, Jeffrey, (404) 639-4976, jlj6@cdc.gov
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	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. 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/STAT 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 jlj6@cdc.gov

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
Pre-Approval Needed	DeVos, Joshua, (404) 639-5442, ext8@cdc.gov Chang, Joy, (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	<p>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.</p> <p>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.</p> <p>Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.</p>
Transport Medium	None
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. All submitted specimens should include two unique identifiers. 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>Plasma: Pack plasma specimens per IATA guidelines and ship on dry ice.</p> <p>DBS: Prior to transport, check the dessicants and humidity indicator cards for presence of humidity. Change if necessary. Transport DBS specimens at ambient</p>

Test Order
HIV-1 Genotype Drug Resistance (International Only)
CDC-10335

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/STAT 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

Test Order
HIV-1 Laboratory Algorithm for Dried Blood Spots (DBS)
CDC-10536

Synonym(s) HIV-1 antibody DBS confirmation, HIV-1 DBS algorithm

Pre-Approval Needed None

Supplemental Information Required On the CDC 50.34 Specimen Submission Form include at least two primary identifiers (e.g. patient first and last name, date of birth, unique patient identifier and date from time of collection); specimen handling; preliminary results; patient exposures; and/or relevant information that may help expedite the accessioning, testing and reporting process.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Dried Blood Spots (DBS) made from fingerstick or venipuncture (EDTA, sodium citrate, heparin) whole blood. Whatman 903 or similar paper, or protein saver cards are acceptable for testing. FTC cards are not acceptable for testing.

Minimum Volume Required Two full blood spots

Collection, Storage, and Preservation of Specimen Prior to Shipping DBS must be placed in a air-tight ziplock bag with 3-5 desiccant packs and 1 humidity indicator card once the blood spot is dried (no more than 24 hours after collection). Bag may be stored at 15-30°C for up to 7 days after collection, at 2-8°C for up to 2 months or at -20°C or colder for long-term storage.

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 DBS are exempt, non-regulated materials. Shipment of DBS stored at ambient temperature must be shipped at ambient temperature, when refrigerated sent with cold packs, and frozen specimens sent on dry-ice.

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/STAT 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 HIV-1 antibody enzyme immunoassay, HIV-1 Western blot

Turnaround Time 3 Weeks

Interferences & Limitations Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation or no documentation or insufficient quantity or have shown evidence of contamination.

Test Order
HIV-1 Laboratory Algorithm for Dried Blood Spots (DBS)
CDC-10536

Additional Information None

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeff Johnson
(404) 639-4976
jjj6@cdc.gov

Test Order
HIV-1 Nucleic Acid Amplification (Qualitative)
CDC-10275

Synonym(s)	HIV-1 RNA qualitative, HIV NAAT, Aptima
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	Whole blood, plasma or serum. Acceptable anticoagulants include EDTA (preferred), sodium citrate, acid citrate dextrose (ACD) and or plasma preparation tubes (PPT).
Minimum Volume Required	1 mL plasma or serum (1.5 mL preferred), 2 mL EDTA whole blood tube
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separated serum or plasma may be stored at 2-8°C within in 7 days of collection. For storage greater than 7 days, store separated serum or plasma at -20°C or colder. Specimen should not have incurred more than 3 freeze-thaw cycles. Do not freeze whole blood. Whole blood tube should be stored at ambient temperature not to exceed 30°C.
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>Shipment of serum or plasma stored at 2-8°C within in 7 days of collection should be on cold pack and frozen specimens on dry-ice. EDTA whole blood tube must be shipped overnight on the collection date 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/STAT 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.</p>
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
Additional Information	For RNA testing, separate the plasma or serum by centrifugation and transfer serum or plasma to a polypropylene screw-cap tube 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). For DNA

Test Order
HIV-1 Nucleic Acid Amplification (Qualitative)
CDC-10275

testing, do not process or freeze the whole blood specimen. Ship the whole blood tubes overnight at ambient temperature to CDC Monday -Thursday to avoid weekend deliveries.

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov

Test Order

HIV-1 PCR (International Only) Qualitative

CDC-10336

Synonym(s)	HIV, EID, PMTCT, Early infant diagnostic, DNA
Pre-Approval Needed	Zeh, Clement, (404) 553-7264, cbz2@cdc.gov Zhang, Guoqing, (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 70µL 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. All submitted specimens should include two unique identifiers. 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 dessicant 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.

Test Order
HIV-1 PCR (International Only) Qualitative
CDC-10336

Ship to:
<Insert CDC Point of Contact>
Centers for Disease Control and Prevention
RDSB/STAT 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

Pre-Approval Needed Zeh, Clement, (404) 553-7264, cbz2@cdc.gov
Zhang, Guoqing, (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: 1.1 mL plasma (3mL ideally)

DBS: At least 3 saturated 13mm circles (preferably 5) containing 70µL 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. All submitted specimens should include two unique identifiers. 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

Test Order
HIV-1 PCR (International Only) Quantitative Viral Load
CDC-10337

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/STAT 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

Test Order

HIV-1 / 2 Antibody (International Only) Rapid Test

CDC-10339

Synonym(s)	HIV, RT
Pre-Approval Needed	Parekh, Bharat, (404) 639-3647, bsp1@cdc.gov Jackson, Keisha, (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. All submitted specimens should include two unique identifiers. 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/STAT 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:

Test Order
HIV-1 /2 Antibody (International Only) Rapid Test
CDC-10339

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 Bharat Parekh
(404) 639-3647
bsp1@cdc.gov
Keisha Jackson
(404) 639-2547
iqz5@cdc.gov

Test Order

HIV-1/2 Laboratory Algorithm

CDC-10272

Synonym(s)	CDC/APHL HIV Diagnostic Algorithm, HIV Serology Testing with reflex to NAT
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 plasma or whole blood tube (EDTA). For plasma, acceptable anticoagulants include EDTA (preferred), heparin and sodium citrate.
Minimum Volume Required	1 mL (serum or plasma) or 2 mL (EDTA whole blood tube)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separated serum or plasma may be stored at 2–8°C within in 7 days of collection. For storage greater than 7 days, store separated serum or plasma at –20°C or colder. Specimen should not have incurred more than 3 freeze–thaw cycles. Do not freeze whole blood. Whole blood tube should be stored at ambient temperature not to exceed 30°C.
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	<p>Shipment of serum or plasma stored at 2–8°C within in 7 days of collection should be on cold pack and frozen specimens on dry–ice. EDTA whole blood tube must be shipped overnight on the collection date 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/STAT 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.</p>
Methodology	HIV antigen/antibody combo 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. Minimize room temperature storage in order to preserve p24 antigen reactivity and HIV-1 RNA.
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

Test Order
HIV-1 / 2 Laboratory Algorithm
CDC-10272

(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov

Test Order

HIV-1 /2 Serology Diagnostic Algorithm (International Only)

CDC-10338

Synonym(s)	HIV, EIA, WB, ELISA
Pre-Approval Needed	Parekh, Bharat, (404) 639-3647, bsp1@cdc.gov Jackson, Keisha, (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 and serum 0.5 mL (2.0 mL recommended). Dried Blood Spots 4 saturated 13mm filter paper circles (recommended 5) 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. All submitted specimens should include two unique identifiers. 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.

Test Order

HIV-1 /2 Serology Diagnostic Algorithm (International Only)

CDC-10338

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/STAT 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 Bharat Parekh
(404) 639-3647
bsp1@cdc.gov
Keisha Jackson
(404) 639-2547

Test Order
HIV-1 /2 Serology Diagnostic Algorithm (International Only)
CDC-10338

iqz5@cdc.gov

Test Order
HIV-2 Nucleic Acid Amplification (Qualitative)
CDC-10429

Synonym(s)	HIV-2 NAAT/NAT, HIV-2 DNA
Pre-Approval Needed	Masciotra, Silvina, (404) 639-1004, svm6@cdc.gov Johnson, Jeffrey, (404) 639-4976, jlj6@cdc.gov
Supplemental Information Required	Include patient clinical history and previous lab results
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Whole blood. Specimen should be collected in EDTA whole blood tubes. Whole blood should not be frozen, but kept at 4°C or ambient temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.
Minimum Volume Required	10 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen should be collected in EDTA whole blood tubes. Whole blood should not be frozen, but kept at 4°C or ambient temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day 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. All submitted specimens should include two unique identifiers. 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	EDTA whole blood tube must be shipped overnight on the collection date 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/STAT 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	Polymerase Chain Reaction (PCR)
Turnaround Time	3 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with PCR amplification.
Additional Information	This test order is for RUO - Research Use Only. The results reported should not be used for diagnosis, treatment, assessment of health or management of the individual patient.

Test Order
HIV-2 Nucleic Acid Amplification (Qualitative)
CDC-10429

Do not process or freeze the whole blood specimen. Ship the whole blood tubes overnight at ambient temperature.

CDC Points of Contact Silvina Masciotra
(404) 639-1004
svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov

Test Order
HIV-2 Serology
CDC-10273

Synonym(s)	HIV-2 antibody
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 plasma or whole blood tube (EDTA). For plasma, acceptable anticoagulants include EDTA (preferred), heparin and sodium citrate.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separated serum or plasma may be stored at 2-8°C within in 7 days of collection. For storage greater than 7 days, store separated serum or plasma at -20°C or colder. Specimen should not have incurred more than 3 freeze-thaw cycles. Do not freeze whole blood. Whole blood tube should be stored at ambient temperature not to exceed 30°C.
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>Shipment of serum or plasma stored at 2-8°C within in 7 days of collection should be on cold pack and frozen specimens on dry-ice. EDTA whole blood tube must be shipped overnight on the collection date 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/STAT 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.</p>
Methodology	HIV antigen/antibody combo immunoassay is followed by an HIV-1/2 differentiation supplemental assay, which may be followed by an HIV-2 Western Blot
Turnaround Time	3 Weeks
Interferences & Limitations	Extensive hemolysis may affect test performance. Minimize room temperature storage in order to preserve p24 antigen reactivity.
Additional Information	None
CDC Points of Contact	Silvina Masciotra (404) 639-1004

Test Order
HIV-2 Serology
CDC-10273

svm6@cdc.gov
Jeffrey Johnson
(404) 639-4976
jjj6@cdc.gov

Test Order
Human Herpesvirus 6 Detection and Subtyping
CDC-10266

Synonym(s) HHV6

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Saliva, cerebrospinal fluid (CSF), or whole blood

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. Whole blood should be collected in EDTA or citrate tubes.

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 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/STAT 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Test Order

Human Herpesvirus 6 Serology

CDC-10497

Synonym(s)	HHV6
Pre-Approval Needed	Schmid, Scott, (404) 639-0066, SSchmid@cdc.gov Folster, Jennifer, (404) 639-3668, JFolster@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	VZV Specimen Collection Form. https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf
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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Human Herpesvirus 6 Serology
CDC-10497

health or management.

CDC Points of Contact Scott Schmid
(404) 639-0066
SSchmid@cdc.gov
Jennifer Folster
(404) 639-3668
JFolster@cdc.gov

Test Order
Human Herpesvirus 7 Detection
CDC-10267

Synonym(s) HHV7

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Saliva, cerebrospinal fluid (CSF), or whole blood

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. Whole blood should be collected in EDTA or citrate tubes.

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 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/STAT 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Test Order
Human Herpesvirus 8 Detection
CDC-10268

Synonym(s)	Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8
Pre-Approval Needed	Dollard, Sheila, (404) 639-2178, sgd5@cdc.gov Schmid, Scott, (404) 639-0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Whole blood or saliva
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. 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Human Herpesvirus 8 Detection
CDC-10268

Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Human Herpesvirus 8 Serology
CDC-10269

Synonym(s)	Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8
Pre-Approval Needed	Dollard, Sheila, (404) 639-2178, sgd5@cdc.gov Schmid, Scott, (404) 639-0066, dss1@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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Human Herpesvirus 8 Serology
CDC-10269

sgd5@cdc.gov
Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order

Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Testing and Sequence Analysis

CDC-10533

Synonym(s)	HIV-1
Pre-Approval Needed	Switzer, Bill, (404) 639-0219, bis3@cdc.gov Jia, Hongwei, (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	<p>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.</p> <p>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.</p>
Transport Medium	Not Applicable
Specimen Labeling	<p>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. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.</p> <p>Identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.</p>
Shipping Instructions which Include Specimen Handling Requirements	<p>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.</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/STAT Unit 227 1600 Clifton Road, NE Atlanta, GA 30329</p>

Test Order
Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Testing
and Sequence Analysis
CDC-10533

<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 1 mL 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

Test Order
Human Papillomavirus (HPV) Special Study
CDC-10131

Synonym(s) None

Pre-Approval Needed Unger, Elizabeth, (404) 639-3533, eru0@cdc.gov
Panicker, Gitika, (404) 639-2269, dhv1@cdc.gov

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 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. 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/STAT 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	Troy Querec (404)639-2864 hep0@cdc.gov
Gitika Panicker (404) 639-2269 dhv1@cdc.gov	

Test Order
Influenza Antiviral Resistance Diagnosis
CDC-10423

Synonym(s) Flu, Influenza Drug resistance, Neuraminidase inhibitor, Influenza Resistance testing

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 Must type/subtype prior to submission. Virus isolates, RNA, respiratory clinical specimens (nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, lower respiratory tract specimens), and others upon consultation with the laboratory.

Minimum Volume Required 0.5 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping 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 Specimens must be in viral 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 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 frozen specimens on dry ice. 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/STAT 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.

Test Order
Influenza Antiviral Resistance Diagnosis
CDC-10423

Methodology Pyrosequencing

Turnaround Time 3 Days

Interferences & Limitations Low viral load (Ct values above 29 are not recommended for submission) or genetic variance can affect test results.

Additional Information Turn around time may be greater than 3 days during holidays. Testing is not performed on the weekends or on federal holidays.

CDC Points of Contact Larisa Gubareva
(404) 639-3204
LGubareva@cdc.gov
David Wentworth
(404) 639-3387
DWentworth@cdc.gov

Test Order
Influenza Molecular Diagnosis
CDC-10421

Synonym(s)	Influenza Real Time PCR, Influenza Diagnostics, Flu
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. 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	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 identifiers. 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. Prior to shipping, notify CDC Influenza Division that you are sending 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/STAT Unit 198 1600 Clifton Road, NE Atlanta, GA 30329

Test Order
Influenza Molecular Diagnosis
CDC-10421

<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

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

Test Order
Influenza Serology
CDC-10424

Synonym(s)	Influenza Hemagglutination inhibition assay, Influenza microneutralization assay
Pre-Approval Needed	Levine, Min, (404) 639-3504, mwl2@cdc.gov Tumpey, Terrence, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Influenza Special Study
CDC-10425

Synonym(s)	None	
Pre-Approval Needed	Wentworth, David, (404) 639-3387, gll9@cdc.gov Dugan, Vivien, (404) 718-5399, lny1@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. All submitted specimens should include two unique identifiers. 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>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/STAT Unit 198 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		
Turnaround Time		
Interferences & Limitations	To be determined	
Additional Information	To be determined	
CDC Points of Contact	David Wentworth (404) 639-3387 gll9@cdc.gov Larisa Gubareva (404) 639-3204 lqg3@cdc.gov	Vivien Dugan (404) 718-5399 lny1@cdc.gov

Test Order

Influenza Surveillance

CDC-10422

Synonym(s)	Flu, Influenza Antigen Characterization
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. All submitted specimens should include two unique identifiers. 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/STAT Unit 200 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
Influenza Surveillance
CDC-10422

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

Test Order

Junin Hemorrhagic Fever Serology and Molecular Detection

CDC-10340

Synonym(s) Argentine Hemorrhagic Fever, AHF, *arenavirus*

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Junin Hemorrhagic Fever Serology and Molecular Detection
CDC-10340

Methodology ELISA

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

Test Order
Kyasanur Forest Disease Testing
CDC-10341

Synonym(s) KFD

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Kyasanur Forest Disease Testing
CDC-10341

Methodology ELISA

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

Test Order
Laguna Hemorrhagic Fever Serology and Molecular Detection
CDC-10342

Synonym(s) HPS, hanta

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Laguna Hemorrhagic Fever Serology and Molecular Detection
CDC-10342

Methodology ELISA

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

Test Order
Lassa Fever Testing
CDC-10343

Synonym(s) *Arenavirus*

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube). Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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)

Test Order
Lassa Fever Testing
CDC-10343

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

Test Order

Legionella species Detection and Identification

CDC-10159

Synonym(s)	<i>Legionella pneumophila</i> , <i>L. pneumophila</i> , <i>Legionella</i> , Legionnaires' disease, LD, Legionellosis, Pontiac fever
Pre-Approval Needed	legionellalab@cdc.gov (Primary Contact), , , Winchell, Jonas, (404) 639-4921, jwinchell@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Human Origin: Isolates or primary specimens for culture. Acceptable clinical specimens are sputum, bronchoalveolar lavage (BAL), lung tissue, endotracheal tube (ETT), tracheal aspirate, and urine. Only samples from implicated environmental sources and their derived isolates are accepted. Consult with CDC POC prior to sending samples.
Minimum Volume Required	Human origin: 0.5 mL preferred for lower respiratory specimens; 0.2 mL minimum for urine Environmental origin: Consult POC for minimum volume required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Human origin: Primary clinical specimens should be frozen at -20°C promptly after collection and shipped on dry ice. Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast Extract (BCYE)] and shipped refrigerated at 4°C. Refer to Additional Information for details. Environmental origin: Consult POC for information on collection, storage, and preservation of samples prior to shipping.
Transport Medium	Buffered Charcoal Yeast Extract (BCYE) or equivalent slants 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. All submitted specimens should include two unique identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23 1600 Clifton Road, NE

Test Order
***Legionella* species Molecular Subtyping**
CDC-10160

Synonym(s)	<i>Legionella pneumophila</i> , <i>L. pneumophila</i> , <i>Legionella</i> , Legionnaires' disease, LD, Legionellosis, Pontiac fever
Pre-Approval Needed	legionellalab@cdc.gov (Primary Contact), , , Winchell, Jonas, (404) 639-4921, jwinchell@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Human Origin: Isolates or primary specimens for culture. Acceptable clinical specimens are sputum, bronchoalveolar lavage (BAL), lung tissue, endotracheal tube (ETT), tracheal aspirate, and urine. Only samples from implicated environmental sources and their derived isolates are accepted.
Minimum Volume Required	Human origin: 0.5 mL preferred (lower respiratory specimens) and 0.2 mL (urine) Environmental origin: Consult POC for minimum volume required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Human origin: Primary clinical specimens should be frozen at -20°C promptly after collection and shipped on dry ice. Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast Extract (BCYE)] and shipped refrigerated at 4°C. Refer to Additional Information for details. Environmental origin: Consult POC for information on collection, storage, and preservation of samples prior to shipping.
Transport Medium	Buffered Charcoal Yeast Extract (BCYE) or equivalent slants 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. All submitted specimens should include two unique identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329

Test Order
***Leishmania* species Identification**
CDC-10238

Synonym(s)	Parasite
Pre-Approval Needed	None
Supplemental Information Required	For tissue specimens: Contact leishmania@cdc.gov prior to specimen collection and CDC will provide the recommended transport medium (Novy-MacNeal-Nicolle (NNN) medium).
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Tissue, whole blood, bone marrow
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Tissue specimens should be collected in the CDC-provided transport medium. Media must be kept refrigerated until it is used (stable for 2-4 weeks) and bring it to room temperature right before inoculation. Whole blood, bone marrow, and inoculated tissue must be kept at room temperature and sent to CDC as soon as possible after collection by overnight mail.
Transport Medium	Unpreserved tissue specimens should be transported in culture medium (typically Novy-MacNeal-Nicolle (NNN) medium). 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	<p>Culture should be kept at room temperature and mailed as soon as possible, as an etiologic agent. Blood and bone marrow should be shipped on wet ice (cold pack).</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/STAT 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) and Sanger sequencing
Turnaround Time	
Interferences & Limitations	Formalin fixed specimens are not recommended for molecular testing and will result in longer turn-around time.
Additional Information	Turnaround Time: 2 Weeks for unpreserved specimens. 4 weeks for preserved specimens.

Test Order
Leishmania species Identification
CDC-10238

CDC Points of Contact

(404) 718-4175
leishmania@cdc.gov
Yvonne Qvarnstrom
(404) 718-4120
bvp2@cdc.gov

Test Order
Leishmaniasis Serology
CDC-10463

Synonym(s)	Leishmaniasis Serology, Visceral leishmaniasis, Kala azar; <i>Leishmania donovoni</i> , <i>Leishmania major</i> , <i>Leishmania</i> , parasite
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	Serum. Plasma is not acceptable.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	No specific requirements
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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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.
CDC Points of Contact	Marcos de Almeida (404) 718-4100 bnz0@cdc.gov DPDx

Test Order
Leishmaniasis Serology
CDC-10463

(404) 718-4110
dpdx@cdc.gov

Test Order
Leptospira species Identification and Genotyping
 CDC-10199

Synonym(s)	Leptospirosis
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/STAT 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	Renee Galloway (404) 639-5461 zul0@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

Test Order
Leptospira species Identification and Genotyping
CDC-10199

Test Order
***Leptospira* species Molecular Detection**
CDC-10200

Synonym(s)	Leptospirosis, PCR
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Clinical specimens (whole blood, CSF, serum, and urine)
Minimum Volume Required	0.25 mL (CSF, serum, and whole blood) and 10 mL (urine)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood specimens should be collected in EDTA or Sodium Citrate tubes and then transferred into appropriately labeled plastic freezing vial with a leak-proof screw cap. 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	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 identifiers. 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	Specimens should be shipped frozen or on 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/STAT 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.

Test Order
Leptospira species Molecular Detection
CDC-10200

Additional Information None

CDC Points of Contact Robyn Stoddard
(404) 639-2053
frd8@cdc.gov
Renee Galloway
(404) 639-5461
zul0@cdc.gov

Test Order
Leptospira species Serology
CDC-10201

Synonym(s)	Leptospirosis serology, MAT, microagglutination test
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	Separate serum from clot, transfer sera to an appropriately labeled plastic freezing vial with a leak-proof screw caps, and store at 4°C.
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. All submitted specimens should include two unique identifiers. 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>Serum should be shipped refrigerated.</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/STAT 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	

Test Order
Leptospira species Serology
CDC-10201

CDC Points of Contact Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Test Order
Leptospira species Study
CDC-10202

Synonym(s) None

Pre-Approval Needed Galloway, Renee, (404) 639-5461, zul0@cdc.gov
Stoddard, Robyn, (404) 639-2053, frd8@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 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. All submitted specimens should include two unique identifiers. 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/STAT 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 Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Test Order
***Listeria* Identification**
CDC-10128

Synonym(s)	<i>Listeria</i>
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	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	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>Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.</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/STAT Unit 20 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 or Genetic Identification
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	None
CDC Points of Contact	Zuzana Kucerova (404) 718-4143

Test Order
Listeria Identification
CDC-10128

zik0@cdc.gov
Cheryl Tarr
(404) 639-2011
ctarr@cdc.gov

Test Order

Listeria monocytogenes Identification and Subtyping

CDC-10129

Synonym(s)	<i>Listeria</i> Typing
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	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	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>Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.</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/STAT Unit 20 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	Genetic Identification and 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.

Test Order
Listeria monocytogenes Identification and Subtyping
CDC-10129

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 Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Cheryl Tarr
(404) 639-2011
ctarr@cdc.gov

Test Order
Listeria Study
CDC-10130

Synonym(s)	None
Pre-Approval Needed	Kucerova, Zuzana, (404) 718-4143, zik0@cdc.gov Tarr, Cheryl, (404) 639-2011, ctarr@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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Listeria Study
CDC-10130

CDC Points of Contact Zuzana Kucerova
(404) 718-4143
zik0@cdc.gov
Cheryl Tarr
(404) 639-2011
ctarr@cdc.gov

Test Order

LRN Biothreat Multi-Agent Screening – Environmental CDC-10430

Synonym(s) Screening for *Bacillus anthracis*, *Brucella spp.*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, *Yersinia pestis*, Orthopoxvirus, and ricin toxin.

Pre-Approval Needed Thomas, Jennifer, (404) 639-4259, fsu8@cdc.gov
Kamal, Nazia, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
LRN Biothreat Multi-Agent Screening – Environmental
CDC-10430

Test Order

Lymphocytic Choriomeningitis (LCM) Testing

CDC-10345

Synonym(s) LCM, *Arenavirus*

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Lymphocytic Choriomeningitis (LCM) Testing
CDC-10345

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

Test Order

Machupo Hemorrhagic Fever Serology and Molecular Detection

CDC-10347

Synonym(s) Bolivian Hemorrhagic Fever, BHF, *Arenavirus*

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Machupo Hemorrhagic Fever Serology and Molecular Detection
CDC-10347

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

Test Order
Malaria Drug Resistance Surveillance
CDC-10235

Synonym(s) Malaria Drug Resistance typing, parasite

Pre-Approval Needed Boundy, Ellen, (770) 488-7788, nciddpdmalaria@cdc.gov
Abanyie, Francisca, (404) 718-4775, why6@cdc.gov

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. All submitted specimens should include two unique identifiers. 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 specimen 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/STAT Unit 221
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, 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.

Test Order
Malaria Drug Resistance Surveillance
CDC-10235

CDC Points of Contact Naomi Lucchi
(404) 718-4406
nlucchi@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

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
Pre-Approval Needed	Boundy, Ellen, (770) 488-7788, nciddpdmalaria@cdc.gov Abanyie, Francisca, (404) 718-4775, why6@cdc.gov
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	Whole blood, blood smear slide
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect a 1-5 ml blood sample in Vacutainer® EDTA tubes prior to anti-parasitic therapy and store at 4°C.
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	Ship specimen on wet ice (cold pack) 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/STAT 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)
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences 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.
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124

Test Order
Malaria Molecular Identification
CDC-10480

tg5@cdc.gov

Test Order
Malaria Serology
CDC-10464

Synonym(s)	<i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium malariae</i> , parasite
Pre-Approval Needed	Boundy, Ellen, (770) 488-7788, nciddpdmalaria@cdc.gov Abanyie, Francisca, (404) 718-4775, why6@cdc.gov
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4-8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at -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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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.

Test Order
Malaria Serology
CDC-10464

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

Test Order

Malaria: Morphologic Identification

CDC-10520

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite
Pre-Approval Needed	Boundy, Ellen, (770) 488-7788, nciddpdmalaria@cdc.gov Abanyie, Francisca, (404) 718-4775, why6@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Whole blood smear and images
Minimum Volume Required	N/A
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	Shipping is specimen specific and available on consultation. 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/STAT 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	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
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.
CDC Points of Contact	Henry Bishop (404) 718-4102 hsb2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

Test Order

Marburg Hemorrhagic Fever Serology and Molecular Detection

CDC-10349

Synonym(s) None

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Marburg Hemorrhagic Fever Serology and Molecular Detection
CDC-10349

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

Test Order
Measles Avidity
CDC-10248

Synonym(s)	Rubeola
Pre-Approval Needed	Mercader, Sara, (404) 639-4568, sjm7@cdc.gov Hickman, Carole, (404) 639-3339, cjh3@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.
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	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/STAT 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	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.
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.

Test Order
Measles Avidity
CDC-10248

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
Carole Hickman
(404) 639-3339
cjh3@cdc.gov

Test Order
Measles Detection and Genotyping
CDC-10240

Synonym(s)	Rubeola
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Naspharyngeal swabs and aspirates, nasal swabs, throat swabs, urine, and viral isolates
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>For naspharyngeal swabs and aspirates, nasal swabs, and throat swabs: 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 × 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	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>Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.</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/STAT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329</p>

Test Order
Measles Detection and Genotyping
CDC-10240

<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), 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 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

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

Test Order
Measles Neutralization Antibody (Not for Immune Status)
CDC-10250

Synonym(s)	Rubeola, PRN test, Plaque-reduction neutralization
Pre-Approval Needed	Hickman, Carole, (404) 639-3339, cjh3@cdc.gov Sowers, Sun, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Measles Neutralization Antibody (Not for Immune Status)
CDC-10250

Sun Sowers
(404) 639-1360
sib9@cdc.gov

Test Order
Measles Serology
CDC-10244

Synonym(s)	Rubeola
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
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	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	<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/STAT 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.</p>
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.
CDC Points of Contact	Carole Hickman (404) 639-3339 cjh3@cdc.gov Don Latner (404) 639-2771 grq2@cdc.gov

Test Order
Measles Special Study
CDC-10251

Synonym(s)	Rubeola
Pre-Approval Needed	Hickman, Carole, (404) 639-3339, cjh3@cdc.gov Latner, Don, (404) 639-2771, grq2@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	<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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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.</p>
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

Test Order
Measles Special Study
CDC-10251

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Don Latner
(404) 639-2771
grq2@cdc.gov

Test Order
Measles Vaccine Virus Detection
CDC-10528

Synonym(s) Rubeola

Pre-Approval Needed Rota, Paul, (404) 639-4181, par1@cdc.gov
Bankamp, Bettina, (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 Naspharyngeal swabs and aspirates, nasal swabs, throat swabs, urine and viral isolates

Minimum Volume Required 0.2 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping For naspharyngeal swabs and aspirates, nasal swabs and throat swabs: 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.

For urine: A minimum volume of 50 mL of urine should be collected in a sterile container and then processed by centrifuging at 2500 × 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.

For isolates: An aliquot should be frozen at -70°C and shipped on dry ice.

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 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/STAT Unit 81
1600 Clifton Road, NE

Test Order
Measles Vaccine Virus Detection
CDC-10528

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

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 flocced 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. Flocced 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 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.

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>

CDC Points of Contact Paul Rota
(404) 639-4181
par1@cdc.gov
Bettina Bankamp
(404) 639-1242
bfb9@cdc.gov

Test Order
MERS–CoV Molecular Detection
CDC–10488

Synonym(s) MERS–CoV PCR, Middle East Respiratory Syndrome Coronavirus PCR

Pre-Approval Needed Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov
Schneider, Eileen, (404) 639–5345, ees2@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 Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, bronchoalveolar lavage, tracheal aspirate, pleural fluid tap, sputum, stool, serum, EDTA blood (plasma), and post-mortem tissue. For more information go to: <http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html>; <http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html>

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/STAT 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

Turnaround Time 2 Days

Test Order
MERS–CoV Molecular Detection
CDC–10488

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.

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>

CDC Points of Contact Xiaoyan Lu
(404) 639–2745
xal9@cdc.gov
Shifaq Kamili
(404) 639–2799
sgk5@cdc.gov

Test Order
MERS-CoV Serology
CDC-10489

Synonym(s)	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) ELISA, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EIA
Pre-Approval Needed	Thornburg, Natalie, (404) 639-3797, nax3@cdc.gov Harcourt, Jennifer, (404) 639-4823, zaq6@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	Serum (single specimen collected >14 days after symptom onset; paired acute and convalescent). For more information go to http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html
Minimum Volume Required	200 µL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect whole blood in a serum separator tube. Allow the blood to clot, centrifuge briefly, and collect all the resulting sera in vials with external caps and internal O-ring seals. If there is no O-ring seal, then seal tightly with the available cap and secure with Parafilm. Do not collect specimen in heparin tubes. Store serum at 4°C. Serum may be frozen, if needed. http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html , http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html
Transport Medium	None
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. 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/STAT Unit 223 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	ELISA
Turnaround Time	3 Days
Interferences & Limitations	Virus isolation in cell culture and initial characterization of viral agents

Test Order
MERS-CoV Serology
CDC-10489

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.

Do not collect specimen in heparin tubes.

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>

CDC Points of Contact Natalie Thornburg
(404) 639-3797
nax3@cdc.gov
Jennifer Harcourt
(404) 639-4823
zaq6@cdc.gov

Test Order
Microsporidia Molecular Identification
CDC-10481

Synonym(s) *Anncaliia*, *Encephalitozoon cuniculi*, *Encephalitozoon hellem*, *Encephalitozoon intestinalis*, *Septata intestinalis*, *Tubulinosema*, *Enterocytozoon bieneusi*, *Nosema*, *Pleistophora*, *Trachipleistophora*, *Vittaforma corneae*, *Nosema corneum*, parasite

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 Tissue, urine, stool (unpreserved or in a PCR-compatible preservative e.g. EcoFix, UniFix, ZN-PVA, TotalFix, ethanol, potassium dichromate). Other specimen types can be accepted after consultation and pre-approval.

Minimum Volume Required 0.5 g (stool) or 1 mL (urine) or 25 mg (tissue)

Collection, Storage, and Preservation of Specimen Prior to Shipping Storage and preservation is specimen specific

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 Ship unpreserved specimen on wet ice (cold pack) as an etiologic agent. Preserved/fixed specimens can 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/STAT 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 LV-PVA are not suitable for molecular studies.

Additional Information None

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

Test Order
Microsporidia Molecular Identification
CDC-10481

Marcos de Almeida
(404) 718-4126
bnz0@cdc.gov

Test Order
***Moraxella* species Identification**
CDC-10140

Synonym(s)	<i>Moraxella</i> , GNDC
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	Pure culture isolate on a suitable agar slant medium such as heart infusion agar or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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

Test Order
Moraxella species Identification
CDC-10140

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

Test Order
MPIR – Study
CDC-10428

Synonym(s)	Anthrax TNA	
Pre-Approval Needed	Schiffer, Jarad, (404) 639-0894, aku3@cdc.gov Li, Han, (404) 639-1306, hbl1@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Paired acute and convalescent sera	
Minimum Volume Required	200 µL	
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum should be separated from whole blood and kept at -80°C	
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 Specimen Handling Requirements	Ship paired sera together and all frozen specimen should be shipped on dry ice. 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/STAT 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	Han Li (404) 639-1306 hbl1@cdc.gov

Test Order
MPIR – Study
CDC-10428

rwd7@cdc.gov

Test Order

Multipathogen Respiratory Panel (Molecular Detection)

CDC-10526

Synonym(s)	TaqMan® Array Card, TAC, Community acquired pneumonia, CAP, respiratory pathogens
Pre-Approval Needed	Winchell, Jonas, (404) 639-4921, jwinchell@cdc.gov Diaz, Maureen, (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 many 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. All submitted specimens should include two unique identifiers. 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	Refrigerated specimens should be shipped 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/STAT 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.

Test Order
Multipathogen Respiratory Panel (Molecular Detection)
CDC-10526

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

Test Order
Mumps Detection and Genotyping
CDC-10241

Synonym(s)	None
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	0.2 mL
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 × 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	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>Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.</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/STAT Unit 81</p>

Test Order
Mumps Detection and Genotyping
CDC-10241

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

Test Order
Mumps Neutralization Antibody (Not for Immune Status)
CDC-10351

Synonym(s)	PRN test, Plaque-reduction neutralization
Pre-Approval Needed	Sowers, Sun, (404) 639-1360, sib9@cdc.gov Hickman, Carole, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Mumps Neutralization Antibody (Not for Immune Status)
CDC-10351

(404) 639-3339
cjh3@cdc.gov

Test Order
Mumps Serology
CDC-10245

Synonym(s)	None
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	300 µL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum should be kept refrigerated, not frozen
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	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/STAT 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	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	Nobia Williams (404) 639-1049 new8@cdc.gov Carole Hickman

Test Order
Mumps Serology
CDC-10245

(404) 639-3339
cjh3@cdc.gov

Test Order
Mumps Special Study
CDC-10252

Synonym(s)	None
Pre-Approval Needed	Hickman, Carole, (404) 639-3339, cjh3@cdc.gov Latner, Don, (404) 639-2771, grq2@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	<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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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.</p>
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

Test Order
Mumps Special Study
CDC-10252

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Don Latner
(404) 639-2771
grq2@cdc.gov

Test Order

Mycobacterium TB Complex – Drug Susceptibility Testing

CDC-10185

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
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 isolate on solid medium or in broth culture
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	<i>Mycobacterium tuberculosis</i> (MTB) Growth 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	<p>Broth should not be shipped frozen.</p> <p>CDC does not accept routine specimens 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/STAT Unit 29 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	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

Test Order
Mycobacterium TB Complex – Drug Susceptibility Testing
CDC-10185

Beverly Metchock
(404) 639-1285
bem1@cdc.gov

Test Order
***Mycobacterium* TB Complex – Identification**
CDC-10187

Synonym(s) MTB DST, TB, Tuberculosis, MTBC

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 culture isolate

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium *Mycobacterium tuberculosis* (MTB) Growth 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 specimens 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/STAT 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
Beverly Metchock
(404) 639-1285
bem1@cdc.gov

Test Order

Mycobacterium TB Complex – Identification and Drug Susceptibility Testing

CDC-10188

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
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 isolate on solid medium or in broth culture
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	<i>Mycobacterium tuberculosis</i> (MTB) Growth 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	<p>Broth should not be shipped frozen.</p> <p>CDC does not accept routine specimens 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/STAT Unit 29 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	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 Beverly Metchock

Test Order
Mycobacterium TB Complex – Identification and Drug Susceptibility
Testing
CDC-10188

(404) 639-1285
bem1@cdc.gov

Test Order
***Mycobacterium* TB Complex – Identification and Pyrazinamide
 Susceptibility Testing**
 CDC-10190

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
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 isolate on solid medium or in broth culture
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	<i>Mycobacterium tuberculosis</i> (MTB) Growth 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	<p>Broth should not be shipped frozen.</p> <p>CDC does not accept routine specimens 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/STAT Unit 29 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	Pyrazinamide (PZA) by MGIT 960, 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 Beverly Metchock (404) 639-1285 bem1@cdc.gov

Test Order
***Mycobacterium* TB Complex – Molecular Detection of Drug Resistance**
(MDDR)
CDC-10186

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
Pre-Approval Needed	TB Lab, , (404) 639-2455, TBLab@cdc.gov Metchock, Beverly, (404) 639-1285, bem1@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-002-00220v01) http://www.cdc.gov/tb/topic/laboratory/MDDRsubmissionform.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Nucleic Acid Amplification positive (NAA+) sediment; pure culture isolate on solid medium or in broth culture; Mixed cultures known to contain MTBC; DNA
Minimum Volume Required	0.5 mL (sediment)
Collection, Storage, and Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	For isolates, <i>Mycobacterium tuberculosis</i> (MTB) Growth 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	Broth should not be shipped frozen. CDC does not accept routine specimens 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/STAT 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	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	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.

Test Order
***Mycobacterium* TB Complex – Molecular Detection of Drug Resistance**
(MDDR)
CDC-10186

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
Beverly Metchock
(404) 639-1285
bem1@cdc.gov

Test Order

Mycobacterium TB Complex – Pyrazinamide Susceptibility Testing

CDC-10189

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
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 isolate on solid medium or in broth culture
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	<i>Mycobacterium tuberculosis</i> (MTB) Growth 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	<p>Broth should not be shipped frozen.</p> <p>CDC does not accept routine specimens 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/STAT Unit 29 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	Pyrazinamide (PZA) by MGIT 960
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov Beverly Metchock (404) 639-1285 bem1@cdc.gov

Test Order
***Mycobacterium* TB Complex – Special Study**
CDC-10191

Synonym(s) MTB DST, TB, Tuberculosis, MTBC

Pre-Approval Needed TB Lab, , (404) 639-2455, TBLab@cdc.gov
Metchock, Beverly, (404) 639-1285, 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. All submitted specimens should include two unique identifiers. 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 specimens 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/STAT 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

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact TB Lab

Test Order
Mycobacterium TB Complex – Special Study
CDC-10191

(404) 639-2455
TBLab@cdc.gov
Beverly Metchock
(404) 639-1285
bem1@cdc.gov

Test Order

Mycobacterium TB Complex (International Only) Identification and Drug Susceptibility Testing

CDC-10352

Synonym(s)	Culture, DST, AST, MTB, MDR TB
Pre-Approval Needed	Hall, Patricia, (404) 718-1440, igg5@cdc.gov DeGruy, Kyle, (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 <i>Mycobacterium tuberculosis</i> 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 <i>Mycobacterial Growth Indicator Tube</i> (MGIT) liquid media
Specimen Labeling	Research or surveillance isolates may be labeled according to protocol. Labels should not include personally identifiable information. All submitted specimens should include two unique identifiers. 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/STAT 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
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

Test Order
***Mycobacterium* TB Complex (International Only) Identification and
Drug Susceptibility Testing**
CDC-10352

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
yzr0@cdc.gov
Mariela Scarbrough
(404) 639-1389
hqz4@cdc.gov

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
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swabs (Nasopharyngeal (NP) and Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM), 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 0.05 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 many contain substances that inhibit some molecular assays (See "Interference & 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	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 identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23 1600 Clifton Road, NE

Test Order
Mycoplasma pneumoniae Macrolide Susceptibility Genotyping
CDC-10513

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 (*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Legionella* species) Molecular Detection (CDC-10157) to confirm the presence of *M. pneumoniae*. Sequencing may also be performed.

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

Test Order
***Mycoplasma pneumoniae* Molecular Detection**
CDC-10155

Synonym(s)	<i>M. pneumoniae</i> , <i>Mycoplasma</i> , Atypical pneumonia, Community acquired pneumonia, CAP, Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Upper respiratory swabs (Nasopharyngeal (NP) and Oropharyngeal (OP)) in viral or universal transport media (VTM, UTM), 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	0.4 mL preferred, 0.2 mL minimum for viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF) 0.05 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 many contain substances that inhibit some molecular assays. 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	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 identifiers. 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	Refrigerated specimens should be shipped 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/STAT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329

Test Order
***Mycoplasma pneumoniae* Molecular Detection**
CDC-10155

<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

Test Order
***Naegleria* Molecular Detection**
CDC-10482

Synonym(s) Free-living amoeba, parasite

Pre-Approval Needed None

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 None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing For *Naegleria fowleri* molecular detection, CSF is the preferred specimen type. We also accept fresh or frozen tissue for *N. fowleri* molecular detection. For *Acanthamoeba* and *Balamuthia* molecular detection, tissue is the preferred specimen type; however, these amoebae can occasionally be detected in cerebrospinal fluid (CSF).

Minimum Volume Required 1 mL CSF; 0.2 g tissue

Collection, Storage, and Preservation of Specimen Prior to Shipping Storage and preservation is specimen specific

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/STAT 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.

Test Order
Naegleria Molecular Detection
CDC-10482

Additional Information None

CDC Points of Contact Jennifer Cope
(404) 718-4878
bjt9@cdc.gov
Ibne Ali
(404) 718-4157
xzn5@cdc.gov

Test Order

NARMS Susceptibility Testing

CDC-10107

Synonym(s)	National Antimicrobial Resistance Monitoring System, NARMS surveillance, AST	
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://www.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. All submitted specimens should include two unique identifiers. 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 at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data.</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/STAT Unit 127 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	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	Hayat Caidi (404) 639-0766

Test Order
NARMS Susceptibility Testing
CDC-10107

Jason Foster
(404) 639-4948
gux8@cdc.gov

foi0@cdc.gov

Test Order
***Neisseria gonorrhoeae* Genetic Analysis**
CDC-10178

Synonym(s) Gonorrhea, gonococcus (GC), *Neisseri*, *Neisseria gonorrhoeae*, Sexually Transmitted Disease (STD), Sexually Transmitted Infection (STI)

Pre-Approval Needed Raphael, Brian, (404) 639-4292, elx9@cdc.gov
Gernert, Kim M, (404) 718-5641, nin1@cdc.gov

Supplemental Information Required Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: Document the "Specimen source (type)": 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 Pure culture isolates of *Neisseria gonorrhoeae*

Minimum Volume Required 0.5-1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Store culture at -70°C to -80°C in suitable transport medium (ex. trypticase soy broth (TSB) with 20% glycerol medium).

Transport Medium TSB with 20% glycerol

Specimen Labeling This is not a CLIA regulated test. 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. 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 Specimens should be shipped on dry ice in two leak proof containers, via overnight express. A copy of the CDC 50.34 Specimen Submission Form must be included in the 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/STAT 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 Whole genome sequencing (WGS)

Turnaround Time 12 Weeks

Interferences & Limitations Viable bacterial culture is required for growth prior to DNA extraction. Low bacterial DNA concentration, low specimen volume, extended time between sample collection and culturing, and transport and handling conditions may

Test Order
Neisseria gonorrhoeae Genetic Analysis
CDC-10178

impact the results. Inability to attain sufficient DNA for WGS sequencing will result in no test being performed or an inconclusive test result.

Additional Information None

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Kim M Gernert
(404) 718-5641
nin1@cdc.gov

Test Order
***Neisseria gonorrhoeae* Identification**
CDC-10101

Synonym(s) *Neisseria*, gonorrhea, gonococcus (GC)

Pre-Approval Needed Raphael, Brian, (404) 639-4292, elx9@cdc.gov
Pham, Cau, (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 For *Neisseria gonorrhoeae* Identification Confirmation, pure culture is the preferred specimen type; however, genital, pharyngeal, and/or rectal swabs with viable organism are also acceptable when gonorrhea culturing capacity is not available. Genital, pharyngeal, and/or rectal swabs should be received at CDC preferably within 24 hours of collection.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Genital, pharyngeal, and/or rectal swabs can be kept at room temperature (22–25°C) if shipped in less than 4–6 hours of collection; otherwise specimen should be streaked on Chocolate II, InTray, or Modified Thayer–Martin medium and incubate at 35–37°C plus 5% carbon-dioxide (CO₂) for 18–20 hrs. The culture plate can be kept at room temperature if shipped in less than 4–6 hours post-incubation; otherwise they should be promptly frozen (using trypticase soy broth with 15–20% glycerol) at –70°C and shipped on dry ice. Freezing of swabs and culture plates should be avoided as this will reduce gonococcal viability.

Transport Medium *Neisseria gonorrhoeae* culture can be sent on Chocolate II plate/slant or InTray transport medium. The culture should be allowed to grow on these media and incubate at 35–37°C plus 5% carbon-dioxide (CO₂) for 18–20 hrs., prior to shipping.

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 and refrigerated specimen should 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 – Thursday via overnight shipping.

Ship to:

<Insert CDC Point of Contact>

Centers for Disease Control and Prevention

RDSB/STAT 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.

Test Order
Neisseria gonorrhoeae Identification
CDC-10101

Methodology Phenotypic, biochemical assays, MALDI-TOF

Turnaround Time 2 Weeks

Interferences & Limitations Anything that can affect viability of gonorrhea will adversely affect the test results.

Additional Information Please provide information on any antibiotics the patient may have been treated with.

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Cau Pham
(404) 718-5642
whi4@cdc.gov

Test Order
Neisseria gonorrhoeae Study
CDC-10103

Synonym(s) None

Pre-Approval Needed Raphael, Brian, (404) 639-4292, elx9@cdc.gov
Pham, Cau, (404) 718-5642, whi4@cdc.gov

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 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. 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/STAT 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

Turnaround Time

Interferences & Limitations To be determined

Additional Information Contact the CDC POC for approval prior to sending isolates pertaining to a collaborative project(s) on gonorrhoea.

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Cau Pham
(404) 718-5642
whi4@cdc.gov

Test Order
***Neisseria gonorrhoeae* Susceptibility Testing**
CDC-10102

Synonym(s)	<i>Neisseria gonorrhoeae</i> Antimicrobial Susceptibility Testing (AST), Gonorrhea (GC) Susceptibility
Pre-Approval Needed	Raphael, Brian, (404) 639-4292, elx9@cdc.gov Pham, Cau, (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	For <i>Neisseria gonorrhoeae</i> Identification Confirmation, pure culture is the preferred specimen type; however, genital, pharyngeal, and/or rectal swabs with viable organism are also acceptable when gonorrhea culturing capacity is not available. Genital, pharyngeal, and/or rectal swabs should be received at CDC preferably within 24 hours of collection.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Genital, pharyngeal, and/or rectal swabs can be kept at room temperature (22-25°C) if shipped in less than 4-6 hours of collection; otherwise specimen should be streaked on Chocolate II, InTray, or Modified Thayer-Martin medium and incubate at 35-37°C plus 5% carbon-dioxide (CO ₂) for 18-20 hrs. The culture plate can be kept at room temperature if shipped in less than 4-6 hours post-incubation; otherwise they should be promptly frozen (using trypticase soy broth with 15-20% glycerol) at -70°C and shipped on dry ice. Freezing of swabs and culture plates should be avoided as this will reduce gonococcal viability.
Transport Medium	<i>Neisseria gonorrhoeae</i> culture can be sent on Chocolate II plate/slant or InTray transport medium. The culture should be allowed to grow on these media and incubate at 35-37°C plus 5% carbon-dioxide (CO ₂) for 18-20 hrs, prior to shipping.
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 and refrigerated specimen should 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 - Thursday by overnight shipment. Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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

Test Order
Neisseria gonorrhoeae Susceptibility Testing
CDC-10102

federal regulations.

Methodology Agar Plate Dilution, E-test

Turnaround Time 4 Weeks

Interferences & Limitations Anything that can affect viability of gonorrhea will adversely affect the test results.

Additional Information Please provide information on any antibiotics the patient may have been treated with.

CDC Points of Contact Brian Raphael
(404) 639-4292
elx9@cdc.gov
Cau Pham
(404) 718-5642
whi4@cdc.gov

Test Order

Neisseria meningitidis Identification and Serogrouping

CDC-10219

Synonym(s) *N. meningitidis* ID and Serogrouping, Nm ID

Pre-Approval Needed None

Supplemental Information Required If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.

Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in Previous Laboratory Results section on the CDC Specimen Submission (50.34) Form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate, frozen stock, primary specimen such as cerebrospinal fluid (CSF), whole blood, and serum. Consult with CDC POC prior to submission of other sterile site specimen types.

Minimum Volume Required 0.25 mL; 0.5 mL or more preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping Primary specimens or stocks should be kept frozen. If submitting live cultures, slants should be incubated overnight at 37°C with 5% carbon dioxide to ensure viability of isolate, and then stored and shipped at ambient temperature.

Transport Medium Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.

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.

If two primary patient identifiers are not available, the submitted specimens will not be tested under this test order. Please submit under Nm Surveillance test order CDC-10220; however, testing completed under CDC-10220 test order is not for diagnostic purposes and an official CLIA report will not be provided to submitter.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens and stocks should be shipped on dry ice. Agar slants (only for shipments of 10 or less isolates) should be shipped at ambient temperature. If applicable, aliquot specimen from glass bottles or vials into plastic prior to shipping.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Whenever possible, email the shipping spreadsheet and tracking number in advance (especially for suspected outbreak specimens or isolates).

Ship to:
 <Insert CDC Point of Contact>
 Centers for Disease Control and Prevention
 RDSB/STAT Unit 10
 1600 Clifton Road, NE
 Atlanta, GA 30329
 <Insert CDC Point of Contact's Telephone Number>

Test Order
***Neisseria meningitidis* Identification and Serogrouping**
CDC-10219

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

Methodology Slide Agglutination Serogrouping (SASG), Real-time Polymerase Chain Reaction (rt-PCR)

Turnaround Time 4 Weeks

Interferences & Limitations Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.

Additional Information Test order results provide or confirm serogroup for potential outbreak specimens or isolates. For research purposes only, additional microbiological and/or molecular testing can be completed as needed. Molecular characterization of *N. meningitidis* isolates can be completed by whole genome sequencing. CDC POC approval is needed for whole genome sequencing.

CDC Points of Contact Melissa Whaley
(404) 639-3920
dbq3@cdc.gov
Caelin Potts
(404) 718-5532
lyi3@cdc.gov
Bacterial Meningitis Laboratory
(404) 639-1380

Test Order
***Neisseria meningitidis* Surveillance**
CDC-10220

Synonym(s) Nm surveillance, Nm study

Pre-Approval Needed None

Supplemental Information Required If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.

Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in Previous Laboratory Results section on the CDC Specimen Submission (50.34) Form or "tests used" column of surveillance submission form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate or frozen stock. If no viable isolate is available and bacterial DNA is detected, submit frozen primary specimens.

Minimum Volume Required No minimum volume required; 0.5 mL or more is preferred for clinical specimens

Collection, Storage, and Preservation of Specimen Prior to Shipping Primary specimens or stocks should be kept frozen. If submitting live cultures, slants should be incubated overnight at 37°C with 5% carbon dioxide to ensure viability of isolate, and then stored and shipped at ambient temperature.

Transport Medium Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.

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.

If results are intended for diagnostic purposes, submit with two primary patient identifiers and use Nm Identification and Serogrouping test order CDC-10219.

Shipping Instructions which Include Specimen Handling Requirements Frozen specimens and stocks should be shipped on dry ice. Agar slants (only for shipments of 10 or less isolates) should be shipped at ambient temperature. If applicable, aliquot specimen from glass bottles or vials into plastic prior to shipping. Please enclose shipping spreadsheets or 50.34(s) in all shipments. If using a spreadsheet for submission, please email prior to shipment.

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/STAT 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.

Test Order
***Neisseria meningitidis* Surveillance**
CDC-10220

Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology Isolates: Whole genome sequencing (WGS), and Real-time Polymerase Chain Reaction (rt-PCR) when applicable; Primary specimens: Real-time Polymerase Chain Reaction (rt-PCR), and when applicable, additional molecular typing

Turnaround Time

Interferences & Limitations Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of 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 completed as needed.

CDC Points of Contact Melissa Whaley
(404) 639-3920
dbq3@cdc.gov
Caelin Potts
(404) 718-5532
lyi3@cdc.gov
Bacterial Meningitis Laboratory
(404) 639-1380

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
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	Pure culture isolate on a suitable agar slant medium such as heart infusion agar or chocolate agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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.

Test Order
Neisseria species (not GC or *meningococcus*) Identification
CDC-10139

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

Test Order
Nipah Virus Testing
CDC-10354

Synonym(s) None

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Nipah Virus Testing
CDC-10354

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

Test Order
***Nocardia* species Identification**
CDC-10150

Synonym(s)	Beaded branching gram-positive rod, aerobic actinomycetes
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	Pure culture isolate on a suitable agar slant medium such as Lowenstein Jensen, trypticase soy agar (with, or without, sheep blood), heart infusion agar, Sabouraud dextrose agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
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. All submitted specimens should include two unique identifiers. 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>Ship 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/STAT 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.

Test Order
Nocardia species Identification
CDC-10150

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

Test Order
Nocardia species Identification and Antimicrobial Susceptibility
 Testing
 CDC-10151

Synonym(s)	None
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	Pure culture isolate on a suitable agar slant medium such as Lowenstein Jensen, trypticase soy agar (with, or without, sheep blood), heart infusion agar, Sabouraud dextrose agar; please consult the laboratory point of contact listed below for other sample/specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen at 4°C if unable to ship immediately to preserve viability.
Transport Medium	Suitable agar slant medium
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 identifiers. 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/STAT 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.

Test Order
Nocardia species Identification and Antimicrobial Susceptibility
Testing
CDC-10151

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

Test Order
Nontuberculous Mycobacteria (NTM) – Identification (ID)
CDC-10225

Synonym(s) *Nontuberculous (Non-TB) Mycobacteria (NTM), Nontuberculous Mycobacteria (NTM), Mycobacterium, Mycobacteria Identification*

Pre-Approval Needed None

Supplemental Information Required Include supplemental documentation as required below on the CDC 50.34 Specimen Submission Form or enclosed with the specimen. Isolates from wounds or surgical sites must have documentation that nontuberculosis mycobacteria (NTM) was abundant on primary culture (3+ to 4+) or was the only organism isolated. Isolates from sputum must have documentation that NTM was from two or more sputum cultures (collected on different days), was the only mycobacterial species present, and had abundant growth on primary culture. For isolate submission, document the the State Public Health Department contact information on 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 Isolates demonstrated to not be part of the *Mycobacterium tuberculosis complex* (MTC).

Isolates from the following samples will be accepted for testing: Sterile sites (e.g., whole blood, cerebral spinal fluid (CSF), other body fluids); Abscess, exudate or skin lesion; Wounds or surgical sites (see Additional Information); Bronchoalveolar lavage (BAL)/bronchial wash; Sputum (see Additional Information); Gastric lavage (pediatric); Animal and environmental isolates with prior approval.

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) if isolate cannot be shipped within 24 hours. For fastidious organisms store at room temperature (15–25°C).

Transport Medium Transport room temperature (15–25°C) or refrigerated (2–8°C) isolates on Lowenstein-Jensen or Middlebrook 7H10/7H11 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 Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on 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/STAT 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

Test Order
Nontuberculous Mycobacteria (NTM) – Identification (ID)
CDC-10225

federal regulations.

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 Contact the CDC POC for approval prior to submitting any specimen type other than isolates from listed sources. If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department.

Isolates from wounds or surgical sites must have documentation that NTM was abundant on primary culture (3+ to 4+) or was the only organism isolated. Isolates from sputum must have documentation that the NTM was from two or more sputum cultures (collected on different days), was the only mycobacterial species present, and have abundant growth on primary culture.

CDC Points of Contact David Lonsway
(404) 639–2825
dul7@cdc.gov
Nadege Toney
(404) 639–1282
ngc6@cdc.gov

Test Order
Norovirus Genotyping
CDC-10356

Synonym(s)	Norovirus
Pre-Approval Needed	Vinje, Jan, (404) 639-3721, ahx8@cdc.gov Barclay, Leslie, (404) 639-1159, gvm3@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Stool, environmental swab
Minimum Volume Required	0.25 g or 0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen must be stored at 2°-8°C
Transport Medium	Not Applicable
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. 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	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/STAT 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

Test Order

Norovirus Molecular Detection and Genotyping

CDC-10358

Synonym(s) Norovirus

Pre-Approval Needed Vinje, Jan, (404) 639-3721, ahx8@cdc.gov
Barclay, Leslie, (404) 639-1159, gvm3@cdc.gov

Supplemental Information Required None

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Stool, environmental swab

Minimum Volume Required 0.25 g or 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Specimen must be stored at 2°-8°C

Transport Medium Not Applicable

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. 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 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/STAT 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

Test Order
***Orientia* Molecular Detection**
CDC-10359

Synonym(s) Scrub typhus

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Specific antibiotic therapy, initiation date, and duration of treatment (e.g., drug name, dates of therapy)
- Specimen type (e.g., serum, whole blood, swab, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings (signs and symptoms, physical exam findings, and pertinent laboratory values)
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Samples (acute) taken within the first week of illness or while symptomatic, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; fresh tissue biopsy; swab (using a dry, sterile cotton swab); serum; collected before or within 48 hours of doxycycline administration

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2–8°C) up to 7 days after draw. If storing over 7 days, freeze at less than or equal to –70°C and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.

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 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/STAT Unit 78
1600 Clifton Road, NE
Atlanta, GA 30329

Test Order
Orientia Molecular Detection
CDC-10359

<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), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Orientia Serology
CDC-10360

Synonym(s) Scrub typhus

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (taken within the first week of illness or while symptomatic)
- convalescent (2-4 weeks after initial sample)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

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/STAT 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.

Test Order
Orientia Serology
CDC-10360

Methodology Indirect immunofluorescence antibody assay (IFA)

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Orientia Special Study
CDC-10500

Synonym(s)	Scrub typhus
Pre-Approval Needed	Condit, Marah, (404) 639-3423, RZBrefdxlab@cdc.gov Zeng, Yan, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177

Test Order
Orientia Special Study
CDC-10500

xcw9@cdc.gov

Test Order
Paragonimiasis Serology
CDC-10465

Synonym(s)	<i>Paragonimus westermani</i> ; <i>Paragonimus kellicotti</i> , parasite
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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

Test Order
Paragonimiasis Serology
CDC-10465

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Parasite – Special Study
CDC-10237

Synonym(s) None

Pre-Approval Needed McAuliffe, Isabel, (404) 718-4100, ibm4@cdc.gov
Qvarnstrom, Yvonne, (404) 718-4123, bvp2@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 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. All submitted specimens should include two unique identifiers. 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/STAT 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 Isabel McAuliffe
(404) 718-4100

Test Order
Parasite – Special Study
CDC-10237

ibm4@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov

Test Order
Parasites: Morphologic Identification
CDC-10234

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite, ova and parasite
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, blood, and tissue. Additional specimens are acceptable on consultation
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	Shipping is specimen specific and available on consultation. 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/STAT 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	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Henry Bishop (404) 718-4102 hsb2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

Test Order

Parechovirus Detection and Identification

CDC-10362

Synonym(s)	Human parechovirus, HPEV, Echovirus 22, Echovirus 23, Ljungan virus, parechovirus
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	Specimens include stool, serum, throat or nasal swab, cerebrospinal fluid (CSF), vesicle fluid or lesion, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs. Fresh or frozen tissues are preferred to Formalin fixed tissues, but will accept both.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Vesicle fluid, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs: 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. Place the swab immediately into a sterile viral containing 2mL of viral transport media without antibiotics, if possible.</p> <p>Stool: Collect in a clean, dry, leak-proof container.</p> <p>Serum: For each serum specimen, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature for a minimum of 30 minutes and centrifuge.</p>
Transport Medium	Viral transport medium. If you do not have viral transport media, place the swab into a sterile vial without viral transport media. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. For NP/OP swabs, both swabs can be placed in the same vial, if desired.
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>Frozen specimen should be shipped on dry ice as an etiologic agent.</p> <p>CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Include the full name, title, complete mailing address, email address, telephone, and fax number of the submitter. This will be the person to whom the final report will be mailed to.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact’s Telephone Number></p>

Test Order
Parechovirus Detection and Identification
CDC-10362

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

Methodology Molecular techniques

Turnaround Time 2 Weeks

Interferences & Limitations Collecting specimens during the first week of illness is ideal although the virus can be shed in stool for several weeks. A specimen set collected in the second week of illness should include a rectal swab or stool sample.

Additional Information Minimum volume for cell culture is 0.5–1 mL, for CSF is 60 uL, and for fresh frozen tissues is 2 mm².

Stool: Stool may be collected within 14 days of symptom onset. Collect 10–20 g of stool in a clean, dry, leak-proof container.

Serum: For each serum specimen, collect (adults and children >6kg: 5 mL, children <6 kg: 2 mL) of whole blood into a serum separator tube (marble or tiger top SST). A minimum of 1 mL of whole blood is needed for testing of pediatric patients. Allow to clot at room temperature for a minimum of 30 minutes and centrifuge.

CDC Points of Contact Alan Nix
(404) 639-1689
wbn0@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Parvovirus B19 Molecular Detection
CDC-10363

Synonym(s)	Fifth Disease
Pre-Approval Needed	Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov Schneider, Ellen, (404) 639-5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum, blood, plasma, and amniotic fluid
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate all specimens promptly after collection. If 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. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted 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.
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 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/STAT 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	Do not use wooden-shafted swabs or calcium alginate swabs
Additional Information	None
CDC Points of Contact	Xiaoyan Lu

Test Order
Parvovirus B19 Molecular Detection
CDC-10363

(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
Parvovirus B19 Serology
CDC-10364

Synonym(s)	Fifth Disease
Pre-Approval Needed	Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov Schneider, Eileen, (404) 639-5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate all specimens promptly after collection. If 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. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted 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.
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 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/STAT 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	IgG and IgM enzyme immunoassay
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect in heparin tubes
Additional Information	None
CDC Points of Contact	Xiaoyan Lu

Test Order
Parvovirus B19 Serology
CDC-10364

(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order

Pathologic Evaluation of Tissues for Possible Infectious Etiologies

CDC-10365

Synonym(s)	Autopsy, necropsy, biopsy, formalin-fixed tissues, FFPE, pathology, paraffin blocks, histopathology, electron microscopy, immunohistochemistry, PCR
Pre-Approval Needed	Infectious Diseases Pathology Branch, , (404) 639-3132, pathology@cdc.gov Reagan-Steiner, Dr. Sarah, (404) 639-2811, sor1@cdc.gov
Supplemental Information Required	Please include the following information with each submission: <ul style="list-style-type: none"> - An electronically completed CDC 50.34 Specimen Submission Form (one copy per case) - The full name, title, complete mailing address, e-mail address, telephone number, and fax number of the submitter (i.e. the person that the IDPB Final Pathology Report will be addressed to) - 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 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	Formalin-fixed paraffin-embedded tissue blocks, formalin-fixed wet tissues, gluteraldehyde-fixed wet tissues for electron microscopy, or epoxy-embedded tissues for electron microscopy. Formalin-fixed paraffin-embedded tissue blocks are preferred if formalin-fixation of the wet tissues has exceeded 2 weeks. Tissue scrolls or unstained slides are not accepted for PCR. For more information, see "Additional Information".
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Paraffin-embedded tissue blocks: this is the preferred specimen and is especially important to submit in cases where tissues have undergone prolonged formalin-fixation (greater than 2 weeks); store at ambient temperature.</p> <p>Formalin-fixed wet tissue: if available, we highly recommend that unprocessed tissues in 10% neutral buffered formalin be submitted in addition to paraffin blocks. The volume of formalin used to fix tissues should be 10x the volume of tissue. Place tissue collected in 10% buffered formalin for three days (72 hours) for biopsies, and a week for thinly-sliced autopsy tissues. After fixation, if not paraffin-embedded, tissues SHOULD be transferred to 70% ethanol for long-term storage; store at ambient temperature.</p> <p>Electron Microscopy (EM) specimens: wet tissue samples should be fixed in gluteraldehyde. After fixation, tissues SHOULD be transferred to a container filled to the top with phosphate buffer for long-term storage; store at 4°C (DO NOT FREEZE). Epoxy-embedded tissues are also accepted; store at ambient temperature.</p>
Transport Medium	Electron microscopy specimens should be fixed in glutaraldehyde and held in phosphate buffer and sent on wet ice. Do not freeze.
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

Test Order

Pathologic Evaluation of Tissues for Possible Infectious Etiologies

CDC-10365

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 identifiers. 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

Paraffin-embedded tissue blocks should be shipped at ambient temperature; during hot weather, ship on gel ice-packs to prevent the paraffin from melting. Formalin-fixed wet tissue should be shipped in leak proof containers at ambient temperature. Gluteraldehyde-fixed wet tissue should be shipped in leak proof containers on wet ice. Epoxy-embedded tissues should be shipped at ambient temperature.

CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. For urgent cases, please contact IDPB immediately.

Ship to:
<Insert CDC Point of Contact>
Centers for Disease Control and Prevention
RDSB/STAT Unit 109
1600 Clifton Rd 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

Turnaround Time 8 Weeks

Interferences & Limitations Prolonged formalin-fixation (greater than 2 weeks) may interfere with some immunohistochemical and PCR assays.

Additional Information 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 for routine Human surgical biopsy cases is 6-8 weeks. Turnaround time for complex cases, routine Human autopsy cases, and Animal cases is 12 weeks.

CDC Points of Contact	Infectious Diseases Pathology Branch (404) 639-3132 pathology@cdc.gov Dr. Sarah Reagan-Steiner (404) 639-2811 sor1@cdc.gov	Wun-Ju Shieh (404) 639-0428 wbs9@cdc.gov Sherif R. Zaki sxz1@cdc.gov (404) 639-3133
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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
Pre-Approval Needed	Nix, Alan, (404) 639-1689, wbn0@cdc.gov Oberste, Steve, (404) 639-5497, mbo2@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	Specimens include stool, serum, throat or nasal swab, cerebrospinal fluid (CSF), vesicle fluid or lesion, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs. Fresh or frozen tissues are preferred to Formalin fixed tissues, but will accept both.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Vesicle fluid, rectal, or nasopharyngeal (NP)/oropharyngeal (OP) swabs: 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. Place the swab immediately into a sterile viral containing 2 mL of viral transport media without antibiotics, if possible. Stool: Collect in a clean, dry, leak-proof container. Serum: For each serum specimen, 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.
Transport Medium	Viral transport medium. If you do not have viral transport media, place the swab into a sterile vial without viral transport media. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. For NP/OP swabs, both swabs can be placed in the same vial, if desired.
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 as an etiologic agent. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Include the full name, title, complete mailing address, email address, telephone, and fax number of the submitter. This will be the person to whom the final report will be mailed to. Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
Picornavirus Detection and Identification (not Hepatitis A, not Rhinovirus)
CDC-10374

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

Methodology Molecular techniques

Turnaround Time 2 Weeks

Interferences & Limitations Collecting specimens during the first week of illness is ideal although the virus can be shed in stool for several weeks. A specimen set collected in the second week of illness should include a rectal swab or stool sample.

Additional Information Minimum volume for cell culture is 0.5–1 mL, for CSF is 60 uL, and for fresh frozen tissues is 2 mm².

Stool: Stool may be collected within 14 days of symptom onset. Collect 10–20 g of stool in a clean, dry, leak-proof container.

Serum: For each serum specimen, collect (adults and children >6 kg: 5 mL, children <6 kg: 2 mL) of whole blood into a serum separator tube (marble or tiger top SST). A minimum of 1 mL of whole blood is needed for testing of pediatric patients. Allow to clot at room temperature for a minimum of 30 minutes and centrifuge.

CDC Points of Contact Alan Nix
(404) 639-1689
wbn0@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Picornavirus Special Study
CDC-10375

Synonym(s)	None
Pre-Approval Needed	Nix, Alan, (404) 639-1689, wbn0@cdc.gov Oberste, Steve, (404) 639-5497, mbo2@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	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. All submitted specimens should include two unique identifiers. 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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 76 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	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	Alan Nix (404) 639-1689

Test Order
Picornavirus Special Study
CDC-10375

wbn0@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Polio Isolation and Genotyping
CDC-10376

Synonym(s) PV, polio virus, Polio sequencing, AFP, acute flaccid paralysis

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, tissue culture, isolate, Fast Technology for Analysis of nucleic acids (FTA) cards, less common clinical specimens include nasopharyngeal and rectal swabs and cerebrospinal fluid (CSF)

Minimum Volume Required 0.05 mL (tissue culture)

Collection, Storage, and Preservation of Specimen Prior to Shipping Keep specimen refrigerated (2°C to 8°C) or frozen (-10°C to -30°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. All submitted specimens should include two unique identifiers. 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 ambient temperature specimens should be shipped with humidity indicator cards and desiccant pouches.

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/STAT 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

Test Order
Polio Isolation and Genotyping
CDC-10376

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

Test Order
Polio Serology
CDC-10377

Synonym(s)	Neutralization assay, NT, MNT
Pre-Approval Needed	Oberste, Steve, (404) 639-5497, mbo2@cdc.gov Jost, Heather, (404) 639-2462, ifa2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Needs to be collected from clotted whole blood or through serum separated tubes (SST). Serum needs to be frozen.
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. All submitted specimens should include two unique identifiers. 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>Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs.</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/STAT Unit 76 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	Neutralization assay
Turnaround Time	4 Weeks
Interferences & Limitations	Red blood cell hemolysis will adversely affect test results
Additional Information	None

Test Order
Polio Serology
CDC-10377

CDC Points of Contact Steve Oberste
(404) 639-5497
mbo2@cdc.gov
Heather Jost
(404) 639-2462
ifa2@cdc.gov

Test Order
Polio Special Study
CDC-10378

Synonym(s)	None
Pre-Approval Needed	Burns, Cara, (404) 639-5499, zqd1@cdc.gov Oberste, Steve, (404) 639-5497, mbo2@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	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. All submitted specimens should include two unique identifiers. 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>Frozen specimen should be shipped on dry ice, refrigerated specimen should be shipped on cold packs and ambient temperature specimens should be shipped with humidity indicator cards and desiccant pouches.</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/STAT Unit 76 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	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.

Test Order
Polio Special Study
CDC-10378

Additional Information Contact the CDC POC for appropriate guidance/relevant information.

CDC Points of Contact Cara Burns
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Poxvirus Molecular Detection
CDC-10515

Synonym(s) *Monkeypox virus, Variola virus, Vaccinia virus, smallpox, sore mouth*

Pre-Approval Needed Poxvirus Inquiry Line, , (404) 639-4129, poxvirus@cdc.gov
Davidson, Whitney, (404) 639-2933, w davidson@cdc.gov

Supplemental Information Required Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form and Poxvirus Submission Form before testing is performed.

Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.

Supplemental Form Supplemental form will be provided after consultation.

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Lesion material (e.g., exudate, tissue, crust) is required for persons with an active lesion or rash. Collection method(s) can include biopsy (non-formalin fixed), scrapings, touch prep or smear slides, or swab(s). Do not add transport media to swab specimens.

Minimum Volume Required Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping Sample each lesion separately and place in an individual collection tube (i.e., one tube per lesion sampled). Use only sterile nylon, polyester, or Dacron swabs with a plastic, wood, or thin aluminum shaft. Write site of collection on each specimen. On the specimen container, identify the part of the body from which the specimen was collected.

Refrigerate (2-8°C) or freeze (less than or equal to -30°C) specimens within an hour after collection.

Transport Medium Do not use viral transport 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 form.

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. 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/STAT Unit 47
1600 Clifton Road NE
Atlanta, GA 30329
<Insert CDC Point of Contact's Telephone Number>

Test Order
Poxvirus Molecular Detection
CDC-10515

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.

Real-time polymerase chain reaction can detect the following poxviruses: variola, monkeypox, vaccinia, cowpox, orf, pseudocowpox, bovine papular stomatitis, 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

Test Order

Poxvirus Serology

CDC-10516

Synonym(s) Orthopoxvirus serology

Pre-Approval Needed Poxvirus Inquiry Line, , (404) 639-4129, poxvirus@cdc.gov
Davidson, Whitney, (404) 639-2933, wdaidson@cdc.gov

Supplemental Information Required Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form and Poxvirus Submission Form before testing is performed.

Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.

Supplemental Form Supplemental form will be provided after consultation.

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum. For patients with suspect smallpox vaccine encephalitis, acute cerebrospinal fluid (CSF) paired with acute serum are required.

Minimum Volume Required 0.5 mL (cerebrospinal fluid (CSF), serum); 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 (less than or equal to -30°C) specimens within an hour after collection.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Poxvirus Serology
CDC-10516

Methodology Enzyme-linked immunosorbent assay (ELISA)

Turnaround Time 5 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).

CDC Points of Contact Poxvirus Inquiry Line
(404) 639-4129
poxvirus@cdc.gov
Whitni Davidson
(404) 639-2933
wdavidson@cdc.gov

Test Order

Puumala Hemorrhagic Fever Serology and Molecular Detection

CDC-10391

Synonym(s) Hanta, HFRS, Nephropathia epidemica

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Puumala Hemorrhagic Fever Serology and Molecular Detection
CDC-10391

Methodology ELISA

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

Test Order

Rabies Antemortem Human Testing

CDC-10392

Synonym(s)	Human Rabies Rule Out Testing
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James, (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/orform.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). Nuchal (skin) biopsy must be a full punch (5–6 millimeters) containing at minimum of 10 hair follicles.
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>1) Saliva: Saliva should be collected prior to mouth cleansing. Using a sterile eyedropper pipette, collect 0.5 mL to 1.0 mL saliva and place in a small sterile container, which can be sealed securely. No preservatives or additional material should be added. If the saliva is difficult to obtain, please collect an oral swab from the patient prior to mouth cleansing.</p> <p>2) Nuchal (skin) biopsy: A full punch biopsy of skin 5 to 6 mm in diameter should be taken 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 specimen on a piece of sterile gauze lightly moistened with sterile water and place in a sealed container. Do not add preservatives or additional fluids.</p> <p>3) Serum: At least 0.5 to 1.0 mL each of serum should be collected; no preservatives should be added. Do not send whole blood.</p> <p>4) Cerebral spinal fluid (CSF): At least 0.5 to 1.0 mL of CSF should be collected; no preservatives should be added.</p> <p>Keep all samples stored at –80°C and ship on dry ice. Serum and CSF can be refrigerated at 4°C before shipping. Please see the supplemental link for specific specimen storage and preservation. https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html</p>
Transport Medium	Saliva and Nuchal (skin) biopsy should not 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)

Test Order
Rabies Antemortem Human Testing
CDC-10392

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/STAT 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 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, 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

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

Test Order
Rabies Antibody Titer (Animal)
CDC-10395

Synonym(s)	Rabies vaccination status
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James A., (404) 639-2693, JEllison@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Animal
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.5 to 1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen can be kept refrigerated at 4°C but prefer frozen at -20°C
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. All submitted specimens should include two unique identifiers. 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 and refrigerated specimens should be shipped on cold packs. 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/STAT 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.

Test Order
Rabies Antibody Titer (Animal)
CDC-10395

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

Test Order
Rabies Antibody Titer (Human)
CDC-10393

Synonym(s)	Serology, Immunization status, Rabies titer
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James, (404) 639-2693, JEllison@cdc.gov
Supplemental Information Required	Supplemental Form not required
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.5 to 1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen can be kept refrigerated at 4°C but prefer frozen at -20°C
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	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 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/STAT 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.

Test Order
Rabies Antibody Titer (Human)
CDC-10393

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James Ellison
(404) 639-2693
JEllison@cdc.gov

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

Pre-Approval Needed Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov
Ellison, James, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Rabies Confirmatory Testing (Animal)
CDC-10394

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	James Ellison
	(404) 639-1050	(404) 639-2693
	Rabies@cdc.gov	JEllison@cdc.gov
	Lillian Orciari	
	(404) 639-1065	
	Lorciari@cdc.gov	

Test Order

Rabies Field Surveillance

CDC-10517

Synonym(s)	Rabies Field Studies (Domestic and International)
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-2693, Rabies@cdc.gov Ellison, James A., (404) 639-2693, JEllison@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	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. All submitted specimens should include two unique identifiers. 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>Frozen specimens should be shipped on dry ice.</p> <p>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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 89 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	Molecular detection, Serology, Culture, Immunohistochemistry (IHC),, Other
Turnaround Time	4 Weeks
Interferences & Limitations	Test is limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.

Test Order
Rabies Field Surveillance
CDC-10517

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.

CDC Points of Contact Rabies Duty Officer
(404) 639-1050
Rabies@cdc.gov
James A. Ellison
(404) 639-2693
JEllison@cdc.gov

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
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James A., (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	<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. All submitted specimens should include two unique identifiers. 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>Frozen specimens should be shipped on dry ice.</p> <p>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.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329</p>

Test Order
Rabies Postmortem Human Testing
CDC-10396

<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)
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Turnaround Time	7 Days
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Interferences & Limitations	Tests are limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
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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.
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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
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James, (404) 639-2693, JEllison@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	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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Rabies Special Study
CDC-10501

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

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
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050, Rabies@cdc.gov Ellison, James A., (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 "Epidemiological 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Rabies Virus Genetic Typing
CDC-10397

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
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Test Order

Respiratory Virus (Non-Influenza) Case Follow-up

CDC-10537

Synonym(s)	None
Pre-Approval Needed	Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov Schneider, Eileen, (404) 639-5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Upper or lower respiratory tract specimens
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerate all specimens promptly after collection. If 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, as this will reduce virus infectivity. Specimens for virus culture should not be frozen at -20° C. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted 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.
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/STAT 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	
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	To be determined

Test Order
Respiratory Virus (Non-Influenza) Case Follow-up
CDC-10537

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
Respiratory Virus (Non-Influenza) Special Study
CDC-10400

Synonym(s) None

Pre-Approval Needed Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov
Schneider, Eileen, (404) 639-5345, ees2@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human and Animal

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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Respiratory Virus Molecular Detection (Non-Influenza)
CDC-10401

Synonym(s) Non-influenza Respiratory Virus

Pre-Approval Needed Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov
Schneider, Eileen, (404) 639-5345, ees2@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Upper or lower respiratory tract specimens; pure culture isolate

Minimum Volume Required 0.25 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Refrigerate all specimens promptly after collection. If 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, as this will reduce virus infectivity. Specimens for virus culture should not be frozen at -20° C. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted 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.

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/STAT 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

Test Order
Respiratory Virus Molecular Detection (Non-Influenza)
CDC-10401

assays.

Additional Information None

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
***Rickettsia* Molecular Detection**
CDC-10402

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group rickettsiosis, typhus group rickettsiosis
Pre-Approval Needed	None
Supplemental Information Required	<p>Information Required on the CDC 50.34 Specimen Submission Form</p> <ul style="list-style-type: none"> - Patient full name, sex, and date of birth - Date of onset of symptoms - Date of specimen collection - Specific antibiotic therapy, initiation date, and duration of treatment (e.g., drug name, dates of therapy) - Specimen type (e.g., serum, whole blood, swab, tissue, etc.) - Shipping medium, if applicable (e.g., saline, formalin, etc.) - Test(s) requested <p>For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:</p> <ul style="list-style-type: none"> - Brief clinical summary and pertinent clinical findings (signs and symptoms, physical exam findings, and pertinent laboratory values) - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Samples (acute) taken within the first week of illness or while symptomatic, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; fresh tissue biopsy; swab (using a dry, sterile cotton swab); serum; collected before or within 48 hours of doxycycline administration
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Ideally keep specimen at a refrigerated temperature (2–8°C) upto 7 days after draw. If storing over 7 days, freeze at less than or equal to –70°C and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.
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	<p>Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with 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/STAT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329</p>

Test Order
***Rickettsia* Molecular Detection**
CDC-10402

<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), polymerase chain reaction (PCR), sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Rickettsia* Serology Spotted Fever Group (RMSF) Serology**
CDC-10403

Synonym(s) Spotted fever group rickettsiosis, Rocky Mountain spotted fever (RMSF)

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Shipping medium, if applicable (e.g., saline, formalin, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (taken within the first week of illness or while symptomatic)
- convalescent (2-4 weeks after initial sample)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 For best results, ensure specimens are shipped on cold packs, if frozen, specimens should be shipped with sufficient dry ice until arrival.

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/STAT 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.

Test Order
***Rickettsia* Serology Spotted Fever Group (RMSF) Serology**
CDC-10403

Methodology Indirect immunofluorescence antibody assay (IFA)

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Rickettsia* Serology Typhus Group Serology**
CDC-10404

Synonym(s) Typhus group rickettsiosis, including epidemic typhus and murine typhus

Pre-Approval Needed None

Supplemental Information Required Information Required on the CDC 50.34 Specimen Submission Form

- Patient full name, sex, and date of birth
- Date of onset of symptoms
- Date of specimen collection
- Antibiotic therapy and date of first dose
- Specimen type (e.g., serum, whole blood, etc.)
- Test(s) requested

For epidemiologic or clinical consultations (RZBEpiDiag@cdc.gov) please provide:

- Brief clinical summary and pertinent clinical findings
 - Brief travel (within 4 weeks of symptom onset) and exposure history (including animals, arthropods, etc.)
-

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

- acute (symptomatic on active stage of illness)
- convalescent (2-4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature (2-8°C), but not frozen. If previously frozen, then keep specimen frozen.

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 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/STAT 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 Indirect immunofluorescence antibody assay (IFA)

Test Order
***Rickettsia* Serology Typhus Group Serology**
CDC-10404

Turnaround Time 6 Weeks

Interferences & Limitations Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html>

CDC Points of Contact Marah Condit
(404) 639-3423
RZBrefdxlab@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
***Rickettsia* Special Study**
CDC-10405

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group rickettsiosis, typhus group rickettsiosis
Pre-Approval Needed	Condit, Marah, (404) 639-3423, RZBrefdxlab@cdc.gov Zeng, Yan, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	Marah Condit (404) 639-3423 RZBrefdxlab@cdc.gov Yan Zeng (404) 639-5177

Test Order
Rickettsia Special Study
CDC-10405

xcw9@cdc.gov

Test Order
Rift Valley Fever (RVF) Testing
CDC-10406

Synonym(s) RVF

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Rift Valley Fever (RVF) Testing
CDC-10406

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

Test Order
Rotavirus Detection
CDC-10408

Synonym(s)	Rotavirus Antigen EIA, Rotavirus Antigen ELISA
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	Human stool
Minimum Volume Required	0.25 g or 0.25 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	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/STAT 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	Contact laboratory for instructions to recover a limited sample from diaper material
CDC Points of Contact	Mike Bowen (404) 639-4922 mkb6@cdc.gov Leanne (Miriam) Ward (404) 639-3265 mrw0@cdc.gov

Test Order

Rotavirus Genotyping

CDC-10409

Synonym(s)	Rotavirus Real Time RT-PCR, Rotavirus RT-PCR, Rotavirus Sequencing
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. All submitted specimens should include two unique identifiers. 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>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/STAT 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	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 Leanne (Miriam) Ward

Test Order
Rotavirus Genotyping
CDC-10409

(404) 639-3265
mrw0@cdc.gov

Test Order
Rubella Detection (PCR) and Genotyping
CDC-10242

Synonym(s) German measles, three day measles

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 any preliminary results available.

Supplemental Form None

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 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 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.

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/STAT 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 for detection, laboratory developed RT-PCR assays for genotyping and Sanger nucleic acid sequencing

Test Order
Rubella Detection (PCR) and Genotyping
CDC-10242

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). The genotyping assays have not cleared or approved by the FDA. The performance characteristics have not been established by VVPDB. Thus, the results of the genotyping assays should not be used for diagnosis, treatment, or assessment of patient health or management.

Additional Information For additional information on rubella RNA detection and 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 Joe Icenogle
(404) 639-4557
jci1@cdc.gov
Emily Abernathy
(404) 639-1249
efa9@cdc.gov

Test Order
Rubella Serology
CDC-10246

Synonym(s)	German measles, three day measles
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 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
Minimum Volume Required	0.1 mL, 0.5–1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect by venipuncture or by finger/heel stick (for infants). Optimum time-point for serum 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. Transfer serum to a sterile plastic vial after centrifugation and prior to shipping. Specimens can be stored at 4°C or frozen at –20°C prior to shipping. For outbreaks or immuno-compromised patients please contact laboratory prior to shipment.
Transport Medium	Transport medium is not required.
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	<p>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.</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/STAT 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.</p>
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

Test Order
Rubella Serology
CDC-10246

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 Joe Icenogle
(404) 639-4557
jci1@cdc.gov
Emily Abernathy
(404) 639-1249
efa9@cdc.gov

Test Order
Rubella Serology (IgM and IgG) and Avidity
CDC-10249

Synonym(s)	German measles, three day measles
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
Minimum Volume Required	0.1 mL, 0.5-1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect by venipuncture or by finger/heel stick (for infants). Optimum time-point for serum 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. Transfer serum to a sterile plastic vial after centrifugation and prior to shipping. Specimens can be stored at 4°C or frozen at -20°C prior to shipping.
Transport Medium	Transport medium is not required.
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	<p>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.</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/STAT 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.</p>
Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by EIA, IgG avidity is determined by a laboratory-developed assay using 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. 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.
Additional Information	For additional information on serology assays, see

Test Order
Rubella Serology (IgM and IgG) and Avidity
CDC-10249

<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 Joe Icenogle
(404) 639-4557
jci1@cdc.gov
Emily Abernathy
(404) 639-1249
efa9@cdc.gov

Test Order
Salmonella Identification and Serotyping
CDC-10110

Synonym(s) *Salmonella* Typing

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 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 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/STAT 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

Test Order
Salmonella Identification and Serotyping
CDC-10110

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 Susan Van Duyne
(404) 639-0186
mdv9@cdc.gov
Ana Lauer
(404) 639-2117
ybp6@cdc.gov

Test Order
***Salmonella* serotype Typhi (only) Serology**
CDC-10453

Synonym(s)	Enteric serology, Typhi serology
Pre-Approval Needed	Aubert, Rachael, (404) 639-3816, vrl7@cdc.gov Fields, Patricia, (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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Salmonella serotype Typhi (only) Serology
CDC-10453

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 Rachael Aubert
(404) 639-3816
vr17@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Test Order
***Salmonella* Study**
CDC-10109

Synonym(s)	None
Pre-Approval Needed	Van Duyn, Susan, (404) 639-0186, mdv9@cdc.gov Lauer, Ana, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Salmonella Study
CDC-10109

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
Ana Lauer
(404) 639-2117
ybp6@cdc.gov

Test Order
Salmonella Subtyping
 CDC-10108

Synonym(s)	<i>Salmonella</i> Typing
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. All submitted specimens should include two unique identifiers. 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 at ambient temperature or frozen with dry ice. There are no time constraints for submitting sequence data.</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/STAT Unit 27 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 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

Test Order
Salmonella Subtyping
CDC-10108

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
Ana Lauer
(404) 639-2117
ybp6@cdc.gov

Test Order
SARS Molecular Detection
CDC-10412

Synonym(s) SARS coronavirus

Pre-Approval Needed Lindstrom, Stephen, (404) 639-1587, SQL5@cdc.gov
Schneider, Eileen, (404) 639-5345, ees2@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, bronchoalveolar lavage, tracheal aspirate, pleural fluid tap, sputum, and post-mortem tissue.
For more information go to <http://www.cdc.gov/sars/guidance/F-lab/app4.html>

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.
For more information go to <http://www.cdc.gov/sars/guidance/F-lab/app4.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/STAT 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/sars/lab/specimen.html>

Methodology Polymerase Chain Reaction (PCR), Sequencing

Turnaround Time 3 Days

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

Test Order
SARS Molecular Detection
CDC-10412

assays.

Additional Information <http://www.cdc.gov/sars/about/index.html>
<http://www.cdc.gov/sars/guidance/F-lab/app5.html>

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xal9@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
SARS Serology
CDC-10413

Synonym(s)	SARS-CoV, SARS-CoV EIA, SARS-CoV ELISA, SARS ELISA, SARS EIA
Pre-Approval Needed	Thornburg, Natalie, (404) 639-3797, nax3@cdc.gov Harcourt, Jennifer, (404) 639-4823, zaq6@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum (acute and convalescent) and plasma For more information go to http://www.cdc.gov/sars/guidance/F-lab/app4.html
Minimum Volume Required	200 µL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect whole blood in a serum separator tube. Allow the blood to clot, centrifuge briefly, and collect all the resulting sera in vials with external caps and internal O-ring seals. If there is no O-ring seal, then seal tightly with the available cap and secure with Parafilm. Collect whole blood in either EDTA tubes or in a clotting tube. For plasma, collect blood in EDTA tubes and place in vials with external caps and internal O-ring seals. Store plasma and serum at 4°C. Serum may be frozen.
Transport Medium	Not Applicable
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. 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/STAT Unit 223 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	ELISA
Turnaround Time	3 Days
Interferences & Limitations	Do not collect in heparin tubes

Test Order
SARS Serology
CDC-10413

Additional Information None

CDC Points of Contact Natalie Thornburg
(404) 639-3797
nax3@cdc.gov
Jennifer Harcourt
(404) 639-4823
zaq6@cdc.gov

Test Order
SARS-2 Serology
CDC-10538

Synonym(s)	COVID-19 serology, 2019 nCoV serology
Pre-Approval Needed	Thornburg, Natalie, (404) 639-3797, nax3@cdc.gov Harcourt, Jennifer, (404) 639-4823, zaq6@cdc.gov
Supplemental Information Required	Provide the serum processing information including: color of tube collection, how long did the tube sit before separation and at what temperature.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.35 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	The serum can be collected in a tiger top tube or serum separator tube. Spin down and aliquot the serum into cryovials and wrap in Parafilm.
Transport Medium	Not Applicable
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. 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/STAT Unit 223 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 and confirmatory microneutralization
Turnaround Time	2 Weeks
Interferences & Limitations	Not Applicable
Additional Information	Not Applicable
CDC Points of Contact	Natalie Thornburg (404) 639-3797 nax3@cdc.gov Jennifer Harcourt (404) 639-4823 zaq6@cdc.gov

Test Order
Schistosomiasis Serology
CDC-10466

Synonym(s)	<i>Schistosoma mansoni</i> , <i>Schistosoma haematobium</i> , <i>Schistosoma japonicum</i> , Bilharzia, parasite
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	<p>Specimens for serology testing should be collected, spun and transferred to leak proof tubes.</p> <p>Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –20°C or lower.</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>Ship specimen at room temperature or cold ice packs, not on dry ice, as an etiologic agent.</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/STAT 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	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.

Test Order
Schistosomiasis Serology
CDC-10466

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

Test Order
Seoul Virus Testing
CDC-10414

Synonym(s) Hanta, HFRS, HPS

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Seoul Virus Testing
CDC-10414

Methodology ELISA

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

Test Order

Sexually Transmitted Infection (STI) Panel – *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, *Trichomonas vaginalis* Study

CDC-10175

Synonym(s)	STI
Pre-Approval Needed	Raphael, Brian, (404) 639-4292, elx9@cdc.gov Katz, Samantha, (404) 639-3710, goy3@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. Additional information required will be determined upon consultation.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Urine, oral pharynx swabs, cervical swabs, vaginal swabs, and rectal swabs collected on any suitable commercially available product, or other specimen types upon consultation with laboratory.
Minimum Volume Required	5 mL for urine in primary collection container. 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	Refer to the appropriate Aptima assay package insert for proper specimen storage conditions.
Transport Medium	Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium including transport media provided in Aptima Collection Kits. For non-Aptima specimens, please contact the lab for further instructions.
Specimen Labeling	This is not a CLIA regulated test. 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. 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>Aptima swabs must be transported in the provided swab specimen transport medium and tube. Refer to package instructions for shipment temperature.</p> <p>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.</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/STAT Unit 31 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number></p>

Test Order

Sexually Transmitted Infection (STI) Panel – *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, *Trichomonas vaginalis* Study

CDC-10175

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

Methodology Polymerase chain reaction (PCR)

Turnaround Time 12 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

Monica Morris
(404) 639-2733
vul8@cdc.gov

Test Order

Shiga Toxin-producing *E. coli* Isolation from Enrichment Broth CDC-10105

Synonym(s)	<i>Escherichia</i> , STEC, <i>E. coli</i> , enrichment broth
Pre-Approval Needed	Strockbine, Nancy, (404) 639-4186, nas6@cdc.gov Martin, Haley, (404) 639-1612, hww0@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 Dr. Nancy Strockbine 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. All submitted specimens should include two unique identifiers. 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 with gel ice-packs. Shiga toxin-positive broths should be shipped as Category A Infectious Substances.</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/STAT Unit 07 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	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

Test Order
Shiga Toxin-producing *E. coli* Isolation from Enrichment Broth
CDC-10105

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	Devon Stoneburg (404) 639-2251 euo4@cdc.gov
	Haley Martin (404) 639-1612 hvw0@cdc.gov	

Test Order
**Simian Immunodeficiency Virus (SIV) and SIV/Human
Immunodeficiency Virus (SHIV) Recombinant Virus Testing**
CDC-10534

Synonym(s) SIV, SHIV (SIV/HIV recombinants)

Pre-Approval Needed Switzer, Bill, (404) 639-0219, bis3@cdc.gov
Masciotra, Silvina, (404) 639-1004, svm6@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 Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes.

Minimum Volume Required 10 mL

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.

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 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/STAT 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 Serology and nucleic acid (DNA and RNA) amplification

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

Test Order
Simian Immunodeficiency Virus (SIV) and SIV/Human
Immunodeficiency Virus (SHIV) Recombinant Virus Testing
CDC-10534

transit or otherwise shown evidence of contamination.

Additional Information None

CDC Points of Contact Bill Switzer
(404) 639-0219
bis3@cdc.gov
Silvina Masciotra
(404) 639-1004
svm6@cdc.gov

Test Order
Special Bacteriology Pathogen Study
CDC-10147

Synonym(s)	None
Pre-Approval Needed	McQuiston, John, (404) 639-0270, zje8@cdc.gov Bell, Melissa, (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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Special Bacteriology Pathogen Study
CDC-10147

jqv7@cdc.gov

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)
Pre-Approval Needed	Lonsway, David, (404) 639-2825, dul7@cdc.gov Karlsson, Maria, (404) 639-0698, fwt4@cdc.gov
Supplemental Information Required	For isolate submission, document the State Health Department contact information on 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	Pure culture isolates
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) if isolate cannot be shipped within 24 hours.
Transport Medium	Transport room temperature (15-25°C) or refrigerated (2-8°C) specimens on suitable agar medium. Transport frozen (-25°C to -15°C) specimens in TSB 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	Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on 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/STAT 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.
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.
CDC Points of Contact	David Lonsway (404) 639-2825

Test Order
Staphylococcal Toxic Shock Syndrome Toxin – Identification (ID)
CDC-10426

dul7@cdc.gov
Maria Karlsson
(404) 639-0698
fwt4@cdc.gov

Test Order
Staphylococcus and Micrococcus – Identification (ID)
 CDC-10226

Synonym(s)	<i>Staph, Micrococcus, Kocuria</i> Identification
Pre-Approval Needed	None
Supplemental Information Required	For isolate submission, document the State Public Health Department contact information on 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	Pure culture isolates
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) if isolate cannot be shipped within 24 hours. For fastidious organisms store at room temperature (15–25°C).
Transport Medium	Transport room temperature (15–25°C) or refrigerated (2–8°C) specimens on suitable agar medium. Transport frozen (–25°C to –15°C) specimens in TSB 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	<p>Ship frozen specimens on dry ice, room temperature specimens at room temperature and refrigerated specimens on ice packs.</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/STAT 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.</p>
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.
CDC Points of Contact	David Lonsway (404) 639–2825 dul7@cdc.gov Maria Karlsson

Test Order
Staphylococcus and Micrococcus – Identification (ID)
CDC-10226

(404) 639-0698
fwt4@cdc.gov

Test Order

Staphylococcus aureus Detection – Foodborne Outbreak

CDC-10113

Synonym(s)	<i>S. aureus</i> , Staphylococcal enterotoxins, SEs
Pre-Approval Needed	Luquez, Carolina, (404) 639-0896, fry6@cdc.gov Gomez, Gerry, (404) 639-0537, goe4@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), emesis and stool specimens (collected within 48 hours of illness onset), and their derived isolates are accepted. 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 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 accepted. 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. Send raw stool or stool with Cary-Blair or Enteric Transport Medium. Send pure culture isolates derived from food, emesis or stool on slants or broths.
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. 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 refrigerated specimens (2–8°C) with gel ice packs and, if already frozen, send frozen specimens (< -20°C) 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/STAT 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

Test Order
Staphylococcus aureus Detection – Foodborne Outbreak
CDC-10113

federal regulations.

Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

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

Turnaround Time 12 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 Carolina Luquez
(404) 639-0896
fyr6@cdc.gov
Gerry Gomez
(404) 639-0537
goe4@cdc.gov

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
Pre-Approval Needed	Beall, Bernard, (404) 639-1237, BBEALL@cdc.gov McGee, Lesley, (404) 639-0455, LMCGEE@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 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. Isolates can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise isolate should be frozen at -70°C. For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	For pure culture isolates the transport media is the same as the storage media; For other specimen/sample types 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. All submitted specimens should include two unique identifiers. These 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>Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.</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/STAT Unit 21 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>

Test Order
***Streptococcus* (Beta Hemolytic Strep) Typing**
CDC-10216

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 Bernard Beall
(404) 639-1237
BBEALL@cdc.gov
Lesley McGee
(404) 639-0455
LMCGEE@cdc.gov

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*

Pre-Approval Needed Beall, Bernard, (404) 639–1237, BBEALL@cdc.gov
Shewmaker, Patricia, (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 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 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. Isolates can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise isolates should be frozen at –70°C. Fastidious bacteria should be stored at room temperature (15°C (59°F) and 25°C (77°F)) and shipped over night delivery within 24 hours or shipped frozen at –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.

Transport Medium For pure culture isolates the transport media is the same as the storage media. For other specimen types contact the CDC POC for appropriate guidance.

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 identifiers. Test 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/STAT Unit 21
1600 Clifton Road, NE

Test Order
***Streptococcus* (Catalase–Negative, Gram–Positive Coccus)**
Identification
CDC–10213

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 Bernard Beall
(404) 639–1237
BBEALL@cdc.gov
Patricia Shewmaker
(404) 639–4826
PSHEWMAKER@cdc.gov

Test Order
***Streptococcus* (Catalase–Negative, Gram–Positive Coccus)**
Identification and Antimicrobial Susceptibility Testing
CDC–10214

Synonym(s)	Streptococci, viridans streptococci , <i>Enterococcus</i> , <i>Abiotrophia</i> , <i>Aerococcus</i> , <i>Alloiococcus</i> , <i>Dolosicoccus</i> , <i>Dolosigranulum</i> , <i>Facklamia</i> , <i>Gemella</i> , <i>Globicatella</i> , <i>Granulicatella</i> , <i>Helcococcus</i> , <i>Ignavigranulum</i> , <i>Lactococcus</i> , <i>Leuconostoc</i> , <i>Pediococcus</i> , <i>Tetragenococcus</i> , <i>Globiticatella</i> , <i>Vagococcus</i> , and <i>Weissella</i> , AST, Sensitivity, MIC testing
Pre-Approval Needed	Beall, Bernard, (404) 639–1237, BBEALL@cdc.gov Shewmaker, Patricia, (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 bacterial isolates; For other specimen types contact the CDC POC for appropriate guidance.
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 4°C if shipped in less than 72 hours of collection; otherwise specimen should be frozen at –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 –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	For pure culture isolates the transport media is the same as the storage 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. All submitted specimens should include two unique identifiers. 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

Test Order
***Streptococcus* (Catalase–Negative, Gram–Positive Coccus)**
Identification and Antimicrobial Susceptibility Testing
CDC–10214

RDSB/STAT 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 identification.

CDC Points of Contact Bernard Beall
(404) 639–1237
BBEALL@cdc.gov
Patricia Shewmaker
(404) 639–4826
PSHEWMAKER@cdc.gov

Test Order
***Streptococcus* ABCs Surveillance Study**
CDC-10218

Synonym(s)	None
Pre-Approval Needed	McGee, Lesley, (404) 639-0455, LMCGEE@cdc.gov Beall, Bernard, (404) 639-1237, BBEALL@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 <i>Streptococcus</i> (GAS), Group B <i>Streptococcus</i> (GBS) and <i>S. pneumoniae</i> 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. All submitted specimens should include two unique identifiers. These 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/STAT 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 Bernard Beall

Test Order
Streptococcus ABCs Surveillance Study
CDC-10218

(404) 639-1237
BBEALL@cdc.gov

Test Order
***Streptococcus pneumoniae* Typing**
CDC-10215

Synonym(s)	Pneumococcus Serotyping
Pre-Approval Needed	Beall, Bernard, (404) 639-1237, BBEALL@cdc.gov McGee, Lesley, (404) 639-0455, LMCGEE@cdc.gov
Supplemental Information Required	Supplemental form required for pre-approval: <i>Streptococcus pneumoniae</i> Testing Request Form. If you have questions, contact the CDC POC.
Supplemental Form	<i>Streptococcus pneumoniae</i> 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 <i>Streptococcus pneumoniae</i> 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 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. Isolates on agar should be shipped in less than 24 hours of collection; otherwise isolate should be frozen at -70°C. For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	For pure culture isolates the transport media is the same as the storage media. For other specimen/sample types 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. All submitted specimens should include two unique identifiers. These 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>Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs.</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/STAT Unit 21 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>

Test Order
Streptococcus pneumoniae Typing
CDC-10215

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 Bernard Beall
(404) 639-1237
BBEALL@cdc.gov
Lesley McGee
(404) 639-0455
LMCGEE@cdc.gov

Test Order

Streptococcus Study

CDC-10217

Synonym(s) None

Pre-Approval Needed Beall, Bernard, (404) 639-1237, BBEALL@cdc.gov
McGee, Lesley, (404) 639-0455, LMCGEE@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 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. Isolates can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise isolates should be frozen at -70°C. For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.

Transport Medium For pure culture isolates the transport media is the same as the storage 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. All submitted specimens should include two unique identifiers. These 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/STAT 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.

Test Order
Streptococcus Study
CDC-10217

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 Bernard Beall
(404) 639-1237
BBEALL@cdc.gov
Lesley McGee
(404) 639-0455
LMCGEE@cdc.gov

Test Order
Strongyloidiasis Serology
CDC-10467

Synonym(s)	Strongyloidiasis, <i>Strongyloides stercoralis</i> , parasite
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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	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

Test Order
Strongyloidiasis Serology
CDC-10467

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order

Syphilis Serology

CDC-10173

Synonym(s)	Treponemal and non-treponemal	
Pre-Approval Needed	Fakile, Yetunde, (404) 639-3784, yfakile@cdc.gov Pettus, Kevin, (404) 639-4338, kbp9@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Serum (preferred), CSF, and/or plasma (possible to perform test but not preferred)	
Minimum Volume Required	1 mL (for serum or plasma)	
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and plasma can be stored at 4°C; if more than 4 days it should be frozen at -20°C. CSF should be stored frozen at -70°C.	
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 Specimen Handling Requirements	<p>Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.</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/STAT Unit 24 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	RPR, TPPA, TrepSURE, CSF-VDRL	
Turnaround Time	2 Weeks	
Interferences & Limitations	Avoid freeze-thaw cycles as this can affect test results.	
Additional Information	None	
CDC Points of Contact	Yetunde Fakile (404) 639-3784 yfakile@cdc.gov Kevin Pettus (404) 639-4338 kbp9@cdc.gov	Yongcheng Sun (404) 639-2905 Yas2@cdc.gov

Test Order
Tick Borne Encephalitis (TBE) Testing
CDC-10415

Synonym(s) None

Pre-Approval Needed Shoemaker, Trevor, (470) 312-0094, spather@cdc.gov
Klena, John, (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 testing, preferred specimen is whole blood (purple, yellow, or blue top tube) or fresh frozen tissue. Serum can also be used if only sample available. For serology testing, submit whole blood or serum. Other samples may be tested with approval from CDC. Contact the CDC POC for approval prior to sending any specimens.

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Tick Borne Encephalitis (TBE) Testing
CDC-10415

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

Test Order
Toxocariasis Serology
CDC-10468

Synonym(s)	Larva migrans, Toxocariasis, <i>Toxocara canis</i> , <i>Toxocara cati</i> , parasite
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	Serum, plasma, or vitreous fluid
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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	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

Test Order
Toxocariasis Serology
CDC-10468

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Toxoplasmosis Special Study
CDC-10492

Synonym(s) None

Pre-Approval Needed Rivera, Hilda, (404) 718-4100, igi2@cdc.gov
DPDx, , (404) 718-4120, dpdx@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From None

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. All submitted specimens should include two unique identifiers. 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/STAT 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 Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Treponema pallidum Molecular Detection Study
 CDC-10176

Synonym(s)	Syphilis
Pre-Approval Needed	Pillay, Allan, (404) 639-2140, apillay@cdc.gov Pettus, Kevin, (404) 639-4338, kbp9@cdc.gov
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: Document the "Specimen source (type): vaginal swab, cervical swab, penile swab, anal swab, rectal swab, skin swab, swab, body fluid, fixed tissue, unfixed tissue, nasal swab. Document the "Specimen source site": vagina, cervix, penis, rectum, anus, skin, mouth, eye, nose. Provide the following information: history of present illness, CSF and serology results, tissue staining results.
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) 0.2 mL cerebrospinal fluid (CSF) (1 mL preferred) 50 µl ocular fluid 0.5 mL amniotic fluid (1 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swabs, whole blood or cord blood in EDTA tube (purple top), body fluids, unfixed biopsy tissue, lymph node aspirate, and nasal discharge (congenital cases) should be stored at -80°C (preferable) or -20°C. Formalin-Fixed Paraffin-Embedded (FFPE) tissue should be stored at room temperature.
Transport Medium	Ulcer/skin lesion swabs should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium (e.g., Universal transport medium (UTM), viral transport medium (VTM), APTIMA Multitest Swab Specimen Collection Kit).
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. 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/STAT Unit 31 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
Treponema pallidum Molecular Detection Study
CDC-10176

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

Methodology PCR

Turnaround Time 2 Weeks

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 purposes. This test is not CLIA regulated or FDA-cleared and the results cannot be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov	Munegowda Koralur (404) 639-1057 mkoralur@cdc.gov
	Kevin Pettus (404) 639-4338 kbp9@cdc.gov	

Test Order
Treponema pallidum Molecular Typing Study
 CDC-10177

Synonym(s)	<i>Treponema pallidum</i> Genotyping, <i>Treponema pallidum</i> Strain Typing, Syphilis Typing
Pre-Approval Needed	Pillay, Allan, (404) 639-2140, apillay@cdc.gov Pettus, Kevin, (404) 639-4338, kbp9@cdc.gov
Supplemental Information Required	Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: Document the "Specimen source (type)": vaginal swab, cervical swab, penile swab, anal swab, rectal swab, skin swab, swab, body fluid, fixed tissue, unfixed tissue, nasal swab. Document the "Specimen source site": vagina, cervix, penis, rectum, anus, skin, mouth, eye, nose. Provide the following information: history of present illness, CSF and serology results, tissue staining results.
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) 0.2 mL cerebrospinal fluid (CSF) (1 mL preferred) 50 µl ocular fluid 0.5 mL amniotic fluid (1 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swabs, whole blood or cord blood in EDTA tube (purple top), body fluids, unfixed biopsy tissue, lymph node aspirate, and nasal discharge (congenital cases) should be stored at -80°C (preferable) or -20°C. Formalin-Fixed Paraffin-Embedded (FFPE) tissue should be stored at room temperature.
Transport Medium	Ulcer/skin lesion swabs should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium (e.g., Universal transport medium (UTM), viral transport medium (VTM), APTIMA Multitest Swab Specimen Collection Kit).
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. 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/STAT Unit 31 1600 Clifton Road, NE Atlanta, GA 30329 <Insert CDC Point of Contact's Telephone Number>

Test Order
Treponema pallidum Molecular Typing Study
CDC-10177

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

Methodology PCR, Sequencing, RFLP

Turnaround Time 4 Weeks

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 purposes. This test is not CLIA regulated or FDA-cleared and the results cannot be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov	Munegowda Koralur (404) 639-1057 mkoralur@cdc.gov
	Kevin Pettus (404) 639-4338 kbp9@cdc.gov	

Test Order
Trichinellosis Serology
CDC-10470

Synonym(s)	Trichinosis, <i>Trichinella spiralis</i> , parasite
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	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transferred to leak proof tubes. Serum or plasma specimens should be stored at 4–8°C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at –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	Ship specimen at room temperature or cold ice packs, not on 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/STAT 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	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

Test Order
Trichinellosis Serology
CDC-10470

igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
***Trichomonas* Susceptibility**
CDC-10239

Synonym(s)	<i>Trichomonas</i> , trich, parasite	
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	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	A live culture of <i>Trichomonas vaginalis</i> in InPouch TV device or Diamond's TYM.	
Minimum Volume Required	Not Applicable	
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens received past 48 hours of collection will be rejected. The specimen should be sent to CDC on the same day it is obtained from the patient. Do not freeze the specimen. Use vaginal swab to inoculate media.	
Transport Medium	InPouch TV (Commercial product) or Diamond's TYM. 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	<p>Ensure the InPouch is properly closed and place it in the mailing container that they arrived in.</p> <p>Ship to: <Insert CDC Point of Contact> Centers for Disease Control and Prevention RDSB/STAT 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	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	Pete Augustini (678) 860-6128 pfa9@cdc.gov

Test Order
Trichomonas Susceptibility
CDC-10239

was4@cdc.gov

Test Order
Trypanosoma cruzi Molecular Detection – Insects
 CDC-10493

Synonym(s)	Chagas, American Trypanosomiasis, trypanosome, parasite, triatomine, kissing bug, <i>T. cruzi</i>
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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Trypanosoma cruzi Molecular Detection – Insects
CDC-10493

(404) 718-4326
gok0@cdc.gov

Test Order
Varicella Zoster Virus (VZV) Avidity
CDC-10256

Synonym(s) Chicken pox, shingles

Pre-Approval Needed Schmid, Scott, (404) 639-0066, dss1@cdc.gov
Radford, Kay, (404) 639-2192, kjr7@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VZV Specimen Collection Form.
https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum or plasma

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. All submitted specimens should include two unique identifiers. 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/STAT 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Varicella Zoster Virus (VZV) Avidity
CDC-10256

Kay Radford
(404) 639-2192
kjr7@cdc.gov

Test Order
Varicella Zoster Virus (VZV) Genotyping (Clade Type)
CDC-10257

Synonym(s) Chicken pox, shingles

Pre-Approval Needed Schmid, Scott, (404) 639-0066, dss1@cdc.gov
Folster, Jennifer, (404) 639-3668, apz5@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form VZV Specimen Collection Form.
https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf

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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Varicella Zoster Virus (VZV) Genotyping (Clade Type)
CDC-10257

CDC Points of Contact Scott Schmid
(404) 639-0066
dss1@cdc.gov
Jennifer Folster
(404) 639-3668
apz5@cdc.gov

Test Order
Varicella Zoster Virus (VZV) Intrathecal Antibody Detection
CDC-10496

Synonym(s)	Chicken pox, shingles
Pre-Approval Needed	Schmid, Scott, (404) 639-0066, SSchmid@cdc.gov Folster, Jennifer, (404) 639-3668, JFolster@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	VZV Specimen Collection Form. https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Paired serum sample and cerebrospinal fluid (CSF) (both samples are required)
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. 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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Varicella Zoster Virus (VZV) Intrathecal Antibody Detection
CDC-10496

(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 Scott Schmid
(404) 639-0066
SSchmid@cdc.gov
Jennifer Folster
(404) 639-3668
JFolster@cdc.gov

Test Order
Varicella Zoster Virus (VZV) Serology
CDC-10255

Synonym(s)	Chicken pox, shingles
Pre-Approval Needed	None
Supplemental Information Required	See Supplemental Form
Supplemental Form	VZV Specimen Collection Form. https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf
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	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 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/STAT 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	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

Test Order
Varicella Zoster Virus Detection (Wild-type vs. Vaccine)
CDC-10254

Synonym(s) Chicken pox, shingles

Pre-Approval Needed None

Supplemental Information Required See Supplemental Form

Supplemental Form VZV Specimen Collection Form.
https://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf

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 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 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/STAT 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
Kay Radford
(404) 639-2192

Test Order
Varicella Zoster Virus Detection (Wild-type vs. Vaccine)
CDC-10254

kjr7@cdc.gov

Test Order

Vibrio cholerae Identification and Subtyping

CDC-10119

Synonym(s)	Cholera
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	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	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>Ship slants at ambient temperature or glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data.</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/STAT Unit 08 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 or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling, Antimicrobial Susceptibility Testing (AST)
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	None
CDC Points of Contact	Cheryl Tarr (404) 639-2011

Test Order
Vibrio cholerae Identification and Subtyping
CDC-10119

ctarr@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Test Order
***Vibrio cholerae* Serology**
CDC-10454

Synonym(s)	Enteric serology
Pre-Approval Needed	Aubert, Rachael, (404) 639-3816, vrl7@cdc.gov Fields, Patricia, (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. All submitted specimens should include two unique identifiers. 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/STAT 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.

Test Order
Vibrio cholerae Serology
CDC-10454

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
vr17@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Test Order
***Vibrio* Subtyping**
CDC-10122

Synonym(s) None

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. All submitted specimens should include two unique identifiers. 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/STAT 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

Test Order
Vibrio Subtyping
CDC-10122

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 Cheryl Tarr
(404) 639-2011
ctarr@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Test Order

Vibrio, Aeromonas, and Related Organisms Identification

CDC-10120

Synonym(s) *Vibrionaceae, Grimontia, Photobacterium*

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 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 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/STAT 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 10 Weeks

Interferences & Limitations *Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2–8°C) may lose viability.

Additional Information None

CDC Points of Contact Cheryl Tarr
(404) 639-2011

Test Order
Vibrio, Aeromonas, and Related Organisms Identification
CDC-10120

ctarr@cdc.gov
Monica Im
(404) 718-1446
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Test Order

Vibrio, *Aeromonas*, and Related Organisms Study

CDC-10121

Synonym(s)	<i>Vibrionaceae</i> , <i>Grimontia</i> , <i>Photobacterium</i>
Pre-Approval Needed	Tarr, Cheryl, (404) 639-2011, ctarr@cdc.gov Im, Monica, (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. All submitted specimens should include two unique identifiers. 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/STAT 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	<i>Vibrio vulnificus</i> isolates that are kept at refrigeration temperatures (2-8°C) may lose viability.
Additional Information	Refer to study protocol for specific requirements.

Test Order
Vibrio, Aeromonas, and Related Organisms Study
CDC-10121

CDC Points of Contact Cheryl Tarr
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Test Order
Waterborne Parasite Special Study
CDC-10527

Synonym(s) None

Pre-Approval Needed Roellig, Dawn, (404) 718-4134, iyd4@cdc.gov
Murphy, Jennifer, (404) 718-4155, iod7@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 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. All submitted specimens should include two unique identifiers. 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 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.

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/STAT 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

Test Order
Waterborne Parasite Special Study
CDC-10527

(404) 718-4155
iod7@cdc.gov

Test Order

Yersinia (non-*Y. pestis*) and Other *Enterobacterales* Subtyping CDC-10124

Synonym(s)	<i>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</i>
Pre-Approval Needed	Tarr, Cheryl, (404) 639-2011, ctarr@cdc.gov Im, Monica, (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	Isolates
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. All submitted specimens should include two unique identifiers. 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/STAT 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 <i>Yersinia</i> serotyping and biotyping

Test Order
Yersinia (non-*Y. pestis*) and Other *Enterobacterales* Subtyping
CDC-10124

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 Cheryl Tarr
(404) 639-2011
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Monica Im
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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*

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 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 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/STAT 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 10 Weeks

Interferences & Limitations Prolonged storage at temperatures warmer than –70°C can result in genetic mutations and could affect results of subtyping tests.

Test Order

Yersinia (non-*Y. pestis*) and Other *Enterobacterales* Identification CDC-10123

Additional Information None

CDC Points of Contact Cheryl Tarr
(404) 639-2011
ctarr@cdc.gov
Monica Im
(404) 718-1446
ixi9@cdc.gov

Test Order
***Yersinia pestis* Culture and Identification**
CDC-10418

Synonym(s)	Plague
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Human: lymph node aspirate, sputum, bronchial/tracheal wash, pleural fluid, blood, blood culture bottles, biopsy/autopsy tissues (sections of lymph node, lung, liver, spleen, bone marrow) Animal: necropsy tissues (lymph node, lung, liver, spleen, bone marrow) Environmental: fleas
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 containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at –70°C. Do not freeze non-tissue samples.
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 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), Bacteriophage Lysis
Turnaround Time	3 Weeks

Test Order
Yersinia pestis Culture and Identification
CDC-10418

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
Luke Kingry
(970) 266-3567
vtx8@cdc.gov

Test Order
***Yersinia pestis* Serology**
CDC-10419

Synonym(s)	Plague
Pre-Approval Needed	None
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
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	<p>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.</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 Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road 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	Passive Hemagglutination, Passive Hemagglutination Inhibition
Turnaround Time	2 Weeks
Interferences & Limitations	Hemolyzed samples may interfere with test results.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266–3524

Test Order
Yersinia pestis Serology
CDC-10419

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(970) 266-3567
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Test Order
***Yersinia pestis* Special Study**
CDC-10420

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266-3524, nzp0@cdc.gov Kingry, Luke, (970) 266-3567, vtx8@cdc.gov
Supplemental Information Required	Provide the following specimen information on the CDC 50.34 Specimen Submission Form: specimen origin; test order name; patient name or unique patient identifier; sex and age or date of birth of the patient; date of onset; specimen collection date; specimen source (type); submitting agency address, contact name, phone number and email address for each submitter.
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. All submitted specimens should include two unique identifiers. 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.</p> <p>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></p> <p>All samples must be shipped in accordance with all applicable local, state and federal regulations.</p>
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.

Test Order
Yersinia pestis Special Study
CDC-10420

CDC Points of Contact Jeannine Petersen
(970) 266-3524
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Luke Kingry
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