# 2016 GDC

INFECTIOUS DISEASES
LABORATORY TEST
DIRECTORY

December 2016, Version 7.0





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 December 9, 2016. 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: <a href="http://www.cdc.gov/laboratory/specimen-submission/list.html">http://www.cdc.gov/laboratory/specimen-submission/list.html</a>.



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

Synonym(s)	Free-living ameba, parasite	
Pre-Approval Needed	None	
	Please provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. images are available please upload to: <a href="http://www.cdc.gov/dpdx">http://www.cdc.gov/dpdx</a>	
Supplemental Form	None	
Performed on Specimens From	Human	
	For <i>Acanthamoeba</i> and <i>Balamuthia</i> molecular detection, tissue is the preferred specimen type; however, these amebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For <i>Naegleria fowleri</i> molecular detection, CSF is the preferred specimen type. For suspected cases of <i>Acanthamoeba Keratitis (AK)</i> , 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 identifier (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 o 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, ar preferred. Additionally, CSF is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection, because a negative CSF test result does not completely rule out infections with these amebae.	
Additional Information	None	
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov	

### 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	
	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	e 28 Days	
Interferences & Limitations	ns 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** *Actinomycetes*–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	
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.	
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.	
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov	

## **Test Order**Actinomycetes-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	
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.	
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.	
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	Erdman, Dean, (404) 639–3727, dde1@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
	Upper or lower respiratory tract specimens, eye swabs, stool, serum, blood or plasma, pure culture isolate
Minimum Volume Required	0.25 mL
	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 betwee 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.
Include Specimen Handling	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), 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 the may contain substances that inactivate some viruses and inhibit some molecular assays.
Additional Information	None
CDC Points of Contact	Dean Erdman (404) 639-3727 dde1@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

### **Test Order**Alkhurma Identification CDC-10274

Synonym(s)	AHFV	
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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	
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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	
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov	

#### **Test Order** Alkhurma Serology CDC-10285

Synonym(s)	AHFV	
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@cdc.gov	
Supplemental Information Required	• • • • • • • • • • • • • • • • • • • •	
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	
	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 specinformation on various specimen types.	
Transport Medium	Not Applicable	
Specimen Labeling	Patient name, patient ID #, specimen type, date collected	
Include Specimen Handling	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	s Specimen must remain frozen; warming or freeze thawing reduces sensitivity	
Additional Information	n 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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov	

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

Synonym(s)	Free-living ameba, Acanthamoeba, Balamuthia, Naegleria fowleri	
Pre-Approval Needed	None	
	Please provide the following information: history of present illness, exposu history, past medical history, treatment history, CSF results, imaging result	
	If images are available please upload to: http://www.cdc.gov/dpdx	
Supplemental Form	None	
Performed on Specimens From	Human and Animal	
	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	
	CSF and fresh, unfixed tissue should be kept at ambient temperatures. Paraffinembedded 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 biops materials please transport in ameba 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 identifie (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.	
	Polymerase Chain Reaction (PCR), Indirect Immunofluorescence (IIF), Immunohistochemical (IHC) staining plus microscopy, Microscopy	
Turnaround Time	·	
Interferences & Limitations	For molecular detection, CSF is the preferred specimen type for <i>N. fowleri</i> only, and it is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i>	

#### 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) 0.120a

Magnesium sulfate (MgSO4.7HOH) 0.004 g Sodium phosphate, dibasic (Na2HPO4) 0.142g Potassium phosphate, monobasic (KH2P O4) 0.136a

Calcium chloride (CaCL2.2HOH) 0.004g Double distilled water to 1000.0 mL

Version: 1.4

#### CDC Points of Contact Jennifer Cope

(404) 718-4878 bit9@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

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

Synonym(s)	Free-living ameba, Acanthamoeba,	Balamuthia. Naegleria fowleri
Pre-Approval Needed		
Supplemental Information	Please provide the following information: history of present illness, exposur history, past medical history, treatment history, CSF results, imaging results	
	If images are available please uplo	ad 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	
	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 identifier (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.	
	packs.	refrigerated or frozen and packed with cold
Methodology	Indirect Immunofluorescence Antib	oody (IFA) assay
Turnaround Time	14 Days	
Interferences & Limitations	<ol> <li>The Ameba Serology test has limited diagnostic value for three reasons:</li> <li>This test cannot differentiate between an old infection (or exposure) and an acute infection.</li> <li>For immunocompromised patients (which is the case for most <i>Acanthamoeb</i> infections, and some of the <i>Balamuthia</i> infections), there may not be any antibody response in the infected patients.</li> <li>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.</li> </ol>	
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 regula business hours, please call the CDC Emergency Operations Center (EOC	

### **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	
	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	
Mathadalass	Specimen stored at room temperature should be shipped at room temperature	
Turnaround Time	16S Sequencing, MALDI-TOF, Phenotypic Testing	
	,	
	Specimen from respiratory, vaginal, and fecal sources are not acceptable	
	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	
	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	
	Acute samples only, anticoagulated whole blood collected in Ethylenediaminetetraacetic acid (EDTA) treated tubes preferred; serum; fresh tissue biopsy	
Minimum Volume Required	1.0 mL	
	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 san collection tube	
Specimen Labeling	Patient name and date of birth	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shoul 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 commercial laboratory.	
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov	

### **Test Order** *Anaplasma* Serology

CDC-10292

Synonym(s)	Human granulocytic anaplasmosis
Pre-Approval Needed	None
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shou be shipped refrigerated on cold packs.
Methodology	Indirect Fluorescence 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 samp and interfere with the ability to get accurate results. Acute and convalescent serum is 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. Routine diagnostic samples should be sent to your State Laboratory or commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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Tuesday, November 29, 2016

## Test Order Anaplasma Special Study CDC-10291

Synonym(s)	Human granulocytic anaplasmosis
Pre-Approval Needed	Kato, Cecilia, (404) 639–1075, ckato@cdc.gov Paddock, Christopher, (404) 639–1309, cdp9@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	Cecilia Kato (404) 639–1075 ckato@cdc.gov Christopher Paddock (404) 639–1309 cdp9@cdc.gov

### 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 specime container and the test requisition.
	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	21 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
	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. <i>Neisseria meningitidis</i> ), 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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	Frozen specimen should be shipped on dry ice
	Ship to:
	Centers for Disease Control & Prevention
	3156 Rampart Road (CSU Foothills Campus)
Mathadalagy	Fort Collins, Colorado 80521 Isolation in cell culture
Turnaround Time	
Interferences & Limitations	
Additional Information	
CDC Points of Contact	
	(970) 221–6440
	rsI2@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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	Frozen specimen should be shipped on dry ice
	Ship to:
	Centers for Disease Control & Prevention
	3156 Rampart Road (CSU Foothills Campus)
	Fort Collins, Colorado 80521
	RT-Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	Hemolysis can affect the test results
Additional Information	None
CDC Points of Contact	
	(970) 221–6440
	rsl2@cdc.gov

## **Test Order**Arbovirus Neutralization Antibody CDC-10283

Synonym(s)	Arbo-PRNT, Chikungunya, <b>Zika Virus</b>
Pre-Approval Needed	None
Supplemental Information Required	None
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 & Prevention 3156 Rampart Road (CSU Foothills Campus) Fort Collins, Colorado 80521
Methodology	Plaque reduction neutralization
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 Serology CDC–10282

Synonym(s)	Arbo-Serology, Chikungunya, <b>Zika Virus</b>
Pre-Approval Needed	None
Supplemental Information Required	None
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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	Frozen specimen should be shipped on dry ice
	Ship to:
	Centers for Disease Control & Prevention
	3156 Rampart Road (CSU Foothills Campus) Fort Collins, Colorado 80521
Methodology	·
Turnaround Time	<u> </u>
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	
	(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, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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 specifinformation on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient Name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

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

Synonym(s)	New World <i>Arenavirus</i> , South American hemorrhagic fever viruses
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

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

Synonym(s)	Old World <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and ker 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

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

Synonym(s)	Babesiosis; <i>Babesia microti</i> , <i>Babesia duncani</i> , parasite
Pre-Approval Needed	None
Supplemental Information Required	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-parasiti 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.
	Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimer on wet ice (cold pack) as an etiologic agent.
Methodology	Conventional PCR, Real Time PCR
Turnaround Time	21 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Samaly dos Santos Souza (404) 718-4786 ynp4@cdc.gov

## **Test Order**Babesiosis Serology CDC-10456

Synonym(s)	Babesia microti, Babesia duncani, Babesia divergens, babesiosis, parasite
Pre-Approval Needed	None
	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 and 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

### 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
	Info on specimens, storage and shipping can be found at: <a href="http://www.cdc.gov/anthrax/labs/recommended_specimen.html">http://www.cdc.gov/anthrax/labs/recommended_specimen.html</a>
Transport Medium	Dependent on specimen type submitted. Info on specimens, storage, and shipping can be found at: <a href="http://www.cdc.gov/anthrax/labs/recommended_specimen.html">http://www.cdc.gov/anthrax/labs/recommended_specimen.html</a>
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: <a href="http://www.cdc.gov/anthrax/labs/recommended_specimen.html">http://www.cdc.gov/anthrax/labs/recommended_specimen.html</a>
	Most samples can be sent $2-8 \circ C$ . 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 of 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

### 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	Confirmed select agents need Form 2 approval by the Select Agent program pricto shipping. The Form 2 can be found at <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a>
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:
CDC Points of Contact	http://www.cdc.gov/anthrax/labs/recommended_specimen.html  Chung Marston (404) 639-4057 cdk5@cdc.gov David Lonsway (404) 639-2825 dul7@cdc.gov

#### 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
	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.
Include Specimen Handling	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	
Interferences & Limitations	Requires acute and convalescent serum for analysis
Additional Information	Turnaround time ranges from 1–2 weeks. See additional info at <a href="http://www.cdc.gov/anthrax/labs/recommended_specimen.html">http://www.cdc.gov/anthrax/labs/recommended_specimen.html</a>
CDC Points of Contact	Chung Marston (404) 639–4057 cdk5@cdc.gov Robyn Stoddard (404) 639–2053 frd8@cdc.gov

#### 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

#### 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
	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
	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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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	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 <i>B. cereus</i> and <i>B. thuringiensis</i>
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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

### 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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

### 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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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	
	Please provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. I images are available please upload to: <a href="http://www.cdc.gov/dpdx">http://www.cdc.gov/dpdx</a>
Supplemental Form	None
Performed on Specimens From	Human
	For <i>Acanthamoeba</i> and <i>Balamuthia</i> molecular detection, tissue is the preferred specimen type; however, these amebae 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 identifie (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 of 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, as preferred. Additionally, CSF is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection, because a negative CSF test result does not completely rule out infections with these amebae.
Additional Information	None
CDC Points of Contact	Jennifer Cope (404) 718–4878 bjt9@cdc.gov Ibne Ali (404) 718–4157 xzn5@cdc.gov

### Bartonella henselae/B. quintana Indirect Fluorescent Antibody (IFA) test

CDC-10486

B. henselae/cat scratch disease, B. quintana/trench fever
None
Please provide submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date of birth, date of symptom onset, sample collection date, and clinical information including symptoms and type and date of treatment patient has received.
None
Human
Serum
500 uL
Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longe period, serum samples may be frozen.
Not Applicable
Specimen identifier and patient name
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
1011 Commis, CO 00321
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on ice packs
Indirect Fluorescent Antibody (IFA)
2 Weeks
Samples with hemolysis, increased lipemia or microbial growth may interfere with test results
Clinical information including symptoms and date of onset must be included; specimens without this accompanying information will not be tested.
Jeannine Peterson
(970) 266–3524
nzp0@cdc.gov Marty Schriefer
(970) 221–6479
mms7@cdc.gov

# Test Order Bartonella Special Study CDC-10297

Synonym(s)	Cat scratch fever, <i>B. henselae,</i> Trench fever, <i>B. quintana</i> , Oroya fever, <i>B. bacilliformis</i>
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

#### Baylisascariasis Serology CDC-10457

Synonym(s)	Baylisascariasis, Raccoon roundworm, parasite
Pre-Approval Needed	None
	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, plasma; Cerebrospinal fluid (CSF)
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 specimer 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

## 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
	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 <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a>
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
	Select agents that have been identified need form 2 approval prior to shipping Form 2 may be found at: <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a>
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
	Bowzard, Brad, (404) 639-3626, jbowzard@cdc.gov Andersen, Lauren, (404) 639-4442, wrh5@cdc.gov
	Please contact Dr. Brad Bowzard at 404 639-3626 or jbowzard@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	Brad Bowzard (404) 639-3626 jbowzard@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
	Serum from patients with two or more weeks of cough, but will accept plasma is serum is unavailable. 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
	Serum specimens may be stored refrigerated $(2^{\circ}-8^{\circ}C)$ for up to 7 days; If greate 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	5 Days
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 mor 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 serur 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
	Pure culture isolates on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar ( <i>B. parapertussis</i> , <i>B. holmesii</i> , or <i>B. bronchiseptica</i> only) or cryopreserved isolates
Minimum Volume Required	Not Applicable
	Isolates can be frozen in cryopreservation medium or refrigerated on Regan- Lowe, Bordet-Gengou, charcoal agar or blood agar ( <i>B. parapertussis</i> , <i>B. holmesia</i> or <i>B. bronchiseptica only</i>
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
Include Specimen Handling	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 fo 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
	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 a 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 reque CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laborator 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
	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	5 Days
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

#### Bordetella species Study

#### CDC-10167

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	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 Cassiday (404) 639–1231 pxc1@cdc.gov Maria Tondella (404) 639–1239 mlt5@cdc.gov

### 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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

### Borrelia burgdorferi (Lyme Disease) Serology CDC-10298

• • •	Lyme Disease, Borreliosis
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date obirth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
	Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longe 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	IgG/IgM ELISA, IgG Western Blot, IgM Western Blot
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed samples may interfere with test results
Additional Information	Two tier testing will be performed. If available, submit any preliminary results. Include the date of onset, antibiotic treatment (type of antibiotics and date administered), date when the sample was collected, signs and symptoms.
	If testing needs to be performed by another laboratory, i.e. arborvirus, please contact laboratory prior to shipping.
CDC Points of Contact	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov

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

Synonym(s)	Lyme Disease, Borreliosis, Relapsing fever
Pre-Approval Needed	Schriefer, Marty, (970) 221–6479, mms7@cdc.gov Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov
Required	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date of birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human
	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
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.
	Contact laboratory prior to shipping for instructions on skin biopsy's transport medium.
	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.
	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
	Culture, Microscopy Confirmation
Turnaround Time	8 Weeks
Interferences & Limitations	Antibiotic treatment will minimize growth potential of culture
Additional Information	Provide any antibiotic treatment information
	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov

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

Synonym(s)	Borreliosis, Recurrent fever, <i>Borrelia</i>
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date o birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
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	
·	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	Two tier testing will be performed. If available, submit any preliminary results. Include the date of onset, antibiotic treatment (type of antibiotics and date administered), date when the sample was collected, signs and symptoms.
	If testing needs to be performed by another laboratory, i.e. arborvirus, please contact laboratory prior to shipping.
CDC Points of Contact	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov

#### **Borrelia** Special Study

CDC-10300

Synonym(s)	None
Pre-Approval Needed	Schriefer, Marty, (970) 221–6479, mms7@cdc.gov Petersen, Jeannine, (970) 266–3524, nzp0@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	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov

# **Test Order**Botulinum Toxin Producing Clostridia Subtyping CDC-10134

(c) 112 a 121 112 (a)	Det Detuliens
• • • • •	Bot, Botulism
Pre-Approval Needed	Luquez, Carolina, (404) 639–0896, fry6@cdc.gov Maslanka, Susan, (404) 639–0895, sht5@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
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries  Package must have proper labeling for infectious substance: UN 2814 Infectious substance, Category A
Methodology	Pulsed field gel electrophoresis (PFGE)
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: <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a> ; Please send to POC: anticipated arrival date, courier, and tracking number.
CDC Points of Contact	Carolina Luquez (Primary POC) (404) 639-0896 fry6@cdc.gov Susan Maslanka (Alternate POC) (404) 639-0895 sht5@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
	Foodborne: serum, stool, vomitus, gastric contents, and food Wound: serum, debrided tissue, swab from wounds, and stool (to rule out foodborne botulism) Infant: stool, rectal swabs, and 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.
Include Specimen Handling	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 (Primary POC) (404) 639-0896 fry6@cdc.gov Susan Maslanka (Alternate POC) (404) 639-0895 sht5@cdc.gov

Version: 1.2

Tuesday, November 29, 2016

## **Test Order**Botulism Special Study CDC-10133

Synonym(s)	None
Pre-Approval Needed	Luquez, Carolina, (404) 639–0896, fry6@cdc.gov Maslanka, Susan, (404) 639–0895, sht5@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 (Primary POC) (404) 639-0896 fry6@cdc.gov Susan Maslanka (Alternate POC) (404) 639-0895 sht5@cdc.gov

### 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.
Include Specimen Handling	Select agents that have been identified need form 2 approval prior to shipping. Form 2 may be found at: <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a> 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 Suseptability, Broth Micr Dilution, MLVA
Turnaround Time	2 Weeks
Interferences & Limitations	None
Additional Information	Turnaround time will vary depending on if an isolate is sent for identification of 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: <a href="http://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf">http://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf</a>
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	
· · ·	
Supplemental Information Required	None
Supplemental Form	http://www.selectagents.gov/forms.html
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	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.
	Select agents that have been identified need form 2 approval prior to shipping. Form 2 can be found at: <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a>
·	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: <a href="http://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf">http://www.asm.org/images/pdf/Clinical/Protocols/brucella10-15-04.pdf</a>
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	
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 <i>B. Canis or RB5</i> 1 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

### 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
	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 specimer container and the test requisition
	Select agents that have been identified need form 2 approval prior to shipping. Form 2 can be found at <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a> 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, Multilocu 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 of 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: <a href="http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf">http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf</a>
CDC Points of Contact	Mindy Elrod (404) 639-4055 wzg0@cdc.gov David Lonsway (404) 639-2825 dul7@cdc.gov

### 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
	Blood, bone marrow, sputum or bronchoscopically obtained specimens, absces 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 specimer container and the test requisition
Include Specimen Handling	Select agents that have been identified need form 2 approval prior to shipping. Form 2 can be found at <a href="http://www.selectagents.gov/forms.html">http://www.selectagents.gov/forms.html</a> 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: <a href="http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf">http://asm.org/images/pdf/Clinical/Protocols/bpseudomallei2008.pdf</a>
CDC Points of Contact	Jay Gee (404) 639-4936 xzg4@cdc.gov Mindy Elrod (404) 639-4055 wzg0@cdc.gov

### 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

#### 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	Serum should be shipped at 4°C
Methodology	IHA-indirect haemagglutantion
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

### 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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

### Campylobacter and Helicobacter Study CDC-10125

C o (a)	Committee and an incident
	Campy, H. pylori
Pre-Approval Needed	Pruckler, Janet, (404) 639–4770, jmp5@cdc.gov Korth, Michael, (404) 639–2099, mqk8@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 Michael Korth (404) 639-2099 mgk8@cdc.gov

### Campylobacter species serology CDC-10455

Synonym(s)	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Korth, Michael, (404) 639–2099, mqk8@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
	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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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 Michael Korth (404) 639-2099 mqk8@cdc.gov

### Campylobacter, Helicobacter, and Related Organisms Identification

#### CDC-10126

Synonym(s)	Campy, H. pylori
Pre-Approval Needed	None
	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
Include Specimen Handling	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 foodborn outbreak activities or due to limited availability of resources.
CDC Points of Contact	Janet Pruckler (404) 639-4770 jmp5@cdc.gov Michael Korth (404) 639-2099 mqk8@cdc.gov

#### Campylobacter, Helicobacter, and Related Organisms Identification and Subtyping

CDC-10127

Synonym(s)	Campy, H. pylori
Pre-Approval Needed	None
	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	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, Penner Serotyping, PFGE, AST
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 foodborn outbreak activities due to limited availability of resources.
CDC Points of Contact	Janet Pruckler (404) 639-4770 jmp5@cdc.gov Michael Korth (404) 639-2099 mqk8@cdc.gov

## **Test Order**Chagas Disease Molecular Detection CDC-10475

Synonym(s)	Trypanosoma cruzi; American trypanosomiasis, parasite
Pre-Approval Needed	None
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)
	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.
	Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimer on wet ice (cold pack) as an etiologic agent.
Methodology	Real-time PCR
Turnaround Time	21 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**Chagas Disease Serology CDC-10458

Synonym(s)	Trypanosoma cruzi, American trypanosomiasis, parasite
Pre-Approval Needed	None
	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	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

## Chlamydia pneumoniae Molecular Detection CDC-10152

	Chlamydia pneumoniae, Atypical pneumonia, CAP, Chlamydia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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
	Specimens can be kept refrigerated if shipped in less than 72 hours of collections 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	
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 <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , and <i>Legionella</i> 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

## Chlamydia psittaci Molecular Detection CDC-10153

Synonym(s)	Psittacosis, Parrot fever, <i>Chlamydia psittaci</i>
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
	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
	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

#### 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 <i>Chlamydia</i> species specifically <i>Chlamydia pneumoniae</i> and <i>Chlamydia psittaci</i> .
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

## 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 o 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
	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	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
	John Papp (404) 639–3785 jwp6@cdc.gov Christi Phillips (404) 639–2147 div2@cdc.gov

## Chlamydia trachomatis, Genital - Study CDC-10193

C	None
Synonym(s)	
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

#### 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 wit 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

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

## Congo-Crimean Hemorrhagic Fever Identification CDC-10302

Synonym(s)	CCHF
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order**Congo-Crimean Hemorrhagic Fever Serology CDC-10303

Synonym(s)	CCHF
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
9	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### Corynebacterium diphtheriae Study

CDC-10172

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	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 Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

## 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
	Pure culture isolates on a suitable agar slant, extracted DNA, or pseudomembrane
Minimum Volume Required	100 uL (DNA)
	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 including 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	5 Days
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 no 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

# Corynebacterium diphtheriae/ ulcerans/ pseudotuberculosis ID and Toxigenicity CDC-10169

Synonym(s)	Diphtheria
Pre-Approval Needed	None
Supplemental Information Required	
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
	Use plastic/glass screw-cap, leak-proof vials. Isolates can be refrigerated on ar 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
Include Specimen Handling	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 including 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	1 Week
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

#### Corynebacterium diphtheriae/ulcerans/pseudotuberculosis Isolation, ID, Toxigenicity CDC-10168

CDC 10100	
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	
Methodology	Culture, Polymerase Chain Reaction (PCR), API Coryne, Elek
Turnaround Time	1 Week
	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 Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

## Corynebacterium species (Not *C. diphtheriae*) ID CDC-10136

Cym c my ma (a)	Dinthorio
Synonym(s)	·
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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

#### Coxiella burnetii Molecular Detection

#### CDC-10304

Synonym(s)	Q fever
Pre-Approval Needed	None
	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
	Acute samples only, anticoagulated whole blood collected in Ethylenediaminetetraacetic acid (EDTA) treated tubes preferred; serum; fresh tissue biopsy
Minimum Volume Required	1.0 mL
	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 and date of birth
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 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 commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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#### Coxiella burnetii Serology

CDC-10305

Synonym(s)	Q fever
Pre-Approval Needed	None
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	
Methodology	Indirect Fluorescence 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 is 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. Routine diagnostic samples should be sent to your State Laboratory or commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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# Test Order Coxiella Special Study CDC-10306

Q fever
Kato, Cecilia, (404) 639–1075, ckato@cdc.gov Paddock, Christopher, (404) 639–1309, cdp9@cdc.gov
None
None
Human, Animal, and Food/Environmental/Medical Devices/Biologics
To be determined
To be determined
To be determined
Cecilia Kato (404) 639–1075 ckato@cdc.gov Christopher Paddock (404) 639–1309 cdp9@cdc.gov

## 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
	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.
Include Specimen Handling	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	21 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, <i>Taenia solium</i> , cysitcercus, EITB, LLGP-EITB, parasite
Pre-Approval Needed	None
	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; Cerebrospinal fluid (CSF)
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.
	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.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	None
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.
Methodology	IgG antibody detected by EIA, IgM antibody detected by EIA
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	None
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
	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
	After blood is allowed to clot, separate serum by centrifugation and keep serum refrigerated at $4^{\circ}$ C or frozen at $-20^{\circ}$ 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 o 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
74.	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 isolatio 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.

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## **Test Order**Dengue Virus Diagnosis CDC-10307

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

## Dengue Virus Special Study CDC-10308

<b>6</b> ()	N.
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, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order**Ebola Serology CDC-10310

Synonym(s)	None
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# Test Order Echinococcosis Serology CDC-10460

Hydatid Disease, <i>Echinococcus granulosus</i> , parasite
None
Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
None
Human
Serum and plasma
0.5 mL
No specific requirements
Not Applicable
Test subject to CLIA regulations require two patient identifiers on the specimer container and the test requisition.
Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.
Immunoblot, Western Blot, Antibody detection
18 Days
Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
None
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 Paddock, Christopher, (404) 639–1309, cdp9@cdc.gov
	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
	Acute samples only, anticoagulated whole blood collected in Ethylenediaminetetraacetic acid (EDTA) treated tubes preferred; serum; fresh tissue biopsy
Minimum Volume Required	1.0 mL
	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 samp collection tube
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shou 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 commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

## **Test Order** *Ehrlichia* Serology

#### CDC-10311

	Human monocytic ehrlichiosis
Pre-Approval Needed	None
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shoul be shipped refrigerated on cold packs.
Methodology	Indirect Fluorescence 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 is 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. Routine diagnostic samples should be sent to your State Laboratory or commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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#### **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 Paddock, Christopher, (404) 639–1309, cdp9@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	Cecilia Kato (404) 639–0152 ckato@cdc.gov Christopher Paddock (404) 639–1309

## Entamoeba histolytica/ dispar Molecular Detection CDC-10478

Synonym(s)	Amebiasis, <i>Entameba histolytica</i> , <i>Entameba dispar</i> , parasite
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Stool, liver aspirate
Minimum Volume Required	0.5 g or 0.5 ml
	Specimens collected in the absence of preservatives must be kept refrigerated (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.
Include Specimen Handling	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	Yvonne Qvarnstrom (404) 718–4123 bvp2@cdc.gov Theresa Benedict (404) 718–4124 tgd5@cdc.gov

## Enteric Isolation - Primary Specimen CDC-10106

Synonym(s)	Enteric Pathogen Culture
Pre-Approval Needed	Martin, Haley, (404) 639–1612, hvw0@cdc.gov Fitzgerald, Collette, (404) 639–0838, chf3@cdc.gov
	Consult with EDLB contact before sending specimens. Targeted organisms include: Salmonella, Shigella, Campylobacter, STEC, 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
	Specimens that are acceptable will be determined upon consultation. Targeted organisms include: <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , STEC, pathogenic <i>Enterobacteriaceae</i> , <i>Listeria</i> , <i>Vibrio</i> , <i>Cronobacter</i> , 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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	Specifics of shipping will depend upon consultation
Methodology	Enrichment, Isolation, Phenotypic 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 Collette Fitzgerald (404) 639-0838 chf3@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, A.Jo, (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 isoloate: n/a
	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.
	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 A.Jo Williams-Newkirk (404) 639-1087 lgy7@cdc.gov

## Test Order Enterovirus Detection and Identification CDC-10312

Synonym(s)	Enterovirus (EV), coxsackieviruses (CVA) (CVB), Echovirus
Pre-Approval Needed	None
Supplemental Information Required	
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	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
	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 the may contain substances that inactivate some viruses and inhibit some molecula 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 swak 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.
	Stool: Stool may be collected within 14 days of symptom onset. Collect 10–20 of stool in a clean, day, look, proof container.

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of stool in a clean, dry, leak-proof container.

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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-Approvai 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**Environmental Microbiology Study CDC-10232

Synonym(s)	None
Pre-Approval Needed	Noble-Wang, Judith, (404) 639-2321, cux2@cdc.gov O'Connell, Heather, (404) 639-4864, ftw2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	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	Judith Noble-Wang (404) 639-2321 cux2@cdc.gov Heather O'Connell (404) 639-4864 ftw2@cdc.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	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.
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

## Escherichia and Shigella Identification, Serotyping, and Virulence Profiling

CDC-10114

Synonym(s)	None
Pre-Approval Needed	None
	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
	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 los 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

# **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
	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 los 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

### Escherichia coli (STEC) serology (not serotyping) CDC-10452

Synonym(s)	Enteric Pathogen
	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Korth, Michael, (404) 639–2099, mqk8@cdc.gov
	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
	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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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 in needed.
CDC Points of Contact	Rachael Aubert (404) 639-3816 vrl7@cdc.gov Michael Korth (404) 639-2099 mqk8@cdc.gov

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

Synonym(s)	E. coli Typing, Shigella Typing
Pre-Approval Needed	None
	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
	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	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
	Phenotypic Serotyping, Genetic Serotyping, Virulence Profiling, AST, PFGE, MLV
Turnaround Time	8 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic element (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lo 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 foodborn outbreak activities or due to limited availability of resources.
CDC Points of Contact	

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#### Fascioliasis Serology

#### CDC-10505

Fascioliasis, Fasciola hepatica, liver fluke
DPDM Public Inquiries, , (404) 718-4745, parasites@cdc.gov DPDx, , , dpdx@cdc.gov
Please contact Public Inquiries at the Division of Parasitic Diseases and Malaria at phone number (404)718-4745 or at <a href="mailto:Parasites@cdc.gov">Parasites@cdc.gov</a> to get pre-approval to order the Fascioliasis serology.
None
Human
Serum and plasma
2.0 ml
No specific requirements
Not applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition
Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice
Immunoblot, Western blot, Antibody detection
18 Days
Substances known to interfere with immunoassays include: bilirubin, lipids and hemoglobin
none
Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120

## **Test Order**Filariasis Serology CDC-10462

Brugia malayi, Wuchereria bancrofti, Bancroftian filariasis, parasite
None
Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
None
Human
Serum or Plasma
0.5 mL
No specific requirements
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.
EIA, ELISA, Antibody Detection
18 Days
Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
None
Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120

### Francisella tularensis Culture and Identification CDC-10313

Synonym(s)	Tularemia
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date of birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human and Animal
	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
	Store specimens containing suspected live bacteria at 2°-8°C to maintain viability. If processing is delayed, tissue samples can be directly frozen at -70°C. Store samples for culture of live bacteria without preservatives (formaldehyde, alcohol), at 2°-8°C (not frozen). Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.
Transport Medium	Respiratory specimens, lymph node aspirates, blood, tissue/biopsy/autopsy/necropsy specimens should all be transported at 4°C. Swabs must be in a Cary-Blair or Amies medium, not frozen. If tissue biopsy/autopsy/necropsy transport is delayed, tissue samples can be directly frozen at -70°C.
Specimen Labeling	Specimen identifier and patient name
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
	Culture, Direct Fluorescent Antibody (DFA), Biochemical subtyping
Turnaround Time	
	Samples for testing by culture should be taken prior to antibiotic treatment
Additional Information	
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Marty Schriefer (970) 221-6479 mms7@cdc.gov

#### Francisella tularensis Serology

CDC-10314

Synonym(s)	Tularemia
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date or birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	500 uL
	Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longe period, serum samples may be frozen.
Transport Medium	Not Applicable
Specimen Labeling	Specimen identifier and patient name
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 Marty Schriefer (970) 221-6479 mms7@cdc.gov

## Francisella tularensis Special Study CDC-10315

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov Schriefer, Marty, (970) 221–6479, mms7@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 Marty Schriefer (970) 221-6479 mms7@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	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

## Fungal Serology – *Basidiobolus* CDC-10183

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.
Include Specimen Handling	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	Immunodiffusion
Turnaround Time	2 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

### 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

## 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.
Include Specimen Handling	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 – *Sporothrix*CDC-10182

Synonym(s)	Fungal serology, fungal complement fixation, fungal immunodiffusion, latex agglutination for <i>Sporothrix</i>
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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	Refrigerated specimen at 4°C should be shipped on cold packs Frozen specimen should be shipped on dry ice
Methodology	Complement Fixation, Immunodiffusion, Latex Agglutination
Turnaround Time	2 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

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

#### CDC-10174

Synonym(s)	GUD
Pre-Approval Needed	None
Supplemental Information Required	
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.
Include Specimen Handling	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 cycl@cdc.gov Kai Chi (404) 639-0694 krc2@cdc.gov

## 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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

## 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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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

Synanym(s)	Gram Positive Rod Identification, GPB, GPR
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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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

#### 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
Include Specimen Handling	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 cycl@cdc.gov Kai Chi (404) 639-0694 krc2@cdc.gov

## Haemophilus influenzae Identification and Serotyping CDC-10221

Synonym(s)	H. influenzae ID and SAST, H. flu, Hi
Pre-Approval Needed	None
	If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section of submission form
Supplemental Form	None
Performed on Specimens From	Human
	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
	Primary specimens or stocks should be kept frozen. After overnight incubation at 37°C with 5% CO2, store slants at an ambient temperature
Transport Medium	Preferred medium include chocolate agar slants or frozen stocks. If possible, for the shipment of 10 or more specimens, please ship frozen stocks.
Specimen Labeling	Tests subject to CLIA regulations require two patient identifiers on the specime container and the test requisition. Label ABCs/Enhanced Surveillance specimer with the state ID & accession number.
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries.
	Frozen specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and if possible, email spreadsheet prior to shipment.
Methodology	Growth, Morphology, Biochemical Testing, Slide Agglutination Serotyping, Real- time PCR
Turnaround Time	30 Days
Interferences & Limitations	Improperly temperature controlled specimens/isolates can give false negative results.
Additional Information	Turnaround time: 30 days for real-time PCR testing of clinical specimens; 90 days for testing of enhanced surveillance submissions
CDC Points of Contact	Melissa Whaley (404) 639–3920 (404) 639–5009 (404) 639–5009 (404) 639–1340 (404)

### Haemophilus influenzae Study

CDC-10222

Synonym(s)	Hi Study
Pre-Approval Needed	Wang, Xin, (404) 639–5474, gqe8@cdc.gov Briere, Elizabeth, (404) 639–0732, ejc0@cdc.gov
Supplemental Information Required	Brief description of study or surveillance program.
	Supplemental Form Required: CDC Meningitis Laboratory: Molecular Typing Request Submission Form (provided upon request by CDC Meningitis Laboratory).
Supplemental Form	
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Pure culture isolate or frozen stock.
Minimum Volume Required	N/A
	Primary specimens or stocks should be kept frozen. After overnight incubation a 37C with 5% CO2, store slants at an ambient temperature.
Transport Medium	Chocolate agar slants or frozen stocks.
Specimen Labeling	Tests subject to CLIA regulations require two patient identifiers on the specimer container and the test requisition.
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries.
	Frozen specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and if possible, email spreadsheet prior to shipment.
Methodology	Multilocus Sequence Typing (MLST), Whole genome sequencing (WGS)
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Xin Wang (404) 639-5474
	gqe8@cdc.gov
	Melissa Whaley
	(404) 639–3920
	dbq3@cdc.gov

## 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
	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, 165 sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

## *Hantavirus* (No. American) Identification CDC-10319

Synonym(s)	Hanta, HPS, HFRS
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### Hantavirus (So. American) Identification CDC-10320

6	Livery LIDC LIEDC
	Hanta, HPS, HFRS
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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	
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order** *Hantavirus* Serology CDC-10321

Synonym(s)	Hanta, HPS, HFRS, Hantaan
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
_	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### 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
	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
Include Specimen Handling	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 404-639-4000If healthcare facility will be submitting samples directly to CDC they must receive prior approval from State Health Department. Provide State Health Department contact informationFor isolate submission, include the test method that was used to identify the specimen in the "Previous Laboratory Results/Comments" section.
CDC Points of Contact	Heather Moulton-Meissner (404) 639-4864 ftw2@cdc.gov Judith Noble-Wang (404) 639-2321 cux2@cdc.gov

## Helicobacter pylori Special Study CDC-10117

Synonym(s)	None
Pre-Approval Needed	Rudolph, Karen, (907) 729-3454, kmr2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Gastric biopsy
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	Store at -70°C
Transport Medium	Cysteine Freeze media
Specimen Labeling	Specimen ID number and area of stomach e.g. antrum or fundus
Shipping Instructions which Include Specimen Handling Requirements	Ship on dry ice
Methodology	Culture
Turnaround Time	15 Days
Interferences & Limitations	To be determined
Additional Information	Please provide shipping information to CDC Points of Contact prior to shipping specimens
CDC Points of Contact	Karen Rudolph (907) 729-3454 kmr2@cdc.gov Julie Morris (907) 729-3445 zbf2@cdc.gov

# **Test Order**Hendra Serology CDC-10324

Synonym(s)	None
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
•	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@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.
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
<u> </u>	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.
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice
	HBsAg by EIA, IgM anti-HBc by Chemiluminescence, Total anti-HBc by Chemiluminescence, Anti-HBs by Chemiluminescence, HBeAg by Chemiluminescence, Anti-Hbe by EIA, HBV DNA by TaqMan IVD, HBV Genotyping by NAT 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 specimer 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 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	(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.
Include Specimen Handling	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 b NAT 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

HDV, Hepatitis D virus
None
None
None
Human
Serum, EDTA Plasma
2 mL
Specimens should be stored frozen
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship specimen Monday -Thursday overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice
Total anti-HDV by EIA, HDV RNA by Real Time qRT-PCR, HDV Genotyping by direct sequence analysis
2 Weeks
Hemolyzed specimen are not accepted
NAT based assays and genotyping may take up to 3 weeks for turn around tim
Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Saleem Kamili (404) 639-4431

## **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.
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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, HE 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 (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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 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

### 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	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.
Methodology	IgG 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**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
	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.
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	
	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		
Methodology	EIA	
Turnaround Time	21 Days	
Interferences & Limitations	s 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	

### HIV Molecular Surveillance Study (International Only) CDC-10332

Synonym(s)	None	
Pre-Approval Needed	Yang, Chunfu, (404) 639–4975, cxy0@cdc.gov DeVos, Joshua, (404) 639–5442, ext8@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	Chunfu Yang (Primary POC) (404) 639-4975 cxy0@cdc.gov Joshua DeVos (Secondary POC) (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	
	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	
	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	
	Ship specimen Monday -Thursday overnight to avoid weekend deliveries	
Include Specimen Handling	Frozen specimen should be shipped on dry ice	
Requirements	Refrigerated specimen should be shipped on cold packs	
Methodology	Enzyme-linked Immunosorbent Assay (ELISA), Western Blot, Rapid Test	
Turnaround Time	21 Days	
Interferences & Limitations	i None	
Additional Information	None	
CDC Points of Contact		
	(404) 639–3850	
	txg1@cdc.gov	
	Bill Switzer	
	(404) 639–0219 bis3@cdc.gov	
	ກາລວພັບແບ່.gov	

### 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

### HIV-1 Drug Resistance Special Study (International Only) CDC-10334

Synonym(s)	None	
Pre-Approval Needed	Yang, Chunfu, (404) 639–4975, cxy0@cdc.gov DeVos, Joshua, (404) 639–5442, ext8@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	Chunfu Yang (Primary POC) (404) 639-4975 cxy0@cdc.gov Joshua DeVos (Secondary POC) (404) 639-5442 ext8@cdc.gov	

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

Synonym(s)	HIV DR, HIV, HIV Sequencing, HIV Susceptibility	
	d Yang, Chunfu, (404) 639–4975, cxy0@cdc.gov DeVos, Joshua, (404) 639–5442, ext8@cdc.gov	
Supplemental Information Required		
	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	
	Plasma, serum, and dried blood spots (DBS). Dried blood spots should be least saturated 13mm circles (preferably 5) containing 100 $\mu$ L of whole blood.	
Minimum Volume Required	1 mL (Plasma or Serum)	
	For plasma or serum keep frozen at $-65^{\circ}$ C to $-80^{\circ}$ C for 6 months. Use the appropriate anticoagulant (EDTA).	
	Dried blood spots should be kept at an ambient temperature ( $15^{\circ}-35^{\circ}$ C) for testing performed within 14 days and frozen at $-70^{\circ}$ C or colder if testing is not performed within 14 days.	
Transport Medium	Plasma or serum should be transported in a 1.5 – 2.0 mL polypropylene tube with screw cap and O-ring. Transport specimens in frozen conditions using dry ice or liquid nitrogen. Dried blood spots should each be wrapped with a folded sheet of glassine paper. Stack 5–10 glassine paper-wrapped cards into a gasimpermeable, sealable, plastic bag containing 5–10 desiccant packs to remove residual moisture along with one humidity indicator card. Ensure the specimen identification is clearly written on both the DBS card and on the plastic bag. Ensure the humidity indicator can be read without opening the bag. Gently app pressure to the partially sealed bag to expel the air before sealing it completely Place 5–10 of the above small bags into a large plastic bag.	
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.	
Include Specimen Handling	For shipments that are in transit for up to 14 days, maintain at ambient temperature ( $20^{\circ}-30^{\circ}$ C) and for greater than 14 days, maintain temperature at $-20^{\circ}$ C or colder with dry ice.	
Methodology	Identification of mutations within HIV-1 pol gene region, Sequencing	
Turnaround Time	24 Weeks	
Interferences & Limitations	Do not use heparin as an anticoagulant. Plasma and serum should not be used	

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

after more than 2 freeze-thaw cycles. Plasma or serum 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.

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 The In-house assay may not detect minor viral species that constitute less than 20% of the circulating virus population. Consultation with an expert in HIV drug resistance is encouraged to facilitate interpretation of genotype test results, and to evaluate which mutations and/or combinations of mutations are associated with drug resistance.

CDC Points of Contact Chunfu Yang (Primary POC)

(404) 639-4975 cxy0@cdc.gov

Joshua DeVos (Secondary POC)

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(404) 639 - 5442ext8@cdc.gov

### 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	
	Serum, plasma or whole blood. Specimens may be collected EDTA, ACD sodium citrate, PPT, or serum tubes. Follow sample tube manufacturer's instructions	
Minimum Volume Required	1 mL	
	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 $<=25^{\circ}\text{C}$ ; 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 separated from the cells may be stored for longer periods of time at $<=20^{\circ}\text{C}$ before testing. Do not freeze whole blood. Long-term storage of serum has not been evaluated.	
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.  Keep specimen at room temperature. If frozen, specimen should be shipped on dry ice.	
Methodology	Nucleic acid amplification	
Turnaround Time		
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 by centrifugation and freeze (-70°C is optimal, -20°C acceptable) as soon as possible after separation (min volume of 1 mL of plasma is required, 5 mLs is optimal). For DNA amplification, (required for HIV-2), freeze the cell pellet after plasma separation (-70°C is optimal, -20°C acceptable). Indicate the original volume of blood used to generate the pellet on the shipping form. If blood separation is not possible, tubes may be shipped overnight at ambient temperature.	
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Tim Granade (404) 639-3850 txg1@cdc.gov	

### **Test Order**HIV-1 Nucleic Acid Amplification (Viral Load) CDC-10276

Synonym(s)	HIV RNA-PCR, HIV RT-PCR, HIV Roche Viral load, HIV Cobas, HIV Abbot Viral	
	load, HIV NAAT	
Pre-Approval Needed	Granade, Tim, (404) 639–3850, txg1@cdc.gov Switzer, Bill, (404) 639–0219, bis3@cdc.gov	
Supplemental Information Required		
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Plasma collected in EDTA anticoagulant.	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Follow manufacturer's instructions for proper collection.	
Minimum Volume Required	1 mL	
•	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 2 hours and at 2–8°C for up to 5 days. Plasma may be frozen at –20°C for up to 6 weeks (42 days); longer storage should be at –70°C or colder. Freeze–thaw cycles should be avoided and should not exceed 3 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.	
Methodology	Real time polymerase chain reaction (RT-PCR)	
Turnaround Time		
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with PCR amplification.	
Additional Information	For RNA testing, separate the plasma by centrifugation and freeze (-70°C is optimal, -20°C acceptable) as soon as possible after separation (min volume of 1 mL of plasma is required, 5 mL is optimal).	
CDC Points of Contact	Tim Granade (404) 639-3850 txg1@cdc.gov Bill Switzer (404) 639-0219 bis3@cdc.gov	

### HIV-1 PCR (International Only) Qualitative CDC-10336

Synonym(s)	HIV, EID, PMTCT, Early infant diagnostic, DNA	
	Hurlston, MacKenzie, (404) 639–1281, wpd9@cdc.gov	
The Approval Necucu	Diallo, Karidia, (404) 639–3568, edu9@cdc.gov	
Supplemental Information Required	Specimens must be accompanied with complete requisition form(s)	
Supplemental Form	None	
Performed on Specimens From	Human	
	Dried Blood Spots (DBS). At least 4 saturated 13mm circles (preferably 5) containing $50-100~\mu L$ of whole blood including capillary blood obtained by finger/toe/heel stick which is dropped directly onto the DBS card.	
Minimum Volume Required	Not Applicable	
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 ( $15^{\circ}-35^{\circ}$ C) for testing performed within 14 days and frozen at $-70^{\circ}$ C if testing is not performe within 14 days.	
Transport Medium	Transport specimen in a gas impermeable plastic bag with desiccant and humidity indicator card. Each DBS card needs to be 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 14 days, maintain at ambient temperature ( $15^{\circ}-35^{\circ}$ C) and shipments that are in transit for greater than 14 days, maintain temperature at $-20^{\circ}$ C or colder with dry ice.	
Methodology	Qualitative PCR	
Turnaround Time	28 Days	
	Do not use heparin as an anticoagulant. Specimen will be rejected if improper 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 specindicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.	
Additional Information	A test result of "HIV-1 Not Detected" or "Target not detected", does not rule our necessarily HIV-1 DNA for the Amplicor test or HIV-1 RNA and DNA for the COBAS AmpliPrep platform. Either nucleic acid (HIV-1 DNA/RNA) concentration below the limit of detection of the assays, the presence of PCR inhibitors in the patient specimen or improper specimen handling can lead to false negative results. PCR may not detect infection in the first weeks of infant's life (< 6 weeks) or within 6 weeks of weaning. 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	

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

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, requests must be submitted and

reviewed by the team lead.

CDC Points of Contact MacKenzie Hurlston (Primary POC)

(404) 639–1281 wpd9@cdc.gov

Karidia Diallo (Secondary POC)

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(404) 639–3568 edu9@cdc.gov

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

	HIV, VL, RNA	
Pre-Approval Needed	Hurlston, MacKenzie, (404) 639–1281, wpd9@cdc.gov Diallo, Karidia, (404) 639–3568, edu9@cdc.gov	
Supplemental Information Required	n Specimens must be accompanied with complete requisition form(s).	
	CDC Form 0.753: Application for Permit to Import Etiological Agents, Hosts, or Vectors Requisition Form	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Plasma	
Minimum Volume Required	0.2 mL	
Storage & Preservation of Specimen Prior to Shipping	The appropriate anticoagulant for whole blood	
	Specimen should be kept at ambient temperature $(20^{\circ}-35^{\circ}C)$ within 14 days at collection, but frozen at $-70^{\circ}C$ if testing is to be performed after 14 days.	
Transport Medium	Transport specimen in a sterile 1.5–2.0 mL polypropylene tube, screw cap with O-ring	
Specimen Labeling	g All primary specimen containers must include 2 unique identifiers at the time collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.	
	Surveillance studies and some protocols require recommends 2 identifiers) de-linked from the patient's name or any other personally identifia reported back to patient.	patient. Do not include the
Include Specimen Handling	For shipments that are in transit for up to 5 days, maintain at (2–8°C) and shipments in transit for greater than 5 days, maintain temperature at -20°C or colder with dry ice.	
Methodology	Quantitative PCR	
Turnaround Time		
Interferences & Limitations	s Do not use heparin as an anticoagulant. Do not use specimens after more than freeze-thaw cycles for the Roche assays and 3 freeze-thaw cycles for the Abbot 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	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:  COBAS® AmpliPrep/COBAS® Taqman® v2.0 is 20-10,000,000 copies/mL(1.30log-7.00log)	
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### HIV-1 PCR (International Only) Quantitative Viral Load CDC-10337

Amplicor® HIV-1 Monitor v1.5 is 400-750,000 copies/mL(2.60log-5.88log) Abbott Real Time HIV-1 assay is 40-10,000,000 copies/mL(1.60-7.00log) The COBAS® AmpliPrep/COBAS® Taqman® HIV-1 v2.0 test exhibits a higher level of sensitivity when compared to the Amplicor® HIV-1 Monitor v1.5 test and the Abbott Real Time HIV-1 test for the m2000 system. NOTE: If a specific testing platform is required, requests must be submitted and reviewed by the Team Lead.

CDC Points of Contact MacKenzie Hurlston (Primary POC)

(404) 639–1281 wpd9@cdc.gov

Karidia Diallo (Secondary POC)

Version: 1.3

(404) 639–3568 edu9@cdc.gov

### HIV-1/2 Antibody (International Only) EIA and Western Blot CDC-10338

Synonym(s)	HIV, EIA, WB, ELISA	
Pre-Approval Needed	d 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	
	Plasma, serum and dried blood spots. Dried Blood Spots should be at least 4 saturated 13mm filter paper circles (preferably 5) containing 75 $\mu$ L of whole blood.	
Minimum Volume Required	0.5 mL (plasma and serum)	
	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 ( $20^{\circ}-30^{\circ}C$ ) if testing is performed within 14 days. Specimen should be frozen at $-20^{\circ}C$ 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 prick 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 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 no reported back to patient.	
	For shipments that are in transit for up to 7 days, maintain temperature at 2-3 For shipments that are in transit for greater than 7 days, maintain temperature at $-20^{\circ}$ C or colder with dry ice.	
	For shipments that are in transit for up to 14 days, maintain at ambient	

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temperature (20-30°C). For shipments that are in transit for greater than 14

### HIV-1/2 Antibody (International Only) EIA and Western Blot CDC-10338

	days, maintain temperature at $-20^{\circ}$ 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 perfumed 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	· · · · · · · · · · · · · · · · · · ·

### 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
	The appropriate anticoagulants for whole blood collection are EDTA or Sodium heparin. Keep specimen at ambient temperature at $15^{\circ}-35^{\circ}$ C if testing will be performed within 48 hours of collection. If testing is to be performed within 7 days keep specimen refrigerated at $2^{\circ}-8^{\circ}$ C. If testing is to be performed after 7 days, keep specimen frozen at $-20^{\circ}$ 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 $2-8$ 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, an 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 (404) 639-2794

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

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chn7@cdc.gov

### 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
• • • •	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
	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
Include Specimen Handling	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

### 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	Serum and plasma
Minimum Volume Required	1 mL
	Specimen should be properly stored in ethylenediaminetetraacetic acid (EDTA) of Acid Citrate Dextrose (ACD) tubes. Serum and plasma can be stored at room temperature. For plasma only collections, Plasma Preparation Tubes (PPT) are suitable.
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
Include Specimen Handling	Ship specimen Monday –Thursday overnight to avoid weekend deliveries.
Requirements	Keep specimen at room temperature. If frozen, specimen should be shipped 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	For RNA testing, separate the plasma by centrifugation and freeze (-70°C is optimal, -20°C acceptable) as soon as possible after separation (min volume of 1 mL of plasma is required, 5 mL is optimal). For DNA amplification, (required for HIV-2), freeze the cell pellet after plasma separation (-70°C is optimal, -20°C acceptable). Indicate the original volume of blood used to generate the pellet of the shipping form. If blood separation is not possible, tubes may be shipped overnight at ambient temperature.
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

Synanym(s)	HIV ELISA, HIV antibody
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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
_	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
•	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Include Specimen Handling	
Requirements	Frozen specimen should be shipped on dry ice
Macha adala su	Refrigerated specimen should be shipped on cold packs
	HIV-1/2 Differentiation Assay, HIV-2 Western Blot
Turnaround Time	·
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) 639-3 Panicker, Gitika, (404) 639-22		
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 (PC	R), 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 EDT/ 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.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 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

### 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
	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	Clearly identify the sample and an associated patient ID number.
	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	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 ar 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 protocol is not operated currently under the CLIA certificate, as it is still in the process of being evaluated and validated; it is for research purposes only.
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.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 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 EDT/ 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.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	None
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.
Methodology	IgG antibody detected by IFA
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
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
Pre-Approval Needed	testing
<u> </u>	
	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
	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
	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 $\leq$ –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 $\leq$ –70°C and tested at a later time. Specimens received frozen should be stored at $\leq$ –70°C until processing. Store any residual specimens at $\leq$ –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 – <a href="www.iata.org">www.iata.org</a> ) 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 (404) 639–3387 LGubareva@cdc.gov Michelle Adamczyk (404) 639–2276 MAdamczyk@cdc.gov

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# **Test Order**Influenza Molecular Diagnosis CDC-10421

Synonym(s)	Influenza Real Time PCR, Influenza Diagnostics, Flu
Pre-Approval Needed	None
	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
	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
	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 $\leq$ -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 $\leq$ -70°C and tested at a later time. Specimens received frozen should be stored at $\leq$ -70°C until processing. Store any residual specimens at $\leq$ -70°C.
Transport Medium	Swabs must be in viral transport medium
	Specimen ID must match the ID on the form
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries. Urgent speciment 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 – <a href="www.iata.org">www.iata.org</a> ) 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	·
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 surveilland studies will take longer than seven days for results.
CDC Points of Contact	

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## **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
	Paired Serum; Acute (less than 7 days post symptoms onset) and convalescent (a least 14 days after acute serum collection)
Minimum Volume Required	.5 mL
<u> </u>	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	
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 Heather Tatum (404) 639–3504 mwl2@cdc.gov gpg7@cdc.gov Jackie Katz (404) 639–4966

# **Test Order**Influenza Special Study CDC-10425

Synonym(s)	None
	Wentworth, David, (404) 639–3387, gll9@cdc.gov Lindstrom, Stephen, (404) 639–1587, sql5@cdc.gov
	Requires additional WHO submission form that can be obtained with yo password
Supplemental Form	http://www.nltn.org/Influenza-Speicmen-submission-Form.xls
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	
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	David Wentworth       Xu Xiyan         (404) 639-3387       (404) 639-1657         gll9@cdc.gov       xxx1@cdc.gov         Stephen Lindstrom       Larisa Gubareva         (404) 639-1587       (404) 639-3204         sql5@cdc.gov       lqg3@cdc.gov

## **Test Order**Influenza Surveillance CDC-10422

Synonym(s)	Flu, Influenza Antigen Characterization
Pre-Approval Needed	None
	Requires additional WHO submission form that can be obtained with your password
Supplemental Form	http://www.nltn.org/Influenza-Speicmen-submission-Form.xls
Performed on Specimens From	Human
	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
	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 $\leq$ -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 $\leq$ -70°C and tested at a later time. Specimens received frozen should be stored at $\leq$ -70°C until processing. Store any residual specimens at $\leq$ -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	
	Refrigerated specimen should be shipped on cold packs.
<u> </u>	Hemagglutination Inhibition (HI) test, Virus Culture
Turnaround Time	
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.
	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	Xiyan Xu (404) 639–1657 xxx1@cdc.gov Wendy Sessions (404) 639–3211 gra6@cdc.gov

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# Test Order Junin Serology CDC-10340

Synonym(s)	Argentine Hemorrhagic Fever, AHF, arenavirus
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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 specifinformation on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

#### **Test Order** Kyasanur Forest Disease Serology CDC-10341

Synonym(s)	KFD
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

#### **Test Order** Laguna Negra Serology CDC-10342

Synonym(s)	HPS, hanta
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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	
Minimum Volume Required	1 mL
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

## **Test Order**Lassa Fever Identification CDC-10343

Synonym(s)	Arenavirus
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order**Lassa Fever Serology CDC-10344

Synonym(s)	Arenavirus
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order** *Legionella* Special Study CDC-10161

Synonym(s)	None	
Pre-Approval Needed	, legionellalab@cdc.gov, , Raphael, Brian, (404) 639–4292, elx9@cc	lc.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	
Include Specimen Handling	Do not ship on Fridays or the day before a shipping instructions for details. <a href="http://www.cdc.gov/legionella/download-2">http://www.cdc.gov/legionella/download-2</a>	•
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	Junetiche cacigov

### 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
	Human Origin: Isolates or primary specime specimens are sputum, bronchoalveolar la tube (ETT), tracheal aspirate, and urine Environmental Origin: Isolates only	
Minimum Volume Required	Contingent on specimen type. Please see a details. <a href="http://www.cdc.gov/legionella/dov">http://www.cdc.gov/legionella/dov</a>	
	Clinical specimens should be frozen immedappropriate slants [Buffered Charcoal Yeas see attached shipping instructions for detahttp://www.cdc.gov/legionella/downloads	t (BCYE)] and shipped at 4°C. Please ails.
Transport Medium	BCYE or equivalent slants for isolates	
Specimen Labeling	Test subject to CLIA regulations and require specimen container and the test requisition	
Include Specimen Handling	Do not ship on Fridays or the day before a shipping instructions for details. http://www.cdc.gov/legionella/downloads	·
Methodology	Culture, Serogrouping, Sequencing, Real T	ime PCR
Turnaround Time	4 Weeks	
Interferences & Limitations	Specimen should be acquired prior to antib storage and handling may result in inconcl	
Additional Information	If only PCR is needed then turn around tim	e 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.govv	

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

Synonym(s)	LD, Legionnaires' disease, Legionellosis, Po	ontiac fever
Pre-Approval Needed	None	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human and Food/Environmental/Medical I	Devices/Biologics
	Human Origin: Isolates, purified nucleic ac clinical specimens are sputum, bronchoalv endotracheal tube (ETT), and tracheal aspi Environmental Origin: Isolates only	eolar lavage (BAL), lung tissue,
Minimum Volume Required	Contingent on specimen type. Please see a details. http://www.cdc.gov/legionella/downloads	
	Clinical specimens should be frozen imme appropriate slants [Buffered Charcoal Yeas see attached shipping instructions for deta http://www.cdc.gov/legionella/downloads	it (BCYE)] and shipped at 4°C. Please ails.
Transport Medium	BCYE or equivalent slants for isolates	
Specimen Labeling	Test subject to CLIA regulations and requi specimen container and the test requisitio	
Include Specimen Handling	Do not ship on Fridays or the day before a shipping instructions for details. <a href="http://www.cdc.gov/legionella/downloads">http://www.cdc.gov/legionella/downloads</a>	•
Methodology	Real Time PCR, Sequencing	
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	None	
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	

#### Leishmania species Identification

#### CDC-10238

Synonym(s)	Parasite
Pre-Approval Needed	None
	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 roo 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.
Include Specimen Handling	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	6 Weeks
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; <i>Leishmania donovoni Leishmania major</i> , <i>Leishmania</i> , parasite
Pre-Approval Needed	None
	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	
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 (EMJI 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	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	Isolates should be shipped at room temperature. All other specimens shipped a $4^{\circ}$ 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 o 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
	Clinical specimens (blood, CSF, and urine). Blood specimens should be collected in EDTA or Sodium Citrate tubes
Minimum Volume Required	250 uL
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.
Include Specimen Handling	
Requirements	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

Leptospirosis
None
None
None
Human and Animal
Serum (acute and convalescent preferred)
100 uL
Store serum at 4°C before shipping
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Serum should be shipped at 4°C
MAT-micro agglutination
2 Weeks
Renee Galloway (404) 639-5461 zul0@cdc.gov Robyn Stoddard (404) 639-2053

#### 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
	Prior approval is not required for human specimens but is required for all othe 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
	Ship isolates or cultures Monday-Thursday, overnight to avoid weekend
Include Specimen Handling Requirements	Ship at ambient temperature in compliance with Federal and local guidelines
rtequil entertes	
	There are no time constraints for submitting sequence data
	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	
	(404) 639–2011
	crt6@cdc.gov Zuzana Kucerova
	(404) 718–4143
	zik0@cdc.gov

### *Listeria monocytogenes* Identification and Subtyping CDC-10129

Synonym(s)	<i>Listeria</i> Typing
Pre-Approval Needed	None
	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.
nequirements	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 foodborn 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

### LRN Biothreat Multi-Agent Screening - Environmental CDC-10430

Screening for <i>Bacillus anthracis</i> , <i>Brucella spp.</i> , <i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> , <i>Francisella tularensis</i> , <i>Yersinia pestis</i> , Orthopoxvirus, and ricin toxin.
Bowzard, Brad, (404) 639–3626, jbowzard@cdc.gov Andersen, Lauren, (404) 639–4442, wrh5@cdc.gov
Please contact Dr. Brad Bowzard at 404 639-3626 or jbowzard@cdc.gov, for the required supplemental form and packaging and shipping requirements.
None
Food/Environmental/Medical Devices/Biologics
Bulk sampling of visible materials (e.g., powders, liquids, etc.) and/or sampling from contaminated surfaces (e.g., with polyester swabs).
Dependent on Specimen Type
Dry swabs or powders can be stored and shipped at room temperature. Liquid samples should be held and shipped at 4°C.
None
No special requirements
Ship Monday-Thursday, overnight to avoid weekend deliveries, if possible. If weekend delivery is necessary, please contact laboratory upon shipment.
Real Time PCR, Culture Isolation, Time-Resolved Fluorescence
Dependent on sample time
Turnaround time is dependent on test and sample type.
Brad Bowzard (404) 639-3626 jbowzard@cdc.gov Lauren Andersen (404) 639-4442

### LRN Biothreat Multi-Agent Surface Samples - Environmental CDC-10495

Synonym(s)	Bacillus anthracis spore environmental swab and wipe processing procedures; 3M™ Sponge Stick®, macrofoam swabs, surface samples
Pre-Approval Needed	Bowzard, Brad, (404) 639–3626, jbowzard@cdc.gov Andersen, Lauren, (404) 639–4442, wrh5@cdc.gov
	Please contact Dr. Brad Bowzard at 404 639-3626 or jbowzard@cdc.gov for th 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	Sampling from surfaces with no visible contamination using Macrofoam swab or 3M <sup>™</sup> Sponge Stick®; currently only applies for <i>B. anthracis</i> .
Minimum Volume Required	For appropriate interpretation of results, defined sampling areas for each devict must be followed: Macrofoam swab = $26 \text{cm}2$ , $3M^{TM}$ Sponge Stick® = $645 \text{ cm}2$ .
Storage & Preservation of Specimen Prior to Shipping	Devices should be held at 4 degrees and shipped on ice within 24 hours of collection.
Transport Medium	None
Specimen Labeling	No special requirements
	Ship Monday-Thursday, overnight to avoid weekend deliveries, if possible. If weekend delivery is necessary, please contact laboratory upon shipment.
Methodology	Culture with RT-PCR confirmation of colonies
Turnaround Time	4 Days
Interferences & Limitations	Large quantities of dust and/or other organisms may reduce limits of detection.
Additional Information	Testing should be initiated within 24 hours of receipt. Turn around time ranges from 1-4 days.
CDC Points of Contact	Brad Bowzard (404) 639-3626 jbowzard@cdc.gov Lauren Andersen (404) 639-4442 wrh5@cdc.gov

### Lymphocytic Choriomeningitis (LCM) Identification CDC-10345

Synonym(s)	LCM, Arenavirus
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to $-70^{\circ}$ C, and ke 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### Lymphocytic Choriomeningitis (LCM) Serology CDC-10346

Synonym(s)	LCM, Arenavirus
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# **Test Order**Machupo Identification CDC-10347

Synonym(s)	Bolivian Hemorrhagic Fever, BHF, <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# Test Order Machupo Serology CDC-10348

Synonym(s)	Bolivian Hemorrhagic Fever, BHF, <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@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-parasiti therapy and store at 4°C.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specime container and the test requisition.
	Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimer on wet ice (cold pack) as an etiologic agent.
Methodology	Conventional PCR, Real-Time PCR
Turnaround Time	21 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Samaly dos Santos Souza (404) 718-4786 ynp4@cdc.gov

## **Test Order**Malaria Serology CDC-10464

Synonym(s)	Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, parasite
Pre-Approval Needed	None
	Travel history REQUIRED, include other relevant risk factors; clinical symptom 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 require two patient identifiers on the specimer 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 patien 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**Marburg Identification CDC-10349

Synonym(s)	None
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

# Test Order Marburg Serology CDC-10350

Synonym(s)	None
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### 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
	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
	Measles: http://www.cdc.gov/measles/lab-tools/ Rubella: http://www.cdc.gov/rubella/lab/index.html
	Also see: <a href="http://www.cdc.gov/vaccines/pubs/surv-manual/index.html">http://www.cdc.gov/vaccines/pubs/surv-manual/index.html</a> <a href="http://www.cdc.gov/measles/lab-tools/index.html">http://www.cdc.gov/measles/lab-tools/index.html</a>
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: <a href="http://www.cdc.gov/measles/lab-tools/">http://www.cdc.gov/measles/lab-tools/</a>
	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 productio by RT-PCR, Viral culture
Turnaround Time	7 Days
Interferences & Limitations	Measles: <a href="http://www.cdc.gov/measles/lab-tools/">http://www.cdc.gov/measles/lab-tools/</a> Rubella: <a href="http://www.cdc.gov/rubella/lab/index.html">http://www.cdc.gov/rubella/lab/index.html</a>
	Also see, <a href="http://www.cdc.gov/vaccines/pubs/surv-manual/index.html">http://www.cdc.gov/vaccines/pubs/surv-manual/index.html</a> <a href="http://www.cdc.gov/measles/lab-tools/index.html">http://www.cdc.gov/measles/lab-tools/index.html</a>
	Please include vaccination history, age, date of symptom onset and sample collection
CDC Points of Contact	Paul Rota (404) 639-4181 parl@cdc.gov Joe Icenogle (404) 639-4557 jcil@cdc.gov

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### **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	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 pricto 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
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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 MMRH Laboratory Branch reserves the right to determine if testing for measles avidity could be beneficial.

CDC Points of Contact Sara Mercader (404) 639–4568

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### Test Order Measles Avidity CDC-10248

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sjm7@cdc.gov 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	
Supplemental Form	None
Performed on Specimens From	Human
	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
	See: <a href="http://www.cdc.gov/measles/lab-tools/rt-pcr.html">http://www.cdc.gov/measles/lab-tools/rt-pcr.html</a> 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: <a href="http://www.cdc.gov/measles/lab-tools/">http://www.cdc.gov/measles/lab-tools/</a>
	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
	Frozen specimen should be shipped on dry ice
Mathadalaav	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: <a href="http://www.cdc.gov/measles/lab-tools/">http://www.cdc.gov/measles/lab-tools/</a> 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: <a href="http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html">http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html</a>
CDC Points of Contact	Paul Rota (404) 639–4181 par1@cdc.gov Rebecca McNall (404) 639–4541 dqo2@cdc.gov

### 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	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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.
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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 prio 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, parl@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 parl@cdc.gov

## Test Order MERS-CoV PCR CDC-10488

• • • • • •	MERS-CoV PCR, Middle East Respiratory Syndrome Coronavirus PCR
Pre-Approval Needed	Erdman, Dean, (404) 639-3727, dde1@cdc.gov
Supplemental Information Required	• •
Supplemental Form	http://www.cdc.gov/coronavirus/mers/downloads/MERS-investigation-short-form.pdf
Performed on Specimens From	Human
	Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, broncheoalveolar lavage, tracheal aspirate, pleural fluid tap, sputum, stool, serum, EDTA blood (plasma), and post-mortem tissue. For more information go to: <a href="http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html">http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html</a> ; <a href="http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html">http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html</a>
Minimum Volume Required	0.25 mL
	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.
Include Specimen Handling	Contact Dean Erdman ( <u>dde1@cdc.gov</u> , 404–639–3727) for shipping address.  See the following link for additional shipping information: <a href="http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html">http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html</a>
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 the may contain substances that inactivate some viruses and inhibit some molecula 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	Dean Erdman (404) 639–3727 dde1@cdc.gov Shifaq Kamili

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### Test Order MERS-CoV PCR 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	Tatti, Kathleen, (404) 639–3797, ket2@cdc.gov Erdman, Dean, (404) 639–3727, dde1@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
	Serum (single specimen collected >14 days after symptom onset; paired acute and convalescent). For more information go to <a href="http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html">http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html</a>
Minimum Volume Required	200μL
	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. <a href="http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html">http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html</a> , <a href="http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html">http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html</a>
Transport Medium	None
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Contact Kathleen Tatti (404–639–3797, ket2@cdc.gov) or Dean Erdman (404–639–3727, dde1@cdc.gov) for shipping address.  See the following link for additional shipping information: <a href="http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html">http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html</a>
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.
Additional Information	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	Kathleen Tatti (404) 639–3797 ket2@cdc.gov Dean Erdman (404) 639–3727 dde1@cdc.gov

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### **Test Order**Microsporidia Molecular Identification CDC-10481

<u> </u>	
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
	Tissue, urine, stool (unpreserved or in a PCR-compatible preservative e.g. EcoFix UniFix, ZN-PVA, TotalFix, ethanol, potassium dichromate). Other specimen type 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.
Include Specimen Handling	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	21 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	
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
	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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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.
	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 no 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

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# Test Order Mumps Detection (PCR) and Genotyping CDC-10241

Synonym(s)	
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
	See: <a href="http://www.cdc.gov/mumps/lab/specimen-collect.html">http://www.cdc.gov/mumps/lab/specimen-collect.html</a> 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: <a href="http://www.cdc.gov/mumps/lab/">http://www.cdc.gov/mumps/lab/</a>
	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 b Nucleic acid sequencing
Turnaround Time	7 Days
Interferences & Limitations	See: <a href="http://www.cdc.gov/mumps/lab/">http://www.cdc.gov/mumps/lab/</a> 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: <a href="http://www.cdc.gov/vaccines/pubs/surv-manual/chpt09-mumps.html">http://www.cdc.gov/vaccines/pubs/surv-manual/chpt09-mumps.html</a>
CDC Points of Contact	Paul Rota (404) 639-4181 parl@cdc.gov Rebecca McNall (404) 639-4541 dqo2@cdc.gov

### 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	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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

## Test Order Mumps Serology CDC-10245

None
None
None
None
Human
Serum
300 uL
Serum should be kept refrigerated, not frozen
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship specimen Monday -Thursday overnight to avoid weekend deliveries  Refrigerated specimen should be shipped on cold packs
CDC IgM Capture, Commercial indirect IgG
7 Days
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.
IgM and IgG assays are qualitative assays
Please include vaccination history, age, date of onset and sample collection
Nobia Williams (404) 639–1049 new8@cdc.gov Carole Hickman (404) 639–3339

## **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

### *Mycobacterium* - Non-tuberculosis Mycobacteria Identification CDC-10225

Synonym(s)	Non-TB Mycobacteria
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	Isolates demonstrated to not be part of the <i>Mycobacterium tuberculosis</i> 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.
	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

### *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	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 – 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

# 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	32 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Beverly Metchock (404) 639-2455 TBLab@cdc.gov

### 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

#### 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
	Nucleic Acid Amplification positive (NAA+) sputum sediment or pure culture isolate on solid medium or in broth culture
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	Pyrosequencing, Sanger sequencing, Agar Proportion DST, MGIT 960 Pyrazinamide (PZA)
Turnaround Time	3 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Beverly Metchock (404) 639-2455 TBLab@cdc.gov Jeff Driscoll (404) 639-2455 TBLab@cdc.gov

## Mycobacterium TB Complex – Pyrazinamide Susceptibility Testing CDC-10189

Synonym(s)	PZA DST, TB, Tuberculosis
Pre-Approval Needed	None
Supplemental Information Required	
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	not be shipped frozen.
Methodology	Pyrazinamide (PZA) by MGIT 960
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 – 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

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

CDC-10352

	020 10002
Synonym(s)	Culture, DST, AST, MTB, MTB complex, TB, MDR TB, ID, Tuberculosis
Pre-Approval Needed	Alexander, Heather, (404) 639–5331, drz5@cdc.gov DeGruy, Kyle, (404) 639–0875, gsz4@cdc.gov
Supplemental Information Required	Supplemental form will be provided upon consultation
	Fill out the ILB-100-F08C TB Requisition Form
	CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of
Supplemental Form	Human Disease. It is a requirement to complete this form.
• • • • • • • • • • • • • • • • • • • •	
Performed on Specimens From	Human
	Suspected <i>Mycobacteria tuberculosis</i> Complex isolates in Middlebrook 7H9 liquid media or MGIT (7H9) broth inoculated with culture isolate
Minimum Volume Required	0.3 mL
	Mycobacterium tuberculosis Complex in Sterile 2.0 mL screw cap cryovial with O-ring. Specimen should be kept frozen at $-70^{\circ}$ C indefinitely, but specimen may be stored at $-20^{\circ}$ C for three months.
Transport Medium	Middlebrook or MGIT (7H9) broth should be inoculated with a culture isolate of a suspected <i>Mycobacterium tuberculosis</i> Complex and transported in a sterile 2.0 mL screw cap cryovial with O-ring.
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	Keep specimen frozen at −70°C or lower by using dry ice.
	Refer to <i>Mycobacterium tuberculosis</i> 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	Nonviable isolates sent for phenotypic DST and contaminated or mixed isolates sent for phenotypic DST will interfere with the test.
	Specimen can be rejected if improperly labeled or unlabeled, insufficient volume for testing, without documentation or with discrepant documentation, and have leaked in transit or otherwise show evidence of contamination.
Additional Information	Turn around time is dependent on batch orders:
	Batches with less than 100 specimens within 150 days Batches with greater than 100, contact Heather Alexander, drz5@cdc.gov.

Version: 1.1

Tuesday, November 29, 2016

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

CDC-10352

Drug Susceptibility Testing on *Mycobacterium tuberculosis* complex performed for first line drugs streptomycin, isoniazid, rifampicin, ethambutol, and pyrazinamide on the BD BACTEC™MGIT™ 960 system and for isoniazid and rifampicin on molecular line probe assay. Drug Susceptibility Testing on *Mycobacterium tuberculosis* complex performed for second line drugs with the modified method of proportion for streptomycin, isoniazid, rifampicin, ethambutol, rifabutin, PAS, ciprofloxacin, ofloxacin, kanamycin, ethionamide, capreomycin, and amikacin. Genotype MTBDRsl tests second line drugs are ofloxacin, ciprofloxacin, moxifloxacin, amikacin, kanamycin, capreomycin, viomycin and ethambutol.

CDC Points of Contact Heather Alexander

(404) 639–5331 drz5@cdc.gov Kyle DeGruy (404) 639–0875 gsz4@cdc.gov

Version: 1.1

Zilma Rey (404) 639-2345 yzr0@cdc.gov

### Mycobacterium TB Complex (International Only) Special Study CDC-10353

Synonym(s)	None	
Pre-Approval Needed	Alexander, Heather, (404) 639- DeGruy, Kyle, (404) 639-0875,	
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	collection. The identifiers must correspond to information on the Surveillance studies and some precommends 2 identifiers) de-li	s must include 2 unique identifiers at the time of be clearly labeled on each specimen and he requisition form.  protocols require 1 unique identifier (the ILB inked from the patient. Do not include the resonally identifiable information. Results are not
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

### *Mycoplasma pneumoniae* Molecular Detection CDC-10155

Synonym(s)	Walking pneumonia, Atypical pneumonia, Community Acquired Pneumoniae (CAP)
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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
	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 <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , and <i>Legionella</i> 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

#### 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
	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: <a href="http://www.cdc.gov/dpdx">http://www.cdc.gov/dpdx</a>
Supplemental Form	None
Performed on Specimens From	Human
	For <i>Naegleria fowleri</i> molecular detection, CSF is the preferred specimen type. We also accept fresh or frozen tissue for N. fowleri molecular detection. For <i>Acanthamoeba</i> and <i>Balamuthia</i> molecular detection, tissue is the preferred specimen type; however, these amebae 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
	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
	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://wwwn.cdc.gov/NARMS/UserLogin.aspx
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Isolates. Specimens accepted according to NARMS guidelines
Minimum Volume Required	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
Include Specimen Handling	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	Christina Scheel (404) 639-3126 zsr3@cdc.gov Jason Foster (404) 639-4948 gux8@cdc.gov

## **Test Order** *Neisseria* (STD) Identification CDC-10101

Synonym(s)	<i>Neisseria</i> , GC
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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.
Include Specimen Handling	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

#### 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
	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.
Include Specimen Handling	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

### Neisseria meningitidis Identification and Serogrouping CDC-10219

Synonym(s)	N. meningitidis ID and SASG, Nm
Pre-Approval Needed	None
	If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section of submission form.
Supplemental Form	None
Performed on Specimens From	Human
	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
	Primary specimens or stocks should be kept frozen. After overnight incubation a 37C with 5% CO2, store slants at an ambient temperature.
Transport Medium	Preferred medium include chocolate agar slants or frozen stocks. If possible, for the shipment of 10 or more specimens, please ship frozen stocks.
Specimen Labeling	Tests subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition. Label ABCs/Enhanced Surveillance specimens with the state ID & accession number.
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries.
	Frozen specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and if possible, email spreadsheet prior to shipment.
Methodology	Growth, Morphology, Biochemical Testing, Slide Agglutination Serogrouping, Real-time PCR
Turnaround Time	30 Days
Interferences & Limitations	Improperly temperature controlled specimens/isolates can give false negative results.
Additional Information	Turnaround time: 30 days for real-time PCR testing of clinical specimens; 90 days for testing of enhanced surveillance submissions
CDC Points of Contact	Melissa Whaley Meningitis Laboratory (404) 639–3920 (404) 639–5009 dbq3@cdc.gov Laurel T. Jenkins (404) 639–1340 knt9@cdc.gov

#### Neisseria meningitidis Study

CDC-10220

Synonym(s)	Nm Study
Pre-Approval Needed	Wang, Xin, (404) 639–5474, gqe8@cdc.gov Briere, Elizabeth, (404) 639–0732, ejc0@cdc.gov
Supplemental Information Required	Brief description of study or surveillance program.
	Supplemental Form Required: CDC Meningitis Laboratory: Molecular Typing Request Submission Form (provided upon request by CDC Meningitis Laboratory).
Supplemental Form	
Performed on Specimens From	Human
	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
	Primary specimens or stocks should be kept frozen. After overnight incubation at 37C with 5% CO2, store slants at an ambient temperature.
Transport Medium	Chocolate agar slants or frozen stocks.
Specimen Labeling	Tests subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which	Ship Monday-Thursday overnight to avoid weekend deliveries.
Include Specimen Handling Requirements	Frozen specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and if possible, email spreadsheet prior to shipment.
Methodology	Multilocus Sequence Typing (MLST), Whole Genome Sequencing (WGS)
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	
	(404) 639–5474 gqe8@cdc.gov
	Melissa Whaley
	(404) 639–3920
	dbq3@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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

## **Test Order**Nipah Virus Serology CDC-10355

Synonym(s)	None
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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
	Pure culture isolate on a suitable agar slant medium; consultation required fo 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	The 3 week turnaround time applies to all tests unless biochemical and/or phenotypic analysis are required, which could take up to 2 months for test results.
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
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.
Include Specimen Handling	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
Requirements	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

## Test Order Norovirus Molecular Detection CDC-10357

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Synonym(s)	
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
<u> </u>	Polymerase Chain Reaction (PCR)
Turnaround Time	·
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
	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	· · · · · · · · · · · · · · · · · · ·
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
	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
	Acute samples only, anticoagulated whole blood collected in Ethylenediaminetetraacetic acid (EDTA) treated tubes preferred; serum; fresh tissue biopsy
Minimum Volume Required	1.0 mL
	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 samp collection tube
Specimen Labeling	Patient name and date of birth
	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 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 commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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## **Test Order** *Orientia* Serology CDC-10360

Synonym(s)	Scrub Typhus
Pre-Approval Needed	None
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect Fluorescence 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 samp and interfere with the ability to get accurate results. Acute and convalescent serum is 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. Routine diagnostic samples should be sent to your State Laboratory or commercial lab.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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## **Test Order**Orientia Special Study CDC-10500

Synonym(s)	Scrub typhus
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov Paddock, Christopher, (404) 639–1309, cdp9@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	Cecilia Kato (404) 639-0152 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

### **Test Order**Paragonimiasis Serology

#### CDC-10465

Synonym(s)	Paragonimus westermani, Paragonimus kellicotti, parasite
Pre-Approval Needed	None
	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 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 require two patient identifiers on the specimer 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

### **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
	Stool specimens, blood, and tissue. Additional acceptable specimens are listed on the supplemental link.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific, see supplemental link
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Ship Monday - Thursday, overnight to avoid weekend deliveries Shipping is specimen specific see supplemental link
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

### 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
	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
	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.
Include Specimen Handling	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.

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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**Parechovirus Detection and Identification CDC-10362

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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	Erdman, Dean, (404) 639-3727, dde1@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
	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	3 Weeks
Interferences & Limitations	Do not use wooden-shafted swabs or calcium alginate swabs
Additional Information	None
CDC Points of Contact	Dean Erdman (404) 639-3727 dde1@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

# **Test Order**Parvovirus B19 Serology CDC-10364

Synonym(s)	Fifth Disease
Pre-Approval Needed	Erdman, Dean, (404) 639-3727, dde1@cdc.gov
Supplemental Information Required	<u> </u>
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.25 mL
	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.
Include Specimen Handling	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	3 Weeks
Interferences & Limitations	Do not collect in heparin tubes
Additional Information	None
CDC Points of Contact	Dean Erdman (404) 639-3727 dde1@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

### Pathologic Evaluation of Tissues for Possible Infectious Etiologies

CDC-10365

	CDC-10303
Synonym(s)	Autopsy, biopsy, formalin fixed tissues, FFPE, pathology, paraffin blocks, histopathology, electron microscopy, immunohistochemistry, PCR
Pre-Approval Needed	Infectious Disease Pathology Branch, , (404) 639–3132, pathology@cdc.gov
	Please include the following information with each submission:  - The full name, title, complete mailing address, e-mail address, and telephone and fax numbers of the submitter. This will be the same person to whom the final pathology report is addressed.  - A completed CDC Form 50.34  - 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
	Paraffin-embedded tissue blocks, formalin-fixed tissues, unstained glass slides, electron microscopy grids or blocks. Frozen tissues may be acceptable in some circumstances and will not be accepted without pre-approval.
	More specific guidelines regarding tissue samples and submission can be found on the IDPB website: <a href="http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html">http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html</a>
Minimum Volume Required	Not Applicable
	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 <u>not</u> 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 pathology laboratory immediately. During hot weather, tissue blocks should be shipped on ice packs to prevent the melting of paraffin. Fresh frozen tissues can only be submitted with pre-approval and should not be submitted in the same package as fixed tissues or paraffin blocks.
	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,

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#### Pathologic Evaluation of Tissues for Possible Infectious Etiologies

CDC-10365

	Electron Microscopy (EM), Tissue Culture, Nucleic Acid Extraction for transfer to other branches
Turnaround Time	6 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: <a href="http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html">http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html</a>
	Turnaround time varies depending upon the complexity of each case, but is approximately 2-6 weeks.
	Digital images can be provided to assist in evaluation and guide testing.
CDC Points of Contact	Infectious Disease Pathology Branch (404) 639–3132 pathology@cdc.gov
	on the IDPB website: <a href="http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html">http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html</a> Turnaround time varies depending upon the complexity of each case, but is approximately 2–6 weeks.  Digital images can be provided to assist in evaluation and guide testing.  Infectious Disease Pathology Branch (404) 639–3132

## **Test Order**Pathology Special Study CDC-10373

Synonym(s)	None
Pre-Approval Needed	Pathology Branch, , (404) 639-3132, 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	Pathology Branch (404) 639–3132 pathology@cdc.gov

### Picornavirus Detection and Identification (not Hepatitis A, not Rhinovirus)

CDC-10374

	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
	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
	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.

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#### Picornavirus Detection and Identification (not Hepatitis A, not Rhinovirus)

CDC-10374

Version: 1.0

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
	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.
Include Specimen Handling	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
	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.
	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

### Poxvirus - Cowpox Specific Molecular Detection CDC-10379

Synonym(s)	
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
	Real Time-PCR
Turnaround Time	
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	

Version: 2.0

### Poxvirus – Encephalitis Work-Up (Post Vaccinia Encephalitis, Monkeypox, etc.)

CDC-10380

C (-)	Mankaymay Post yassinial ansambalitis
<u> </u>	Monkeypox, Post-vaccinial encephalitis
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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	Cerebrospinal fluid (CSF) and serum must be submitted
Minimum Volume Required	1 mL
	Keep specimen refrigerated. 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, date of collection and body location.
Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries
	Refrigerated specimen should be shipped on cold packs
<u> </u>	ELISA, Real Time PCR
Turnaround Time	2 Days
Interferences & Limitations	In order to accurately interpret test results generated from CSF specimens, paired serum must be submitted
Additional Information	Turnaround time: Urgent cases  - Testing is completed within 48 hours of specimen receipt when results direct impact patient care; Routine cases  - Testing is completed within 5-7 days of specimen receipt. For serology testing, please notify the lab prior to shipment so reagents can be prepared
CDC Points of Contact	· ·

#### Poxvirus – Molluscum Contagiosum Specific Molecular Detection

#### CDC-10381

CDC-10301	
Synonym(s)	MCV
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	-

Version: 2.1

### Poxvirus - Monkeypox Specific Molecular Detection CDC-10382

Synonym(s)	None
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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.
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	

Version: 1.0

#### Poxvirus – Orthopoxvirus Serology (Includes Vaccinia virus) CDC-10384

Synonym(s)	Orthopoxvirus, Vaccincia Antibody detection
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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 Sample
Minimum Volume Required	1 mL
	Keep specimen refrigerated. 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, 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	
Turnaround Time	
Interferences & Limitations	Collection in either heparin and/or EDTA will interfere with results
Additional Information	Turnaround time: Urgent cases -Testing is completed within 48 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed within 5-7 days of specimen receipt. For serology testing, please notify the lab prior to shipment so reagents can be prepared
CDC Points of Contact	• •

### Poxvirus - Pan-Poxvirus Molecular Detection (Human Infections)

CDC-10385

Synonym(s)	None
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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.
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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	Polymerase Chain Reaction (PCR)
Turnaround Time	
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt. Formalin fixed material is first tested by the Infectious Disease Pathology Brancl (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	

Version: 2.0

### Poxvirus – Parapoxvirus Generic Molecular Detection CDC-10383

Svnonvm(s)	Sore mouth, scabby mouth, contagious ecthyma
• • • • • •	Help Desk, , (404) 639–4129,
Supplemental Information	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	

Version: 2.1

### Poxvirus – Parapoxvirus Molecular Detection CDC-10386

Synonym(s)	
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (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	

Version: 2.0

### Poxvirus - Sealpox Specific Molecular Detection CDC-10387

Synonym(s)	
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (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	

Version: 2.0

### Poxvirus – Smallpox (Variola Virus) Specific Molecular Detection

CDC-10388

Synonym(s)	None
Pre-Approval Needed	DEOC, , (770) 488-7100,
	Call CDC Emergency Operations Center prior to contacting laboratory 770-488-7100
Supplemental Form	http://www.bt.cdc.gov/agent/smallpox/
Performed on Specimens From	Human
	Lesion fluid and/or material, serum, and blood must all be submitted. Lesion fluid and/or material: vesicle / pustule skin or fluid, scab, crust, etc.; collection method: touch prep slide, swab, biopsy
Minimum Volume Required	1 mL (blood and serum)
	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. Whole blood should be collected in a blood tub containing ethylenediaminetetraacetic acid (EDTA).
	Keep specimen refrigerated. It is extremely important not to cross-contaminate specimens (i.e., one specimen per container). Viral transport media should not be added to specimens. All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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	Approval must be obtained prior to the shipment of potential smallpox patient clinical specimens to CDC
Methodology	Real Time-PCR
Turnaround Time	1 Day
Interferences & Limitations	Cotton swabs may cause PCR inhibition and should not be used. Heparin may cause PCR inhibition and should not be used to collect whole blood.
Additional Information	A suspected case of smallpox must be immediately reported to appropriate local state, or territorial health departments. After review, if smallpox is still suspected, the case should be immediately reported to CDC's Emergency Operations Center.
	Specimens should be collected as outlined in Guide D on the CDC website: Http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-d.pdf
CDC Points of Contact	DEOC (770) 488-7100

### Poxvirus - Tanapox Specific Molecular Detection CDC-10389

Synonym(s)	
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (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	

Version: 2.0

### Poxvirus - Vaccinia Specific Molecular Detection CDC-10390

Synonym(s)	Smallpox Vaccine
Pre-Approval Needed	Help Desk, , (404) 639-4129,
	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
	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.
Minimum Volume Required	Not Applicable
	All specimens should be stored at 4°C until shipment. Swabs without individual holders may be stored in a sterile container. Dry swabs are preferred but a minimal amount of viral transport media may be added.
Transport Medium	Prefer swabs dry but will accept specimen in a minimum viral transport medium
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
Turnaround Time	1 Day
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. The addition of viral transport media to swab specimens will dilute any viral DN present.
Additional Information	Turnaround time: Urgent cases -Testing is completed and reported within 24 hours of specimen receipt when results directly impact patient care; Routine cases -Testing is completed and reported within 5 business days of specimen receipt Formalin fixed material is first tested by the Infectious Disease Pathology Branc (IDPB) and will only identify poxviruses to the genus level. DNA may be extracte from paraffin block embedded lesion material and tested by the Poxvirus Program. Fresh, non-frozen tissue is preferred by IDPB.
CDC Points of Contact	-

## **Test Order**Puumala Serology CDC-10391

Synonym(s)	Hanta, HFRS, Nephropathia epidemica
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
9	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

## **Test Order**Rabies Antemortem Human Testing CDC-10392

Synonym(s)	
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050,
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	All four of the following are required for testing: serum, CSF, nuchal (skin) biopsy, and saliva
Minimum Volume Required	500 uL (serum, CSF, saliva)
	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	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

### 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	3 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
	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	
	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

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# **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
	All four of the following are required for antemortem testing: serum, CSF, Nucha (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)
	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	IgG by IFA (Serum and CSF), DFA (Nuchal (skin) biopsy and for rabies virus antigen), 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 Postmortem Human Testing CDC-10396

Rabies DFA
Rabies Duty Officer, , (404) 639-1050,
See Supplemental Form
http://www.cdc.gov/rabies/pdf/rorform.pdf
Human
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.
Not Applicable
Stored at -80°C and should be kept on dry ice
Not Applicable
Two patient identifiers on the specimen container and the test requisition, sample type and date of collection
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
DFA for rabies virus antigen, RT-PCR, Direct Rapid Immunohistochemistry test (DRIT), Virus Isolation, Sequence Analysis, Antigenic Typing
7 Days
Tests are limited by decomposed tissues due to denaturation of viral proteins
Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing.
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

## **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	• •
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
Performed on Specimens From	Human and Animal
• • • •	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 anima specimen, date of collection and specimen type
	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	Urgent specimens will be reported within 24 hours if the test does not need to be repeated. Non-urgent specimen may take longer than 7 days.
CDC Points of Contact	Rabies Duty Officer (404) 639–1050

## Respiratory Agents (*Chlamydia*, *Legionella*, *Mycoplasma*) Molecular Detection CDC-10157

Synonym(s)	Atypical pneumonia, CAP, <i>Chlamydia pneumoniae</i> , Legionnaires' disease or LD, Legionellosis, Pontiac fever, Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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
	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.
Include Specimen Handling	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 prio to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	None
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

# Test Order Respiratory Virus (Not Influenza) Special Study CDC-10400

Synonym(s)	None
Pre-Approval Needed	Erdman, Dean, (404) 639-3727, dde1@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	Dean Erdman (404) 639-3727 dde1@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

### Respiratory Virus Molecular Detection (Not Influenza) CDC-10401

Synonym(s)	Non-influenza Respiratory Virus
Pre-Approval Needed	Erdman, Dean, (404) 639-3727, dde1@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
	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 an 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 betwee 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.
Include Specimen Handling	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	•
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 the may contain substances that inactivate some viruses and inhibit some molecula assays.
Additional Information	None
CDC Points of Contact	Dean Erdman (404) 639-3727 dde1@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 Rickettsia (SFG), Typhus group Rickettsia (TG)
Pre-Approval Needed	
	Prior approval is required if the following information is not provided:
	- Suspected Agent
	- Travel and exposure history (including animals, arthropods, etc.)
	<ul><li>Date of illness onset (and time if available)</li><li>Specimen type (e.g., serum, whole blood, tissue, etc.)</li></ul>
	- Test requested
	- Brief clinical summary (including details of antibiotic therapy and dates) and
Complemental Forms	pertinent clinical findings
Supplemental Form	
Performed on Specimens From	Human
Acceptable Sample/ Specimen	Acute samples only, anticoagulated whole blood collected in:
Type for Testing	Ethylenediaminetetraacetic acid (EDTA), Anticoagulant Citrate Dextrose Solution
	A (ACD-A), Sodium Citrate, or Heparin treated tubes are acceptable; serum; fres tissue biopsy
Minimum Volume Required	
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	For blood; Ethylenediaminetetraacetic acid (EDTA), Anticoagulant Citrate
	Dextrose Solution A (ACD-A), Sodium Citrate, or Heparin blood tubes for blood; for tissue in a sample collection tube – please request guidance
Specimen Labeling	Patient name, date of birth, and date of collection
Shipping Instructions which	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen
Include Specimen Handling	
Requirements	
Methodology	Real Time Polymerase chain Reaction (PCR), Polymerase Chain Reaction (PCR),
Turnara d Tima	Sequencing
Turnaround Time	
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	•
	(404) 639–0152
	ckato@cdc.gov
	Ida Chung (404) 639-0500

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### *Rickettsia* Serology Spotted Fever Group (RMSF) Serology CDC-10403

Synonym(s)	Spotted fever group Rickettsiosis, Rocky Mountain Spotted Fever (RMSF)
Pre-Approval Needed	None
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	IFA (Immunofluorescence Assay)
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 is needed for accurate diagnosis and if unable to collect both please contact lab 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. Routine diagnostic samples should be sent to your State Laboratory or commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@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
	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
	Ideally keep specimen at a refrigerated temperature not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name and date of birth
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect Fluorescence 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 is 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. Routine diagnostic samples should be sent to your State Laboratory or commercial laboratory.
CDC Points of Contact	Cecilia Kato (404) 639-1075 ckato@cdc.gov Christopher Paddock (404) 639-1309 cdp9@cdc.gov

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# **Test Order** *Rickettsia* Special Study CDC-10405

Synonym(s)	Rickettsiosis, Rocky Mountain Spotted Fever (RMSF), Spotted fever group <i>Rickettsia</i> (SFG), Typhus group <i>Rickettsia</i> (TG)
Pre-Approval Needed	Kato, Cecilia, (404) 639–1075, ckato@cdc.gov Paddock, Christopher, (404) 639–1309, cdp9@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	Cecilia Kato (404) 639–1075 ckato@cdc.gov Christopher Paddock (404) 639–1309 cdp9@cdc.gov

## **Test Order**Rift Valley Fever (RVF) Identification CDC-10406

Synonym(s)	RVF
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kep 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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### **Test Order**Rift Valley Fever (RVF) Serology CDC-10407

Synonym(s)	RVF
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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
<u> </u>	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 specifi information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

### **Test Order**Rotavirus Detection CDC-10408

	Rotavirus Antigen EIA, Rotavirus Antigen ELISA, Rotavirus RT-PCR
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
	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.
Include Specimen Handling	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), RT-PCR
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) 639–0885 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	0.25 g or 0.25 mL
	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 clas 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.
Include Specimen Handling	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	4 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) 639–0885 vmf4@cdc.gov

## **Test Order**Rubella Detection (PCR) and Genotyping CDC-10242

<u> </u>	German measles, three day measles
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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: <a href="http://www.cdc.gov/rubella/lab/lab-specimens.html">http://www.cdc.gov/rubella/lab/lab-specimens.html</a> 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: <a href="http://www.cdc.gov/rubella/lab/index.html">http://www.cdc.gov/rubella/lab/index.html</a> for information on the interferences and limitiations
Additional Information	Please include vaccination history, age, date of onset and sample collection.
	For additional information please refer to: <a href="http://www.cdc.gov/vaccines/pubs/surv-manual/index.html">http://www.cdc.gov/vaccines/pubs/surv-manual/index.html</a> <a href="http://www.cdc.gov/measles/lab-tools/index.html">http://www.cdc.gov/measles/lab-tools/index.html</a>
CDC Points of Contact	<del></del>

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#### **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	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	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 pric to shipment
CDC Points of Contact	Joe Icenogle (404) 639-4557 jcil@cdc.gov Emily Abernathy (404) 639-1249 efa9@cdc.gov

### 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 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
	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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Requirements	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 foodborn outbreak activities or due to limited availability of resources.
CDC Points of Contact	Susan Van Duyne (404) 639-0186 Mdv9@cdc.gov Patricia Fields (404) 639-1748 pif1@cdc.gov

### Salmonella serovar Typhi (only) serology CDC-10453

Synonym(s)	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Korth, Michael, (404) 639–2099, mqk8@cdc.gov
	Date of illness onset, date of serum collection, clinical diagnosis. Indicate if patient is currently on antibiotics. Indicate if patient is suspect chronic carrie
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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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 Michael Korth (404) 639-2099 mgk8@cdc.gov

## Test Order Salmonella Study CDC-10109

Synonym(s)	None
Pre-Approval Needed	Van Duyne, Susan, (404) 639–0186, mdv9@cdc.gov Fields, Patricia, (404) 639–1748, pif1@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 Patricia Fields (404) 639-1748 Pif1@cdc.gov

## Test Order Salmonella Subtyping CDC-10108

Synonym(s)	Salmonella Typing
Pre-Approval Needed	None
	Prior approval is not required for human specimen, but is required for all othe 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	Not Applicable
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries
	Ship at ambient temperature in compliance with Federal and local guidelines
	Serotyping, PFGE, MLVA, AST
Turnaround Time	
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 Patricia Fields (404) 639-1748 Pif1@cdc.gov

### **Test Order**SARS Molecular Detection CDC-10412

Synonym(s)	SARS coronavirus
Pre-Approval Needed	Erdman, Dean, (404) 639-3727, dde1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, broncheoalveolar lavage, tracheal aspirate, pleural fluid tap, sputum, and postmortem tissue.  For more information go to <a href="http://www.cdc.gov/sars/guidance/F-lab/app4.htm">http://www.cdc.gov/sars/guidance/F-lab/app4.htm</a>
Minimum Volume Required	0.25 mL
	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 <a href="http://www.cdc.gov/sars/quidance/F-lab/app4.htm">http://www.cdc.gov/sars/quidance/F-lab/app4.htm</a>
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 <a href="http://www.cdc.gov/sars/lab/specimen.html">http://www.cdc.gov/sars/lab/specimen.html</a>
Methodology	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	· · · · · · · · · · · · · · · · · · ·
Interferences & Limitations	Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocked swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as the may contain substances that inactivate some viruses and inhibit some molecula 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	Dean Erdman (404) 639-3727 dde1@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	Haynes, Lia, (404) 639–4004, loh5@cdc.gov Erdman, Dean, (404) 639–3727, dde1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	Serum (acute and convalescent) and plasma For more information go to <a href="http://www.cdc.gov/sars/guidance/F-lab/app4.htm">http://www.cdc.gov/sars/guidance/F-lab/app4.htm</a>
Minimum Volume Required	200 uL
	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 an 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 tube 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.
Include Specimen Handling	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	Lia Haynes (404) 639-4004 loh5@cdc.gov Dean Erdman (404) 639-3727 dde1@cdc.gov

Version: 1.1

### **Test Order**Schistosomiasis Serology CDC-10466

Synonym(s)	Schistosoma mansoni, Schistosoma haematobium, Schistosoma japonicum;
, , ,	Bilharzia, parasite
Pre-Approval Needed	None
	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 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 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, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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	
Minimum Volume Required	1 mL
	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
Include Specimen Handling	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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov

## Shiga Toxin-producing *E. coli* Isolation from Enrichment Broth CDC-10105

Synonym(s)	STEC, E. coli 0157
Pre-Approval Needed	None
	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
	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	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 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 Devon Stripling (404) 639–4186 (404) 639–2251 nas6@cdc.gov euo4@cdc.gov Nancy Garrett (404) 639–1964 dgi3@cdc.gov

# Test Order Special Bacterial Pathogen Study CDC-10147

None
McQuiston, John, (404) 639-0270, zje8@cdc.gov Whitney, Anne, (404) 639-1374, amw0@cdc.gov
None
None
Human and Food/Environmental/Medical Devices/Biologics
To be determined
To be determined
To be determined
John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374

# **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.
	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

# Staphylococcus - Micrococcus Identification CDC-10226

Synonym(s)	Staph, <i>Micrococcus</i> , 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.
	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
	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
	Ship specimen Monday –Thursday overnight to avoid weekend deliveries at roo 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

# 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
	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
	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	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	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
	Toxin Detection in Food, Culture, PCR
Turnaround Time	
Interferences & Limitations	None
	Direct toxin detection requires food samples
CDC Points of Contact	Carolina Luquez (404) 639-0896 fyr6@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.
	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

# 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
	Urine, oral pharynx swabs, cervical swabs, vaginal swabs, and rectal swabs collected on any commercially available product, and other specimen types upo 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	
Methodology	PCR
Turnaround Time	12 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Cheng Chen (404) 639-3154 cycl@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 <i>S.pneumoniae</i> that meet the ABCs inclusion criteria
Minimum Volume Required	Not applicable
	For isolates, store on blood or chocolate agar, in transport media or as a froze 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	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	
Interferences & Limitations	
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	
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.
Include Specimen Handling	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 Patricia Shewmaker (404) 639-4826 paw3@cdc.gov

## 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
	For isolates, store on blood or chocolate agar, in transport media or as a froze 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.
Include Specimen Handling	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

## 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
	Pure culture isolate on a suitable agar slant medium; Prior consultation require 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 stocis 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	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 At room temperature for any etiologic agents
Methodology	Phenotypic Testing, Molecular Testing, Broth microdilution MIC
Turnaround Time	
Interferences & Limitations	
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 David Lonsway (404) 639-1237 (404) 639- 2825 BBEALL@cdc.gov dul7@cdc.gov Patricia Shewmaker (404) 639-2825 paw3@cdc.gov

### Streptococcus pneumoniae Typing

CDC-10215

<u> </u>	Pneumococcus Serotyping	
Pre-Approval Needed	Beall, Bernard, (404) 639–1237, bbeall@cdc.gov	
	Online form required for pre-approval: <a href="http://www.cdc.gov/streplab/s-pneumoniae-qa.html">http://www.cdc.gov/streplab/s-pneumoniae-qa.html</a> If you have questions, contact Bernard Beall, bbeall@cdc.gov, 404-639-1	
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	
	of For isolates, store on blood or chocolate agar, in transport media or as a frog 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 specin container and the test requisition.	
Include Specimen Handling	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice	
Requirements	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	
_	f For isolates blood or chocolate agar; transport media or frozen glycerol stoog 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

Strongyloidiasis, <i>Strongyloides stercoralis,</i> parasite
None
Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
None
Human
Serum or Plasma
0.5 mL
No specific requirements
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.
EIA, ELISA, Antibody Detection
18 Days
Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
None
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-trepon	emal	
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)		
	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.		
Include Specimen Handling	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, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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	
	f Specimen must be placed in plastic screw capped vials, frozen to -70°C, and 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	
Include Specimen Handling	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 sens Heparin may cause interference with the molecular tests and should be		
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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov	

## **Test Order**Tick Borne Encephalitis (TBE) Serology

CDC-10416

Synonym(s)	None		
Pre-Approval Needed	Klena, John, (404) 639–0114, irc4@cdc.gov Rollin, Pierre, (404) 639–1124, pyr3@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		
	f 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 specinformation on various specimen types.		
Transport Medium	Not Applicable		
Specimen Labeling	Patient name, patient ID #, specimen type, date collected		
Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries. Specimen shous 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 (404) 639-0114 irc4@cdc.gov Pierre Rollin (404) 639-1124 pyr3@cdc.gov		

### Toxocariasis Serology

CDC-10468

Larva migrans, Toxocariasis, <i>Toxocara canis</i> , <i>Toxocara cati</i> , parasite
None
Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.
None
None
Serum, plasma, or vitreous fluid
0.5
No specific requirements
Not Applicable
Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Ship Monday - Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature, not on dry ice, as an etiologic agent.
EIA, ELISA, Antibody Detection
18 Days
Substances known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
None
Isabel McAuliffe (404) 718-4100 ibm4@cdc.gov DPDx (404) 718-4120

# 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	(404) 718-4100 igi2@cdc.gov DPDx (404) 718-4120
	dpdx@cdc.gov

# Test Order Treponema pallidum Molecular Detection

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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
	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.
Include Specimen Handling	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

Version: 1.1

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# **Test Order** *Treponema pallidum* Molecular Typing CDC-10177

6 ()	
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
	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.
Include Specimen Handling	Ship Monday - Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice, refrigerated specimen should be shippe 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, <i>Trichinella spiralis,</i> parasite	
Pre-Approval Needed	None	
	Exposure and travel history, include other relevant risk factors (consumpti 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	

### *Trichomonas* Susceptibility

CDC-10239

Synonym(s)	Trichomonas, trich, parasite
Pre-Approval Needed	None
	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 was 4 @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
	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	

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### *Trichomonas* Susceptibility

CDC-10239

Interferences & Limitations	None
Additional Information	None
	Evan Secor (404) 718-4141 was4@cdc.gov

# *Trypanosoma cruzi* Molecular Detection CDC-10493

Synonym(s)	Chagas, American Trypanosomiasis, parasite, triatomine, kissing bug
Pre-Approval Needed	None
	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.
Include Specimen Handling	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 i 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

## 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, (404) 639–2192
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 <a href="http://www.cdc.gov/cdc-info/requestform.html">http://www.cdc.gov/cdc-info/requestform.html</a> 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	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.
Methodology	IgG avidity
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 (404) 639-2192

## 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 <a href="http://www.cdc.gov/cdc-info/requestform.html">http://www.cdc.gov/cdc-info/requestform.html</a> 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
	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.
	Ship specimen Monday-Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.
Methodology	Polymerase Chain Reaction (PCR), DNA sequencing
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Jennifer Folster (404) 639-3668 apz5@cdc.gov

## 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
	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	Clearly identify the samples as either serum or CSF and an associated patient ID number
	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 protocol is not operated currently under the CLIA certificate, as it is still in the process of being evaluated and validated; it is for research purposes only.
CDC Points of Contact	Scott Schmid (404) 639-0066 SSchmid@cdc.gov Jennifer Folster (404) 639-3668 JFolster@cdc.gov

### **Test Order** Varicella Zoster Virus (VZV) Serology CDC-10255

Synonym(s)	Chicken pox, shingles
Pre-Approval Needed	None
Supplemental Information Required	See Supplemental Form. Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <a href="http://www.cdc.gov/cdc-info/requestform.html">http://www.cdc.gov/cdc-info/requestform.html</a> 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.
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

## 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 <a href="http://www.cdc.gov/cdc-info/requestform.html">http://www.cdc.gov/cdc-info/requestform.html</a> 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
	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.
	Ship specimen Monday-Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.
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

## Vibrio cholerae ID, Serotyping, and Virulence Profiling CDC-10119

Synonym(s)	Cholera
Pre-Approval Needed	None
	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	
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	Ship Monday-Thursday, overnight to avoid weekend deliveries
Include Specimen Handling Requirements	Every suspect <i>Vibrio cholerae</i> 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

### Vibrio cholerae serology

### CDC-10454

	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Korth, Michael, (404) 639–2099, mqk8@cdc.gov
	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
	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	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 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 Michael Korth (404) 639-2099 mqk8@cdc.gov

# Test Order Vibrio Subtyping CDC-10122

Synonym(s)	None
Pre-Approval Needed	None
	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 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

Version: 1.1

Tuesday, November 29, 2016

## Vibrio, Aeromonas, and Related Organisms Identification CDC-10120

Synonym(s)	Grimontia species, Photobacterium species, Salinivibrio species
Pre-Approval Needed	None
	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
	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 foodborn 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

## 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

## Yersinia (non-Y. pestis) & other Enterobacteriaceae subtyping CDC-10124

Synonym(s)	None
Pre-Approval Needed	None
	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	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
·	Serotyping, PFGE, MLST
Turnaround Time	
Interferences & Limitations	
	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 Jonathan Jackson (404) 718-4165 wsy9@cdc.gov

## Yersinia (non-Y. pestis) and Other Enterobacteriaceae Identification

### CDC-10123

	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
	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
<u> </u>	Ship at ambient temperature in compliance with Federal and local guidelines
	Phenotypic Identification, Genetic Identification
Turnaround Time Interferences & Limitations	
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 Jonathan Jackson (404) 718-4165 wsy9@cdc.gov

## Yersinia pestis Culture and Identification CDC-10418

Synonym(s)	Plague
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date of birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	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); Environmental: fleas
Minimum Volume Required	Not Applicable
	Store specimens containing suspected live bacteria at 2°-8°C to maintain viability. If processing is delayed, tissue samples can be directly frozen at -70°C. Store samples for culture of live bacteria without preservatives (formaldehyde, alcohol), at 2°-8°C (not frozen). Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.
Transport Medium	Respiratory specimens, lymph node aspirates, blood, tissue/biopsy/autopsy/necropsy specimens should all be transported at 4°C. Swabs must be in a Cary-Blair or Amies medium, not frozen. If tissue biopsy/autopsy/necropsy transport is delayed, tissue samples can be directly frozen at -70°C.
Specimen Labeling	Specimen identifier and patient name
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
	Culture, Direct Fluorescent Antibody (DFA), Bacteriophage Lysis
Turnaround Time	
Interferences & Limitations	Samples for testing by culture should be taken prior to antibiotic treatment
Additional Information	None
CDC Points of Contact	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov

### Yersinia pestis Serology

### CDC-10419

Synonym(s)	Plague
Pre-Approval Needed	None
	Please include submitting agency, contact name, address, phone number, specimen identifier, patient name, specimen source and type, sex and date or birth, symptoms of onset, sample collection date, and clinical information including type and date of treatment patient has received.
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	500 uL
	Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longe period, serum samples may be frozen.
Transport Medium	Not Applicable
Specimen Labeling	Specimen identifier and patient name
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	(970) 221–6479
	mms7@cdc.gov Jeannine Petersen
	(970) 266–3524
	nzp0@cdc.gov

## Yersinia pestis Special Study CDC-10420

Synonym(s)	None
	Schriefer, Marty, (970) 221-6479, mms7@cdc.gov Petersen, Jeannine, (970) 266-3524, nzp0@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	Marty Schriefer (970) 221-6479 mms7@cdc.gov Jeannine Petersen (970) 266-3524 nzp0@cdc.gov