

2018

CDC

INFECTIOUS DISEASES LABORATORY TEST DIRECTORY

May 2018, Version 8.1



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 May 4, 2018. All information contained herein is subject to change.

For the most current test information, please view the 508 compliant version of 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

Storage & 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 patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package. 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. Please send the shipment tracking number on the day of shipment by e-mail to the CDC Point of Contacts (see below).

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 *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
Actinomyces Anaerobic ID
CDC-10483

Synonym(s) Anaerobe ID, Bacterial Identification, Anaerobe

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 Anaerobic bacteria from clinically relevant sources, pure culture isolate in suitable anaerobic transport medium (e.g., Chopped Meat Glucose Broth). Prior approval from laboratory required for other sample/specimen types.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Store anaerobically

Transport Medium Pure culture isolate in Chopped Meat Glucose broth, thioglycolate broth or frozen in TSB plus glycerol

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries, as an etiologic agent.

Frozen specimen should be shipped on dry ice
Specimen stored at room temperature should be shipped at room temperature

Methodology 16s Sequencing, MALDI-TOF, Phenotypic Testing

Turnaround Time 28 Days

Interferences & Limitations Specimens from respiratory, vaginal, and fecal sources are not acceptable

Additional Information None

CDC Points of Contact David Lonsway
(404) 639-2825
Dlonsway@cdc.gov
Kamile Rasheed
(404) 639-3247
jkr1@cdc.gov

Test Order
***Actinomyces*-Aerobic -ID**
CDC-10148

Synonym(s) *Nocardia, Streptomyces*

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately.

Transport Medium Suitable agar slant medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary culture based on specimen type, 16S sequence based identification, MALDI-TOF

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
***Actinomyces*-Aerobic -ID and AST**
CDC-10149

Synonym(s) Actinos

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology AST by broth microdilution, Primary Culture based on specimen type, 16S sequence based identification, MALDI-TOF

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
Adenovirus Molecular Detection and Typing
CDC-10170

Synonym(s) None

Pre-Approval Needed Schneider, Eileen, (404) 639-5345, ees2@cdc.gov
Kamili, Shifaq, (404) 639-2799, sgk5@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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Ship specimen Monday-Thursday, overnight to avoid weekend deliveries

Requirements Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

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 assays.

Additional Information None

CDC Points of Contact Xiaoyan Lu
(404) 639-2745
xa19@cdc.gov
Shifaq Kamili
(404) 639-2799
sgk5@cdc.gov

Test Order
Alkhurma Identification
CDC-10274

Synonym(s) AHFV

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen, warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Alkhurma Serology
CDC-10285

Synonym(s) AHFV

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@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

Storage & 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 patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday-Thursday, overnight. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package, and send the shipment tracking number on the day of shipment by e-mail to the CDC Point of Contacts (see below).

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.

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*

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

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 (MgSO₄.7H₂O) 0.004 g
Sodium phosphate, dibasic (Na₂HPO₄) 0.142g
Potassium phosphate, monobasic (KH₂P O₄) 0.136g
Calcium chloride (CaCl₂.2H₂O) 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

Storage & 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 patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package.

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

Methodology Indirect Immunofluorescence Antibody (IFA) assay

Turnaround Time 14 Days

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

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

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

If 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

Storage & 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 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

Anaerobic Bacteria Identification

CDC-10227

Synonym(s)	Anaerobe ID, Bacterial Identification, Anaerobe
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	Anaerobic bacteria from clinically relevant sources, pure culture isolate in suitable anaerobic transport medium (e.g., Chopped Meat Glucose Broth). Prior approval from laboratory required for other sample/specimen types.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Store anaerobically
Transport Medium	Pure culture isolate in Chopped Meat Glucose broth, thioglycolate broth or frozen in TSB plus glycerol
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday overnight to avoid weekend deliveries, as an etiologic agent. Frozen specimen should be shipped on dry ice Specimen stored at room temperature should be shipped at room temperature
Methodology	16S Sequencing, MALDI-TOF, Phenotypic Testing
Turnaround Time	28 Days
Interferences & Limitations	Specimen from respiratory, vaginal, and fecal sources are not acceptable
Additional Information	See separate test order for <i>C. difficile</i>
CDC Points of Contact	David Lonsway (404) 639-2825 Dlonsway@cdc.gov Kamile Rasheed (404) 639-3247 jkr1@cdc.gov

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

Synonym(s) Human granulocytic anaplasmosis

Pre-Approval Needed None

Supplemental Information Required Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples only, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA) or heparin treated tubes preferred; serum; fresh tissue biopsy; swab

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium For tissue, place in sterile specimen cup with gauze pad moistened with sterile saline

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology Real Time 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.

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@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 Prior approval is required if the following information is not provided:
 – Suspected Agent
 – Travel and exposure history (including animals, arthropods, etc.)
 – Date of illness onset (and time if available)
 – Specimen type (e.g., serum, whole blood, tissue, etc.)
 – Test requested
 – Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
 –acute (during active stage of illness)
 –convalescent (2–4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
 (404) 639-1075
 ckato@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 Kato, Cecilia, (404) 639-1075, ckato@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, Other

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@cdc.gov
Yan Zeng
(404) 639-5177
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 200 uL

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

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship specimen on wet ice (cold pack) as an etiologic agent.

Methodology Real Time PCR

Turnaround Time 14 Days

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 Susceptibility Testing – Bacterial

CDC-10223

Synonym(s) AST, Sensitivity, MIC testing

Pre-Approval Needed None

Supplemental Information Required Confirmation of unusual resistance is required before sending specimen for testing; please specify antibacterial agent of interest and provide previous results and testing method

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 suitable agar medium

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep refrigerated if isolate cannot be shipped immediately. For fastidious organisms (e.g. *Neisseria meningitidis*), store at room temperature.

Transport Medium Pure culture isolate on suitable agar medium or frozen in TSB plus glycerol

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday overnight to avoid weekend deliveries, as an etiologic agent.

Refrigerated specimen should be shipped on ice packs
Specimen stored at room temperature should be shipped at room temperature

Methodology Broth Microdilution, Disk Diffusion, Additional Phenotypic Testing, Molecular detection of resistance markers

Turnaround Time 18 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact David Lonsway
(404) 639-2825
Dlonsway@cdc.gov
Kamile Rasheed
(404) 639-3247
JRasheed@cdc.gov

Test Order
Arbovirus Isolation and Identification
CDC-10281

Synonym(s) Arbo-Isolation, Chikungunya, Zika Virus

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum, cerebrospinal fluid (CSF), and fresh frozen tissue specimen

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping Specimen should be kept at 4°C or colder

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Ship to:
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521

Methodology Isolation in cell culture

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Robert Lanciotti
(970) 221-6440
rsl2@cdc.gov

Test Order
Arbovirus Molecular Detection
CDC-10280

Synonym(s) Arbo-RT-PCR, Chikungunya, Zika Virus

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum, cerebrospinal fluid (CSF), and fresh frozen tissue specimen

Minimum Volume Required 0.25 mL

Storage & Preservation of Specimen Prior to Shipping Specimen should be kept at 4°C or colder

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Ship to:
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521

Methodology RT-Polymerase Chain Reaction (PCR)

Turnaround Time 1 Week

Interferences & Limitations Hemolysis can affect the test results

Additional Information None

CDC Points of Contact Robert Lanciotti
(970) 221-6440
rsl2@cdc.gov

Test Order
Arbovirus Neutralization Antibody
CDC-10283

Synonym(s) Arbo-PRNT

Pre-Approval Needed None

Supplemental Information Required onset date, collection date, travel history and IgM test result 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

Storage & Preservation of Specimen Prior to Shipping Specimen should be kept at 4°C or colder

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Ship to:
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521

Methodology Plaque reduction neutralization

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Robert Lanciotti
(970) 221-6440
rsl2@cdc.gov

Test Order
Arbovirus Serology
CDC-10282

Synonym(s) Arbo-Serology,

Pre-Approval Needed None

Supplemental Information Required onset date, collection date, travel dates & locations

Supplemental Form None

Performed on Specimens From Human

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

Minimum Volume Required 0.25 mL

Storage & Preservation of Specimen Prior to Shipping Specimen should be kept at 4°C or colder

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Ship to:
Centers for Disease Control and Prevention
Arbovirus Diagnostic and Reference Laboratory
3156 Rampart Rd
Fort Collins, CO 80521

Methodology ELISA, MIA

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Robert Lanciotti
(970) 221-6440
rsl2@cdc.gov

Test Order
Arbovirus Special Study
CDC-10284

Synonym(s) Zika Virus

Pre-Approval Needed Lanciotti, Robert, (970) 221-6440, rsl2@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

Storage & 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 Robert Lanciotti
(970) 221-6440
rsl2@cdc.gov

Test Order
Arenavirus (New World) – Serology
CDC-10484

Synonym(s) Junin virus, Machupo virus, Guanarito virus, Chapare virus, Sabia virus serology

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood, Serum

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient Name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations None

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

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

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

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

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

Synonym(s) Old World *Arenavirus*

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

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

Synonym(s) Babesiosis; *Babesia microti*; *Babesia duncani*, parasite

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Collect a 1–5 ml blood sample in Vacutainer® EDTA tubes prior to anti-parasitic therapy and ship at 4°C

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen on wet ice (cold pack) as an etiologic agent.

Methodology Conventional PCR, Real Time PCR

Turnaround Time 14 Days

Interferences & Limitations None

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) *Babesia microti*; *Babesia duncani*; *Babesia divergens*, babesiosis, parasite

Pre-Approval Needed None

Supplemental Information Required Exposure and travel history, include other 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Indirect Fluorescent Antibody assay, Antibody detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Hilda Rivera
(404) 718-4100
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 None

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing http://www.cdc.gov/anthrax/labs/recommended_specimen.html

Minimum Volume Required 100 uL – see Additional Information

Storage & Preservation of Specimen Prior to Shipping Info on specimens, storage and shipping can be found at:
http://www.cdc.gov/anthrax/labs/recommended_specimen.html

Transport Medium Dependent on specimen type submitted. Info on specimens, storage, and shipping can be found at:
http://www.cdc.gov/anthrax/labs/recommended_specimen.html

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Info on appropriate specimens and shipping can be found at:
http://www.cdc.gov/anthrax/labs/recommended_specimen.html
 Most samples can be sent 2-8 C. Fresh tissue should be sent frozen and fixed tissue can be sent at room temperature.

Methodology Culture, 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 1 week.

Minimal volume: limited testing can be done with 100 ul, however 0.5- 1 ml is optimal to increase number of tests which can be performed and increase assay sensitivity.

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 Select Agent Form 2 required for submission of all confirmed Select Agents.

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 *B. anthracis* isolates

Minimum Volume Required N/A

Storage & Preservation of Specimen Prior to Shipping Store isolates at room temperature

Transport Medium Appropriate microbiological media for *Bacillus*

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Room temperature

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>

Methodology Genotyping (i.e., MLVA and genome sequence), Broth Microdilution, Rapid Antimicrobial Susceptibility Test (AST)

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information Rapid AST turnaround is 12-24 h.
Genotyping and broth microdilution is ~1 week.
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

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

**Supplemental Information
Required** None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum (acute and convalescent required)

Minimum Volume Required 250 uL

Storage & Preservation of Specimen Prior to Shipping Separate serum from clot; sera should be frozen immediately following separation and stored frozen at -20°C or colder, and should be shipped frozen on dry ice to CDC, in appropriately labeled plastic screw cap vials. For more information on specimen processing and storage, see link in "Additional Information".

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice. See additional info at http://www.cdc.gov anthrax/labs/recommended_specimen.html .

Methodology Antibody detection by ELISA and TNA

Turnaround Time 2 Weeks

Interferences & Limitations Requires acute and convalescent serum for analysis

Additional Information Turnaround time ranges from 1–2 weeks. See additional info at 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

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

Storage & 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 Alex Hoffmaster
(404) 639-0852
amh9@cdc.gov

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

Synonym(s) None

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 EDLB contact before sending specimens. Provide preliminary results if available.

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Isolates, food, stool. Only specimens from foodborne outbreaks accepted. Consult with Carolina Luquez before sending specimens.

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

Storage & Preservation of Specimen Prior to Shipping Food and stool should be maintained at 4°C

Transport Medium Not Applicable

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Carolina Luquez (fry6@cdc.gov) and Gerry Gomez (goe4@cdc.gov) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology Toxin Detection in food, Culture, PCR

Turnaround Time 2 Months

Interferences & Limitations None

Additional Information Direct toxin detection requires food samples

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 None

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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Any medium can be submitted, but preferably agar slants

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday overnight to avoid weekend deliveries
Agar slants need to be shipped at room temperature

Methodology Multilocus sequence typing (MLST)

Turnaround Time 2 Weeks

Interferences & Limitations None

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

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

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

Synonym(s) *Bacillus* Identification

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary culture based on specimen type, 16S sequence based identification, MALDI-TOF

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
Bacterial ID from Clinical Specimen (16S rRNA PCR)
CDC-10146

Synonym(s) None

Pre-Approval Needed McQuiston, John, (404) 639-0270, zje8@cdc.gov
Whitney, Anne, (404) 639-1374, amw0@cdc.gov

Supplemental Information Required Please notify laboratory prior to 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

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

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

Synonym(s) Bacterial Identification

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

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

Synonym(s) Free-living ameba, 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.

Minimum Volume Required 0.2 g tissue: 1 mL fluids

Storage & 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 patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package. 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. Please send the shipment tracking number on the day of shipment by e-mail to the CDC Point of Contacts (see below).

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 *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
***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 In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 500 uL

Storage & Preservation of Specimen Prior to Shipping Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longer period, serum samples may be frozen.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
 Bacterial Diseases Branch
 Attn: John Young
 3156 Rampart Road
 Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on ice packs

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 Clinical information including symptoms and date of onset must be included; specimens without this accompanying information will not be tested.

CDC Points of Contact Jeannine Peterson
 (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 Schriefer, Marty, (970) 221-6479, mms7@cdc.gov
Peterson, Jeannine, (970) 266-3524, nzp0@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

Storage & 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 Molecular detection, Serology, Culture, Immunohistochemistry (IHC), Other
Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Marty Schriefer
(970) 221-6479
mms7@cdc.gov
Jeannine Peterson
(970) 266-3524
nzp0@cdc.gov

Test Order
Baylisascariasis Serology
CDC-10457

Synonym(s) Baylisascariasis, Raccoon roundworm, parasite

Pre-Approval Needed None

Supplemental Information Required Exposure and travel history, include 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Immunoblot, Western Blot, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@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

Storage & 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 is subject to CLIA regulations and requires two patient identifiers 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>

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

Test Order
Biothreat Study
CDC-10432

Synonym(s) None

Pre-Approval Needed Thomas, Jennifer, (404) 639-4259, fsu8@cdc.gov
Andersen, Lauren, (404) 639-4442, wrh5@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 Human, Animal, and Food/Environmental/Medical Devices/Biologics

Acceptable Sample/ Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Storage & 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
Lauren Andersen
(404) 639-4442
wrh5@cdc.gov

Test Order
Blood Disorders Coagulation Study
CDC-10271

Synonym(s) Coag

Pre-Approval Needed Driggers, Jennifer, (404) 639-1269, jgq2@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

Storage & 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 Driggers
(404) 639-1269
jgq2@cdc.gov

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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum from patients with two or more weeks of cough. Centrifuge the tube of blood at 1100-1300 x g for approximately 10 minutes to separate the cells from the serum.

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping 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 lower). For long-term storage, the serum should be frozen (-20°C or colder).

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Serum specimens may be shipped refrigerated (2°-8°C) for up to 7 days. For shipments that are in transit for more than 7 days, specimens should be kept frozen (-20°C or lower). Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contact the laboratory by email or phone before shipping.

Methodology Enzyme-linked Immunosorbent Assay (ELISA)

Turnaround Time 2 Weeks

Interferences & Limitations Serum collected from patients with less than 2 weeks of cough are not appropriate for this test. Samples should not be used if they have incurred more than 5 freeze-thaw cycles. Specimens with unacceptable preservatives such as anti-coagulants would invalidate the results.

In addition, hemolyzed and lipemic specimens are considered suboptimal serum specimens for this assay.

Additional Information Please include patient age and duration of cough on specimen submission form

CDC Points of Contact Lucia Pawloski
(404) 639-4506
ecz6@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Test Order
Bordetella species ID/Confirmation of Isolates
 CDC-10164

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

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolates on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (*B. parapertussis*, *B. holmesii*, or *B. bronchiseptica* only) or cryopreserved isolates

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Isolates can be frozen in cryopreservation medium or refrigerated on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (*B. parapertussis*, *B. holmesii*, or *B. bronchiseptica* only)

Transport Medium Isolates can be frozen in cryopreservation medium or for best results a fresh subculture on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (*B. parapertussis*, *B. holmesii*, or *B. bronchiseptica* only) should be sent refrigerated. Calcium alginate and cotton swabs are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Isolates should be shipped refrigerated (2°-8°C) as soon as possible, between 24-48 hours. Frozen isolates should be sent on dry ice. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.

Methodology Culture, Identification

Turnaround Time 2 Weeks

Interferences & Limitations Prior antibiotic treatment will adversely affect results and patients coughing more than two weeks will likely not be culture positive.

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* species Isolation and ID**
CDC-10163

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

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Nasopharyngeal (NP) swabs and aspirates; calcium alginate and cotton swabs are not acceptable

Minimum Volume Required 0.5 mL aspirate

Storage & Preservation of Specimen Prior to Shipping Nasopharyngeal (NP) swabs should be collected on Dacron (polyester), rayon or nylon. Specimens should be kept refrigerated. Use plastic/glass screw-cap, leak-proof vials.

Transport Medium Regan-Lowe transport medium is recommended for specimens. Amies Charcoal transports are acceptable, but may decrease the probability of isolation.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Swabs in transport or isolates should be shipped refrigerated (2°–8°C) as soon as possible, between 24–48 hours. Aspirates can be shipped with ice packs or frozen (–20°C or lower). Frozen isolates should be sent on dry ice. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.

Methodology Culture

Turnaround Time 2 Weeks

Interferences & Limitations Prior antibiotic treatment will adversely affect results. Patients coughing more than two weeks will likely not be culture positive.

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* species Molecular Detection**
CDC-10165

Synonym(s)	None
Pre-Approval Needed	Cassiday, Pam, (404) 639-1231, pxc1@cdc.gov Tondella, Maria, (404) 639-1239, mlt5@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Prefer nasopharyngeal aspirate but will also accept nasopharyngeal swab. Calcium alginate and cotton swabs are not acceptable.
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens should be kept refrigerated or frozen. Use plastic/glass screw-cap, leak-proof vials
Transport Medium	Dry swabs in sterile tubes are preferred; if only one swab is collected for both culture and PCR, the swabs should be sent in Regan-Lowe transport.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Note: surveillance studies may label specimens according to protocol.
Shipping Instructions which Include Specimen Handling Requirements	Swabs should be shipped refrigerated (2°-8°C) as soon as possible, between 24-48 hours. Aspirates can be shipped with ice packs or frozen (-20°C or lower). Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Polymerase Chain Reaction (PCR), Real Time Polymerase Chain Reaction (PCR), Multi target Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	Prior antibiotic treatment will adversely affect results. Specimens collected from patients with more than 4 weeks of cough are not appropriate for this test. Samples should not be used if they have incurred more than 2 freeze-thaw cycles. Clinical specimens collected subsequent to initiation of antimicrobial treatment may not be positive for <i>Bordetella</i> spp. Due to reduction of organisms. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Bordetella</i> 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
Bordetella species Study
CDC-10167

Synonym(s) None

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

Storage & 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 Pam Cassidy
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Test Order
Bordetella spp. ID (Not *B. pertussis*/*B. parapertussis*)
CDC-10143

Synonym(s) *Bordetella* Identification

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

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

Synonym(s) Lyme Disease, Borreliosis

Pre-Approval Needed None

Supplemental Information Required In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longer period, serum samples may be frozen.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
Bacterial Diseases Branch
Attn: John Young
3156 Rampart Road
Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

Methodology ELISA, Western Blot

Turnaround Time 3 Weeks

Interferences & Limitations Hemolyzed samples may interfere with test results

Additional Information If available, please include date of onset, antibiotic treatment (type of antibiotics and date administered), date when the sample was collected, signs and symptoms.

CDC Points of Contact Jeannine Peterson
(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 In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Blood, skin biopsy (Erythema Migrans Rash) and others upon consultation (i.e. cultures, blood smears for confirmation, spinal fluid, synovial fluid)

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping For a skin biopsy, contact laboratory prior to collection and/or shipment for specific requirements. Blood may be collected in heparin, citrate or EDTA. All specimen should be collected and shipped prior to antibiotic treatment if possible.

Transport Medium Contact laboratory prior to shipping for instructions on skin biopsy's transport medium.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
Bacterial Diseases Branch
Attn: John Young
3156 Rampart Road
Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

Methodology Culture, Microscopy Confirmation

Turnaround Time 8 Weeks

Interferences & Limitations Antibiotic treatment will minimize growth potential of culture

Additional Information Provide any antibiotic treatment information

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, *Borrelia*

Pre-Approval Needed None

Supplemental Information Required In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
Bacterial Diseases Branch
Attn: John Young
3156 Rampart Road
Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

Methodology IgM/IgG ELISA

Turnaround Time 3 Weeks

Interferences & Limitations Hemolyzed specimen can affect the results

Additional Information If available, please include date of onset, antibiotic treatment (type of antibiotics and date administered), date when the sample was collected, signs and symptoms.

CDC Points of Contact Jeannine Petersen
(970) 266-3524
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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Storage & 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 Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Elizabeth Dietrich
(970) 494-6618
wul2@cdc.gov

Test Order

Botulinum Toxin Producing Clostridia Subtyping

CDC-10134

Synonym(s) Bot, Botulism

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

Supplemental Information Required APHIS/CDC Form 2 Request to Transfer Select Agents and Toxins is required

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

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Chopped Meat Glucose Starch (CMGS) or Trypticase Peptone Glucose Yeast extract (TPGY) media.

Specimen Labeling Not Applicable

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Package must have proper labeling for infectious substance: UN 2814 Infectious substance, Category A

Methodology WGS

Turnaround Time 12 Weeks

Interferences & Limitations None

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. APHIS/CDC Form 2 must be approved prior to shipping. Form 2 may be found at: <http://www.selectagents.gov/forms.html> ; Please send to POC: anticipated arrival date, courier, and tracking number.

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

Test Order
Botulism Laboratory Confirmation
CDC-10132

Synonym(s) Bot, Botulism

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 Foodborne: serum, stool, vomitus, gastric contents, food
Wound: serum, debrided tissue, swab from wounds, stool (only if foodborne is also suspected)
Infant: stool, rectal swabs, potential sources

Minimum Volume Required See Additional Information

Storage & Preservation of Specimen Prior to Shipping Maintain specimen at 4°C

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Packages may arrive on weekends
Ship with on cold packs. Package must have proper labeling for biological hazards: UN 3373 biological substance, Category B.

Methodology Mouse Bioassay, ELISA, Mass Spectrometry (MS), Polymerase Chain Reaction (PCR)

Turnaround Time 12 Weeks

Interferences & Limitations None

Additional Information Serum samples must be collected before antitoxin treatment.

Adult patients: 5 to 15 ml of serum (without anticoagulant); 10 to 20 g of feces (if an enema is needed, use sterile non-bacteriostatic water). Infant patients: ideally, 10g to 20g of feces should be collected; however, smaller quantities can provide confirmatory test results (if an 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 suspected foods can also be recovered and submitted for testing.

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) None

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

Storage & 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 Carolina Luquez
(404) 639-0896
fry6@cdc.gov
Janet Dykes
(404) 639-3625
jkd1@cdc.gov

Test Order
Brucella species Identification, Genotyping, and AST
 CDC-10207

Synonym(s)	Brucellosis
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/serum, tissue, joint fluid, environmental/nonclinical samples and culture isolates
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Agar slants preferred for shipping isolates
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and 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 Select agents must be shipped Monday through Wednesday to prevent weekend arrivals Agar slants should be shipped at room temperature and specimens at 4°C.
Methodology	Polymerase Chain Reaction (PCR), Biochemicals, Phage Susceptibility, Broth Micro Dilution, MLVA
Turnaround Time	2 Weeks
Interferences & Limitations	None
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 1 week and susceptibility testing is completed within 2 weeks, while isolation from specimens and subsequent ID may take up to 3 weeks. For additional information please refer to the ASM sentinel laboratory guide: http://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf
CDC Points of Contact	Rebekah Tiller (404) 639-4507 eto3@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 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/serum, tissue, joint fluid, environmental/nonclinical samples. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin).

Minimum Volume Required 250 uL

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Blood specimens should be transported in EDTA or Sodium Citrate tubes at 4°C

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and 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 can be found at: <http://www.selectagents.gov/forms.html>
Select agents must be shipped Monday through Wednesday to prevent weekend arrivals. Specimens should be shipped at 4°C.

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://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf>

CDC Points of Contact Rebekah Tiller
(404) 639-4507
eto3@cdc.gov
Alex Hoffmaster
(404) 639-0852
amh9@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 Serum (acute and convalescent preferred)

Minimum Volume Required 100 uL

Storage & Preservation of Specimen Prior to Shipping Serum needs to be stored at 4°C

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Ship serum at 4°C

Methodology *Brucella* microagglutination test (BMAT)

Turnaround Time 2 Weeks

Interferences & Limitations Acute and convalescent sera are preferred
No serology available for *B. Canis* or *RB51*
May have poor sensitivity for chronic or complicated brucellosis

Additional Information Acute and convalescent sera are preferred

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

Storage & 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 Robyn Stoddard
(404) 639-2053
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 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 Isolates, clinical specimens (blood, bone marrow, sputum or bronchoscopically obtained specimens, abscess material or wound swabs, and urine)

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Agar slants preferred for isolates

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and 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 can be found at <http://www.selectagents.gov/forms.html>
 Select agents must be shipped Monday through Wednesday to prevent weekend arrivals. Specimens should be shipped at 4°C.

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 None

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.
 For additional information please refer to the ASM sentinel laboratory guide: <http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf>

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 uL

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Dependent on specimen type

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and 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 can be found at <http://www.selectagents.gov/forms.html>
 Select agents must be shipped Monday through Wednesday to prevent weekend arrivals. Specimens should be shipped at 4°C. Select agents must be shipped Monday through Wednesday to prevent weekend arrivals. Agar slants should be shipped at room temperature and specimens at 4°C.

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
 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 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

Storage & 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 Mindy Elrod
(404) 639-4055
wzg0@cdc.gov
Jay Gee
(404) 639-4936
xzg4@cdc.gov

Test Order
Burkholderia pseudomallei Serology
CDC-10198

Synonym(s) Melioidosis

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 (acute and convalescent required)

Minimum Volume Required 100 uL

Storage & Preservation of Specimen Prior to Shipping Store serum at 4°C before shipping

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Serum should be shipped at 4°C

Methodology IHA–indirect haemagglutination

Turnaround Time 2 Weeks

Interferences & Limitations Acute and convalescent are required.

Additional Information Turnaround time may be shorter depending on risk and need

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

Test Order
Burkholderia spp. ID (Not *B. mallei*/*B. pseudomallei*)
CDC-10144

Synonym(s) *Burkholderia* Identification

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Campylobacter and Helicobacter Study
CDC-10125

Synonym(s) *Campy, H. pylori*

Pre-Approval Needed Pruckler, Janet, (404) 639-4770, jmp5@cdc.gov
Aubert, Rachael, (404) 639-3816, vrl7@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

Storage & 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 Janet Pruckler
(404) 639-4770
jmp5@cdc.gov
Rachael Aubert
(404) 639-3816
vrl7@cdc.gov

Test Order
Campylobacter species serology
CDC-10455

Synonym(s) Enteric Pathogen

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

Supplemental Information Required Date of illness onset, date of serum collection, clinical diagnosis (i.e. Guillain Barré).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Paired serum is preferred. Serum is always preferred but plasma is acceptable. Do not pool specimens.

Minimum Volume Required 100 uL (More Preferred)

Storage & Preservation of Specimen Prior to Shipping Maintain serum at 4°C (preferred); frozen specimens acceptable

Transport Medium Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Rachael Aubert (vrl7@cdc.gov, (404) 639-3816) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology EIA

Turnaround Time 3 Months

Interferences & Limitations None

Additional Information Paired serum specimens always preferred.

Please send one tube per specimen submission form. Submit multiple forms if needed.

CDC Points of Contact Rachael Aubert
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

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

Synonym(s) *Campy, H. pylori*

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens; Please call for approval prior to sending other specimen types. Provide any preliminary results 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship overnight growth on nonselective blood-based slant/stab (preferably not TSA); screw cap tubes preferred

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers for all submissions, on the specimen container, and test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries.
 Ship with cold packs in compliance with federal and local guidelines.

There are no time constraints for submitting sequence data

Methodology Phenotypic Identification, Genetic Identification

Turnaround Time 8 Weeks

Interferences & Limitations None

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 Janet Pruckler
 (404) 639-4770
 jmp5@cdc.gov
 Rachael Aubert
 (404) 639-3816
 vrl7@cdc.gov

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

Synonym(s) *Campy, H. pylori*

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens; Please call for approval prior to sending other specimen types. Provide any preliminary results 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship overnight growth on nonselective blood-based slant/stab (preferably not TSA); screw cap tubes preferred

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries. Ship with cold packs in compliance with federal and local guidelines.

There are no time constraints for submitting sequence data

Methodology PFGE, AST, WGS, Penner serotyping

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation requested if available.

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

CDC Points of Contact Janet Pruckler
(404) 639-4770
jmp5@cdc.gov
Rachael Aubert
(404) 639-3816
vrl7@cdc.gov

Test Order
Chagas Disease Molecular Detection
CDC-10475

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

Pre-Approval Needed Gray, Elizabeth, (404) 718-4725, djn8@cdc.gov
Benedict, Theresa, (404) 718-4124, tg5@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Blood, Heart Biopsy Tissue, and CSF

Minimum Volume Required 2.2 ml (pediatric 0.2 ml)

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen on wet ice (cold pack) as an etiologic agent.

Methodology Real-time PCR

Turnaround Time 14 Days

Interferences & Limitations None

Additional Information This assay is used in clinically indicated situations such as acute or congenital infections, post-transplant from a donor with confirmed *T. cruzi* 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
Theresa Benedict
(404) 718-4124
tg5@cdc.gov

Test Order
Chagas Disease Serology
CDC-10458

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

Pre-Approval Needed None

Supplemental Information Required 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Indirect Fluorescent Antibody Assay, EIA, ELISA, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

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

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

Synonym(s) *Chlamydia pneumoniae*, Atypical pneumonia, CAP, Chlamydia

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, and any lower respiratory tract specimen including bronchoalveolar lavage (BAL) and sputum; tissue, cerebral spinal fluid, isolates and purified nucleic acid; Others upon consultation with laboratory.

Minimum Volume Required Contingent upon specimen type. Please call for consultation

Storage & Preservation of Specimen Prior to Shipping Specimens can be kept refrigerated if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen. Store swabs in universal transport medium.

Transport Medium Universal transport medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries
 Refrigerated specimen should be sent on ice packs
 Frozen specimen should be sent on dry ice

Methodology Real-Time PCR

Turnaround Time 7 Days

Interferences & Limitations Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.

Additional Information All specimens are tested as a part of a multiplex qPCR detecting *M. pneumoniae*, *C. pneumoniae*, and *Legionella* species. See also CDC-10157

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

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

Synonym(s)	Atypical pneumonia, CAP, Chlamydia, <i>Chlamydia pneumoniae</i> , <i>Chlamydia psittaci</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
Acceptable Sample/ Specimen Type for Testing	Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, and any lower respiratory tract specimen including bronchoalveolar lavage (BAL) and sputum; tissue, cerebral spinal fluid , isolates and purified nucleic acid; Others upon consultation with laboratory.
Minimum Volume Required	Contingent upon specimen type. Please call for consultation
Storage & Preservation of Specimen Prior to Shipping	Tissues should be kept frozen. All other specimens can be kept refrigerated if shipped less than 72 hrs of collection; otherwise specimens should be kept frozen. Store swabs in universal transport medium.
Transport Medium	Universal transport medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries Refrigerated specimen should be sent on ice packs Frozen specimen should be sent on dry ice
Methodology	Real Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Do not send fixed tissues. Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	If specimen is not of human origin please contact Dr. Branson Ritchie at the University of Georgia
CDC Points of Contact	Jonas Winchell (404) 639-4921 jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

Test Order
Chlamydia species Study
CDC-10158

Synonym(s) None

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 To be determined

Minimum Volume Required To be determined

Storage & 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 This test only refers to studies involving respiratory *Chlamydia* species specifically *Chlamydia pneumoniae* and *Chlamydia psittaci*.

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

Test Order
Chlamydia trachomatis, Genital – Molecular Detection
CDC-10192

Synonym(s) *Chlamydia trachomatis* (CT) NAATS, *Chlamydia*

Pre-Approval Needed None

Supplemental Information Required 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 Oral pharynx swabs, cervical swabs, vaginal swabs, and rectal swabs collected on any commercially available product, and urine

Minimum Volume Required 5 mL (urine)

Storage & Preservation of Specimen Prior to Shipping Adhere to product insert instructions for swabs

Transport Medium Adhere to product insert instructions for swabs

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice if previously frozen, as an etiologic agent.

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 John Papp
(404) 639-3785
jwp6@cdc.gov
Christi Phillips
(404) 639-2147
div2@cdc.gov

Test Order
Chlamydia trachomatis, Genital – Study
CDC-10193

Synonym(s) None

Pre-Approval Needed Papp, John, (404) 639-3785, jwp6@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

Storage & 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 John Papp
(404) 639-3785
jwp6@cdc.gov
Christi Phillips
(404) 639-2147
div2@cdc.gov

Test Order
Clinical Microbiology Reference Study
CDC-10231

Synonym(s) None

Pre-Approval Needed Rasheed, Kamile, (404) 639-3247, JRasheed@cdc.gov
Limbago, Brandi, (404) 639-2162, Blimbago@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

Storage & 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 Kamile Rasheed
(404) 639-3247
JRasheed@cdc.gov
Brandi Limbago
(404) 639-2162
Blimbago@cdc.gov

Test Order
Clostridium difficile Identification
 CDC-10228

Synonym(s) *C. Difficile* ID, *C. diff*

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Pure culture isolates in suitable anaerobic transport medium (e.g., Chopped Meat Glucose Broth)

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Store anaerobically

Transport Medium Pure culture isolate in Chopped Meat Glucose Broth, thioglycolate broth or frozen in TSB plus glycerol

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries, as an etiologic agent.

Frozen specimen should be shipped on dry ice
 Specimen stored at room temperature should be shipped at room temperature

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information This test does not include strain typing or characterization

CDC Points of Contact David Lonsway
 (404) 639-2825
 Dlonsway@cdc.gov
 Kamile Rasheed
 (404) 639-3247
 jkr1@cdc.gov

Test Order
***Clostridium difficile* Outbreak Strain Typing**
CDC-10229

Synonym(s) *C. Difficile* Toxin, *C. difficile* Characterization

Pre-Approval Needed Rasheed, Kamile, (404) 639-3247, JRasheed@cdc.gov
 Karlsson, Maria, (404) 639-0698, fwt4@cdc.gov

Supplemental Information Required Prior approval and Epidemiologic consultation required.

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Pure culture isolate. Additional specimen types accepted upon consultation with laboratory

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Store anaerobically

Transport Medium Pure culture isolate in Chopped Meat Glucose Broth, thioglycolate broth or frozen in TSB plus glycerol

Specimen Labeling Include date of isolation and unique specimen identifier

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries, as an etiologic agent.

Frozen specimen should be shipped on dry ice
 Specimen stored at room temperature should be shipped at room temperature

Methodology Molecular Strain Typing, Phenotypic Testing

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information Not CLIA compliant testing; for epidemiologic purposes only

CDC Points of Contact Kamile Rasheed
 (404) 639-3247
 JRasheed@cdc.gov
 Maria Karlsson
 (404) 639-0698
 fwt4@cdc.gov

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

Synonym(s) *C. perfringens*

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 EDLB contact before sending specimens. Provide any preliminary results available.

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Isolates, stool and food. Only specimens from foodborne outbreaks accepted. Consult with Carolina Luquez and Gerry Gomez before sending specimens.

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

Storage & Preservation of Specimen Prior to Shipping Maintain stool and food at 4°C

Transport Medium Not Applicable

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Carolina Luquez (fry6@cdc.gov) and Gerry Gomez (goe4@cdc.gov) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology Toxin Detection in Stool, Culture, PCR

Turnaround Time 2 Months

Interferences & Limitations None

Additional Information Direct toxin detection requires stool specimens

CDC Points of Contact Carolina Luquez
(404) 639-0896
fry6@cdc.gov
Gerry Gomez
(404) 639-0537
goe4@cdc.gov

Test Order

Colonization Screening for Antimicrobial Resistant Bacteria

CDC-10521

Synonym(s)	Surveillance Screening for Antimicrobial Resistant Bacteria	
Pre-Approval Needed	Malik, Sarah, (404) 718-3393, vgg9@cdc.gov Lonsway, David, (404) 639-2825, dul7@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Rectal swab (double-swab)	
Minimum Volume Required	N/A (Visible fecal material on swab, but do not overinoculate)	
Storage & Preservation of Specimen Prior to Shipping	Swabs in the transport tube can be stored at 15-28 °C for up to five days.	
Transport Medium	Copan double-swab, Cepheid catalog #900-0370	
Specimen Labeling	Test requires two patient identifiers on the specimen container and the test requisition.	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday Wednesday with cold packs for next day delivery	
Methodology	Molecular and/or Culture-based Methods (e.g., Cepheid Xpert Carba-R routinely used for PCR-based detection of blaKPC, blaNDM, blaVIM, blaOXA-48-like, and blaIMP-1 group genes), 2nd swab can be cultured for possible typing of isolate	
Turnaround Time	5 Days	
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 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	If strain typing (e.g., PFGE or other molecular method) will be needed for an outbreak investigation, then this testing request needs to be approved at the beginning of the investigation by staff at haioutbreak@cdc.gov so that the paired rectal swab of a positive Cepheid test can be cultured without delay. Culture-based methods for surveillance screening may take up to 21 days for TAT.	
CDC Points of Contact	Sarah Malik (404) 718-3393 vgg9@cdc.gov David Lonsway (404) 639-2825 dlonsway@cdc.gov	Kamile Rasheed (404)639-3247 jkr1@cdc.gov

Test Order
Congo–Crimean Hemorrhagic Fever Identification
CDC–10302

Synonym(s) CCHF

Pre-Approval Needed Klena, John, (470) 312–0094, spather@cdc.gov
Rollin, Pierre, (470) 312–0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to –70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312–0094
spather@cdc.gov
Pierre Rollin
(470) 312–0094
spather@cdc.gov

Test Order
Congo–Crimean Hemorrhagic Fever Serology
CDC–10303

Synonym(s) CCHF

Pre-Approval Needed Klena, John, (470) 312–0094, spather@cdc.gov
Rollin, Pierre, (470) 312–0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312–0094
spather@cdc.gov
Pierre Rollin
(470) 312–0094
spather@cdc.gov

Test Order
Corynebacterium diphtheriae Study
CDC-10172

Synonym(s) None

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

Storage & 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 Pam Cassidy
(404) 639-1231
pxc1@cdc.gov
Maria Tondella
(404) 639-1239
mlt5@cdc.gov

Test Order

Corynebacterium diphtheriae Toxin – Molecular Detection

CDC-10171

Synonym(s)	Diphtheria, Real Time PCR
Pre-Approval Needed	Cassiday, Pam, (404) 639-1231, pxc1@cdc.gov Tondella, Maria, (404) 639-1239, mlt5@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Pure culture isolates on a suitable agar slant, extracted DNA, or pseudomembrane
Minimum Volume Required	100 uL (DNA)
Storage & Preservation of Specimen Prior to Shipping	Specimens should be kept refrigerated or frozen. Use plastic/glass screw-cap, leak-proof vials. Pseudo-membrane should be sent in leak-proof container with saline, not formalin.
Transport Medium	Common transport media such as Amies or Stuart may be used for swabs. Isolates should be sent on blood agar slants or TSA. Pseudo-membrane should be sent in leak-proof container with saline not formalin.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Note: surveillance studies may label specimens according to protocol
Shipping Instructions which Include Specimen Handling Requirements	Once specimens are collected they should be shipped to the laboratory as soon as possible, between 24-48 hours. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Real Time Polymerase Chain Reaction (RT-PCR)
Turnaround Time	1 Week
Interferences & Limitations	Prior antibiotic treatment will adversely affect results. Suboptimal volumes of specimens may adversely affect the sensitivity of tests performed therefore it is very important to obtain an acceptable volume and a quality specimen. Clinical specimens collected subsequent to initiation of antimicrobial treatment may not be positive for <i>Corynebacterium</i> species due to reduction of organisms. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Corynebacterium</i> species.
Additional Information	Diphtheria Antitoxin (DAT) testing should be performed on the patient prior to requesting molecular testing from CDC. <i>Corynebacterium</i> PCR testing is not currently used for diagnostic purposes for diphtheria and is not considered a confirmatory test.
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 ID
 and Toxigenicity
 CDC-10169

Synonym(s) Diphtheria

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Fresh subculture (24-48 hours old) of a pure culture isolate on a suitable agar slant

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Use plastic/glass screw-cap, leak-proof vials. Isolates can be refrigerated on an agar slant or common culture medium or frozen in TSB with glycerol or other liquid medium.

Transport Medium Common transport medium such as blood agar, TSA, nutrient agar, slants/plates, or frozen

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Once specimens are collected they should be shipped to the laboratory as soon as possible, between 24-48 hours. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.

Methodology Culture, API Coryne, Elek, Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Isolates passed within 24-48 hours are preferred

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
Isolation, ID, Toxigenicity
CDC-10168

Synonym(s)	Diphtheria
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Throat, nasal and wound swabs, pseudo-membrane, and sputum
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Use plastic/glass screw-cap, leak-proof vials. Store refrigerated.
Transport Medium	Common transport media such as Amies or Stuart may be used for swabs. Pseudo-membrane should be sent in leak-proof container with saline not formalin.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Note: surveillance studies may label specimens according to protocol
Shipping Instructions which Include Specimen Handling Requirements	Once specimens are collected they should be shipped to the laboratory as soon as possible, between 24-48 hours. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Culture, Polymerase Chain Reaction (PCR), API Coryne, Elek
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment will adversely affect results. Suboptimal volumes of specimens may adversely affect the sensitivity of tests performed therefore it is very important to obtain an acceptable volume and a quality specimen. Clinical specimens collected subsequent to initiation of antimicrobial treatment may not be positive for <i>Corynebacterium</i> species due to reduction of organisms. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Corynebacterium</i> species.
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 (Not *C. diphtheriae*) ID
CDC-10136

Synonym(s) Diphtheria

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Coxiella burnetii Molecular Detection
 CDC-10304

Synonym(s) Q fever

Pre-Approval Needed None

Supplemental Information Required Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples only, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA) or heparin treated tubes preferred; serum; fresh tissue biopsy; swab

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium For tissue, place in sterile specimen cup with gauze pad moistened with sterile saline

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

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.

CDC Points of Contact Cecilia Kato
 (404) 639-1075
 ckato@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 Prior approval is required if the following information is not provided:
 – Suspected Agent
 – Travel and exposure history (including animals, arthropods, etc.)
 – Date of illness onset (and time if available)
 – Specimen type (e.g., serum, whole blood, tissue, etc.)
 – Test requested
 – Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
 –acute (during active stage of illness)
 –convalescent (2–4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
 (404) 639-1075
 ckato@cdc.gov
 Yan Zeng
 (404) 639-5177
 xcw9@cdc.gov

Test Order
Coxiella Special Study
CDC-10306

Synonym(s) Q fever

Pre-Approval Needed Kato, Cecilia, (404) 639-1075, ckato@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, other

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@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

Storage & 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

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) *Cyclospora cayetenensis*, 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

Storage & Preservation of Specimen Prior to Shipping Stool collected in 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 Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. 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.

Methodology Real-Time PCR

Turnaround Time 14 Days

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
(404) 718-4124
tgd5@cdc.gov

Test Order
Cysticercosis Serology
CDC-10459

Synonym(s) Neurocysticercosis, *Taenia solium*, cysitcercus, EITB, LLGP-EITB, parasite

Pre-Approval Needed None

Supplemental Information Required 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; cerebrospinal fluid (CSF) only when paired with serum or plasma

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Immunoblot, Western Blot, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@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, and blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not Applicable

Specimen Labeling Provide a specimen ID. Do not send specimen labeled with patient's name.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 1 Week

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Shelia Dollard
(404) 639-2178
sgd5@cdc.gov
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 500 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Provide a specimen ID. Do not send specimen labeled with patient's name.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology IgG antibody detected by EIA, IgM antibody detected by EIA

Turnaround Time 1 Week

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Dengue Virus Diagnosis
CDC-10307

Synonym(s) Dengue fever, Dengue

Pre-Approval Needed None

Supplemental Information Required Dengue case investigation form must be filled out- See supplemental Form

Additional Information on submitting specimen and the Spanish version of case investigation form are located at:

<http://www.cdc.gov/dengue/clinicalLab/laboratory.html>

Supplemental Form http://www.cdc.gov/dengue/resources/dengueCaseReports/DCIF_English.pdf

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and others upon consultation with laboratory. The blood sample should be taken in a red-top or tiger-top tube.

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping After blood is allowed to clot, separate serum by centrifugation and keep serum refrigerated at 4°C or frozen at -20°C (preferred).

Citrate (collected in yellow top tubes) and heparin plasma (green top tubes) can be tested by RT-PCR. Violet-top (with EDTA) is not recommended for RT-PCR testing. Violet and or green-top tubes should not be used for serology testing (convalescent sample). Please refer to collection devices manufacturer instructions for more details.

We recommend freezing the serum immediately after it is separated and to send on dry ice. If dry ice is not available, we recommend that the serum is kept refrigerated and delivered to the CDC Dengue Branch in cold packs.

Transport Medium Not Applicable

Specimen Labeling Include complete name, age, and sex of patient, home address, date of onset of symptoms, date sample was obtained, complete name and mailing address of the physician, laboratory, clinic, or hospital

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

Ship To:
CDC Dengue Branch and Puerto Rico Department of Health
1324 Calle Cañada, San Juan, P. R. 00920-3860

Methodology IgM by ELISA, NS1 Antigen Test, Polymerase Chain Reaction (PCR), Viral isolation, IgG seroconversion by ELISA

Turnaround Time 7 Days

Interferences & Limitations Serological tests can cross react with other Flavivirus, such as West Nile Virus. Recent vaccinations for Yellow Fever Virus and Japanese Encephalitis Virus, Tick-borne Encephalitis Virus can cause cross reactive test results. Natural infections with St. Louis Encephalitis Virus and West Nile can cause cross reactive results. Hemolyzed or contaminated samples are not acceptable for serology testing. EDTA will affect PCR and serology results and Nitrate tubes will affect IgM results.

Test Order
Dengue Virus Diagnosis
CDC-10307

Additional Information To diagnose dengue, the laboratory requires a serum sample obtained during the acute phase of the infection (DPO=0-5). If this sample is negative, then a second convalescent serum sample (that can be taken from day 6 after the onset of symptoms) is required to confirm the case. The case is confirmed with antibody (IgM or IgG) seroconversion. Informing the patient about the importance of returning for a second sample, and providing an appointment for a specific day and hour, will increase the probability of obtaining the second sample. Samples will be rejected if they are sent without form, form without sample, incomplete or illegible form especially regarding date of onset of symptoms, date of sample collection and samples received more than a month after onset of illness.

CDC Points of Contact Elizabeth Hunsperger
(787) 706-2472
enh4@cdc.gov
Jorge Munoz
(787) 706-2460
ckq2@cdc.gov

Test Order
Dengue Virus Special Study
CDC-10308

Synonym(s) None

Pre-Approval Needed Hunsperger, Elizabeth, (787) 706-2472, enh4@cdc.gov
Munoz, Jorge, (787) 706-2469, ckq2@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

Storage & 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 Elizabeth Hunsperger
(787) 706-2472
enh4@cdc.gov
Jorge Munoz
(787) 706-2469
ckq2@cdc.gov

Test Order
Ebola Identification
CDC-10309

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Ebola Serology
CDC-10310

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Echinococcosis Serology
CDC-10460

Synonym(s) Hydatid Disease, *Echinococcus granulosus*, parasite

Pre-Approval Needed None

Supplemental Information Required 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Immunoblot, Western Blot, Antibody detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@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 Kato, Cecilia, (404) 639-0152, ckato@cdc.gov
Zeng, Yan, (404) 639-5177, xcw9@cdc.gov

Supplemental Information Required Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples only, anticoagulated whole blood collected in Ethylenediaminetetraacetic acid (EDTA) treated tubes preferred; serum; fresh tissue biopsy

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Ethylenediaminetetraacetic acid (EDTA) blood tubes for blood; tissue in a sample collection tube

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology Real Time Polymerase Chain Reaction (PCR), Sequencing

Turnaround Time 6 Weeks

Interferences & Limitations Hemolysis in whole blood specimen will interfere with results. Multiple freeze thaw cycles and sample storage above refrigerated temperatures will interfere with proper nucleic acid extraction. If a specimen is drawn at convalescence it will reduce the chance of the target organism being present in blood. Avoid collection of blood specimen in heparin tubes.

Additional Information The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids State Laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. Routine diagnostic samples should be sent to your State Laboratory or a commercial laboratory.

CDC Points of Contact Cecilia Kato
(404) 639-0152
ckato@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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
-acute (during active stage of illness)
-convalescent (2-4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday-Thursdays, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@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 Kato, Cecilia, (404) 639-0152, ckato@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, Other

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Cecilia Kato
(404) 639-0152
ckato@cdc.gov
Yan Zeng
(404) 639-5177
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
Whitney, Anne, (404) 639-1374, amw0@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

Storage & 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 John McQuiston
(404) 639-0270
zje8@cdc.gov
Anne Whitney
(404) 639-1374
amw0@cdc.gov

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

Synonym(s) Amebiasis, *Entameba histolytica*, *Entameba dispar*, 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. 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.

Methodology Real-Time PCR

Turnaround Time 21 Days

Interferences & Limitations Specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.

Additional Information None

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

Test Order
Enteric Isolation – Primary Specimen
CDC-10106

Synonym(s) Enteric Pathogen Culture

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

Supplemental Information Required Consult with EDLB contact before sending specimens. Targeted organisms include: *Salmonella*, *Shigella*, *Campylobacter*, STEC and other diarrheagenic *Escherichia coli*, pathogenic *Enterobacteriaceae*, *Listeria*, *Vibrio*, *Cronobacter*, and related foodborne and waterborne pathogens. Provide any preliminary results available.

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. Targeted organisms include: *Salmonella*, *Shigella*, *Campylobacter*, STEC and other diarrheagenic *Escherichia coli*, pathogenic *Enterobacteriaceae*, *Listeria*, *Vibrio*, *Cronobacter*, and related foodborne and waterborne pathogens.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Storage and preservation are dependent upon consultation

Transport Medium Transport medium is dependent upon consultation

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Specifics of shipping will depend upon consultation

Methodology Enrichment, Isolation, Identification, Serotyping, PCR testing for virulence markers

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information None

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: 4ml unless lower volume preapproved; pathogen isolate: n/a

Storage & 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 Specimens must be labeled with one of the anonymized sample identifier stickers provided to study participants. No personally identifiable information can be present on the sample or accompanying documentation.

Shipping Instructions which Include Specimen Handling Requirements Stool samples must be shipped on dry ice. Ship pathogen isolates at ambient temperature. All samples must be packaged in accordance with all applicable state and federal regulations. Ship only Monday - Thursday overnight to avoid weekend deliveries.

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
AJo 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 Not Applicable

Storage & 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 2mL 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 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.

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.

Methodology Molecular techniques

Turnaround Time 14 Days

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.

Test Order
Enterovirus Detection and Identification
CDC-10312

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
Entomology Special Study
CDC-10494

Synonym(s) None

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

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Animal

Acceptable Sample/ Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Storage & 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 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 blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 1 Week

Interferences & Limitations None

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) None

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens; Please call for approval prior to sending other specimen types.

Provide any preliminary results 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

Storage & Preservation of Specimen Prior to Shipping Store and ship isolates at ambient temperatures not to exceed 35°C or at 4°C. Isolates held for more than a month should be frozen.

Ship in compliance with Federal and local guidelines. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances.

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers for all submissions, on the specimen container, and test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries.
 Ship at ambient temperature in compliance with Federal and local guidelines. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances.

There are no time constraints for submitting sequence data

Methodology Phenotypic Identification, Genetic Identification, Serotyping and Virulence Profiling, PCR for STEC and other pathotype-specific virulence genes

Turnaround Time 8 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.

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation 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 Nancy Strockbine
 (404) 639-4186
 nas6@cdc.gov
 Devon Stripling
 (404) 639-2251
 euo4@cdc.gov

Haley Martin
 (404) 639-1612
 hvw0@cdc.gov

Test Order
Escherichia and *Shigella* Study
 CDC-10115

Synonym(s) None

Pre-Approval Needed Strockbine, Nancy, (404) 639-4186, nas6@cdc.gov
 Stripling, Devon, (404) 639-2251, euo4@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 As directed by study protocol

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Ship as directed by study protocol in compliance with Federal and local guidelines. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight growth on nonselective slant/stab such as TSA, HIA, etc.; screw cap tubes preferred or as directed by the study protocol.

Methodology

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.

Additional Information None

CDC Points of Contact Nancy Strockbine
 (404) 639-4186
 nas6@cdc.gov
 Devon Stripling
 (404) 639-2251
 euo4@cdc.gov

Haley Martin
 (404) 639-1612
 hvw0@cdc.gov

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

Synonym(s) Enteric Pathogen

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

Supplemental Information Required Date of illness onset, date of serum collection, clinical diagnosis. Indicate if patient has HUS and onset date. If patient has undergone plasmaphoresis indicate date on submission form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Paired serum is preferred. Serum is always preferred but plasma is acceptable. Do not pool specimens.

Minimum Volume Required 100 uL (More Preferred)

Storage & Preservation of Specimen Prior to Shipping Maintain serum at 4°C (preferred); frozen specimens acceptable.

Transport Medium Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Rachael Aubert (vrl7@cdc.gov, (404) 639-3816) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology EIA

Turnaround Time 3 Months

Interferences & Limitations None

Additional Information Paired serum specimens always preferred.

Please send one tube per specimen submission form. Submit multiple forms if needed.

CDC Points of Contact Rachael Aubert
 (404) 639-3816
 vrl7@cdc.gov
 Patricia Fields
 (404) 639-1748
 pif1@cdc.gov

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

Synonym(s) *E. coli* Typing, *Shigella* Typing

Pre-Approval Needed None

Supplemental Information Required Isolates should be identified to the species level by the sender. Provide any preliminary results available. Indicate subtyping method(s) requested on 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, Sequence Data

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Store isolates at ambient temperatures not to exceed 35°C or at 4°C. Isolates held for more than a month should be frozen

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries.
 Ship at ambient temperature in compliance with Federal and local guidelines. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances.

There are no time constraints for submitting sequence data

Methodology Phenotypic Serotyping, Genetic Serotyping, Virulence Profiling, AST, PFGE, MLVA, WGS

Turnaround Time 8 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 form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation 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 Nancy Strockbine
 (404) 639-4186
 nas6@cdc.gov
 Devon Stripling
 (404) 639-2251
 euo4@cdc.gov

Haley Martin
 (404) 639-1612
 hvw0@cdc.gov

Test Order
Fascioliasis Serology
CDC-10505

Synonym(s) Fascioliasis, *Fasciola hepatica*, liver fluke

Pre-Approval Needed None

Supplemental Information Required 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice

Methodology Immunoblot, Western blot, Antibody detection

Turnaround Time 18 Days

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

Additional Information none

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Filariasis Serology
CDC-10462

Synonym(s) *Brugia malayi*, *Wuchereria bancrofti*; Bancroftian filariasis, parasite

Pre-Approval Needed None

Supplemental Information Required 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology EIA, ELISA, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@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 In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Human: lymph node aspirate, sputum, bronchial/tracheal wash, pleural fluid, blood, ulcer swab, biopsy/autopsy specimens (sections of lymph node, lung, liver, spleen); Animal: Necropsy specimen (lymph node, lung, liver or spleen).

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Refrigerate specimens containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.

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 patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
 Bacterial Diseases Branch
 Attn: John Young
 3156 Rampart Road
 Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on ice packs

Methodology Culture, Direct Fluorescent Antibody (DFA), Biochemical subtyping

Turnaround Time 3 Weeks

Interferences & Limitations Samples for testing by culture should be taken prior to antibiotic 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 In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 500 uL

Storage & Preservation of Specimen Prior to Shipping Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longer period, serum samples may be frozen.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
Bacterial Diseases Branch
Attn: John Young
3156 Rampart Road
Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

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
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 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

Storage & 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 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Specimen should be shipped at ambient temperature

Methodology Phenotypic Testing, DNA Sequencing

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov
Mark Lindsley
(404) 639-4340
mil6@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
Storage & 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 patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday, overnight to avoid weekend deliveries Refrigerated specimen at 4°C should be shipped on cold packs Frozen specimen should be shipped on dry ice
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	Mark Lindsley (404) 639-4340 mil6@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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Refrigerated specimen at 4°C should be shipped on cold packs
Frozen specimen should be shipped on dry ice

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 Mark Lindsley
(404) 639-4340
mil6@cdc.gov
Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov

Test Order
Fungal Study
CDC-10181

Synonym(s) None

Pre-Approval Needed Lockhart, Shawn, (404) 639-2569, gyi2@cdc.gov
Lindsley, Mark, (404) 639-4340, mil6@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

Storage & 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 None

CDC Points of Contact Shawn Lockhart
(404) 639-2569
gyi2@cdc.gov
Mark Lindsley
(404) 639-4340
mil6@cdc.gov

Test Order
Gastroenteritis Virus Special Study
CDC-10316

Synonym(s) None

Pre-Approval Needed Vinje, Jan, (404) 639-3721, ahx8@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

Storage & 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 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

Pre-Approval Needed None

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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship FFPE at room temperature and frozen specimen should be shipped on dry ice, as an etiologic agent.

Methodology PCR

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Cheng Chen
(404) 639-3154
cyc1@cdc.gov
Kai Chi
(404) 639-0694
krc2@cdc.gov

Test Order
Gram Negative Bacillus (Non-enteric/Nonfermenter) ID
CDC-10135

Synonym(s) GNR, Gram Negative Rod

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Gram Negative Coccus (Not GC or *meningococcus*) ID
CDC-10138

Synonym(s) *Neisseria* Identification, GNC

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Gram Positive Bacillus ID
CDC-10137

Synonym(s) Gram Positive Rod Identification, GPB, GPR

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
Haemophilus ducreyi Molecular Detection
CDC-10511

Synonym(s) GUD

Pre-Approval Needed None

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 n/a

Storage & 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 patient identifiers on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship FFPE at room temperature and frozen specimen should be shipped on dry ice, as an etiologic agent.

Methodology PCR

Turnaround Time 2 Weeks

Interferences & Limitations none

Additional Information none

CDC Points of Contact Cheng Chen
(404) 639-3154
cyc1@cdc.gov
Kai Chi
(404) 639-0694
krc2@cdc.gov

Test Order

Haemophilus influenzae Identification and Serotyping

CDC-10221

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

Pre-Approval Needed None

Supplemental Information Required If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or tests used column of submission form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate, frozen stock, primary specimen such as CSF, whole blood, serum, and other sterile site specimen types upon consultation.

Minimum Volume Required 0.25 mL

Storage & 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% CO₂ 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 Tests subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries and enclose a shipping spreadsheet or submission form in all shipments. Frozen specimens and stocks should be shipped on dry ice. Whenever possible, email the shipping spreadsheet and tracking number in advance (especially for suspected outbreak specimens or isolates).

Methodology Real-time PCR

Turnaround Time 30 Days

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 testing (biochemical testing and slide agglutination serotyping) completed as needed.
For research purposes only, molecular characterization of *H. influenzae* isolates will be completed by whole genome sequencing with prior approval from the Bacterial Meningitis Laboratory.
Provides or confirms serotype for potential outbreak specimens or isolates.

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

Test Order
Haemophilus influenzae Study
 CDC-10222

Synonym(s) Hi Surveillance

Pre-Approval Needed , , ,

Supplemental Information Required If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or tests used column of submission form.

Supplemental Form

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 N/A

Storage & 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% CO₂ and then stored and shipped at ambient temperature.

Transport Medium Chocolate agar slants or frozen stocks.

Specimen Labeling Tests require at least one patient identifier on the specimen container and the test requisition. Label specimens with the state ID & accession number, and if applicable surveillance (ABCs or Enhanced Surveillance) ID.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Frozen specimens should be shipped on dry ice. Please include a shipping spreadsheet and email spreadsheet prior to shipment.

Methodology Real-time 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
 Caelin Potts
 (404) 718-5532
 lyi3@cdc.gov

Test Order
Haemophilus species (Not *H. influenzae*/*H. ducreyi*) ID
CDC-10141

Synonym(s) None

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Biochemical analysis Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Hantavirus (No. American) Identification
CDC-10319

Synonym(s) Hanta, HPS, HFRS

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
***Hantavirus* (So. American) Identification**
CDC-10320

Synonym(s) Hanta, HPS, HFRS

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Testing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Hantavirus Serology
CDC-10321

Synonym(s) Hanta, HPS, HFRS, Hantaan

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations None

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order

Healthcare-associated Outbreak Identification and Typing

CDC-10162

Synonym(s) Healthcare Outbreak or Nosocomial Outbreak

Pre-Approval Needed Noble-Wang, Judith, (404) 639-2321, cux2@cdc.gov
Moulton-Meissner, Heather, (404) 639-4864, ftw2@cdc.gov

Supplemental Information Required Supplemental Line List required contact laboratory for more information

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 (swabs, wipes, water and other fluids, medical devices). In addition, fluids and products used for patient care.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature until ready for shipping

Transport Medium Use an agar slant not a agar plate for isolates

Specimen Labeling No patient identifiers. Please include specimen identifiers on Line List

Shipping Instructions which Include Specimen Handling Requirements Ship isolates at ambient temperatures and ship environmental specimens on cold-packs. Ship overnight, Monday through Thursday, for delivery within 24 hours of collection.

Methodology Phenotypic and Molecular Identification, PFGE, Culture, Other

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.

Additional Information Turnaround time for nontuberculosis mycobacteria may take up to 8 weeks.

Criteria for submission:

-Prior consultation with CDC/DHQP Prevention and Response Branch on epidemiological investigation. Contact info: haioutbreak@cdc.gov or (404) 639-4000.

-If healthcare facility will be submitting samples directly to CDC they must receive prior approval from State Health Department. Provide State Health Department contact information.

-For isolate submission, include the test method that was used to identify the specimen in the "Previous Laboratory Results/Comments" section.

The identification methods used and the results reported are for investigational or research purposes. These test results may not be used for diagnosis, treatment, or for the assessment of a patient's health.

CDC Points of Contact Heather Moulton-Meissner
(404) 639-4864
ftw2@cdc.gov
Judith Noble-Wang
(404) 639-2321

Test Order
Healthcare-associated Outbreak Identification and Typing
CDC-10162

cux2@cdc.gov

Test Order
Healthcare-associated Outbreak Isolate Sequencing and
Analysis
CDC-10518

Synonym(s) Whole genome sequencing

Pre-Approval Needed Perry, K. Allison, (404) 639-0272, hex1@cdc.gov
Laufer Halpin, Alison, (404) 639-1776, vif0@cdc.gov

Supplemental Information None
Required

Supplemental Form None

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

Acceptable Sample/ Specimen Pure culture isolates
Type for Testing

Minimum Volume Required N/A

Storage & Preservation of Keep specimen at a refrigerated temperature until ready for shipping
Specimen Prior to Shipping

Transport Medium Use an agar slant not an agar plate for isolates

Specimen Labeling No patient identifiers. Please include specimen identifiers on Line List.

Shipping Instructions which Ship isolates on cold-packs. Ship overnight, Monday through Thursday, for
Include Specimen Handling delivery within 24 hours of collection
Requirements

Methodology Whole genome sequencing

Turnaround Time 4 Weeks

Interferences & Limitations Isolates not maintained under specific selective pressure may lose mobile antibiotic resistance elements. The methods used and the results reported are for investigational or research purposes. These test results may not be used for diagnosis, treatment, or for the assessment of a patient's health.

Additional Information Turnaround time for nontuberculosis mycobacteria may take up to 12 weeks

Criteria for Submission

- Prior consultation with CDC/DHQP Prevention and Response Branch on epidemiological investigation. Contact info: haioutbreak@cdc.gov or 404-639-4000.
- If healthcare facility will be submitting samples directly to CDC, they must receive prior approval from State Health Department. Provide State Health Department contact information.
- For isolate submission, include the test method used to identify the specimen in the "Previous Laboratory Results/Comments" section.

CDC Points of Contact K. Allison Perry
(404) 639-0272
hex1@cdc.gov

Test Order
Healthcare-associated Outbreak Isolate Sequencing and
Analysis
CDC-10518

Alison Laufer Halpin
(404) 639-1776
vif0@cdc.gov

Test Order

Healthcare-associated Outbreak Metagenomic Sequencing and Analysis

CDC-10519

Synonym(s) Metagenomic sequencing (shotgun, amplicon-based)

Pre-Approval Needed Perry, K. Allison, (404) 639-0272, hex1@cdc.gov
Laufer Halpin, Alison, (404) 639-1776, vif0@cdc.gov

Supplemental Information Required None

Supplemental Form N/A

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

Acceptable Sample/ Specimen Type for Testing Primary clinical or Food/Environmental/Medical Device/Biologic specimens

Minimum Volume Required N/A

Storage & Preservation of Specimen Prior to Shipping Keep specimen at a refrigerated temperature until ready for shipping

Transport Medium If sending stool specimens, an approved stool preservation collection tube should be used

Specimen Labeling No patient identifiers. Please include specimen identifiers on Line List.

Shipping Instructions which Include Specimen Handling Requirements Ship primary specimens on cold-packs. Ship overnight, Monday through Thursday, for delivery within 24 hours of collection

Methodology Metagenomic sequencing (shotgun, amplicon-based)

Turnaround Time 12 Weeks

Interferences & Limitations Holding samples at room temperature >1 hour after collection may impact sample microbial composition. The methods used and the results reported are for investigational or research purposes. These test results may not be used for diagnosis, treatment, or for the assessment of a patient's health.

Additional Information Criteria for Submission

- Prior consultation with CDC/DHQP Prevention and Response Branch on epidemiological investigation. Contact info: haioutbreak@cdc.gov or 404-639-4000.
- If healthcare facility will be submitting samples directly to CDC, they must receive prior approval from State Health Department. Provide State Health Department contact information.

CDC Points of Contact K. Allison Perry
(404) 639-0272
hex1@cdc.gov
Alison Laufer Halpin
(404) 639-1776
vif0@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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing gastric biopsy or *H. pylori* bacterial isolate

Minimum Volume Required To be determined

Storage & Preservation of Specimen Prior to Shipping Store at -70°C

Transport Medium cysteine freeze media-provided by Arctic Investigations Program laboratory

Specimen Labeling patient name, date of birth, medical record number, area of stomach e.g. antrum or fundus and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship on dry ice

Methodology culture and susceptibility testing for amoxicillin, tetracycline, and clarithromycin

Turnaround Time 7 Weeks

Interferences & Limitations To be determined

Additional Information Please provide shipping information to CDC Points of Contact prior to shipping specimens

CDC Points of Contact Brenna Simons-Petrusa
(907) 729-3452
imd4@cdc.gov
Julie Morris
(907) 729-3445
zbf2@cdc.gov

Test Order
Hendra Serology
CDC-10324

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Hepatitis A Serology, NAT and Genotyping
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 plasma, stool

Minimum Volume Required 1.5 mL

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Methodology Total anti-HAV by Chemiluminescence, IgM anti-HAV by Chemiluminescence, HAV RNA, HAV Genotyping by NAT P2B Sequencing

Turnaround Time 1 Week

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 Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov

Test Order
Hepatitis B Serology, NAT and Genotyping
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 plasma.
Note: For Quantitative anti-HBs test – Serum only

Minimum Volume Required 2 mL

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Methodology HBsAg by Chemiluminescence, IgM anti-HBc by Chemiluminescence, Total anti-HBc by Chemiluminescence, Anti-HBs by Chemiluminescence, HBeAg by ELISA, Anti-HBe by ELISA, HBV DNA by Real Time PCR, HBV Genotyping by PCR S Gene Sequencing

Turnaround Time 1 Week

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 Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov

Test Order
Hepatitis B Surface Antigen Confirmatory Test
CDC-10451

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 Plasma

Minimum Volume Required 300uL

Storage & Preservation of Specimen Prior to Shipping Specimens should be stored frozen at -20°C

Transport Medium None

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on cold packs

Methodology Neutralization

Turnaround Time 10 Days

Interferences & Limitations Do not send whole blood or hemolyzed serum

Additional Information None

CDC Points of Contact Jan Drobenuic
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov

Test Order
Hepatitis C Serology, NAT 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Methodology Anti-HCV by Chemiluminescence, HCV RNA by TaqMan IVD, HCV Genotyping by Molecular Hybridization, PCR NS5B Gene Sequencing

Turnaround Time 1 Week

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 Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Methodology Total anti-HDV by EIA, HDV RNA by Real Time qRT-PCR, HDV Genotyping by direct sequence analysis

Turnaround Time 2 Weeks

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 Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov

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

Synonym(s) HEV, Hepatitis E virus

Pre-Approval Needed Drobeniuc, Jan, (404) 639-3790, jqd6@cdc.gov
Kamili, Saleem, (404) 639-4431, sek6@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/hepatitis/HEV/LabTestingRequests.htm>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum, EDTA plasma, and stool

Minimum Volume Required 2 mL

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice

Methodology IgM anti-HEV by EIA, IgG anti-HEV by EIA, HEV RNA by Real Time qRT-PCR, HEV Genotyping by direct sequence analysis

Turnaround Time 2 Weeks

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 Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@cdc.gov

Test Order
Hepatitis Outbreak Investigation
CDC-10330

Synonym(s) HAV, HBV, HCV, HDV, HEV, Hepatitis A virus, Hepatitis B virus, Hepatitis C virus, Hepatitis D virus, Hepatitis E virus

Pre-Approval Needed Drobeniuc, Jan, (404) 639-3790, jqd6@cdc.gov
Kamili, Saleem, (404) 639-4431, sek6@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 Not Applicable

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements None

Methodology

Turnaround Time

Interferences & Limitations None

Additional Information None

CDC Points of Contact Jan Drobeniuc
(404) 639-3790
jqd6@cdc.gov
Saleem Kamili
(404) 639-4431
sek6@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 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

Storage & 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 None

Methodology

Turnaround Time

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

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 200 uL (CSF, saliva)

Storage & Preservation of Specimen Prior to Shipping Skin lesions should be kept dry and saliva can be kept either refrigerated or frozen.

Transport Medium Not Applicable

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight on cold packs or dry ice. Skin lesions should be shipped dry. Ship as an etiologic agent. See standard shipping instructions for biologic agent

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

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
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 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen.

Transport Medium Not Applicable

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology IgG antibody detected by EIA

Turnaround Time 7 Days

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
Kay Radford
(404) 639-2192
kjr7@cdc.gov

Test Order
Herpesvirus Encephalitis Panel
CDC-10262

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 Cerebrospinal fluid (CSF), saliva, whole blood, or skin lesions

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes. Skin lesions should be kept dry.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

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
kjr7@cdc.gov

Test Order
Herpesvirus Special Study
CDC-10270

Synonym(s) None

Pre-Approval Needed 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 To be determined

Minimum Volume Required Not Applicable

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

Test Order
HIV antigen/antibody Combo
CDC-10485

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 or Plasma

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping 2 days at ambient temperature; 7 days at 2–8°C. Specimens should be stored at –20°C for long-term storage and should not have more than 4 freeze/thaw cycles.

Transport Medium

Specimen Labeling Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred

Shipping Instructions which Include Specimen Handling Requirements For best results, specimens should be shipped frozen on dry ice for overnight delivery to the HIV reference laboratory.

Methodology EIA

Turnaround Time 21 Days

Interferences & Limitations Do not heat inactivate specimens

Additional Information None

CDC Points of Contact Timothy Granade
(404) 639-3850
txg1@cdc.gov
Bill Switzer
(404) 639-0219
bis3@cdc.gov

Test Order

HIV Molecular Surveillance Study (International Only)

CDC-10332

Synonym(s) HIV subtypes, HIV molecular epidemiology, HIV outbreak

Pre-Approval Needed Ramos, Arthur, (404) 718-4518, cer9@cdc.gov
DeVos, Joshua, (404) 639-5442, ext8@cdc.gov

Supplemental Information Required Specimens must be accompanied with completed International Laboratory Drug Resistance and Molecular Surveillance Test Requisition Form. Contact CDC Points of Contact for this test order to obtain requisition and approval for testing as well as 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 separated from whole blood in the presence of EDTA as anticoagulant, or dried blood spots (DBS) collected from finger/heel prick or venous blood collected on a 903 sample collection card or similar.

Minimum Volume Required 0.5 mL of plasma or at least four (preferably five) DBS of 100 µL in each of the 13mm printed circles on blood collection cards

Storage & Preservation of Specimen Prior to Shipping Freeze plasma and DBS samples as soon as possible at -80°C before shipment, 6 month maximum. If a -80°C freezer is not available, store samples at -20°C before shipment, 1 month maximum. Higher temperatures and longer lengths of time in storage may compromise sample quality and invalidate test results.

Aliquot plasma samples in 1.5 – 2.0 mL polypropylene tube with screw cap and O-ring.

Five to 10 DBS cards must be separated or wrapped individually by glassine paper and placed in a laboratory-grade, gas-impermeable ziplock bags, containing five desiccant packs and one humidity indicator. Humidity indicators must be visible inside the ziplock bags without opening it. Gently apply pressure to the partially sealed bag to expel the air before sealing it completely. Stabilize ziplock bags to ambient temperature before opening, in case desiccant packs and humidity indicators need to be replaced, to avoid exposure of samples to humidity. Avoid freeze/thaw cycles as much as possible.

Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.

Transport Medium Plasma samples and DBS samples must be transported in the 1.5 – 2.0 mL polypropylene tubes with screw cap and O-ring used for preparing aliquots.

DBS cards must be transported in the properly packaged zip-lock bags.

Specimen Labeling All primary specimen containers must include two unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form. Surveillance studies and some study protocols require de-linked patient information, which should not accompany samples, or provided to CDC.

Shipping Instructions which Include Specimen Handling Requirements Transport plasma specimens in frozen conditions using dry ice or liquid nitrogen.

DBS can be transported at ambient temperature (20°–30°C) for shipments that are in transit for up to 7 days. Avoid direct exposure to sunlight and use the most

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

direct shipping route to expedite delivery. For shipments that are in transit more than 7 days, maintain specimens at -20°C or colder with dry ice.

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 seq

Turnaround Time 16 Weeks

Interferences & Limitations To be determined

Additional Information Do not use heparin as an anticoagulant. Plasma should not be used after more than two freeze-thaw cycles. Plasma and DBS samples will be rejected if improperly labeled or unlabeled, with discrepant documentation, insufficient volume, without documentation, and evidence of leakage or contamination.

CDC Points of Contact Artur Ramos
(404) 718-4518
cer9@cdc.gov
Joshua DeVos
(404) 639-5442
ext8@cdc.gov

Test Order
HIV Serology NHANES
CDC-10279

Synonym(s) HIV ELISA, HIV antibody

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and/or plasma. The following anticoagulants are acceptable: EDTA, sodium citrate, CPD, CPDA-1, and ACD. SST and PPT are also acceptable.

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimens may be stored at 2–8°C for 7 days. Long-term storage should be at –20°C or colder and specimens should not have incurred more than 5 freeze-thaw cycles.

Transport Medium Not Applicable

Specimen Labeling Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred

Shipping Instructions which Include Specimen Handling Ship specimen Monday –Thursday overnight to avoid weekend deliveries

Requirements Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Enzyme-linked Immunosorbent Assay (ELISA), Western Blot, Rapid Test

Turnaround Time 21 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Tim Granade
(404) 639-3850
txg1@cdc.gov
Bill Switzer
(404) 639-0219
bis3@cdc.gov

Test Order
HIV Serology Study (International Only)
CDC-10333

Synonym(s) None

Pre-Approval Needed Parekh, Bharat, (404) 639-3647, bsp1@cdc.gov
Kalou, Mireille, (404) 639-2794, chn7@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

Storage & Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.

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 Bharat Parekh
(404) 639-3647
bsp1@cdc.gov
Mireille Kalou
(404) 639-2794
chn7@cdc.gov

Test Order
HIV Special Study
CDC-10278

Synonym(s) None

Pre-Approval Needed Switzer, Bill, (404) 639-0219, bis3@cdc.gov
Granade, Tim, (404) 639-3850, txg1@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

Storage & 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 Bill Switzer
(404) 639-0219
bis3@cdc.gov
Tim Granade
(404) 639-3850
txg1@cdc.gov

Test Order

HIV-1 Genotype Drug Resistance (International Only)

CDC-10335

Synonym(s) HIV drug resistance (DR), HIV susceptibility to antiretroviral drugs

Pre-Approval Needed Ramos, Artur, (404) 718-4518, cer9@cdc.gov
DeVos, Joshua, (404) 639-5442, ext8@cdc.gov

Supplemental Information Required Specimens must be accompanied with completed International Laboratory Drug Resistance and Molecular Surveillance Test Requisition Form. Contact POCs listed below to obtain requisition and approval for testing as well as 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 separated from whole blood in the presence of EDTA as anticoagulant, or dried blood spots (DBS) collected from finger/heel prick or venous blood collected on a 903 sample collection card or similar.

Minimum Volume Required 0.5 mL of plasma, or at least four (preferably five) DBS of 100 µL in each of the 13mm printed circles on blood collection cards

Storage & Preservation of Specimen Prior to Shipping Freeze plasma and DBS samples as soon as possible at -80°C (may be stored for a maximum of 6 months). In the event a -80°C freezer is not available, samples may be stored at -20°C for a maximum of one month prior to shipment. Higher temperatures and longer lengths of time in storage can damage sample quality and invalidate test results.

Aliquot plasma samples in 1.5 – 2.0 mL polypropylene tube with screw cap and O-ring.

Five to 10 DBS cards must be separated or wrapped individually by glassine paper and placed in a laboratory-grade, gas-impermeable zip-lock bags, containing five desiccant packs and one humidity indicator. Humidity indicators must be visible inside the zip-lock bags without opening it. Gently apply pressure to the partially sealed bag to expel the air before sealing it completely. Stabilize zip-lock bags to ambient temperature before opening, in case desiccant packs and humidity indicators need to be replaced, to avoid exposure of samples to humidity. Avoid freeze/thaw cycles as much as possible.

Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.

Transport Medium Plasma samples and DBS samples must be transported in the 1.5 – 2.0 mL polypropylene tubes with screw cap and O-ring used for preparing aliquots.

Specimen Labeling All primary specimen containers must include two unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form. Surveillance studies and some study protocols require de-linked patient information, which should not accompany samples, or provided to CDC.

Shipping Instructions which Include Specimen Handling Requirements Transport plasma specimens in frozen conditions using dry ice or liquid nitrogen.

DBS can be transported at ambient temperature (20°-30°C) for shipments that are in transit for up to 7 days. Avoid direct exposure to sun light and use the most direct shipping route to expedite delivery. For shipments that are in transit more than 7 days, maintain specimens at -20°C or colder with dry ice.

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

Methodology Identification of mutations within HIV-1 pol gene region by RNA extraction, PCR amplification, DNA sequencing, and drug resistance analysis

Turnaround Time 16 Weeks

Interferences & Limitations Do not use heparin as an anticoagulant. Plasma should not be used after more than two freeze-thaw cycles. Plasma and DBS samples will be rejected if improperly labeled or unlabeled, with discrepant documentation, insufficient volume, without documentation, and evidence of leakage or contamination.

Additionally, DBS samples will be rejected if packaged without humidity indicators and desiccants, demonstrating any indication of humidity in the zip-lock bags, containing blood clots or clumps, with a halo around the blood spot indicating hemolysis, if spots are congruent or show evidence of commingling, and collected onto inappropriate filter paper.

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 Artur Ramos
(404) 718-4518
cer9@cdc.gov
Joshua DeVos
(404) 639-5442
ext8@cdc.gov

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

Synonym(s)	HIV NAAT
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 whole blood. 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 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.
Minimum Volume Required	1 ml plasma or serum; 10 ml whole blood
Storage & Preservation of Specimen Prior to Shipping	Specimen stability is affected by elevated temperature. Whole blood, plasma or serum may be stored for up to 72 hours from time of draw at 25°C; temperatures not to exceed 30°C are acceptable for no more than 24 hours. Specimens may be stored an additional five days at 2 to 8°C following centrifugation. Plasma and serum specimens may be stored at -20°C for up to 6 months; however, storage at these temperatures for longer periods has not been fully evaluated. Do not freeze whole blood.
Transport Medium	Not Applicable
Specimen Labeling	Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday overnight to avoid weekend deliveries. Ship unprocessed whole blood specimens overnight at ambient temperature. If serum or plasma is collected, these specimen should be shipped frozen overnight on dry ice.
Methodology	Nucleic acid amplification
Turnaround Time	21 Days
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 1 mL of plasma/sera is required, 5 mLs is optimal). For DNA 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	Bill Switzer (404) 639-0219 bis3@cdc.gov Tim Granade (404) 639-3850 txg1@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
Hurlston, Mackenzie, (404) 639-1281, wpd9@cdc.gov

Supplemental Information Required Supplemental forms will be provided upon consultation:
-Fill out the ILB-160-F08E Viral Load-EID Requisition Form CDC Form 0.753:
-Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this form.
-International Laboratory Branch Test Directory with shipping instructions sent upon request.

Supplemental Form None

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.

Storage & 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 Please email the contacts listed above for this test in order to receive a job aid with specific packing guidance. Specimens should be transported in a gas impermeable plastic bag with desiccant and humidity indicator card.

Specimen Labeling All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to 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 laboratory prior to submission.

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.

Methodology Qualitative PCR

Turnaround Time 28 Days

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

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

indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.

Additional Information Turnaround time for batches with less than 100 specimens is within 28 days. The turnaround times listed are reflective of specimens sent for retesting or study purposes. Contact Clement Zeh, cbz2@cdc.gov for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing.

A test result of "HIV-1 Not Detected" or Target not detected , does not necessarily rule out the presence of HIV-1 DNA or RNA. Nucleic acid (HIV-1 DNA/RNA) concentrations may be below the limit of detection of the assays, presence of PCR inhibitors in the patient specimen or improper specimen handling can lead to false negative results. HIV-1 may not be detected immediately after exposure. The diagnosis of HIV-1 infection is based on clinical presentation and results from additional diagnostic tests such as DNA PCR. Diagnosis should not be based solely on a single HIV-1 test. False positive test results may be caused by PCR contamination.

NOTE: If a specific testing platform is required, please contact Clement Zeh (cbz2@cdc.gov).

CDC Points of Contact Clement Zeh
(404) 553-7264
cbz2@cdc.gov
Mackenzie Hurlston
(404) 639-1281
wpd9@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
Hurlston, Mackenzie, (404) 639-1281, wpd9@cdc.gov

Supplemental Information Required Supplemental forms will be provided upon consultation:
-Fill out the ILB-160-F08E Viral Load-EID Requisition Form CDC Form 0.753:
-Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this form.
-International Laboratory Branch Test Directory with shipping instructions sent upon request.

Supplemental Form None

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

Storage & 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 Plasma:
Transport specimen in a sterile 1.5-2.0 mL polypropylene tube, screw cap with O-ring.

DBS:
Please email the contacts listed above for this test in order to receive a job aid with specific packing guidance. Specimens should be transported in a gas impermeable plastic bag with desiccant and humidity indicator card.

Specimen Labeling All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to 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 laboratory prior to submission. To maintain temperature of -20°C or colder, plasma should be shipped on dry ice.

Test Order

HIV-1 PCR (International Only) Quantitative Viral Load

CDC-10337

DBS: Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug
Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact laboratory prior to submission.

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.

Methodology Quantitative PCR

Turnaround Time 28 Days

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 Turnaround time for batches with less than 100 specimens is within 28 days. The turnaround times listed are reflective of specimens sent for retesting or study purposes. Contact Clement Zeh, cbz2@cdc.gov for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing.

An interpretation of "Target Not Detected", "HIV-1 RNA Not Detected", and "Not Detected" does not rule out the presence of PCR inhibitors or HIV-1 RNA concentrations below the level of detection of the assay. Care should be taken in the interpretation of any single viral load determination. The clinical significance of changes in HIV-1 RNA measurements has not been fully established; however, a change of 0.5 log copies/mL may be significant.

The linear range of each assay is as follows:

Plasma:

COBAS® AmpliPrep/COBAS® Taqman® HIV-1 v2.0 is 20–10,000,000 copies/mL (1.30–7.00log)

Abbott Real Time HIV-1 assay is 40–10,000,000 copies/mL (1.60–7.00log)

DBS:

COBAS® AmpliPrep/COBAS® Taqman® Free Virus Elution Protocol is 701–10,000,000 copies/mL (2.85–7.00log)

Abbott Real Time HIV-1 assay is 839–10,000,000 copies/mL (2.92–7.00log)

NOTE: If a specific testing platform is required, please contact Clement Zeh (cbz2@cdc.gov).

CDC Points of Contact Clement Zeh
(404) 553-7264
cbz2@cdc.gov
Mackenzie Hurlston
(404) 639-1281
wpd9@cdc.gov

Test Order

HIV-1 /2 Antibody (International Only) EIA and Western Blot

CDC-10338

Synonym(s) HIV, EIA, WB, ELISA

Pre-Approval Needed Parekh, Bharat, (404) 639-3647, bsp1@cdc.gov
Kalou, Mireille, (404) 639-2794, chn7@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. Dried Blood Spots should be at least 4 saturated 13mm filter paper circles (preferably 5) containing 75 µL of whole blood.

Minimum Volume Required 0.5 mL (plasma and serum)

Storage & Preservation of Specimen Prior to Shipping Keep plasma and serum refrigerated at 2°-8°C if testing is performed within 7 days. If testing is performed after 7 days of collection, the specimen should be kept frozen at -20°C or colder.

Dried blood spots should be stored at an ambient temperature (20°-30°C) if testing is performed within 14 days. Specimen should be frozen at -20°C or colder if testing is not performed within 14 days.

Plasma: The appropriate anticoagulants for whole blood collection are either EDTA, Sodium heparin or Lithium heparin.

Dried Blood Spots: For DBS prepared from whole blood collected into tubes, the appropriate anticoagulant for DBS whole blood collection is EDTA. Finger pricks without anti-coagulant dropped directly onto filter paper is also acceptable.

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 All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.

Shipping Instructions which Include Specimen Handling Requirements For shipments that are in transit for up to 7 days, maintain temperature at 2-8°C. For shipments that are in transit for greater than 7 days, maintain temperature at -20°C or colder with dry ice.

For shipments that are in transit for up to 14 days, maintain at ambient

Test Order
HIV-1 /2 Antibody (International Only) EIA and Western Blot
CDC-10338

temperature (20–30°C). For shipments that are in transit for greater than 14 days, maintain temperature at –20°C or colder with dry ice.

Methodology Enzyme Immunoassay, Enzyme-linked Immunosorbent Blot Technique (Western Blot)

Turnaround Time 90 Days

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 highly specific method (i.e. Western Blot). Western Blot with an EIA–positivity has combined specificity of greater than 99.9%.

Testing for EIA and Western Blot is performed in batches and the turnaround times are the following:

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
Mireille Kalou
(404) 639–2794
chn7@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
Kalou, Mireille, (404) 639-2794, chn7@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 0.5 mL

Storage & Preservation of Specimen Prior to Shipping The appropriate anticoagulants for whole blood collection are EDTA or Sodium heparin. Keep specimen at ambient temperature at 15°-35°C if testing will be performed within 48 hours of collection. 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 All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.

Shipping Instructions which Include Specimen Handling Requirements For shipments that are in transit for up to 7 days, maintain temperature at 2-8°C and for shipments that are in transit for greater than 7 days, maintain temperature at -20°C or colder with dry ice.

Methodology Immuno-concentration

Turnaround Time 90 Days

Interferences & Limitations Do not use specimens after more than 5 freeze-thaw cycles. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.

Additional Information Turn around times are dependent on batch specimen:

Batch with less than 200 specimens within 50 days
Batch with 200-600 within 70 days
Batch with greater than 600 specimens within 90 days

CDC Points of Contact Bharat Parekh
(404) 639-3647
bsp1@cdc.gov
Mireille Kalou

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

(404) 639-2794
chn7@cdc.gov

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

Synonym(s) HIV ELISA, HIV antibody

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and/or plasma. The following anticoagulants are acceptable: EDTA, sodium citrate, CPD, CPDA-1, and ACD. SST and PPT are also acceptable.

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimens may be stored at 2–8°C for 7 days. Long-term storage should be at –20°C or colder and specimens should not have incurred more than 5 freeze-thaw cycles.

Transport Medium Not Applicable

Specimen Labeling Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology HIV antigen/antibody combo ELISA or HIV antibody ELISA, HIV-1 /2 differentiation assay, Rapid Test, HIV-1 Nucleic acid amplification (qualitative)

Turnaround Time 21 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Tim Granade
(404) 639-3850
txg1@cdc.gov
Bill Switzer
(404) 639-0219
bis3@cdc.gov

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

Synonym(s) HIV NAAT

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Whole blood. Specimen should be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Whole blood should not be frozen, but can be kept at 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.

Minimum Volume Required 20 mL

Storage & Preservation of Specimen Prior to Shipping Whole blood should not be frozen, but can be kept at 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.

Transport Medium Not Applicable

Specimen Labeling Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries.
 Ship unprocessed whole blood specimens overnight at ambient temperature. If serum or plasma is collected, these specimen should be shipped frozen overnight on dry ice.

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 21 Days

Interferences & Limitations Collections in heparin coated tubes are unacceptable due to heparin interference with PCR amplification.

Additional Information 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 Bill Switzer
 (404) 639-0219
 bis3@cdc.gov
 Tim Granade
 (404) 639-3850
 txg1@cdc.gov

Test Order
HIV-2 Serology
CDC-10273

Synonym(s) HIV ELISA, HIV antibody

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and/or plasma. The following anticoagulants are acceptable: EDTA, sodium citrate, CPD, CPDA-1, and ACD. SST and PPT are also acceptable.

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Plasma should be properly stored in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes.

Transport Medium Not Applicable

Specimen Labeling Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology HIV-1/2 Differentiation Assay, HIV-2 Western Blot

Turnaround Time 21 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Tim Granade
(404) 639-3850
txg1@cdc.gov
Bill Switzer
(404) 639-0219
bis3@cdc.gov

Test Order
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

Storage & 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 Polymerase Chain Reaction (PCR), Serology

Turnaround Time

Interferences & Limitations To be determined

Additional Information

CDC Points of Contact Elizabeth Unger
(404) 639-3533
eru0@cdc.gov
Gitika Panicker
(404) 639-2269
dhv1@cdc.gov

Troy Querec
(404)639-2864
hep0@cdc.gov

Test Order
Human Herpes Virus 6 (HHV6) 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 blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.

Transport Medium None

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

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
kjr7@cdc.gov

Test Order
Human Herpes Virus 6 (HHV6) Serology
CDC-10497

Synonym(s) None

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 http://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 200 uL

Storage & Preservation of Specimen Prior to Shipping Fresh serum or plasma samples may be stored at 4 degrees C for up to one week. Serum or plasma separated from red blood cells should be stored frozen (-20 degrees C) until ready for testing.

Transport Medium No transport medium.

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If stored at 4 degrees C can be overnighted on cold packs in well-sealed O-ring vials; if frozen can be overnighted on dry ice in well-sealed O-ring vials

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology 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.

This test order is for research or epidemiological purposes only. The test(s) 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 Scott Schmid
(404) 639-0066
SSchmid@cdc.gov
Jennifer Folster
(404) 639-3668
JFolster@cdc.gov

Test Order
Human Herpes Virus 7 (HHV7) 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 blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

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
kjr7@cdc.gov

Test Order
Human Herpes Virus 8 (HHV8) 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 Blood or saliva

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not Applicable

Specimen Labeling Provide a specimen ID. Do not send specimen labeled with patient's name.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 1 Week

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Scott Schmid
(404) 639-0066
dss1@cdc.gov

Test Order
Human Herpes Virus 8 (HHV8) 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 or plasma

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen.

Transport Medium Not Applicable

Specimen Labeling Provide a specimen ID. Do not send specimen labeled with patient's name.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology IgG antibody detected by IFA

Turnaround Time 7 Days

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Sheila Dollard
(404) 639-2178
sgd5@cdc.gov
Scott Schmid
(404) 639-0066
dss1@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 additional WHO submission form that can be obtained with your password
Supplemental Form	http://www.nltn.org/Influenza-Specimen-submission-Form.xlsx
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
Storage & 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 -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 -70°C and tested at a later time. Specimens received frozen should be stored at -70°C until processing. Store any residual specimens at -70°C.
Transport Medium	Swabs must be in viral transport medium
Specimen Labeling	Specimen ID must match the ID on the form
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries. 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 extracted RNA and frozen specimen on dry ice. Refrigerated specimens should be shipped on cold packs.
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. 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 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 additional WHO submission form that can be obtained with your password

Supplemental Form <http://www.nltn.org/Influenza-Specimen-submission-Form.xlsx>

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

Storage & 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 Specimen ID must match the ID on the form

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. 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 extracted RNA and frozen specimen on dry ice.
Refrigerated specimen should be shipped on cold packs.

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 Stephen Lindstrom
(404) 639-1587
sql5@cdc.gov
LaShondra Berman
(404) 639-1686
zhj5@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
Katz, Jackie, (404) 639-4966, jmk9@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 .5 mL

Storage & 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 Please include patient identification number, patients age, date of collection and symptoms onset date. Do not include names.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Obtain approval prior to shipping

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
Jackie Katz
(404) 639-4966
jmk9@cdc.gov

Test Order
Influenza Special Study
CDC-10425

Synonym(s) None

Pre-Approval Needed Wentworth, David, (404) 639-3387, gll9@cdc.gov
Lindstrom, Stephen, (404) 639-1587, sql5@cdc.gov

Supplemental Information Required Requires additional WHO submission form that can be obtained with your password

Supplemental Form <http://www.nltm.org/Influenza-Specimen-submission-Form.xlsx>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing To be determined

Minimum Volume Required To be determined

Storage & 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 David Wentworth
(404) 639-3387
gll9@cdc.gov
Stephen Lindstrom
(404) 639-1587
sql5@cdc.gov

Xu Xiyan
(404) 639-1657
xxx1@cdc.gov
Larisa Gubareva
(404) 639-3204
lqg3@cdc.gov

Test Order

Influenza Surveillance

CDC-10422

Synonym(s) Flu, Influenza Antigen Characterization

Pre-Approval Needed None

Supplemental Information Required Requires additional WHO submission form that can be obtained with your password

Supplemental Form <http://www.nltn.org/Influenza-Specimen-submission-Form.xlsx>

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

Storage & 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 -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 -70° C and tested at a later time. Specimens received frozen should be stored at -70°C until processing. Store any residual specimens at -70°C.

Transport Medium Swabs must be in viral transport medium

Specimen Labeling Specimen ID must match the ID on the form

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Urgent specimen can be shipped at 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 extracted RNA and frozen specimen on dry ice.
Refrigerated specimen should be shipped on cold packs.

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 Xiyun Xu
(404) 639-1657
xxx1@cdc.gov
Wendy Sessions
(404) 639-3211
gra6@cdc.gov

Test Order
Junin Serology
CDC-10340

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

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Kyasanur Forest Disease Serology
CDC-10341

Synonym(s) KFD

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Laguna Negra Serology
CDC-10342

Synonym(s) HPS, hanta

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Lassa Fever Identification
CDC-10343

Synonym(s) *Arenavirus*

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Lassa Fever Serology
CDC-10344

Synonym(s) *Arenavirus*

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Legionella Special Study
CDC-10161

Synonym(s) None

Pre-Approval Needed , legionellalab@cdc.gov, ,
Raphael, Brian, (404) 639-4292, elx9@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Do not ship on Fridays or the day before a federal holiday. Please see attached shipping instructions for details.
<http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf>

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact legionellalab@cdc.gov (Primary Contact) Jonas Winchell (Emergency)
(404)639-4921
jwinchell@cdc.gov

Brian Raphael (Emergency)
(404) 639-4292
elx9@cdc.gov

Test Order

Legionella species Detection and Identification

CDC-10159

Synonym(s)	Legionnaires' disease or LD, Legionellosis, Pontiac fever	
Pre-Approval Needed	None	
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 Environmental Origin: Isolates only	
Minimum Volume Required	Contingent on specimen type. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf	
Storage & Preservation of Specimen Prior to Shipping	Clinical specimens should be frozen immediately. Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast (BCYE)] and shipped at 4°C. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf	
Transport Medium	BCYE or equivalent slants for isolates	
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.	
Shipping Instructions which Include Specimen Handling Requirements	Do not ship on Fridays or the day before a federal holiday. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf	
Methodology	Culture, Serogrouping, Sequencing, Real Time PCR	
Turnaround Time	4 Weeks	
Interferences & Limitations	Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.	
Additional Information	If only PCR is needed then turn around time will be shorter than 4 weeks	
CDC Points of Contact	legionellalab@cdc.gov (Primary Contact)	Jonas Winchell (Emergency) (404)639-4921 jwinchell@cdc.gov
	Brian Raphael (Emergency) (404) 639-4292 elx9@cdc.gov	

Test Order
Leishmania species Identification
CDC-10238

Synonym(s) Parasite

Pre-Approval Needed None

Supplemental Information Required Must contact CDC prior to sample collection at bnz0@cdc.gov, and CDC will provide the culture medium (typically Novy-MacNeal-Nicolle (NNN) medium).

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Tissue, blood, bone marrow

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Culture medium (typically Novy-MacNeal-Nicolle (NNN) medium). Keep media refrigerated until it is used (stable for 2-4 weeks) and bring it to room temperature right before inoculation. Once inoculated, keep the culture at room temperature and send to CDC as soon as possible by overnight mail.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. 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).

Methodology PCR and DNA sequencing, Culture

Turnaround Time 14 Days

Interferences & Limitations Formalin fixed specimens are not suitable for culture

Additional Information None

CDC Points of Contact Marcos de Almeida
(404) 718-4175
bnz0@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov

Test Order
Leishmaniasis Serology
CDC-10463

Synonym(s) Leishmaniasis Serology, Visceral leishmaniasis, Kala azar; *Leishmania donovoni*,
Leishmania major, *Leishmania*, parasite

Pre-Approval Needed None

Supplemental Information Required 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 and Plasma

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Antibody detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Marcos de Almeida
(404) 718-4175
bnz0@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov

Test Order
Leptospira species Identification and Genotyping
 CDC-10199

Synonym(s) Leptospirosis

Pre-Approval Needed Galloway, Renee, (404) 639-5461, zul0@cdc.gov
 Stoddard, Robyn, (40) 463-9205, frd8@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Isolate and media inoculated with clinical specimens (blood, tissue and urine)

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Cultures should be stored at room temperature

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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries

Isolates should be shipped at room temperature. All other specimens shipped at 4°C.

Methodology Multilocus sequence typing (MLST), Pulsed field gel electrophoresis (PFGE), Microscopy, Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information Turnaround time will vary depending on if an isolate is sent for identification or a specimen is sent for isolation. Primary isolation from clinical specimens takes up to 6 months.

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

Test Order
Leptospira species Molecular Detection
CDC-10200

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 Clinical specimens (blood, CSF, serum, and urine). Blood specimens should be collected in EDTA or Sodium Citrate tubes

Minimum Volume Required 250 uL for blood, CSF, and serum; 10 mL for urine

Storage & Preservation of Specimen Prior to Shipping Keep frozen at -20°C

Transport Medium Blood specimens transported in EDTA or Sodium Citrate tubes

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Specimens should be shipped frozen at -20°C

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Blood specimens collected in heparin are not acceptable

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

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 (acute and convalescent preferred)

Minimum Volume Required 100 uL

Storage & Preservation of Specimen Prior to Shipping Store serum at 4°C before shipping

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Serum should be shipped at 4°C

Methodology MAT–micro agglutination

Turnaround Time 2 Weeks

Interferences & Limitations

Additional Information

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

Storage & 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 Renee Galloway
(404) 639-5461
zul0@cdc.gov
Robyn Stoddard
(404) 639-2053
frd8@cdc.gov

Test Order
Listeria Identification
 CDC-10128

Synonym(s) *Listeria*

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens but is required for all other specimen types.

Provide any preliminary results that are 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship growth on nonselective slant/stab such as TSA, HIA, etc.; screw cap tubes preferred.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers for all submissions, on the specimen container, and test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries.
 Ship at ambient temperature in compliance with Federal and local guidelines

There are no time constraints for submitting sequence data

Methodology Phenotypic Identification, Genetic Identification

Turnaround Time 4 Weeks

Interferences & Limitations None

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
 crt6@cdc.gov
 Zuzana Kucerova
 (404) 718-4143
 zik0@cdc.gov

Test Order
Listeria monocytogenes Identification and Subtyping
 CDC-10129

Synonym(s) *Listeria* Typing

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens, but is required for all other specimen types.

Provide any preliminary results available. Indicate subtyping method(s) requested on 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, Sequence Data

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship growth on nonselective slant/stab such as TSA, HIA, etc.; screw cap tubes preferred.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers for all submissions, on the specimen container, and test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship isolates or cultures Monday–Thursday, overnight to avoid weekend deliveries.

Ship at ambient temperature in compliance with Federal and local guidelines

There are no time constraints for submitting sequence data

Methodology Phenotypic Identification, Genetic Identification, PFGE

Turnaround Time 8 Weeks

Interferences & Limitations None

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 Cheryl Tarr
 (404) 639-2011
 crt6@cdc.gov
 Zuzana Kucerova
 (404) 718-4143
 zik0@cdc.gov

Test Order
Listeria Study
CDC-10130

Synonym(s) None

Pre-Approval Needed Tarr, Cheryl, (404) 639-2011, crt6@cdc.gov
Kucerova, Zuzana, (404) 718-4143, zik0@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

Storage & 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 Cheryl Tarr
(404) 639-2011
crt6@cdc.gov
Zuzana Kucerova
(404) 718-4143
zik0@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
Andersen, Lauren, (404) 639-4442, wrh5@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

Storage & 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 No special requirements

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries, if possible. If weekend delivery is necessary, please contact laboratory upon shipment.

Methodology Real Time PCR, Culture Isolation, Time-Resolved Fluorescence

Turnaround Time

Interferences & Limitations Dependent on sample time

Additional Information Turnaround time is dependent on test and sample type.

CDC Points of Contact Jennifer Thomas
(404) 639-4259
fsu8@cdc.gov
Lauren Andersen
(404) 639-4442
wrh5@cdc.gov

Test Order
Lymphocytic Choriomeningitis (LCM) Identification
CDC-10345

Synonym(s) LCM, *Arenavirus*

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood, serum, and CSF

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Lymphocytic Choriomeningitis (LCM) Serology
CDC-10346

Synonym(s) LCM, *Arenavirus*

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing CSF, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Machupo Identification
CDC-10347

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

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Machupo Serology
CDC-10348

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

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Malaria Molecular Identification
CDC-10480

Synonym(s) *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium malariae*, *Plasmodium ovale*, parasite

Pre-Approval Needed None

Supplemental Information Required Please include the blood smear slides in the shipment

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Blood; Please include the blood smear slides in the shipment

Minimum Volume Required 200 uL

Storage & 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 require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen on wet ice (cold pack) as an etiologic agent.

Methodology Conventional PCR, Real-Time PCR

Turnaround Time 14 Days

Interferences & Limitations None

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
Malaria Serology
CDC-10464

Synonym(s) *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium malariae*, parasite

Pre-Approval Needed None

Supplemental Information Required Travel history REQUIRED, 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Indirect Fluorescent Antibody Assay, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

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

Test Order
Malaria Surveillance
CDC-10235

Synonym(s) Malaria Drug Resistance typing, parasite

Pre-Approval Needed None

Supplemental Information Required Supplemental form not needed

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Blood collected in EDTA tubes

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Blood should be collected in EDTA tubes

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Do not ship specimen frozen.

Methodology Polymerase Chain Reaction (PCR), DNA Sequencing, In-vitro culture

Turnaround Time

Interferences & Limitations None

Additional Information Turnaround time is determined by the surveillance project, no individual patient reports are issued

Please provide information on travel history and history of anti-malarial usage

CDC Points of Contact Venkatachalam Udhayakumar
(404) 718-4418
vxu0@cdc.gov
Naomi Lucchi
(404) 718-4406
nlucchi@cdc.gov

Test Order
Malaria: Morphologic Identification
CDC-10520

Synonym(s) Parasitology, Malaria parasite identification, Blood parasite

Pre-Approval Needed None

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

Storage & 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 patient identifiers on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries
Shipping is specimen specific and available on consultation

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
Marburg Identification
CDC-10349

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Marburg Serology
CDC-10350

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order

Measles and Rubella Detection (PCR) and Genotyping

CDC-10243

Synonym(s)	Measles, Rubeola, Rubella, German measles; three day measles
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Throat swab in viral medium, Nasopharyngeal aspirate or swab, urine, cataracts, lens aspirate, oral fluid, cerebrospinal fluid (CSF), dry blood spots, and tissue samples
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Measles: http://www.cdc.gov/measles/lab-tools/ Rubella: http://www.cdc.gov/rubella/lab/index.html Also see: http://www.cdc.gov/vaccines/pubs/surv-manual/index.html http://www.cdc.gov/measles/lab-tools/index.html
Transport Medium	Viral transport medium for swabs and appropriate culture medium. Make sure tubes are all in leak proof containers.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Clearly label specimen type.
Shipping Instructions which Include Specimen Handling Requirements	The laboratory requests that the sender contacts the laboratory by email or phone before shipping. For shipping address see: http://www.cdc.gov/measles/lab-tools/ Ship specimen Monday –Thursday overnight to avoid weekend deliveries Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	Real time RT-PCR, Genotyping by nucleic acid sequencing, Template production by RT-PCR, Viral culture
Turnaround Time	7 Days
Interferences & Limitations	Measles: http://www.cdc.gov/measles/lab-tools/ Rubella: http://www.cdc.gov/rubella/lab/index.html Also see, http://www.cdc.gov/vaccines/pubs/surv-manual/index.html http://www.cdc.gov/measles/lab-tools/index.html
Additional Information	Please include vaccination history, age, date of symptom onset and sample collection
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Joe Icenogle (404) 639-4557 jci1@cdc.gov

Test Order
Measles and Rubella Serology
CDC-10247

Synonym(s) Measles, Rubeola, Rubella, German measles, three day measles

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and others upon consultation with laboratory

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Clearly label specimen type.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries. Refrigerated or frozen specimen should be shipped on cold packs. laboratory will instruct on how to ship for other specimen types.

Methodology Commercial capture IgM, Commercial indirect IgG

Turnaround Time 7 Days

Interferences & Limitations IgM positive may not occur until 5 days post-rash onset

Additional Information IgM and IgG assays are qualitative assays. For outbreaks or immuno-compromised patients please contact laboratory prior to shipment.

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Joe Icenogle
(404) 639-4557
jci1@cdc.gov

Test Order

Measles Avidity

CDC-10248

Synonym(s) None

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

Supplemental Information Required See additional information

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 300 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated, not frozen

Transport Medium Not Applicable

Specimen Labeling Provide a unique identifier on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology Measles avidity

Turnaround Time 30 Days

Interferences & Limitations None

Additional Information <http://www.cdc.gov/vaccines/pubs/surv-manual/index.html>

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. Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with measles vaccine.

Samples must be measles IgG positive for testing

The following information is required for result interpretation:

- Records of vaccination status, with the number of doses and dates of administration
- Date of birth
- Date of rash onset
- Date of sample collection
- Clinical symptoms.

The Viral Vaccine Preventable Diseases Branch reserves the right to determine if testing for measles avidity could be beneficial.

CDC Points of Contact Sara Mercader
(404) 639-4568
sjm7@cdc.gov

Test Order
Measles Avidity
CDC-10248

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

Test Order

Measles Detection (PCR) 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	Throat swab in viral transport medium, nasopharyngeal aspirate or swab, urine, oral fluid, cerebrospinal fluid (CSF), dry blood spots, and tissue samples
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	See: http://www.cdc.gov/measles/lab-tools/rt-pcr.html for detailed information on storage and preservation of specimen
Transport Medium	Viral transport medium for swabs. Make sure tubes are all leak proof containers.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Clearly label specimen type.
Shipping Instructions which Include Specimen Handling Requirements	The laboratory requests that the sender contacts the laboratory by email or phone before shipping See instructions and shipping address: http://www.cdc.gov/measles/lab-tools/ Ship specimen Monday –Thursday overnight to avoid weekend deliveries Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	Viral culture, Genotyping by Nucleic acid sequencing, Real time RT-PCR, Template production by RT-PCR
Turnaround Time	7 Days
Interferences & Limitations	See: http://www.cdc.gov/measles/lab-tools/ for information on the interferences and limitations of this test
Additional Information	Please include vaccination history, age, date of rash onset and date of sample collection For additional information, please see measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Rebecca McNall (404) 639-4541 dgo2@cdc.gov

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

Synonym(s) 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 See Supplemental Form

Supplemental Form <http://www.cdc.gov/vaccines/pubs/surv-manual/index.html>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 300 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated, not frozen

Transport Medium Not Applicable

Specimen Labeling Provide a unique identifier on the specimen container and the test requisition

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology Neutralization assay - quantitative serological assay

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Sun Sowers
(404) 639-1360
sib9@cdc.gov

Test Order
Measles Serology
CDC-10244

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 Serum and others upon consultation

Minimum Volume Required 300 uL (50 uL)

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries

Refrigerated specimen should be shipped on cold packs
Laboratory will instruct on how to ship for other specimen types

Methodology CDC capture IgM, Commercial indirect IgG

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

For outbreaks or immuno-compromised patients please contact laboratory prior to shipment

Please include vaccination history, age, date of onset and sample collection

CDC Points of Contact Carole Hickman
(404) 639-3339
cjh3@cdc.gov
Nobia Williams
(404) 639-1049
new8@cdc.gov

Test Order
Measles Special Study
CDC-10251

Synonym(s) Rubeola

Pre-Approval Needed Rota, Paul, (404) 639-4181, par1@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

Storage & 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 Paul Rota
(404) 639-4181
par1@cdc.gov

Test Order
MERS-CoV Molecular Detection
CDC-10488

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

Pre-Approval Needed 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements 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

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
xa19@cdc.gov
Shifaq Kamili

Test Order
MERS-CoV Molecular Detection
CDC-10488

(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
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	200µL
Storage & 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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	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 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

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 See Additional Information

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship unpreserved specimen on wet ice (cold pack) as an etiologic agent. Preserved/fixed specimens can be shipped at room temperature.

Methodology Conventional PCR

Turnaround Time 14 Days

Interferences & Limitations Stool specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.

Additional Information Minimum Volume Required: 0.5 g of stool or 1ml of urine or 25 mg tissue

CDC Points of Contact Yvonne Qvarnstrom
(404) 718-4123
bvp2@cdc.gov
Marcos de Almeida
(404) 718-4126
bnz0@cdc.gov

Test Order
Moraxella species ID
CDC-10140

Synonym(s) *Moraxella*, GNDC

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
MPIR – Study
CDC-10428

Synonym(s) Anthrax TNA

Pre-Approval Needed Quinn, Conrad, (404) 639-2858, caq7@cdc.gov
Schiffer, Jarad, (404) 639-0894, aku3@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 uL

Storage & 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 patient identifiers on the specimen container and the test requisition including patient ID, date of collection, submitter information, and specimen ID number.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Contact laboratory prior to shipment.

Ship paired sera together and all frozen specimen should be shipped on dry ice

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 None

CDC Points of Contact Conrad Quinn
(404) 639-2858
caq7@cdc.gov
Jarad Schiffer
(404) 639-0894
aku3@cdc.gov

Test Order

Mumps Detection (PCR) 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 swab, nasal swab, throat swab, urine, oral fluid and cerebrospinal fluid (CSF)
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	See: http://www.cdc.gov/mumps/lab/specimen-collect.html for detailed information on the storage and preservation of the specimen
Transport Medium	http://www.cdc.gov/mumps/lab/
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Clearly label specimen type.
Shipping Instructions which Include Specimen Handling Requirements	The laboratory requests that the sender contacts the laboratory by email or phone before shipping See shipping instructions: http://www.cdc.gov/mumps/lab/ Ship specimen Monday –Thursday overnight to avoid weekend deliveries Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	Real time RT-PCR, Template production by RT-PCR, Viral culture, Genotyping by Nucleic acid sequencing
Turnaround Time	7 Days
Interferences & Limitations	See: http://www.cdc.gov/mumps/lab/ for information on the interferences and limitations of this test
Additional Information	Please include vaccination history, age, date of symptom onset and date of sample collection For additional information about mumps surveillance please see: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt09-mumps.html
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Rebecca McNall (404) 639-4541 dgo2@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

Minimum Volume Required 300 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated, not frozen.

Transport Medium Not Applicable

Specimen Labeling Provide a unique identifier on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology Neutralization assay - quantitative serological assay

Turnaround Time 4 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Sun Sowers
(404) 639-1360
sib9@cdc.gov
Carole Hickman
(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 uL

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

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
(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

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

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

Test Order

Mycobacterium – Non-tuberculosis Mycobacteria Identification

CDC-10225

Synonym(s) Non-TB Mycobacteria, Mycobacteria

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 Isolates demonstrated to not be part of the *Mycobacterium tuberculosis* complex
 Isolates from the following specimens will be accepted for testing:
 Sterile sites (e.g., blood, CSF, body fluids)
 Abscess, exudate or skin lesion
 Wounds or surgical sites (see Additional Information)
 BAL/ bronch wash
 Sputum (see Additional Information)
 Gastric lavage (pediatric)
 Animal and environmental isolates with prior consultation

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen at room temperature

Transport Medium Lowenstein-Jensen or Middlebrook 7H10/7H11 agar

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries at room temperature as an etiologic agent.

Methodology 16S Sequencing, MALDI-TOF, Phenotypic Testing

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information 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
 Dlonsway@cdc.gov
 Nadege Toney
 (404) 639-1282
 ngc6@cdc.gov

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

Synonym(s) MTB DST, TB, Tuberculosis

Pre-Approval Needed None

Supplemental Information Required None

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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Broth should not be shipped frozen.

Methodology Agar proportion, Pyrazinamide (PZA) by MGIT 960

Turnaround Time 40 Days

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

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

Synonym(s) TB, Tuberculosis

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate

Minimum Volume Required Not Applicable

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries.

Methodology Genetic based testing

Turnaround Time 14 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Beverly Metchock
(404) 639-2455
TBLab@cdc.gov

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

Synonym(s) TB, Tuberculosis

Pre-Approval Needed None

**Supplemental Information
 Required** None

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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Broth should not be shipped frozen.

Methodology Genetic based testing, Pyrazinamide (PZA) by MGIT 960, Agar Proportion

Turnaround Time 40 Days

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

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

Synonym(s) TB, Tuberculosis

Pre-Approval Needed None

**Supplemental Information
 Required** None

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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Broth should not be shipped frozen.

Methodology Pyrazinamide (PZA) by MGIT 960, Genetic based testing

Turnaround Time 32 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Beverly Metchock
 (404) 639-2455
 TBLab@cdc.gov

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

Synonym(s) MDDR, TB, Tuberculosis

Pre-Approval Needed Metchock, Beverly, (404) 639-2455, TBLab@cdc.gov
Driscoll, Jeff, (404) 639-2455, TBLab@cdc.gov

**Supplemental Information
Required** See Supplemental Form

Supplemental Form <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)

**Storage & 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 patient identifiers on the specimen container and the test requisition.

**Shipping Instructions which
Include Specimen Handling
Requirements** Ship Monday – Thursday, overnight to avoid weekend deliveries. Sediments and broth cultures should not be shipped frozen.

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.

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 Beverly Metchock
(404) 639-2455
TBLab@cdc.gov
Jeff Driscoll
(404) 639-2455
TBLab@cdc.gov

Test Order
***Mycobacterium* TB Complex – Pyrazinamide Susceptibility Testing**
CDC-10189

Synonym(s) PZA DST, TB, Tuberculosis

Pre-Approval Needed None

Supplemental Information Required None

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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Broth should not be shipped frozen.

Methodology Pyrazinamide (PZA) by MGIT 960

Turnaround Time 30 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact Beverly Metchock
(404) 639-2455
TBLab@cdc.gov

Test Order
Mycobacterium TB Complex – Special Study
CDC-10191

Synonym(s) None

Pre-Approval Needed Metchock, Beverly, (404) 639-2455, TBLab@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

Storage & 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 Beverly Metchock
(404) 639-2455
TBLab@cdc.gov

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

Synonym(s) Culture, DST, AST, MTB, MTB complex, TB, MDR TB, ID, Tuberculosis

Pre-Approval Needed Campbell, Patricia, (404) 718-1440, igg5@cdc.gov
DeGruy, Kyle, (404) 639-0875, gsz4@cdc.gov

Supplemental Information Required Supplemental forms will be provided upon consultation
Fill out the ILB-160-F08C TB Requisition Form

CDC Form 0.753:
Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Suspected *Mycobacterium tuberculosis* Complex isolates in Middlebrook 7H9 liquid media or MGIT (7H9) broth inoculated with culture isolate

Minimum Volume Required 0.3 mL

Storage & Preservation of Specimen Prior to Shipping *Mycobacterium tuberculosis* Complex in Sterile 2.0 mL screw cap cryovial with O-ring. Specimen should be kept frozen at -70°C indefinitely, but specimen may be stored at -20°C for three months.

Transport Medium Inoculate Middlebrook 7H9 or MGIT (7H9) liquid media with culture isolate of a suspected *Mycobacterium tuberculosis* complex microorganism. Transfer culture material to a sterile 2.0 ml screw cap cryovial with o-ring for transport.

Specimen Labeling All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.

Shipping Instructions which Include Specimen Handling Requirements Keep specimen frozen at -70°C or lower by using dry ice.

Refer to *Mycobacterium tuberculosis* Isolate Preparation & Shipments on page 7 of International Laboratory Branch Test Directory or contact laboratory prior to submission.

Methodology Phenotypic and genotypic ID with reflex to drug susceptibility

Turnaround Time 150 Days

Interferences & Limitations Phenotypic DST will not be performed on nonviable, contaminated or mixed isolates.

Specimens may be rejected if improperly labeled, submission of missing or discrepant documentation, insufficient volume for testing, or leaking specimens.

Additional Information Turnaround time for batches with less than 100 specimens is within 150 days. Contact Patricia Campbell, igg5@cdc.gov for turnaround times for batches with greater than 100 specimens.

Phenotypic drug susceptibility testing (DST) on *Mycobacterium tuberculosis* complex for first line drugs is performed using the BD BACTEC MGIT 960 system

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

for streptomycin, isoniazid, rifampicin, and ethambutol. Phenotypic DST is performed for second line drugs using the modified agar proportion method (Middlebrook 7H10).

Genotypic DST for *Mycobacterium tuberculosis* is performed using Hain Lifescience GenoType MTBDRplus, Hain Lifescience GenoType MTBDRsl and Cepheid Xpert MTB/RIF assays.

CDC Points of Contact Patricia Campbell
(404) 718-1440
igg5@cdc.gov
Kyle DeGruy
(404) 639-0875
gsz4@cdc.gov

Zilma Rey
(404) 639-2345
yzr0@cdc.gov

Test Order
Mycobacterium TB Complex (International Only) Special Study
 CDC-10353

Synonym(s) None

Pre-Approval Needed Alexander, Heather, (404) 639-5331, drz5@cdc.gov
 DeGruy, Kyle, (404) 639-0875, gsz4@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

Storage & Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.

Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.

Shipping Instructions which Include Specimen Handling Requirements To be determined

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information

CDC Points of Contact Heather Alexander
 (404) 639-5331
 drz5@cdc.gov
 Kyle DeGruy
 (404) 639-0875
 gsz4@cdc.gov

Zilma Rey
 (404) 639-2345
 yzr0@cdc.gov

Test Order
***Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping**
CDC-10513

Synonym(s)	Atypical pneumonia, Community Acquired Pneumonia (CAP), macrolide resistance, Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, any lower respiratory tract specimen (ie. bronchoalveolar lavage (BAL)), sputum, tissue, cerebrospinal fluid (CSF), isolate, and purified nucleic acid. Upon consultation with CDC laboratory points of contact, other specimen types may be acceptable.
Minimum Volume Required	Contingent upon specimen type. Please consult with CDC laboratory point of contact.
Storage & Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated if shipped within 72 hours of collection; otherwise specimen should be frozen. Store swabs in universal transport medium.
Transport Medium	Universal transport medium (swabs)
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries. Refrigerated specimens should be packed with cold packs. Frozen specimens should be packed with dry ice.
Methodology	Real-time PCR with high-resolution melt (HRM)
Turnaround Time	7 Days
Interferences & Limitations	Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	Sequencing may also be performed. All specimens are tested for the presence of <i>M. pneumoniae</i> using test order Respiratory Agents (Chlamydia, Legionella, Mycoplasma) Molecular Detection (CDC-10157).
CDC Points of Contact	Jonas Winchell (404) 639-4921 jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

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

Synonym(s)	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	Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, and any lower respiratory tract specimen including bronchoalveolar lavage (BAL) and sputum; tissue, cerebral spinal fluid, isolates and purified nucleic acid; Others upon consultation with laboratory.
Minimum Volume Required	Contingent upon specimen type. Please call for consultation
Storage & Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen. Store swabs in universal transport medium.
Transport Medium	Universal transport medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries Refrigerated specimen should be sent on ice packs Frozen specimen should be sent on dry ice
Methodology	Real Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	All specimens are tested as part of a multiplex qPCR assay for detection of <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , and <i>Legionella</i> species (CDC-10157). Specimens in which <i>M. pneumoniae</i> is detected will be subjected to <i>M. pneumoniae</i> Macrolide Susceptibility Genotyping (CDC-10513).
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

Test Order
Mycoplasma species Study
CDC-10156

Synonym(s) None

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 To be determined

Minimum Volume Required To be determined

Storage & 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 Jonas Winchell
(404) 639-4921
jwinchell@cdc.gov
Maureen Diaz
(404) 639-4534
mdiaz1@cdc.gov

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

Synonym(s) Free-living ameba, 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

Storage & 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 patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Please contact laboratory prior to shipping any specimen and include unit 53 on the outside of package. 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. Please send the shipment tracking number on the day of shipment by e-mail to the CDC Point of Contacts (see below).

Methodology Real-Time PCR

Turnaround Time 7 Days

Interferences & Limitations Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred over the formalin-fixed specimens.

Additional Information None

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

Test Order
NARMS Susceptibility Testing
CDC-10107

Synonym(s) National Antimicrobial Resistance Monitoring System, NARMS surveillance

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 <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 Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Please refer to guidance for specific organism

Specimen Labeling State or local public health laboratory number

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries.
Please refer to guidance for specific organism.

Methodology Broth Microdilution Antimicrobial Susceptibility (AST), E-Test Susceptibility Testing

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information The turn around time depends on the nature of subtyping performed; and, results are typically reported directly to the surveillance databases.

CDC Points of Contact Jean Whichard
(404) 639-2000
zyr3@cdc.gov
Jason Foster
(404) 639-4948
gux8@cdc.gov

Test Order
***Neisseria* (STD) Identification**
CDC-10101

Synonym(s) *Neisseria*, GC

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Genital, pharyngeal, and/or rectal swabs. In addition, bacterial culture or isolate on appropriate culture media

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Specimen needs to be stored in a manner that will maintain viability of gonorrhea

Transport Medium Any acceptable medium for gonorrhea transport

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.

Methodology Phenotypic identification

Turnaround Time 1 Week

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 John Papp
(404) 639-3785
jwp6@cdc.gov
Kevin Pettus
(404) 639-4338
kbp9@cdc.gov

Test Order
Neisseria gonorrhoeae Study
CDC-10103

Synonym(s) None

Pre-Approval Needed Papp, John, (404) 639-3785, jwp6@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 To be determined

Minimum Volume Required To be determined

Storage & 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 John Papp
(404) 639-3785
jwp6@cdc.gov
Kevin Pettus
(404) 639-4338
kbp9@cdc.gov

Test Order
Neisseria gonorrhoeae Susceptibility Testing
 CDC-10102

Synonym(s) *Neisseria* AST, GC Susceptibility

Pre-Approval Needed None

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Genital, pharyngeal, and/or rectal swabs. In addition, bacterial culture or isolate on appropriate growth media

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Specimen needs to be stored in a manner that will maintain viability of gonorrhea

Transport Medium Any acceptable medium for gonorrhea transport

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.

Methodology Agar Plate Dilution, E-test, Disk Diffusion

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 John Papp
 (404) 639-3785
 jwp6@cdc.gov
 Kevin Pettus
 (404) 639-4338
 kbp9@cdc.gov

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

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

Pre-Approval Needed None

Supplemental Information Required If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or tests used column of submission form.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Pure culture isolate, frozen stock, primary specimen such as CSF, whole blood, serum, and other sterile site specimen types upon consultation.

Minimum Volume Required 0.25 mL

Storage & 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% CO₂ 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 Tests subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries and enclose a shipping spreadsheet or submission form in all shipments.

Frozen specimens and stocks should be shipped on dry ice. Whenever possible, email the shipping spreadsheet and tracking number in advance (especially for suspected outbreak specimens or isolates).

Methodology Slide Agglutination Serogrouping, Real-time PCR

Turnaround Time 30 Days

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 testing completed as needed.
 For research purposes only, molecular characterization of *N. meningitidis* isolates will be completed by whole genome sequencing.
 Provides or confirms serogroup for potential outbreak specimens or isolates.

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

Test Order
Neisseria meningitidis Study
 CDC-10220

Synonym(s) Nm Surveillance

Pre-Approval Needed , , ,

Supplemental Information Required If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or tests used column of submission form.

Supplemental Form

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 N/A

Storage & 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% CO₂ and then stored and shipped at ambient temperature.

Transport Medium Chocolate agar slants or frozen stocks.

Specimen Labeling Tests require at least one patient identifier on the specimen container and the test requisition. Label specimens with the state ID & accession number, and if applicable surveillance (ABCs, Enhanced Surveillance, or GISP) ID.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries.

Frozen stocks and specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and email spreadsheet prior to shipment.

Methodology Isolates: Whole genome sequencing (WGS), Primary specimens: rt-PCR and when applicable, multilocus sequence typing (MLST)

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. Primary specimens with particularly low volume or bacterial DNA may not amplify in MLST PCR reactions necessary for multilocus sequence typing and finotyping.

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

Test Order
Neisseria species (Not GC or *meningococcus*) ID
 CDC-10139

Synonym(s) *Neisseria*, GNDC

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; Consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
 Anne Whitney
 (404) 639-1374
 amw0@cdc.gov

Test Order
Nipah Virus Identification
CDC-10354

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Nipah Virus Serology
CDC-10355

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

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

Synonym(s) None

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639–1374
amw0@cdc.gov

Test Order
Nocardia species ID and AST
CDC-10151

Synonym(s) None

Pre-Approval Needed None

Supplemental Information Required Please notify laboratory prior to 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; consultation required for other sample/specimen types

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated if unable to ship immediately

Transport Medium Suitable agar slant medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight to avoid weekend deliveries

Methodology Primary Culture based on specimen type, MALDI–TOF, 16S sequence based identification, AST by broth microdilution

Turnaround Time 3 Weeks

Interferences & Limitations None

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
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
Norovirus Genotyping
CDC-10356

Synonym(s) Norovirus

Pre-Approval Needed Vinje, Jan, (404) 639-3721, ahx8@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

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

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

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
CDC-10357

Synonym(s) Norovirus

Pre-Approval Needed Vinje, Jan, (404) 639-3721, ahx8@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

Storage & Preservation of Specimen Prior to Shipping Specimen should be stored at 2°-8°C

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 2 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

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

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

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples only, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA) or heparin treated tubes preferred; serum; fresh tissue biopsy; swab

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium For tissue, place in sterile specimen cup with gauze pad moistened with sterile saline

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

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.

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
-acute (during active stage of illness)
-convalescent (2-4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Orientia Special Study
CDC-10500

Synonym(s) Scrub typhus

Pre-Approval Needed Kato, Cecilia, (404) 639-0152, ckato@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, Other

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Cecilia Kato
(404) 639-0152
ckato@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Paragonimiasis Serology
CDC-10465

Synonym(s) *Paragonimus westermani*; *Paragonimus kellicotti*, parasite

Pre-Approval Needed None

Supplemental Information Required Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and previous test results.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum or plasma

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology Immunoblot, Western Blot, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Parasite – Morphologic Identification (O+P)
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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries
Shipping is specimen specific and available on consultation

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
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

Storage & 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 Isabel McAuliffe
(404) 718-4100
ibm4@cdc.gov
Yvonne Qvarnstrom
(404) 718-4123
bvp2@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	Not Applicable
Storage & 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 patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	<p>Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.</p> <p>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>
Methodology	Molecular techniques
Turnaround Time	14 Days
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	<p>Minimum volume for cell culture is 0.5–1 mL, for CSF is 60 uL, and for fresh frozen tissues is 2 mm².</p> <p>Stool: Stool may be collected within 14 days of symptom onset. Collect 10–20 g of stool in a clean, dry, leak-proof container.</p>

Test Order
Parechovirus Detection and Identification
CDC-10362

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 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs
Frozen specimen should be shipped on dry ice

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
(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 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

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
(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, biopsy, formalin fixed tissues, FFPE, pathology, paraffin blocks, histopathology, electron microscopy, immunohistochemistry, PCR

Pre-Approval Needed Infectious Diseases Pathology Branch, , , pathology@cdc.gov

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

- The full name, title, complete mailing address, e-mail address, telephone, and fax numbers of the submitter. This will be the same person to whom the final pathology report is addressed.

- An electronically completed CDC Form 50.34 (one copy per case)

- A cover letter 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); images (clinical and/or gross autopsy photos).

Please include a key to the identification of the blocks

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Paraffin-embedded tissue blocks, formalin-fixed tissues, unstained glass slides, electron microscopy grids or blocks. 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 testing per IDPB s CLIA approved protocols.

More specific guidelines regarding tissue samples and submission can be found on the IDPB website:

<http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html>

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping **Consultation with IDPB is required prior to specimen submission to determine appropriate storage and preservation conditions.** In general, wet tissues should be submitted in 10% neutral buffered formalin after adequate fixation; wet tissues and paraffin-embedded tissues should be preserved at ambient temperature; unstained slides should be sectioned at 3-5 microns; specimens submitted for electron microscopy should be fixed in glutaraldehyde and held in phosphate buffer.

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 All submitted specimens should be labeled with at least two identifiers. The tissues contained within paraffin-embedded blocks should be clearly indicated on submitted paperwork.

Shipping Instructions which Include Specimen Handling Requirements Ship specimens overnight from Monday-Thursday. For urgent cases, please contact the Infectious Diseases Pathology Branch immediately. During hot weather, tissue blocks should be shipped on ice packs to prevent the melting of paraffin.

Test Order
Pathologic Evaluation of Tissues for Possible Infectious Etiologies
CDC-10365

The full name, title, complete mailing address, e-mail address, telephone and fax numbers are required for each submitted specimen. This will be to whom the final pathology report is addressed.

Methodology Histopathology (H&E-stained sections), Cytochemistry (special stains), Immunohistochemistry (IHC), Polymerase Chain Reaction (PCR) and Sequencing, Electron Microscopy (EM), Tissue Culture, Nucleic Acid Extraction for transfer to other branches

Turnaround Time 8 Weeks

Interferences & Limitations Prolonged fixation (>2 weeks) may interfere with some immunohistochemical and molecular diagnostic assays

Additional Information More specific guidelines regarding tissue sampling and submission can be found on the IDPB website:

<http://www.cdc.gov/nceid/dhcpp/idpb/specimen-submission/index.html>

Turnaround time varies depending upon the complexity of each case ranging from 2-8 weeks.

Digital images can be provided to assist in evaluation and guide testing.

CDC Points of Contact Infectious Diseases Pathology Branch
(404) 639-3132
pathology@cdc.gov

Test Order
Pathology Special Study
CDC-10373

Synonym(s) None

Pre-Approval Needed Infectious Diseases Pathology Branch, , , pathology@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

Storage & 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 To be determined

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Infectious Diseases Pathology Branch
(404) 639-3132
pathology@cdc.gov

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
Storage & 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 2mL 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 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 patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent. 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.
Methodology	Molecular techniques
Turnaround Time	14 Days
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 mm ² .

Test Order
**Picornavirus Detection and Identification (not Hepatitis A, not
Rhinovirus)**
CDC-10374

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 To be determined

Minimum Volume Required To be determined

Storage & 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 Alan Nix
(404) 639-1689
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 50 uL (tissue culture)

Storage & Preservation of Specimen Prior to Shipping Keep specimen refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.

Methodology Molecular techniques, Cell culture

Turnaround Time 21 Days

Interferences & Limitations None

Additional Information If case investigation form is readily available, please submit with specimen

CDC Points of Contact
Cara Burns
(404) 639-5499
zqd1@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@cdc.gov

Test Order
Polio Serology
CDC-10377

Synonym(s) Neutralization assay, NT, MNT

Pre-Approval Needed Weldon, William, (404) 639-5485, wiw4@cdc.gov
Oberste, Steve, (404) 639-5497, mbo2@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 200 uL

Storage & 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 Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice as an etiologic agent.

Methodology Neutralization assay

Turnaround Time 4 Weeks

Interferences & Limitations Red blood cell hemolysis will adversely affect test results

Additional Information None

CDC Points of Contact William Weldon
(404) 639-5485
wiw4@cdc.gov
Steve Oberste
(404) 639-5497
mbo2@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 To be determined

Minimum Volume Required To be determined

Storage & Preservation of Specimen Prior to Shipping To be determined

Transport Medium To be determined

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

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 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) None

Pre-Approval Needed Poxvirus Inquiry Line, , (404) 639-4129,

Supplemental Information Required **Clinical consultation with the Poxvirus Program is required prior to specimen shipment to determine testing urgency. A supplemental form will be supplied after initial consultation.**

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Lesion fluid and/or material: vesicle/pustule skin or fluid, scab, crust, etc. Collection method: fresh or frozen, swab, biopsy, touch prep slides, formalin fixed, paraffin block. Swabs should be made of nylon, polyester, or Dacron material.

Cerebrospinal fluid (CSF) and serum should be collected for patients with encephalitis.

Minimum Volume Required Not applicable

Storage & Preservation of Specimen Prior to Shipping All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container.

Transport Medium None

Specimen Labeling Test requires two patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (name, date of birth/age, etc.), provide specimen type, date of collection and body location.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology Real–Time PCR, Standard PCR

Turnaround Time 5 Days

Interferences & Limitations Swabs intended for the collection and transport of bacterial specimens should not be used. Cotton swabs may cause PCR inhibition and should not be used. Do not add viral transport media to swab specimens as this will dilute any viral DNA present.

Additional Information Can detect the following poxviruses with real–time PCR: variola, monkeypox, vaccinia, cowpox, orf, psuedocowpox, bovine papular stomatitis, sealpox, molluscum contagiosum, and tanapox virus. Can detect new poxviruses and the following genera with standard PCR: Orthopoxvirus, Parapoxvirus, Molluscipoxvirus, Yatapoxvirus, Suipoxvirus, Capripoxvirus, and Leporipoxvirus.

Formalin fixed material is first tested by the Infectious Disease Pathology Branch (IDPB) and will only identify poxviruses to the genus level. DNA may be extracted from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non–frozen tissue is preferred by IDPB.

CDC Points of Contact Poxvirus Inquiry Line
(404) 639-4129

Test Order
Poxvirus Serology
CDC-10516

Synonym(s) None

Pre-Approval Needed Poxvirus Inquiry Line, , (404) 639-4129,

Supplemental Information Required Clinical consultation with the Poxvirus Program is required prior to specimen shipment to determine testing urgency. A supplemental form will be supplied after initial consultation.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum; Cerebrospinal fluid (CSF) and serum should be collected for patients with encephalitis.

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping All specimens should be stored at 4°C until shipment. Serum should be collected in a venous blood tube containing a clot activator and/or gel. Blood tubes should be spun prior to shipment or an aliquot of the collected serum can be shipped.

Transport Medium Not Applicable

Specimen Labeling Test requires two patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (name, date of birth/age, etc.), provide specimen type, tube collection type, and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs

Methodology ELISA

Turnaround Time 5 Days

Interferences & Limitations Collection in either heparin and/or EDTA tubes will interfere with results. Antibody detection is dependent upon the number of days post symptom or rash onset. A previous history of smallpox vaccination may affect result interpretation.

Additional Information ELISA will detect an antibody response in persons infected with variola, monkeypox, vaccinia, or cowpox virus.

CDC Points of Contact Poxvirus Inquiry Line
(404) 639-4129

Test Order
Puumala Serology
CDC-10391

Synonym(s) Hanta, HFRS, Nephropathia epidemica

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Rabies Antemortem Human Testing
CDC-10392

Synonym(s) None

Pre-Approval Needed Rabies Duty Officer, , (404) 639-1050,

Supplemental Information Required Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted

Supplemental Form <http://www.cdc.gov/rabies/pdf/rorform.pdf>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing All four of the following are required for testing: serum, CSF, nuchal (skin) biopsy, and saliva

Minimum Volume Required 500 uL (serum, CSF, saliva)

Storage & Preservation of Specimen Prior to Shipping Keep all samples stored at -80°C and ship on dry ice. Serum and CSF can be refrigerated before shipping. Please see the supplemental link for specific specimen storage and preservation.

Transport Medium Saliva and Nuchal (skin) biopsy should not be put in a transport medium

Specimen Labeling Two patient identifiers on the specimen container and the test requisition, sample type and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Form 50.34 is required for each of the 4 samples (serum, CSF, skin biopsy, and saliva)

Methodology IgG by IFA (Serum and CSF), IgM by IFA (Serum and CSF), Viral Neutralizing Antibodies by RFFIT (Serum and CSF), DFA (Nuchal (skin) biopsy), RT-PCR (Nuchal (skin) biopsy), RT-PCR (Saliva), Sequencing

Turnaround Time 5 Days

Interferences & Limitations 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 Sequencing will only be performed if the RT-PCR test is positive. Nuchal (skin) biopsy has to be a full punch (5-6 millimeters). If testing needs to be repeated results may take up to 7 days.

CDC Points of Contact Rabie Duty Officer
(404) 639-1050

Test Order
Rabies Antibody – Pre/Post–exposure Prophylaxis
CDC–10393

Synonym(s) Serology, Immunization status, Rabies titer

Pre-Approval Needed Rabies Duty Officer, , (404) 639–1050,

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/rabies/pdf/rorform.pdf>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 500 uL

Storage & Preservation of Specimen Prior to Shipping Specimen can be kept refrigerated but prefer frozen

Transport Medium Not Applicable

Specimen Labeling Two patient identifiers on the specimen container and the test requisition, sample type and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Viral Neutralizing Antibodies RFFIT

Turnaround Time 10 Days

Interferences & Limitations Hemolyzed samples interfere with test results

Additional Information If testing needs to be repeated results may take up to 7 days

CDC Points of Contact Rabies Duty Officer
(404) 639–1050

Test Order
Rabies Confirmatory Testing (Animal)
CDC-10394

Synonym(s) Rabies DFA

Pre-Approval Needed Rabies Duty Officer, , (404) 639-1050,

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From 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). Other specimens may be submitted upon consultation with Rabies Duty Officer.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Stored at -80°C and should be kept on dry ice

Transport Medium Not Applicable

Specimen Labeling One patient identifier on the specimen container and the test requisition, sample type and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package

Frozen specimen should be shipped on dry ice

Methodology DFA for rabies virus antigen, Direct Rapid Immunohistochemistry test (DRIT), Real Time RT-PCR, Virus Isolation, Antigenic Typing, Sequence Analysis

Turnaround Time 3 Days

Interferences & Limitations Test is limited by decomposed tissues due to denaturation of viral proteins

Additional Information May take up longer if repeat testing and additional procedures are required to rule-out rabies

CDC Points of Contact Rabies Duty Officers
(404) 639-1050

Test Order
Rabies Confirmatory Testing (Human)
CDC-10395

Synonym(s) None

Pre-Approval Needed Rabies Duty Officer, , (404) 639-1050,

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/rabies/pdf/rorform.pdf>

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing All four of the following are required for antemortem testing: serum, CSF, Nuchal (skin) biopsy, and saliva. Fresh-frozen brain tissues for postmortem testing: full cross section of brain stem and cerebellum (vermis right and left lateral lobes).

Minimum Volume Required 500 uL (serum, CSF, saliva)

Storage & Preservation of Specimen Prior to Shipping Keep all samples stored at -80°C and ship on dry ice. Serum and CSF can be refrigerated before shipping. Please see the supplemental link for specific specimen storage and preservation.

Transport Medium Saliva and nuchal (skin) biopsy should not be put in a transport medium

Specimen Labeling Two patient identifiers on the specimen container and the test requisition, sample type and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.

Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on cold packs

Methodology IgM & IgG by IFA (Serum & CSF), DFA for rabies virus antigen (Nuchal skin biopsy), Antigenic Typing (brain), RT-PCR, Sequence Analysis, Isolation, Direct Rapid Immunohistochemistry test (DRIT), IHC, Viral Neutralizing Antibodies by RFFIT (Serum and CSF)

Turnaround Time 3 Days

Interferences & Limitations Saliva and CSF specimen should be free of blood because blood may interfere with test results due to the inhibitors present in blood. Test is limited by decomposed tissues due to denaturation of viral proteins.

Additional Information Sequencing will only be performed if the RT-PCR test is positive. Nuchal (skin) biopsy has to be a full punch (5-6 millimeters). If testing needs to be repeated results may take up to 7 days.

CDC Points of Contact Rabies Duty Officer
 (404) 639-1050

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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, Immunohistochemistry (IHC),, Other
Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact James A. Ellison
(404) 639-2693
Jellison@cdc.gov

Test Order

Rabies Postmortem Human Testing

CDC-10396

Synonym(s)	Rabies DFA
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050,
Supplemental Information Required	See Supplemental Form
Supplemental Form	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 cerebellum (vermis, right and left lateral lobes). Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Stored at -80°C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition, sample type and date of collection
Shipping Instructions which Include Specimen Handling Requirements	Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package Frozen specimen should be shipped on dry ice
Methodology	DFA for rabies virus antigen, RT-PCR, Direct Rapid Immunohistochemistry test (DRIT), Virus Isolation, Sequence Analysis, Antigenic Typing
Turnaround Time	7 Days
Interferences & Limitations	Tests are limited by decomposed tissues due to denaturation of viral proteins
Additional Information	Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing.
CDC Points of Contact	Rabies Duty Officer (404) 639-1050

Test Order
Rabies Special Study
CDC-10501

Synonym(s) None

Pre-Approval Needed Rabies Duty Officer, , (404) 639-1050,
Singletary-Meadows, Kristi, (404) 639-2833, kts9@cdc.gov

**Supplemental Information
Required** See Supplemental Form

Supplemental Form <http://www.cdc.gov/rabies/pdf/rorform.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

Storage & Preservation of Specimen Prior to Shipping Stored at -80C and should be kept on dry ice.

Transport Medium To be determined

Specimen Labeling To be determined

Shipping Instructions which Include Specimen Handling Requirements

Methodology

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Kristi Singletary-Meadows
(404) 639-2833
kts9@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,
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
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	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Stored at -80°C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Two unique identifiers for human specimen and one unique identifier for animal specimen, date of collection and specimen type
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries and provide the CDC Point of Contact with the tracking number of package Frozen specimen should be shipped on dry ice
Methodology	DFA, IFA, Sequence Analysis, RT-PCR, Isolation
Turnaround Time	7 Days
Interferences & Limitations	Tests are limited by decomposed tissues due to denaturation of viral proteins
Additional Information	Samples for genetic typing may be a single sample, part of a large study or the entire number of annual positive samples from a state for typing. The amount of testing required will depend on the reason for the testing and tests range from antigenic typing to whole genome sequencing and comparison with regional samples. Urgent samples for typing or molecular epidemiology are tested rapidly.
CDC Points of Contact	Rabies Duty Officer (404) 639-1050

Test Order
Respiratory Agents (*Chlamydia*, *Legionella*, *Mycoplasma*)
Molecular Detection
CDC-10157

Synonym(s)	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	Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, and any lower respiratory tract specimen including bronchoalveolar lavage (BAL) and sputum. Others upon consultation with laboratory.
Minimum Volume Required	1 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen. Store swabs in universal transport medium.
Transport Medium	Universal transport medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday overnight to avoid weekend deliveries Refrigerated specimen should be sent on ice packs Frozen specimen should be sent on dry ice
Methodology	Real Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	All specimens in which <i>M. pneumoniae</i> is detected will be subjected to <i>M. pneumoniae</i> Macrolide Susceptibility Genotyping (CDC-10513). Specimens in which <i>Legionella</i> species is detected will be subjected to <i>Legionella</i> species Detection and Identification (CDC-10159) and/or <i>Legionella</i> species Molecular Subtyping (CDC-10160).
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

Test Order
Respiratory Virus (Non-Influenza) Special Study
CDC-10400

Synonym(s) None

Pre-Approval Needed 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

Storage & 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 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 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Polymerase Chain Reaction (PCR)

Turnaround Time 2 Weeks

Interferences & Limitations Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocced swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.

Additional Information None

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

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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Acute samples only, anticoagulated whole blood collected in: ethylenediaminetetraacetic acid (EDTA), anticoagulant citrate dextrose solution A (ACD-A), sodium citrate, or heparin treated tubes are acceptable; serum; fresh tissue biopsy

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium For tissue, place in sterile specimen cup with gauze pad moistened with sterile saline

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

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.

CDC Points of Contact Cecilia Kato
(404) 639-0152
ckato@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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
 -acute (during active stage of illness)
 -convalescent (2-4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
 (404) 639-1075
 ckato@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 Prior approval is required if the following information is not provided:

- Suspected Agent
- Travel and exposure history (including animals, arthropods, etc.)
- Date of illness onset (and time if available)
- Specimen type (e.g., serum, whole blood, tissue, etc.)
- Test requested
- Brief clinical summary (including details of antibiotic therapy and dates) and pertinent clinical findings

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum
-acute (during active stage of illness)
-convalescent (2-4 weeks after acute stage)

Minimum Volume Required 1.0 mL

Storage & Preservation of Specimen Prior to Shipping Ideally keep specimen at a refrigerated temperature, but not frozen. If previously frozen, then keep specimen frozen.

Transport Medium Not Applicable

Specimen Labeling Patient name, date of birth, and collection date

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.

Methodology 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.

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@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 Kato, Cecilia, (404) 639-1075, ckato@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 To be determined

Minimum Volume Required To be determined

Storage & 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 Molecular detection, Serology, Culture, Other

Turnaround Time

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Cecilia Kato
(404) 639-1075
ckato@cdc.gov
Yan Zeng
(404) 639-5177
xcw9@cdc.gov

Test Order
Rift Valley Fever (RVF) Identification
CDC-10406

Synonym(s) RVF

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Rift Valley Fever (RVF) Serology
CDC-10407

Synonym(s) RVF

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Wednesday, overnight to avoid weekend deliveries
 Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on cold packs

Include a hardcopy list of specimens with your shipment. Please notify Mike Bowen (mkb6@cdc.gov) and Charity Perkins (vmf4@cdc.gov) when you are going to send specimens, and include the shipment tracking number if possible.

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
 Charity Perkins
 (404) 639-4545
 vmf4@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

Storage & 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 Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Wednesday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Include a hardcopy list of specimens with your shipment. Please notify Mike Bowen (mkb6@cdc.gov) and Charity Perkins (vmf4@cdc.gov) when you are going to send specimens, and include the shipment tracking number if possible.

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
Charity Perkins
(404) 639-4545
vmf4@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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Throat swab in viral medium, nasopharyngeal aspirate or swab, Urine, cataracts, lens aspirate, oral fluid, cerebrospinal fluid (CSF), dry blood spots, and tissue samples

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping See: <http://www.cdc.gov/rubella/lab/lab-specimens.html> for collection and storage protocol

Transport Medium Viral transport medium for swabs and appropriate culture medium. Make sure tubes are all in leak proof containers.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Clearly label specimen type.

Shipping Instructions which Include Specimen Handling Requirements The laboratory requests that the sender contacts the laboratory by email or phone before shipping

Ship specimen Monday –Thursday overnight to avoid weekend deliveries

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Template production by RT-PCR, Real time RT-PCR, Viral culture, Genotyping by Nucleic acid sequencing

Turnaround Time 7 Days

Interferences & Limitations See: <http://www.cdc.gov/rubella/lab/index.html> for information on the interferences and limitations

Additional Information Please include vaccination history, age, date of onset and sample collection.

For additional information please refer to:
<http://www.cdc.gov/vaccines/pubs/surv-manual/index.html> and
<http://www.cdc.gov/measles/lab-tools/index.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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum and others upon consultation

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Clearly label specimen type.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries

Refrigerated or frozen specimen should be shipped on cold packs
Laboratory will instruct on how to ship for other specimen types

Methodology Commercial capture IgM, Commercial indirect IgG

Turnaround Time 7 Days

Interferences & Limitations IgM positive may not occur until 5 days post-rash onset

Additional Information IgM and IgG assays are qualitative assays
For outbreaks or immuno-compromised patients please contact laboratory prior to shipment

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 None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Serum should be kept refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Clearly label specimen type.

Shipping Instructions which Include Specimen Handling Requirements The laboratory requests that the sender contacts the laboratory by email or phone before shipping

Ship specimen Monday -Thursday overnight to avoid weekend deliveries

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology CDC IgG avidity assay

Turnaround Time 7 Days

Interferences & Limitations Date of onset is necessary for accurate interpretation

Additional Information Date of onset, vaccination status, age, date of collection and pregnancy status if applicable.

CDC Points of Contact Joe Icenogle
(404) 639-4557
jci1@cdc.gov
Emily Abernathy
(404) 639-1249
efa9@cdc.gov

Test Order
Rubella Special Study
CDC-10253

Synonym(s) German measles, three day measles

Pre-Approval Needed Icenogle, Joe, (404) 639-4557, jci1@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

Storage & 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 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 Prior approval is not required for human specimens; Please call for approval prior to sending, other specimen types. Provide any preliminary results 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries

Ship at ambient temperature in compliance with Federal and local guidelines

Methodology Phenotypic identification, Phenotypic serotyping, Genetic identification, Genetic serotyping

Turnaround Time 8 Weeks

Interferences & Limitations None

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 serovar Typhi (only) serology
CDC-10453

Synonym(s) Enteric Pathogen

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

Supplemental Information Required Date of illness onset, date of serum collection, clinical diagnosis. Indicate if patient is currently on antibiotics. Indicate if patient is suspect chronic carrier.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum, paired serum preferred. Do not pool specimens.

Minimum Volume Required 200 uL (More preferred)

Storage & Preservation of Specimen Prior to Shipping Maintain serum at 4°C (preferred); frozen specimens acceptable

Transport Medium Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Rachael Aubert (vrl7@cdc.gov, (404) 639-3816) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology Various methods utilized; Consultation required

Turnaround Time 3 Months

Interferences & Limitations Plasma is not acceptable for typhoid testing

Additional Information Paired serum specimens always preferred.

Please send one tube per specimen submission form. Submit multiple forms if needed.

CDC Points of Contact Rachael Aubert
(404) 639-3816
vrl7@cdc.gov
Patricia Fields
(404) 639-1748
pif1@cdc.gov

Test Order
Salmonella Study
CDC-10109

Synonym(s) None

Pre-Approval Needed Van Duyne, Susan, (404) 639-0186, mdv9@cdc.gov
Lauer, Ana, (404) 639-2117, ybp6@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

Storage & 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 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) *Salmonella* Typing

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimen, but is required for all other types of specimen.

Indicate subtyping method(s) requested; provide PulseNet cluster code and PFGE pattern numbers if appropriate.

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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries

Ship at ambient temperature in compliance with Federal and local guidelines

Methodology PFGE, MLVA, AST, WGS

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation requested if available.

Turn around time depends on the nature of subtyping performed; and, results are typically not reported directly back to the submitter, but deposited in surveillance databases. If the surveillance database is not accessible to submitters, results are posted on the PulseNet and OutbreakNet discussion board. Specific turn around time and a report are available upon request.

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 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

Storage & 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 patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
<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 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

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 uL

Storage & 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 Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Refrigerated specimen should be shipped on cold packs
Frozen specimen should be shipped on dry ice

<http://www.cdc.gov/sars/lab/specimen.html>

Methodology ELISA

Turnaround Time 3 Days

Interferences & Limitations Do not collect in heparin tubes

Additional Information None

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

Test Order
Schistosomiasis Serology
CDC-10466

Synonym(s) *Schistosoma mansoni*, *Schistosoma haematobium*, *Schistosoma japonicum*, Bilharzia, parasite

Pre-Approval Needed None

Supplemental Information Required Travel history REQUIRED, 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology FAST-ELISA, Immunoblot, Western Blot, MAMA, HAMA, JAMA, Antibody Detection

Turnaround Time 21 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Seoul Virus Serology
CDC-10414

Synonym(s) Hanta, HFRS, HPS

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order

Shiga Toxin-producing *E. coli* Isolation from Enrichment Broth CDC-10105

Synonym(s) STEC, *E. coli* O157

Pre-Approval Needed None

Supplemental Information Required Only Stx+ broths that produce growth on subculture should be submitted. Consult with EDLB contact before sending other specimens. Provide any preliminary results available.

Supplemental Form None

Performed on Specimens From Human

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)

Storage & Preservation of Specimen Prior to Shipping Maintain specimen at 4°C

Transport Medium Not Applicable

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries
Ship with cold packs in compliance with federal and local guidelines. Shiga toxin–positive broths should be shipped as Category A Infectious Substances.

Methodology Isolation, Phenotypic Identification Including Serotyping, PCR Testing for Virulence Markers

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information A final report for CDC-10105 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. Broths from which an STEC is isolated will be reflexively assigned test CDC-10114 *Escherichia* and *Shigella* identification, serotyping, and virulence profiling, and a final report will be issued when results for CDC-10114 are complete. Consult with Dr. Nancy Strockbine if a preliminary report for CDC-10105 is needed.

CDC Points of Contact Nancy Strockbine
(404) 639-4186
nas6@cdc.gov
Nancy Garrett
(404) 639-1964
dgi3@cdc.gov

Haley Martin
(404) 639-1612
hvw0@cdc.gov

Test Order
Special Bacterial Pathogen Study
CDC-10147

Synonym(s) None

Pre-Approval Needed McQuiston, John, (404) 639-0270, zje8@cdc.gov
Whitney, Anne, (404) 639-1374, amw0@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 To be determined

Minimum Volume Required To be determined

Storage & 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 John McQuiston
(404) 639-0270
zje8@cdc.gov
Anne Whitney
(404) 639-1374
amw0@cdc.gov

Test Order
Staphylococcal Toxic Shock Syndrome Toxin (TSST-1)
CDC-10426

Synonym(s) Staph Toxin, Toxic Shock Syndrome

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 on suitable agar medium

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Isolate should be stored at room temperature

Transport Medium Pure culture isolate on suitable agar medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries at room temperature as an etiologic agent.

Methodology 16S sequencing, MALDI-TOF, Phenotypic Testing, SEA – SHE, PVL

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information SEA-SHE and PVL testing performed only with prior approval

CDC Points of Contact David Lonsway
(404) 639-2825
Dlonsway@cdc.gov
Kamile Rasheed
(404) 639-3247
jkr1@cdc.gov

Test Order
Staphylococcus – Micrococcus Identification
CDC-10226

Synonym(s) Staph, *Micrococcus*, Kocuria 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 on suitable agar medium

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Isolate should be stored at room temperature

Transport Medium Pure culture isolate on suitable agar medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday –Thursday overnight to avoid weekend deliveries at room temperature as an etiologic agent.

Methodology 16S Sequencing, MALDI-TOF, Phenotypic Testing

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information None

CDC Points of Contact David Lonsway
(404) 639-2825
Dlonsway@cdc.gov
Valerie Albrecht
(404) 639-4552
gpy8@cdc.gov

Test Order

Staphylococcus and MRSA Outbreak Strain Typing

CDC-10230

Synonym(s) Staph Typing, MRSA Typing, Staphylococcal Typing

Pre-Approval Needed Rasheed, Kamile, (404) 639-3247, JRasheed@cdc.gov
Albrecht, Valerie, (404) 639-4552, gpy8@cdc.gov

Supplemental Information Required Prior approval and Epidemiologic consultation required

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 suitable agar medium. Additional specimen types upon consultation with laboratory.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Isolate should be stored at room temperature

Transport Medium Pure culture isolate on suitable agar medium or frozen in TSB plus glycerol

Specimen Labeling Include date of isolation and unique specimen identifier

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday overnight to avoid weekend deliveries at room temperature as an etiologic agent.

Methodology 16S Sequencing, MALDI-TOF, Phenotypic Testing, Molecular Strain Typing

Turnaround Time 28 Days

Interferences & Limitations None

Additional Information Not CLIA compliant testing; for epidemiologic purposes only

CDC Points of Contact Kamile Rasheed
(404) 639-3247
JRasheed@cdc.gov
Valerie Albrecht
(404) 639-4552
gpy8@cdc.gov

Test Order
***Staphylococcus aureus* Detection – Foodborne Outbreak**
CDC-10113

Synonym(s) None

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 EDLB contact before sending specimens. Provide any preliminary results if available.

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Isolates, vomitus, stool, food. Only specimens from foodborne outbreaks accepted. Consult with Carolina Luquez and Gerry Gomez before sending specimens.

Minimum Volume Required 25 g (food), 10 g (vomitus, stool)

Storage & Preservation of Specimen Prior to Shipping Maintain food, vomitus and stool at 4°C

Transport Medium Not Applicable

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Carolina Luquez (fry6@cdc.gov) and Gerry Gomez (goe4@cdc.gov) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology Toxin Detection in Food, Culture, PCR

Turnaround Time 2 Months

Interferences & Limitations None

Additional Information Direct toxin detection requires food samples

CDC Points of Contact Carolina Luquez
 (404) 639-0896
 fry6@cdc.gov
 Gerry Gomez
 (404) 639-0537
 goe4@cdc.gov

Test Order
STD Bacterial Molecular Diagnostic Evaluation
CDC-10178

Synonym(s) Sexually Transmitted Disease

Pre-Approval Needed Trees, David, (404) 639-2134, dlt1@cdc.gov
Johnson, Steve, (404) 639-2879, sbj1@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Gonococcal bacterial culture

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Store culture at -70°C in TSA with 20% glycerol medium

Transport Medium TSA with 20% glycerol

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice, as an etiologic agent.

Methodology Molecular cloning, PCR, Whole genome sequencing

Turnaround Time 12 Weeks

Interferences & Limitations None

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

CDC Points of Contact David Trees
(404) 639-2134
dlt1@cdc.gov
Steve Johnson
(404) 639-2879
sbj1@cdc.gov

Test Order
 STD International QA – *N. gonorrhoeae*, *C. trachomatis*, *M. genitalium*, *T. vaginalis*
 CDC-10175

Synonym(s) Sexually Transmitted Disease

Pre-Approval Needed Cheng, Cheng, (404) 639-3154, cyc1@cdc.gov
 Chi, Kai, (404) 639-0694, krc2@cdc.gov

Supplemental Information Required 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 commercially available product, and other specimen types upon consultation with laboratory

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Swabs must be kept frozen

Transport Medium Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium

Specimen Labeling Please include country of origin, de-linked identifier and date of collection

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice, as an etiologic agent.

Methodology PCR

Turnaround Time 12 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Cheng Chen
 (404) 639-3154
 cyc1@cdc.gov
 Kai Chi
 (404) 639-0694
 krc2@cdc.gov

Test Order
Strep ABCs Surveillance Study
CDC-10218

Synonym(s) None

Pre-Approval Needed McGee, Lesley, (404) 639-0455, afi4@cdc.gov
Beall, Bernard, (404) 639-1237, bbeall@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/abcs/downloads/ABCs-case-rpt-form.pdf>

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

Acceptable Sample/ Specimen Type for Testing Sterile site Isolates of GAS, GBS and *S.pneumoniae* that meet the ABCs inclusion criteria

Minimum Volume Required Not applicable

Storage & 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 Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 8 Weeks

Interferences & Limitations Based on consultation

Additional Information None

CDC Points of Contact Lesley McGee
(404) 639-0455
afi4@cdc.gov
Bernard Beall
(404) 639-1237
bbeall@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

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/streplab/other-streptococci-ga.html>

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

Acceptable Sample/ Specimen Type for Testing Isolates and clinical/environmental specimens and others as approved upon consultation

Minimum Volume Required Not Applicable

Storage & 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 Dependent on specimen type to be determined upon consultation

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Ship specimen Monday -Thursday, overnight to avoid weekend deliveries

Requirements Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 2 Weeks

Interferences & Limitations Based on consultation

Additional Information Please complete questionnaire on website

CDC Points of Contact Bernard Beall
(404) 639-1237
bbeall@cdc.gov
Patricia Shewmaker
(404) 639-4826
paw3@cdc.gov

Test Order
***Streptococcus* (Catalase negative, Gram Positive Coccus)**
Identification
CDC-10213

Synonym(s) Streptococci, enterococci, viridans streptococci

Pre-Approval Needed Beall, Bernard, (404) 639-1237, bbeall@cdc.gov
 Shewmaker, Patricia, (404) 639-4826, paw3@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/streplab/other-streptococci-qa.html>

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

Acceptable Sample/ Specimen Type for Testing Isolates and clinical/environmental specimens and others as approved upon consultation

Minimum Volume Required Not Applicable

Storage & 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 Dependent on specimen type to be determined upon consultation

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
 Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on cold packs

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 8 Weeks

Interferences & Limitations Based on consultation

Additional Information Please complete questionnaire on website

CDC Points of Contact Bernard Beall
 (404) 639-1237
bbeall@cdc.gov
 Patricia Shewmaker
 (404) 639-4826
paw3@cdc.gov

Test Order
Streptococcus (Catalase negative, Gram Positive Coccus)
Identification and AST
CDC-10214

Synonym(s) Streptococci, enterococci, viridans streptococci

Pre-Approval Needed Beall, Bernard, (404) 639-1237, BBEALL@cdc.gov
 Shewmaker, Patricia, (404) 639-4826, paw3@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 Pure culture isolate on a suitable agar slant medium; Prior consultation required for other sample/specimen types

Minimum Volume Required Not applicable

Storage & Preservation of Specimen Prior to Shipping Keep refrigerated if cannot ship immediately

Transport Medium Suitable agar slant medium (example: blood or chocolate); Frozen glycerol stock is also acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
 Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on cold packs
 At room temperature for any etiologic agents

Methodology Phenotypic Testing, Molecular Testing, Broth microdilution MIC

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Preliminary susceptibility results may be available within 28 days or less. If susceptibility has been performed, indicate the method and results. Date of specimen collection and original submitter.

CDC Points of Contact

Bernard Beall (404) 639-1237 BBEALL@cdc.gov	David Lonsway (404) 639- 2825 dul7@cdc.gov
Patricia Shewmaker (404) 639-2825 paw3@cdc.gov	

Test Order
Streptococcus pneumoniae Typing
CDC-10215

Synonym(s) Pneumococcus Serotyping

Pre-Approval Needed Beall, Bernard, (404) 639-1237, bbeall@cdc.gov

Supplemental Information Required Online form required for pre-approval: <http://www.cdc.gov/streplab/s-pneumoniae-qa.html>
If you have questions, contact Bernard Beall, bbeall@cdc.gov, 404-639-1237

Supplemental Form None

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

Acceptable Sample/ Specimen Type for Testing Isolates and clinical/environmental specimens and others as approved upon consultation

Minimum Volume Required Not Applicable

Storage & 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 Dependent on specimen type to be determined upon consultation

Specimen Labeling Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 2 Weeks

Interferences & Limitations Based on consultation

Additional Information Please complete questionnaire on website

CDC Points of Contact Bernard Beall
(404) 639-1237
bbeall@cdc.gov
Lesley McGee
(404) 639-0455
afi4@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, afi4@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 Isolates and clinical/environmental specimens and others as approved upon consultation

Minimum Volume Required To be determined

Storage & Preservation of Specimen Prior to Shipping For isolates blood or chocolate agar; transport media or frozen glycerol stock; additional details and directions will be provided upon consultation.

Transport Medium To be determined

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Note: surveillance studies may label specimens according to protocol

Shipping Instructions which Include Specimen Handling Requirements To be determined

Methodology Phenotypic Testing, Molecular Testing

Turnaround Time 8 Weeks

Interferences & Limitations To be determined

Additional Information To be determined

CDC Points of Contact Bernard Beall
(404) 639-1237
bbeall@cdc.gov
Lesley McGee
(404) 639-0455
afi4@cdc.gov

Test Order
Strongyloidiasis Serology
CDC-10467

Synonym(s) Strongyloidiasis, *Strongyloides stercoralis*, parasite

Pre-Approval Needed None

Supplemental Information Required 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology EIA, ELISA, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Syphilis Serology
CDC-10173

Synonym(s) Treponemal and non-treponemal

Pre-Approval Needed None

Supplemental Information Required Need to supply date of birth

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Serum (preferred), CSF, and/or plasma (possible to preform test but not preferred)

Minimum Volume Required 1 mL (for serum or plasma)

Storage & Preservation of Specimen Prior to Shipping Serum and Plasma can be stored at 4°C unless for more than 4-5 days it should be frozen. CSF should be stored frozen at -70°C.

Transport Medium None

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.

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
Andre Hopkins
(404) 639-0731
Fvn4@cdc.gov

Yongcheng Sun
(404) 639-2905
Yas2@cdc.gov

Test Order
Tick Borne Encephalitis (TBE) Identification
CDC-10415

Synonym(s) None

Pre-Approval Needed Klena, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Frozen tissue, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be placed in plastic screw capped vials, frozen to -70°C , and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped frozen on dry ice. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology Molecular Typing, Polymerase Chain Reaction (PCR)

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity. Heparin may cause interference with the molecular tests and should be avoided.

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 John Klena
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Tick Borne Encephalitis (TBE) Serology
CDC-10416

Synonym(s) None

Pre-Approval Needed Klana, John, (470) 312-0094, spather@cdc.gov
Rollin, Pierre, (470) 312-0094, spather@cdc.gov

Supplemental Information Required See Supplemental Form

Supplemental Form <http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf>

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing CSF, blood and serum

Minimum Volume Required 1 mL

Storage & Preservation of Specimen Prior to Shipping Specimen must be kept cold (at or below 4°C). If possible place specimen in plastic screw capped vials. See link to supplemental submission form for specific information on various specimen types.

Transport Medium Not Applicable

Specimen Labeling Patient name, patient ID #, specimen type, date collected

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday overnight to avoid weekend deliveries. Specimen should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.

Methodology ELISA

Turnaround Time 10 Days

Interferences & Limitations Specimen must remain frozen; warming or freeze thawing reduces sensitivity

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 John Klana
(470) 312-0094
spather@cdc.gov
Pierre Rollin
(470) 312-0094
spather@cdc.gov

Test Order
Toxocariasis Serology
CDC-10468

Synonym(s) Larva migrans, Toxocariasis, *Toxocara canis*, *Toxocara cati*, parasite

Pre-Approval Needed None

Supplemental Information Required 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, plasma, or vitreous fluid

Minimum Volume Required 0.5 mL

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology EIA, ELISA, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 718-4100
ibm4@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

Storage & 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 Hilda Rivera
(404) 718-4100
igi2@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Treponema pallidum Molecular Detection
CDC-10176

Synonym(s) Syphilis

Pre-Approval Needed Pillay, Allan, (404) 639-2140, apillay@cdc.gov
Chi, Kai, (404) 639-0694, krc2@cdc.gov

Supplemental Information Required None

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Swab of an ulcer or skin lesion, blood collected in an EDTA tube, body fluids, frozen tissue and/or Formalin-Fixed, Paraffin-Embedded (FFPE) tissue

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Specimens should be frozen unless FFPE tissue which can be stored at room temperature

Transport Medium Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday Thursday, overnight to avoid weekend deliveries. 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.

Methodology PCR

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Allan Pillay
(404) 639-2140
apillay@cdc.gov
Kai Chi
(404) 639-0694
krc2@cdc.gov

Test Order
***Treponema pallidum* Molecular Typing**
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 Chen, Cheng, (404) 639-3154, cyc1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Swab of an ulcer or skin lesion, blood collected in an EDTA tube, body fluids, frozen tissue and/or Formalin-Fixed, Paraffin-Embedded (FFPE) tissue
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Specimens should be frozen except for FFPE tissue, which can be stored at room temperature
Transport Medium	Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition. Also, include date collected.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. 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.
Methodology	PCR, Sequencing, RFLP
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov Cheng Chen (404) 639-3154 cyc1@cdc.gov

Test Order
Trichinellosis Serology
CDC-10470

Synonym(s) Trichinosis, *Trichinella spiralis*, parasite

Pre-Approval Needed None

Supplemental Information Required Exposure and travel history, include other relevant risk factors (consumption of raw or undercooked pork or game meat); 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

Storage & Preservation of Specimen Prior to Shipping No specific requirements

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.

Methodology EIA, ELISA, Antibody Detection

Turnaround Time 18 Days

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

Additional Information None

CDC Points of Contact Isabel McAuliffe
(404) 719-4100
ibm4@cdc.gov
DPDx
(404) 718-4120
dpdx@cdc.gov

Test Order
Trichomonas Susceptibility
CDC-10239

Synonym(s) *Trichomonas*, trich, parasite

Pre-Approval Needed None

Supplemental Information Required Please fill out the supplemental form provided in the specimen collection kit. Please call 404-718-4141 or 404-718-4142 to request a kit with media and forms. Alternatively, send mailing address and phone number to was4@cdc.gov to request a kit.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Must be a live culture. Use vaginal swab to inoculate media.

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping Do not freeze specimen. If the specimen cannot be sent within 24-48 hours of collection, it is better to wait to collect the specimen.

Transport Medium InPouch TV (Commercial product) or Diamond s TYM
Please call 404-718-4141 or 404-718-4142 to request a kit with media and forms. Alternatively, send mailing address and phone number to was4@cdc.gov to request a kit.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements The isolate should be sent to CDC by overnight courier (not USPS) on the same day it is obtained from the patient.

Insure the InPouch is properly closed and place it in the mailing container that they arrived in and send by OVERNIGHT delivery service (recommended: Federal Express) to:

Pete Augostini
CDC/Parasitic Disease Branch
1600 Clifton Rd. NE, MS D65
Bldg. 23, 10th Floor, Rm. 108
Atlanta, GA 30329-4081
678-860-6128

NOTE:

- a) Delivery to the reference laboratory within 24 hours is essential to ensure organism survival.
 - B) The laboratory can only accept sample delivery Monday through Friday. Please plan to ship your samples Monday, Tuesday, Wednesday, or Thursday in order for the laboratory to receive the overnight delivery the next day.
 - C) While we provide the testing as a no-cost service, we do not have the funds to pay for shipment of the organism. Therefore, please do not mark recipient as the party responsible for payment of shipment costs. If this occurs, we will refer the shipping company back to you for payment of costs.
- Please include the metronidazole treatment history and request forms with your sample.
-

Methodology Antimicrobial susceptibility

Turnaround Time 7 Weeks

Test Order
Trichomonas Susceptibility
CDC-10239

Interferences & Limitations None

Additional Information None

CDC Points of Contact Evan Secor
(404) 718-4141
was4@cdc.gov

Test Order
Trypanosoma cruzi Molecular Detection
CDC-10493

Synonym(s) Chagas, American Trypanosomiasis, parasite, triatomine, kissing bug

Pre-Approval Needed None

Supplemental Information Required Please include detailed information where the insect was found (kitchen, bed, porch, etc.).

Supplemental Form None

Performed on Specimens From Animal

Acceptable Sample/ Specimen Type for Testing Triatomine insect

Minimum Volume Required N/A

Storage & Preservation of Specimen Prior to Shipping Dry or in 70% ethanol

Transport Medium None or in 70% ethanol

Specimen Labeling One submitter identifier or SPHL ID on the specimen container and date of collection.

Shipping Instructions which Include Specimen Handling Requirements Place insect in a crush-proof container with paper towel cushioning for dry specimens or in 70% ethanol with no cushioning. Ship at ambient temperature in compliance with local and Federal guidelines. Send by regular mail or overnight Monday–Thursday to avoid weekend deliveries.

Methodology Conventional PCR

Turnaround Time 3 Weeks

Interferences & Limitations None

Additional Information None

CDC Points of Contact Gena Lawrence
(404) 718-4315
geg7@cdc.gov
Alice Sutcliffe
(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.
Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <http://www.cdc.gov/cdc-info/requestform.html> and use subject "508 Accommodation PR#31", or by calling 800-232-4636 (TTY number: 888-232-6348) and ask for 508 Accommodation PR#31.

Supplemental Form http://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 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen

Transport Medium Not Applicable

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology IgG avidity

Turnaround Time 1 Week

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 Scott Schmid
(404) 639-0066
dss1@cdc.gov
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.
Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <http://www.cdc.gov/cdc-info/requestform.html> and use subject "508 Accommodation PR#31", or by calling 800-232-4636 (TTY number: 888-232-6348) and ask for 508 Accommodation PR#31.

Supplemental Form http://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, and whole blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Frozen or refrigerated for saliva, cerebrospinal fluid (CSF), urine or whole blood. Room temperature, dry skin lesions and scabs. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not Applicable

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR), DNA sequencing

Turnaround Time 2 Weeks

Interferences & Limitations None

Additional Information **This test order is for research or epidemiological purposes only.** The test(s) 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 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) None

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 http://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 (both samples required)

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Can be stored at 4 degrees C for several days; frozen at -20 degrees C if samples will be held longer.

Transport Medium No transport medium.

Specimen Labeling Requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements If stored at 4 degrees C can be overnighted on cold packs in well-sealed O-ring vials; if frozen can be overnighted on dry ice in well-sealed O-ring vials

Methodology gpELISA

Turnaround Time 7 Days

Interferences & Limitations At least one of the specificity controls must be both positive in serum and negative in 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-CMV antibody).

Additional Information gpELISA VZV antibody detection method used to determine presence of specific antibody in both CSF and serum. HSV-1, HSV-2 and HHV-6 antibody measurements are performed as specificity controls on both samples. A ratio of 1:10 CSF to serum VZV 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.

This test order is for research or epidemiological purposes only. The test(s) 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 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 See Supplemental Form.

Required Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <http://www.cdc.gov/cdc-info/requestform.html> and use subject "508 Accommodation PR#31", or by calling 800-232-4636 (TTY number: 888-232-6348) and ask for 508 Accommodation PR#31.

Supplemental Form http://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 200 uL

Storage & Preservation of Specimen Prior to Shipping Keep specimen either refrigerated or frozen

Transport Medium None

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology IgG antibody detected by EIA, IgM antibody detected by EIA

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
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.
Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <http://www.cdc.gov/cdc-info/requestform.html> and use subject "508 Accommodation PR#31", or by calling 800-232-4636 (TTY number: 888-232-6348) and ask for 508 Accommodation PR#31.

Supplemental Form http://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, and whole blood

Minimum Volume Required 200 uL

Storage & Preservation of Specimen Prior to Shipping Frozen or refrigerated for saliva, cerebrospinal fluid (CSF), urine or whole blood. Room temperature, dry skin lesions and scabs. Blood should be collected in EDTA or citrate tubes.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship specimen Monday–Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.

Please ship to the attention of:
Scott Schmid
National VZV Laboratory
404-639-0066

Methodology Polymerase Chain Reaction (PCR)

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
kjr7@cdc.gov

Test Order

Vibrio cholerae ID, Serotyping, and Virulence Profiling

CDC-10119

Synonym(s) Cholera

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens; Please call for approval prior to sending, other specimen types.

Provide any preliminary results 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Every suspect *Vibrio cholerae* isolate should be sent to EDLB as soon as possible. Ship at ambient temperature in compliance with Federal and local guidelines.

Methodology Phenotypic Characterization (Serogrouping for O1, O139, O75, and O141), PCR for Virulence Markers (Toxin and tcpA biotype)

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Every suspect *Vibrio cholerae* isolate should be sent to EDLB as soon as possible

CDC Points of Contact Cheryl Tarr
(404) 639-2011
crt6@cdc.gov
Monica Santovenia
(404) 718-1446
ixi9@cdc.gov

Test Order
Vibrio cholerae serology
CDC-10454

Synonym(s) Enteric Pathogen

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

Supplemental Information Required Date of illness onset, date of serum collection, clinical diagnosis. Indicate if patient is currently on antibiotics.

Supplemental Form None

Performed on Specimens From Human

Acceptable Sample/ Specimen Type for Testing Paired serum is preferred. Serum is always preferred but plasma is acceptable. Do not pool specimens.

Minimum Volume Required 100 uL (more preferred)

Storage & Preservation of Specimen Prior to Shipping Maintain serum at 4°C (preferred); frozen specimens acceptable

Transport Medium Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed.

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries. Please notify Rachael Aubert (vrl7@cdc.gov, (404) 639-3816) once specimens have been shipped to provide the tracking number.

Ship with cold packs in compliance with federal and local guidelines

Methodology Various methods utilized; Consultation required

Turnaround Time 3 Months

Interferences & Limitations None

Additional Information Paired serum specimens always preferred.

Please send one tube per specimen submission form. Submit multiple forms if needed.

CDC Points of Contact Rachael Aubert
(404) 639-3816
vrl7@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 Prior approval is not required for human specimens, but is required for all other specimen types.

Specify type of subtyping requested in 'Previous Laboratory Results' on back of form.

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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Not Applicable

Shipping Instructions which Include Specimen Handling Requirements Ship Monday-Thursday, overnight to avoid weekend deliveries

Ship at ambient temperature in compliance with Federal and local guidelines

Methodology PFGE, MLST, MLVA, AST

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Turn around time depends on the nature of subtyping performed; and, results are typically not reported directly back to the submitter, but deposited in surveillance databases. If the surveillance database is not accessible to submitters, results are posted on the PulseNet and OutbreakNet discussion board.

CDC Points of Contact Cheryl Tarr
(404) 639-2011
crt6@cdc.gov
Monica Santovenia
(404) 718-1446
ixi9@cdc.gov

Test Order
Vibrio, Aeromonas, and Related Organisms Identification
 CDC-10120

Synonym(s) *Grimontia* species, *Photobacterium* species, *Salinivibrio* species

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens, but is required for all other specimen types.

Provide any preliminary results that are 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries

Ship at ambient temperature in compliance with Federal and local guidelines

Methodology Phenotypic Identification, Genetic Identification

Turnaround Time 8 Weeks

Interferences & Limitations None

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
 crt6@cdc.gov
 Monica Santovenia
 (404) 718-1446
 ixi9@cdc.gov

Test Order
Vibrio, Aeromonas, and Related Organisms Study
CDC-10121

Synonym(s) None

Pre-Approval Needed Tarr, Cheryl, (404) 639-2011, crt6@cdc.gov
Santovenia, Monica, (404) 718-1446, ixi9@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

Storage & 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 Cheryl Tarr
(404) 639-2011
crt6@cdc.gov
Monica Santovenia
(404) 718-1446
ixi9@cdc.gov

Test Order
Yersinia (non-*Y. pestis*) & other *Enterobacteriaceae* subtyping
 CDC-10124

Synonym(s) None

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens, but is required for all other specimen types.

Indicate subtyping method(s) requested on 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

Minimum Volume Required Not Applicable

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Two patient identifiers on the specimen container and the test requisition are required

Shipping Instructions which Include Specimen Handling Requirements Ship Monday–Thursday, overnight to avoid weekend deliveries

Ship at ambient temperature in compliance with Federal and local guidelines

Methodology Serotyping, PFGE, MLST, WGS

Turnaround Time 8 Weeks

Interferences & Limitations None

Additional Information Specify type of subtyping requested in 'Previous Laboratory Results' on back of form.

Turn around time depends on the nature of subtyping performed; and, results are typically not reported directly back to the submitter, but deposited in surveillance databases. If the surveillance database is not accessible to submitters, results are posted on the PulseNet and OutbreakNet discussion board.

CDC Points of Contact Cheryl Tarr
 (404) 639-2011
 crt6@cdc.gov
 Monica Santovenia
 (404) 718-1446
 ixi9@cdc.gov

Test Order
Yersinia (non-*Y. pestis*) and Other *Enterobacteriaceae*
 Identification
 CDC-10123

Synonym(s) *Arsenophonus, Biostraticola, Brenneria, Buchnera, Budvicia, Buttiauxella, Calymmatobacterium, Cedecea, Citrobacter, Cosenzaea, Cronobacter, Dickeya, Edwardsiella, Enterobacter, Erwinia, Ewingella, Gibbsiella, Hafnia, Klebsiella, Kluyvera, Leclercia, Leminorella, Levinea, Lonsdalea, Mangrovibacter, Moellerella, Morganella, Obesumbacterium, Pantoea, Pectobacterium, Phaseolibacter, Photorhabdus, Plesiomonas, Pragia, Proteus, Providencia, Rahnella, Raoultella, Saccharobacter, Samsonia, Serratia, Shimwellia, Sodalis, Tatumella, Thorsellia, Trabulsiella, Wigglesworthia, Xenorhabdus, Yersinia, Yokenella*

Pre-Approval Needed None

Supplemental Information Required Prior approval is not required for human specimens, but is required for all other specimen types.

Provide any preliminary results that are 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

Storage & Preservation of Specimen Prior to Shipping No Specific Requirements

Transport Medium Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.

Shipping Instructions which Include Specimen Handling Ship Monday–Thursday, overnight to avoid weekend deliveries

Requirements Ship at ambient temperature in compliance with Federal and local guidelines

Methodology Phenotypic Identification, Genetic Identification

Turnaround Time 8 Weeks

Interferences & Limitations None

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
 crt6@cdc.gov
 Monica Santovenia
 (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 In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

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 Not Applicable

Storage & Preservation of Specimen Prior to Shipping Refrigerate specimens containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.

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 patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
 Bacterial Diseases Branch
 Attn: John Young
 3156 Rampart Road
 Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
 Refrigerated specimen should be shipped on ice packs

Methodology Culture, Direct Fluorescent Antibody (DFA), Bacteriophage Lysis

Turnaround Time 3 Weeks

Interferences & Limitations Samples for testing by culture should be taken prior to antibiotic treatment

Additional Information None

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

Test Order
Yersinia pestis Culture and Identification
CDC-10418

vtx8@cdc.gov

Test Order
***Yersinia pestis* Serology**
CDC-10419

Synonym(s) Plague

Pre-Approval Needed None

Supplemental Information Required In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.

Supplemental Form None

Performed on Specimens From Human and Animal

Acceptable Sample/ Specimen Type for Testing Serum

Minimum Volume Required 500 uL

Storage & Preservation of Specimen Prior to Shipping Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longer period, serum samples may be frozen.

Transport Medium Not Applicable

Specimen Labeling Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.

Shipping Instructions which Include Specimen Handling Requirements Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:

Centers for Disease Control and Prevention
Bacterial Diseases Branch
Attn: John Young
3156 Rampart Road
Fort Collins, CO 80521

Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs

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

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** 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

Storage & 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 Jeannine Petersen
(970) 266-3524
nzp0@cdc.gov
Luke Kingry
(970) 266-3567
vtx8@cdc.gov
