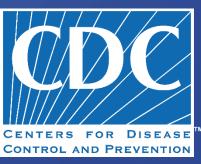
# 2018 CDC

INFECTIOUS DISEASES
LABORATORY TEST
DIRECTORY

January 2019, Version 9.1





This document was created under National Center for Emerging and Zoonotic Diseases/ Office of Infectious Diseases (NCEZID/OD). The printed version of CDC's Infectious Diseases Laboratory Test Directory contains information that is current as of January 9, 2019. All information contained herein is subject to change.

For the most current test information, please view the 508 compliant version of the CDC's Infectious Diseases Laboratory Test Directory on: http://www.cdc.gov/laboratory/specimensubmission/list.html.



### 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 identifi (sex, date of birth, name, etc.), provide specimen type and date of collection.	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package. Ship specimen at room temperature, not on dry ice, as an etiologic agent, unless the specimen has been previously frozen. Frozen specimens may be shipped in cold with ice–packs. Please send the shipment tracking number on the day of shipment by e–mail to the CDC Point of Contacts (see below).	
Methodology	Real-Time PCR	
Turnaround Time	7 Days	
Interferences & Limitations	Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, a preferred. Additionally, CSF is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i> detection, because a negative CSF test result do not completely rule out infections with these amebae.	
Additional Information	n None	
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov	

January 9, 2019 Version: 1.3 Page 1 of 364

## **Test Order** *Actinomyces*-Anaerobic ID CDC-10483

Synonym(s)	Anaerobe ID, Bacterial Identification, Anaerobe	
Pre-Approval Needed	None	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics	
	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 ar etiologic agent.	
·	Frozen specimen should be shipped on dry ice	
	Specimen stored at room temperature should be shipped at room temperature	
	16s Sequencing, MALDI–TOF, Phenotypic Testing	
Turnaround Time	•	
	Specimens from respiratory, vaginal, and fecal sources are not acceptable	
Additional Information	1 None	
CDC Points of Contact	David Lonsway (404) 639–2825 Dlonsway@cdc.gov Kamile Rasheed (404) 639–3247 jkr1@cdc.gov	

January 9, 2019 Version: 1.1 Page 2 of 364

## **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	None	
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.	
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.	
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov	

January 9, 2019 Version: 1.2 Page 3 of 364

### 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 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, 16S sequence based identification, MALDI-TOF	
Turnaround Time	3 Weeks	
Interferences & Limitations	None	
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.	
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.	
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov	

January 9, 2019 Version: 1.4 Page 4 of 364

## Test Order Adenovirus Molecular Detection and Typing CDC-10170

Synonym(s)	None	
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics	
	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 between specimens, including changing gloves between specimens.	
Transport Medium	Swabs may be shipped in commercial viral transport media.	
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.	
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		
Interferences & Limitations	Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocke 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	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov	

January 9, 2019 Version: 1.3 Page 5 of 364

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

Synonym(s)	AHFV	
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, and serum	
Minimum Volume Required	1 mL	
	Specimen must be placed in plastic screw capped vials, frozen to -70°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 avoide	
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.	
CDC Points of Contact	John Klena (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 6 of 364

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

Synonym(s)	AHFV	
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	• •	
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 shou 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		
Turnaround Time	10 Days	
Interferences & Limitations	Specimen must remain frozen; warming or freeze thawing reduces sensitivity	
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.	
CDC Points of Contact	John Klena (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 7 of 364

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

Synonym(s)	Free-living ameba, <i>Acanthamoeba</i> , <i>Balamuthia</i> , <i>Naegleria fowleri</i>	
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 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 biopsy 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 identifiers (sex, date of birth, name, etc.), provide specimen type and date of collection.	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight. Please contact laboratory prior to shipping any specimen and include "Unit 53" on the outside of package, and send the shipment tracking number on the day of shipment by e-mail to the CDC Point of Contacts (see below).	
	Ship all fresh specimens such as CSF, tissue biopsy (e.g., brain, lungs, skin) and all deep corneal scraping, etc., as an etiologic agent, within 24 hours of collection. Fresh, unfixed specimens (i.e., CSF and tissue), and formalin-fixed tissue specimens should be sent at ambient temperature by overnight priority mail. Please ship these specimens separately from other chilled or frozen samples being shipped.	
	If specimen has been previously frozen, please send these specimens by overnight priority mail on ice-packs.	
Methodology	Polymerase Chain Reaction (PCR), Indirect Immunofluorescence (IIF), Immunohistochemical (IHC) staining plus microscopy, Microscopy	
Turnaround Time	7 Days	
Interferences & Limitations	For molecular detection, CSF is the preferred specimen type for <i>N. fowleri</i> only, and it is NOT the preferred specimen type for <i>Acanthamoeba</i> or <i>Balamuthia</i>	

January 9, 2019 Version: 1.4 Page 8 of 364

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

detection. A negative CSF test result does not completely rule out infection with Acanthamoeba or Balamuthia. Fresh or frozen (unfixed) tissue specimens are preferred for Balamuthia or Acanthamoeba detection. Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred over the formalin-fixed specimens.

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

> For deep scraping and biopsy materials please provide the following information to the laboratorians: patient name (first, last and middle initials), age & date of birth, sex, date specimen collected, Specimen source (cornea, vitreous fluid), specimen type (deep scraping, biopsy, vitreous fluid), suspected infection (keratitis, conjunctivitis, endophthalmitis), transport medium used.

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

#### CDC Points of Contact Jennifer Cope

(404) 718-4878 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

Version: 1.4 Page 9 of 364 January 9, 2019

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

Synonym(s)	Free-living ameba, Acanthamoeba, E	Balamuthia, Naegleria fowleri
Pre-Approval Needed	None	
	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 uploa	d 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 a	part)
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.  Serum samples should be shipped refrigerated or frozen and packed with cold	
NA sale a dia la succ	packs.	J. (IFA)
	Indirect Immunofluorescence Antibo	ody (IFA) assay
Turnaround Time	· · · · · · · · · · · · · · · · · · ·	
Interferences & Limitations	The Ameba Serology test has limited diagnostic value for three reasons:  1. This test cannot differentiate between an old infection (or exposure) and an acute infection.  2. For immunocompromised patients (which is the case for most <i>Acanthamoel</i> infections, and some of the <i>Balamuthia</i> infections), there may not be any antibody response in the infected patients.  3. There may not be enough time to mount an antibody response during an active N. fowleri (PAM) infection since the time from the onset of infection to fulminant disease (and death) is usually only 2–8 days.	
Additional Information	Include the address of sender and physician contact information with the specimen	
CDC Points of Contact	Jennifer Cope (404) 718–4878 bjt9@cdc.gov Ibne Ali (404) 718–4157 xzn5@cdc.gov	If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100

January 9, 2019 Version: 2.0 Page 10 of 364

#### **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 CD Emergency Operations Center (EOC (770) 488-7100	

January 9, 2019 Version: 1.2 Page 11 of 364

## **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 ar etiologic agent.	
·	Frozen specimen should be shipped on dry ice	
Marks and all and	Specimen stored at room temperature should be shipped at room temperature	
	16S Sequencing, MALDI-TOF, Phenotypic Testing	
Turnaround Time	·	
	Specimen from respiratory, vaginal, and fecal sources are not acceptable	
Additional Information	See separate test order for <i>C. difficile</i>	
CDC Points of Contact	David Lonsway (404) 639-2825 Dlonsway@cdc.gov Kamile Rasheed (404) 639-3247 jkr1@cdc.gov	

January 9, 2019 Version: 1.0 Page 12 of 364

### Anaplasma Molecular Detection

CDC-10290

Synonym(s)	Human granulocytic anaplasmosis	
Pre-Approval Needed	d 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) an pertinent clinical findings	
Supplemental Form	None	
Performed on Specimens From	Human	
	Acute samples only, anticoagulated whole blood collected in ethylenediaminetetraacetic acid (EDTA), citrate dextrose solution A (ACD-A), o sodium citrate treated tubes preferred; serum; fresh tissue biopsy; swab	
Minimum Volume Required	1.0 mL	
	Ideally keep specimen at a refrigerated temperature (4°C) within 7 days of dra If specimen age is over 7 days, then freeze and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.	
Transport Medium	For tissue, place in sterile specimen cup with gauze pad slightly moistened wit sterile saline.	
Specimen Labeling	Patient name, date of birth, and collection date	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with ice.	
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing	
Turnaround Time	6 Weeks	
	Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cyand sample storage above refrigerated temperatures can interfere with proportional nucleic acid extraction. Molecular detection methods have decreasing sensitive after febrile (acute) stage of illness.	
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>	
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov	

January 9, 2019 Version: 2.2 Page 13 of 364

### *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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 14 of 364

### Anaplasma Special Study

CDC-10291

Synonym(s)	Human granulocytic anaplasmosis
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov Zeng, Yan, (404) 639–5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with drice.
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 2.2 Page 15 of 364

### 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	14 Days
Interferences & Limitations	Formalin fixed specimens are not suitable for molecular studies
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov

January 9, 2019 Version: 2.1 Page 16 of 364

## **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
	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 ar 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

January 9, 2019 Version: 2.1 Page 17 of 364

## **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.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice
	Ship to: Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521
Methodology	Isolation in cell culture
Turnaround Time	2 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Robert Lanciotti (970) 221–6440 rsl2@cdc.gov

January 9, 2019 Version: 1.2 Page 18 of 364

## **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.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice
	Ship to: Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521
Methodology	RT-Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	Hemolysis can affect the test results
Additional Information	None
CDC Points of Contact	Robert Lanciotti (970) 221–6440 rsl2@cdc.gov

January 9, 2019 Version: 1.2 Page 19 of 364

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

Synonym(s)	Arbo-PRNT
Pre-Approval Needed	None
Supplemental Information Required	onset date, collection date, travel history and IgM test result for requested virus
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum and cerebrospinal fluid (CSF)
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimen should be kept at 4°C or colder
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice
	Ship to: Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521
Methodology	Plaque reduction neutralization
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Robert Lanciotti (970) 221–6440 rsl2@cdc.gov

January 9, 2019 Version: 1.2 Page 20 of 364

### **Test Order** Arbovirus Serology

CDC-10282

Synonym(s)	Arbo-Serology,
Pre-Approval Needed	None
Supplemental Information Required	onset date, collection date, travel dates & locations
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum and cerebrospinal fluid (CSF)
Minimum Volume Required	0.25 mL
Storage & Preservation of Specimen Prior to Shipping	Specimen should be kept at 4°C or colder
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice  Ship to: Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd
	Fort Collins, CO 80521
Methodology	ELISA, MIA
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Robert Lanciotti (970) 221–6440 rsl2@cdc.gov

January 9, 2019 Version: 1.2 Page 21 of 364

## 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

January 9, 2019 Version: 1.0 Page 22 of 364

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

Synonym(s)	Junin virus, Machupo virus, Guanarito virus, Chapare virus, Sabia virus serology
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood, Serum
Minimum Volume Required	1.0 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.0 Page 23 of 364

## **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, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 24 of 364

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

Synonym(s)	Old World <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 25 of 364

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

Synonym(s)	Atypical pneumonia, Community Acquired Pneumonia (CAP), Legionnaires'
	disease (LD), Legionellosis, Pontiac fever, Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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	All specimens in which <i>M. pneumoniae</i> is detected will be subjected to <i>M. pneumoniae</i> Macrolide Susceptibility Genotyping (CDC-10513). Specimens in which <i>Legionella</i> species is detected will be subjected to <i>Legionella</i> species Detection and Identification (CDC-10159) and/or <i>Legionella</i> species Molecular Subtyping (CDC-10160).
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

January 9, 2019 Version: 2.0 Page 26 of 364

## 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	14 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov

January 9, 2019 Version: 1.5 Page 27 of 364

## **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 or plasma
Minimum Volume Required	0.5mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to leak proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 a room temperature or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tube for each test requested.
CDC Points of Contact	Hilda Rivera (404) 718-4100 igi2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 28 of 364

### 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 μL – 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°C. Fresh tissue should be sent frozen and fixed tissue can be sent at room temperature.
Methodology	Culture, PCR, Immunohistochemistry (IHC), Toxin detection
Turnaround Time	2 Weeks
Interferences & Limitations	Varies depending on tests used. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin). Tissues for IHC should be formalin fixed.
Additional Information	Turnaround time will vary depending on methods selected for detection at CDC. Some methods may require up to 1 week.
	Minimal volume: limited testing can be done with $100~\mu l$ , however $0.51~mL$ 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

January 9, 2019 Version: 2.0 Page 29 of 364

### 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 hr.  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

January 9, 2019 Version: 2.0 Page 30 of 364

### 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 μL
	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 <a href="http://www.cdc.gov/anthrax/labs/recommended_specimen.html">http://www.cdc.gov/anthrax/labs/recommended_specimen.html</a> .
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

January 9, 2019 Version: 2.0 Page 31 of 364

### 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

January 9, 2019 Version: 1.0 Page 32 of 364

### 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 10 g (stool)
Storage & Preservation of Specimen Prior to Shipping	Food and stool should be maintained at 4°C.
Transport Medium	Not Applicable
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required.
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	(404) 639–0896 fry6@cdc.gov Gerry Gomez (404) 639–0537
	goe4@cdc.gov

January 9, 2019 Version: 1.3 Page 33 of 364

### Bacillus cereus Genotyping

CDC-10206

ne ne man, Animal, and Food/Environmental/Medical Devices/Biologics lates t Applicable Specific Requirements y medium can be submitted, but preferably agar slants. st subject to CLIA regulations and requires two patient identifiers on the
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st subject to CLIA regulations and requires two patient identifiers on the
ecimen container and the test requisition.
ip specimen Monday – Thursday, overnight to avoid weekend deliveries.
ar slants need to be shipped at room temperature.
Itilocus sequence typing (MLST)
Veeks
ne
sting can be done on <i>B. cereus</i> and <i>B. thuringiensis.</i>
ex Hoffmaster 04) 639–0852 nh9@cdc.gov
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January 9, 2019 Version: 1.0 Page 34 of 364

# 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	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 35 of 364

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

Synonym(s)	None
Pre-Approval Needed	McQuiston, John, (404) 639-0270, zje8@cdc.gov Whitney, Anne, (404) 639-1374, amw0@cdc.gov
Supplemental Information Required	Please notify laboratory prior to shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Primary specimens with prior approval
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Keep specimen refrigerated if unable to ship immediately.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory is concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 36 of 364

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

	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	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 37 of 364

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

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. 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 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 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, 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

January 9, 2019 Version: 1.3 Page 38 of 364

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

CDC-10486

Synonym(s)	B. henselae/cat scratch disease, B. quintana/trench fever
Pre-Approval Needed	None
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	500 uL
	Sera may be stored at $2^{\circ}-8^{\circ}C$ 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
Mathadalami	Refrigerated specimen should be shipped on ice packs
Turnaround Time	Indirect Fluorescent Antibody (IFA)
	Samples with hemolysis, increased lipemia or microbial growth may interfere with test results
Additional Information	Clinical information including symptoms and date of onset must be included; specimens without this accompanying information will not be tested.
CDC Points of Contact	Jeannine Peterson (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.2 Page 39 of 364

# 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	Peterson, Jeannine, (970) 266–3524, nzp0@cdc.gov Kingry, Luke, (970) 266–3567, vtx8@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	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	To be determined
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jeannine Peterson (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.4 Page 40 of 364

## 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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
Transport Medium	Not Applicable
Specimen Labeling	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 specimer at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718-4100 ibm4@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 41 of 364

## **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

January 9, 2019 Version: 2.2 Page 42 of 364

# Test Order Biothreat Study CDC-10432

Synonym(s)	None
Pre-Approval Needed	Thomas, Jennifer, (404) 639–4259, fsu8@cdc.gov Kamal, Nazia, (404) 639–4733, ird7@cdc.gov
	Please contact Dr. Jennifer Thomas at (404) 639-4259 or fsu8@cdc.gov, for the required supplemental form and packaging and shipping requirements.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jennifer Thomas (404) 639–4259 fsu8@cdc.gov Nazia Kamal (404) 639–4733 ird7@cdc.gov

January 9, 2019 Version: 1.6 Page 43 of 364

# **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

January 9, 2019 Version: 1.1 Page 44 of 364

## 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. Centrifuge the tube of blood at $1100-1300 \times g$ for approximately 10 minutes to separate the cells from the serum.
Minimum Volume Required	0.5 mL
	Serum specimens may be stored refrigerated $(2-8^{\circ}\text{C})$ for up to 7 days. If greater than 7 days, serum must be kept frozen $(-20^{\circ}\text{C} \text{ or lower})$ . For long-term storage the serum should be frozen $(-20^{\circ}\text{C} \text{ or colder})$ .
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.
Include Specimen Handling	Serum specimens may be shipped refrigerated (2–8°C) for up to 7 days. For shipments that are in transit for more than 7 days, specimens should be kept frozen (–20°C or lower). Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contact the laboratory by email or phone before shipping.
Methodology	Enzyme-linked Immunosorbent Assay (ELISA)
Turnaround Time	2 Weeks
Interferences & Limitations	Serum collected from patients with less than 2 weeks of cough are not appropriate for this test. Samples should not be used if they have incurred more than 5 freeze-thaw cycles. Specimens with unacceptable preservatives such as anti-coagulants would invalidate the results.
	In addition, hemolyzed and lipemic specimens are considered suboptimal 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

January 9, 2019 Version: 1.1 Page 45 of 364

# 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. holmesii</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 <i>(B. parapertussis, B. holmesii, or B. bronchiseptica</i> 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 $(2-8^{\circ}C)$ as soon as possible, between 24–48 hours. Frozen isolates should be sent on dry ice. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Culture, Identification
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment will adversely affect results and patients coughing more than two weeks will likely not be culture positive.
Additional Information	None
CDC Points of Contact	Pam Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

January 9, 2019 Version: 1.0 Page 46 of 364

# 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 as possible, between 24–48 hours. Aspirates can be shipped with ice packs or frozen (–20°C or lower). Frozen isolates should be sent on dry ice. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Culture
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment will adversely affect results. Patients coughing more than two weeks will likely not be culture positive.
Additional Information	None
CDC Points of Contact	Pam Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

January 9, 2019 Version: 1.1 Page 47 of 364

# **Test Order** *Bordetella* species Molecular Detection CDC-10165

Synonym(s)	None
, ,	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	1 Week
	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

January 9, 2019 Version: 1.1 Page 48 of 364

## 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

January 9, 2019 Version: 1.0 Page 49 of 364

# 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	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 50 of 364

# Borrelia burgdorferi (Lyme Disease) Serology CDC-10298

Synonym(s)	Lyme Disease, Borreliosis
Pre-Approval Needed	None
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
	Sera may be stored at 2°-8°C for up to 14 days. If testing is delayed for a longer period, serum samples may be frozen.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:  Centers for Disease Control and Prevention Bacterial Diseases Branch Attn: John Young 3156 Rampart Road Fort Collins, CO 80521  Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on ice packs
Methodology	ELISA, Western Blot
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed samples may interfere with test results
Additional Information	If available, please include date of onset, antibiotic treatment (type of antibiotic and date administered), date when the sample was collected, signs and symptoms.
CDC Points of Contact	Jeannine Peterson (970) 266–3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494–6618 wul2@cdc.gov

January 9, 2019 Version: 1.6 Page 51 of 364

### Borrelia Culture and Identification

CDC-10299

Synonym(s)	Lyme Disease, Borreliosis, Relapsing fever
Pre-Approval Needed	Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov Dietrich, Elizabeth, (970) 494–6618, wul2@cdc.gov
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human
	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
	For a skin biopsy, contact laboratory prior to collection and/or shipment for specific requirements. Blood may be collected in heparin, citrate or EDTA. All specimen should be collected and shipped prior to antibiotic treatment if possible.
Transport Medium	Contact laboratory prior to shipping for instructions on skin biopsy's transport medium.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:
·	Centers for Disease Control and Prevention
	Bacterial Diseases Branch Attn: John Young
	3156 Rampart Road
	Fort Collins, CO 80521
	Frozen specimen should be shipped on dry ice
Mathadalagy	Refrigerated specimen should be shipped on ice packs
Turnaround Time	Culture, Microscopy Confirmation
	Antibiotic treatment will minimize growth potential of culture
	Provide any antibiotic treatment information
CDC Points of Contact	Jeannine Petersen (970) 266–3524
	nzp0@cdc.gov
	Elizabeth Dietrich
	(970) 494–6618
	wul2@cdc.gov

January 9, 2019 Version: 1.3 Page 52 of 364

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

Synonym(s)	Borreliosis, Recurrent fever, <i>Borrelia</i>
Pre-Approval Needed	None
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:  Centers for Disease Control and Prevention Bacterial Diseases Branch Attn: John Young 3156 Rampart Road Fort Collins, CO 80521  Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on ice packs
Methodology	IgM/IgG ELISA
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed specimen can affect the results
Additional Information	If available, please include date of onset, antibiotic treatment (type of antibiotic and date administered), date when the sample was collected, signs and symptoms.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

January 9, 2019 Version: 2.4 Page 53 of 364

## **Borrelia** Special Study

CDC-10300

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov Dietrich, Elizabeth, (970) 494–6618, wul2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov

January 9, 2019 Version: 1.3 Page 54 of 364

# Botulinum Toxin Producing Clostridia Subtyping CDC-10134

Synonym(s)	Bot, Botulism
Pre-Approval Needed	Luquez, Carolina, (404) 639–0896, fry6@cdc.gov Dykes, Janet, (404) 639–3625, jkd1@cdc.gov
Supplemental Information Required	APHIS/CDC Form 2 Request to Transfer Select Agents and Toxins is required.
Supplemental Form	http://www.selectagents.gov/forms.html
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Isolates
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Chopped Meat Glucose Starch (CMGS) or Trypticase Peptone Glucose Yeast extract (TPGY) media.
Specimen Labeling	Not Applicable
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries.
Requirements	Package must have proper labeling for infectious substance: UN 2814 Infectious substance, Category A.
Methodology	WGS
Turnaround Time	12 Weeks
Interferences & Limitations	None
Additional Information	Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. APHIS/CDC Form 2 must be approved prior to shipping. Form 2 may be found at: <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 (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov

January 9, 2019 Version: 1.2 Page 55 of 364

# **Test Order**Botulism Laboratory Confirmation CDC-10132

Synonym(s)	Bot, Botulism
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Foodborne: serum, stool, vomitus, gastric contents, food
	Wound: serum, debrided tissue, swab from wounds, stool (only if foodborne is also suspected)
	Infant: stool, rectal swabs, potential sources
Minimum Volume Required	See Additional Information.
Storage & Preservation of Specimen Prior to Shipping	Maintain specimen at 4°C.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling	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 (PC
Turnaround Time	12 Weeks
Interferences & Limitations	None
Additional Information	Serum samples must be collected before antitoxin treatment.
	Adult patients: 5 mL to 15 mL of serum (without anticoagulant); 10 g to 20 g of feces (if an enema is needed, use sterile non-bacteriostatic water). Infant patients: ideally, 10 g to 20 g of feces should be collected; however, smaller quantities can provide confirmatory test results (if an enema is needed, use sterile non-bacteriostatic water).
	Foods should be left in their original containers or placed in sterile unbreakable containers. Empty containers with remnants of suspected foods can also be recovered and submitted for testing.
CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov

January 9, 2019 Version: 1.3 Page 56 of 364

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

Synonym(s)	None
Pre-Approval Needed	Luquez, Carolina, (404) 639–0896, fry6@cdc.gov Dykes, Janet, (404) 639–3625, jkd1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov

January 9, 2019 Version: 1.2 Page 57 of 364

# 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.
	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	Antimicrobial susceptibility testing (AST) for test order CDC-10207 'Brucella species ID, genotyping and AST' will only be performed upon special request. Please consult with David Lonsway for the AST request prior to sample submission.
CDC Points of Contact	Rebekah Tiller (404) 639–4507 eto3@cdc.gov David Lonsway (404) 639–2825 dul7@cdc.gov

January 9, 2019 Version: 1.1 Page 58 of 364

# Test Order Brucella species Molecular Detection CDC-10208

Synonym(s)	Brucella PCR	
Pre-Approval Needed	None	
Supplemental Information Required	None	
Supplemental Form	http://www.selectagents.gov/forms.html	
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics	
	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 μL	
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.	
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.	
Methodology	Polymerase Chain Reaction (PCR)	
Turnaround Time	2 Weeks	
Interferences & Limitations Blood specimens should be collected in EDTA or Sodium Citrate tubes 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	

January 9, 2019 Version: 1.0 Page 59 of 364

# Test Order Brucella species Serology CDC-10197

Synonym(s)	BMAT	
Pre-Approval Needed	None	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Serum (acute and convalescent preferred)	
Minimum Volume Required	100 μL	
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.	
Include Specimen Handling	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 o 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	

January 9, 2019 Version: 1.1 Page 60 of 364

# 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

January 9, 2019 Version: 1.0 Page 61 of 364

# 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 specimen 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 weeken arrivals. Specimens should be shipped at 4°C.	
Methodology	Polymerase Chain Reaction (PCR), Biochemicals, Broth Micro Dilution, Multilocus sequence typing (MLST), Multiple-Locus Variable number tandem repeat Analysis (MLVA)	
Turnaround Time	2 Weeks	
Interferences & Limitations	None	
Additional Information	Turnaround time will vary depending on if an isolate is sent for identification specimen is sent for isolation. Identification of isolates generally is completed within 3 days while isolation from specimens and subsequent ID may take up 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	

January 9, 2019 Version: 1.0 Page 62 of 364

# 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, abscess material or wound swabs, urine, and serum; blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin)	
Minimum Volume Required	250 μL	
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 specime 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. Agar slants should be shipped at room temperature and specimens at 4 C.	
Methodology	Polymerase Chain Reaction (PCR)	
Turnaround Time	2 Weeks	
Interferences & Limitations	s 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	

January 9, 2019 Version: 1.0 Page 63 of 364

## Burkholderia mallei/pseudomallei Study

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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

January 9, 2019 Version: 1.0 Page 64 of 364

## Burkholderia pseudomallei Serology

CDC-10198

C 4 (-)	Maliaidasia
Synonym(s)	
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 μL
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.
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

January 9, 2019 Version: 1.0 Page 65 of 364

# 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	None	
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.	
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.	
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov	

January 9, 2019 Version: 1.2 Page 66 of 364

## Campylobacter and Helicobacter Study

CDC-10125

Synonym(s)	Campy, H. pylori
Pre-Approval Needed	Pruckler, Janet, (404) 639–4770, jmp5@cdc.gov Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Janet Pruckler (404) 639-4770 jmp5@cdc.gov Rachael Aubert (404) 639-3816 vrl7@cdc.gov

January 9, 2019 Version: 1.3 Page 67 of 364

# Test Order Campylobacter species serology CDC-10455

Synonym(s)	Enteric Pathogen	
	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Fields, Patricia, (404) 639–1748, pif1@cdc.gov	
Supplemental Information Required	Date of illness onset, date of serum collection, clinical diagnosis (i.e. Guillain Barré).	
Supplemental Form	None	
Performed on Specimens From	Human	
	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	f Maintain serum at 4°C (preferred); frozen specimens acceptable	
Transport Medium	Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed	
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required	
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 Patricia Fields (404) 639-1748 pif1@cdc.gov	

January 9, 2019 Version: 1.3 Page 68 of 364

# Campylobacter, Helicobacter, and Related Organisms Identification

CDC-10126

Synonym(s)	Campy, <i>H. pylori</i>
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	Ship isolates or cultures Monday – Thursday, overnight to avoid weekend deliveries.
Requirements	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 Rachael Aubert (404) 639-3816 vrl7@cdc.gov

January 9, 2019 Version: 1.4 Page 69 of 364

# Campylobacter, Helicobacter, and Related Organisms 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	Two patient identifiers on the specimen container and the test requisition are required.
Shipping Instructions which Include Specimen Handling Requirements	Ship isolates or cultures Monday – Thursday, overnight to avoid weekend deliveries.  Ship with cold packs in compliance with federal and local guidelines.
	There are no time constraints for submitting sequence data.
Methodology	PFGE, AST, WGS, Penner serotyping
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation requested if available.
	Turnaround times for routine isolates may be extended during major foodborn outbreak activities due to limited availability of resources.
CDC Points of Contact	Janet Pruckler (404) 639-4770 jmp5@cdc.gov Rachael Aubert (404) 639-3816 vrl7@cdc.gov

January 9, 2019 Version: 2.0 Page 70 of 364

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

Synonym(s)	Trypanosoma cruzi; American trypanosomiasis, parasite
Pre-Approval Needed	Gray, Elizabeth, (404) 718–4725, djn8@cdc.gov Benedict, Theresa, (404) 718–4124, tgd5@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Blood, Heart Biopsy Tissue, and CSF
Minimum Volume Required	2.2 ml (pediatric 0.2 ml)
	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 specimen on wet ice (cold pack) as an etiologic agent.
Methodology	Real-time PCR
Turnaround Time	14 Days
Interferences & Limitations	None
Additional Information	This assay is used in clinically indicated situations such as acute or congenital infections, post-transplant from a donor with confirmed <i>T. cruzi</i> infection, or risk of reactivation due to immunocompromise in patients with chronic Chagas disease. Serological testing is the preferred method to diagnose chronic infection patients.
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov

January 9, 2019 Version: 1.5 Page 71 of 364

## **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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}$ C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}$ C or lower.
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 specimer at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Hilda Rivera (404) 718-4100 igi2@cdc.gov Sue Montgomery (404) 718-4731 zqu6@cdc.gov

January 9, 2019 Version: 1.3 Page 72 of 364

### Chlamydia pneumoniae Molecular Detection CDC-10152

Synonym(s)	Chlamydia pneumoniae, Atypical pneumonia, CAP, Chlamydia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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.
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries.  Refrigerated specimen should be sent on ice packs. Frozen specimen should be
Requirements	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	Laboratory test results may also include results for <i>Mycoplasma pneumoniae</i> , <i>Chlamydia psittaci</i> , and <i>Legionella species</i> due to multiplex real time PCR assay.
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534

January 9, 2019 Version: 2.1 Page 73 of 364

mdiaz1@cdc.gov

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

Synonym(s)	Atypical pneumonia, CAP, Chlamydia, <i>Chlamydia pneumoniae</i> , <i>Chlamydia psittaci</i> , Parrot fever, Psittacosis
Pre-Approval Needed	Winchell, Jonas, (404) 639–4921, Jwinchell@cdc.gov Diaz, Maureen, (404) 639–4534, mdiaz1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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.
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 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	Laboratory test results may also include results for <i>Mycoplasma pneumoniae</i> , <i>Chlamydia pneumoniae</i> , and <i>Legionella species</i> due to multiplex real time PCR assay.
CDC Points of Contact	Jonas Winchell (404) 639–4921 Jwinchell@cdc.gov Maureen Diaz (404) 639–4534 mdiaz1@cdc.gov

January 9, 2019 Version: 3.2 Page 74 of 364

## Chlamydia Species (Respiratory) Molecular Detection CDC-10525

Synonym(s)	Chlamydia pneumoniae, Atypical pneumonia, CAP, Chlamydia, Chlamydia psittac Parrot fever, Psittacosis
Pre-Approval Needed	Winchell, Jonas, (404) 639–4921, jwinchell@cdc.gov Diaz, Maureen, (404) 639–4534, mdiaz1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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. Other specimens can be kept refrigerated if shipped within 72 hours 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 (e.g. patient name and date of birth) on the specimen container and on the test requisition.
	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	Multiplex real-time PCR assay
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	None
CDC Points of Contact	Jonas Winchell (404) 639-4921 jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

January 9, 2019 Version: 1.0 Page 75 of 364

#### Chlamydia species (Respiratory) 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	To be determined
CDC Points of Contact	Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov

January 9, 2019 Version: 3.0 Page 76 of 364

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

Synonym(s)	Chlamydia trachomatis (CT) NAATS, Chlamydia
Pre-Approval Needed	Phillips, Christi, (404) 639–2147, div2@cdc.gov Morris, Monica, (404) 639–2733, vul8@cdc.gov
Supplemental Information Required	Please indicate the product or medium used for storage and/or transport.
Supplemental Form	None
Performed on Specimens From	Human
	Oral pharynx swabs, cervical swabs, vaginal swabs, and rectal swabs collected on any commercially available product, and urine
Minimum Volume Required	5 mL (urine)
Storage & Preservation of Specimen Prior to Shipping	Adhere to product insert instructions for swabs.
Transport Medium	Adhere to product insert instructions for swabs.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice if previously frozen, as an etiologic agent.
Methodology	Nucleic Acid Amplification Tests (NAATS)
Turnaround Time	2 Weeks
Interferences & Limitations	Adhere to product insert instructions for swabs.
Additional Information	None
CDC Points of Contact	Christi Phillips (404) 639–2147 div2@cdc.gov Monica Morris (404) 639–2733 vul8@cdc.gov

January 9, 2019 Version: 2.0 Page 77 of 364

### Chlamydia trachomatis LGV Molecular Detection Study CDC-10523

Synonym(s)	Lymphogranuloma venereum, Chlamydia trachomatis (CT) NAATS, Chlamydia
Pre-Approval Needed	Bowden, Katie, (404) 639–2661, wzi1@cdc.gov Ridpath, Alison, (770) 488–3685, etf4@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	Probable LGV, <i>Chlamydia trachomatis</i> -positive oral pharynx swabs, cervical swabs, vaginal swabs, penile swabs, rectal swabs, and ulcer swabs collected on any commercially available product.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Adhere to product insert instructions for swabs
Transport Medium	Adhere to product insert instructions for swabs
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers (e.g. patier name and date of birth) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice if previously frozen, as an etiologic agent.
Methodology	Nucleic Acid Amplification Tests (NAATS)
Turnaround Time	2 Weeks
Interferences & Limitations	Adhere to product insert instructions for swabs
Additional Information	None
CDC Points of Contact	Katie Bowden (404) 639-2661 wzil@cdc.gov Damien Danavall (404) 639-4964 bpu8@cdc.gov

January 9, 2019 Version: 1.0 Page 78 of 364

## Chlamydia trachomatis, Genital - Study CDC-10193

Synonym(s)	None
Pre-Approval Needed	Phillips, Christi, (404) 639–2147, div2@cdc.gov Morris, Monica, (404) 639–2733, vul8@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	Christi Phillips (404) 639-2147 div2@cdc.gov Monica Morris (404) 639-2733 vul8@cdc.gov

January 9, 2019 Version: 1.2 Page 79 of 364

## 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

January 9, 2019 Version: 1.1 Page 80 of 364

#### Clostridium difficile Identification

#### CDC-10228

Synonym(s)	C. Difficile ID, C. diff, Clostridioides (Clostridium) difficile
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

January 9, 2019 Version: 1.1 Page 81 of 364

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

Synonym(s)	C. Difficile Toxin, C. Difficile Characterization, Clostridioides (Clostridium) difficile
Pre-Approval Needed	Rasheed, Kamile, (404) 639–3247, JRasheed@cdc.gov Karlsson, Maria, (404) 639–0698, fwt4@cdc.gov
Supplemental Information Required	Prior approval and Epidemiologic consultation required.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Pure culture isolate. Additional specimen types accepted upon consultation with laboratory
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Store anaerobically
Transport Medium	Pure culture isolate in Chopped Meat Glucose Broth, thioglycolate broth or frozen in TSB plus glycerol
Specimen Labeling	Include date of isolation and unique specimen identifier
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday overnight to avoid weekend deliveries, as an etiologic agent.
	Frozen specimen should be shipped on dry ice
	Specimen stored at room temperature should be shipped at room temperature
Methodology	Molecular Strain Typing, Phenotypic Testing
Turnaround Time	28 Days
Interferences & Limitations	None
Additional Information	Not CLIA compliant testing; for epidemiologic purposes only
CDC Points of Contact	Kamile Rasheed (404) 639-3247 JRasheed@cdc.gov Maria Karlsson (404) 639-0698 fwt4@cdc.gov

January 9, 2019 Version: 1.3 Page 82 of 364

### 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	Two patient identifiers on the specimen container and the test requisition are required.
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

January 9, 2019 Version: 1.3 Page 83 of 364

### Colonization Screening for Antimicrobial Resistant Bacteria CDC-10521

Synonym(s)	Surveillance Screening for Antimicrobial Resistant Bacteria
Pre-Approval Needed	Malik, Sarah, (404) 718–3393, vgg9@cdc.gov Lonsway, David, (404) 639–2825, dul7@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Rectal swab (double-swab)
Minimum Volume Required	N/A (Visible fecal material on swab, but do not overinoculate)
Storage & Preservation of Specimen Prior to Shipping	Swabs in the transport tube can be stored at 15-28 °C for up to five days.
Transport Medium	Copan double-swab, Cepheid catalog #900-0370
Specimen Labeling	Test requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Wednesday with cold packs for next day delivery
Methodology	Molecular and/or Culture-based Methods (e.g., Cepheid Xpert Carba-R routinely used for PCR-based detection of blaKPC, blaNDM, blaVIM, blaOXA-48-like, and blaIMP-1 group genes), 2nd swab can be cultured for possible typing of isolate
Turnaround Time	5 Days
Interferences & Limitations	For Cepheid: Interfering substances: barium sulfate at $>0.1\%$ w/v, Pepto-Bismol at $>0.01\%$ w/v; or fecal fat $\ge 0.25\%$ w/v (for blaVIM detection). Level of detection (LOD) of targets for Cepheid system (per package insert) ranged from 74-815 cfu/swab (specificity reported as 100%). If more than one PCR target is present i the sample, one target may not be detected. However, it is unusual for carbapenemase-producing isolates to have more than one carbapenemase gene
Additional Information	If strain typing (e.g., PFGE or other molecular method) will be needed for an outbreak investigation, then this testing request needs to be approved at the beginning of the investigation by staff at <a href="mailto:haioutbreak@cdc.gov">haioutbreak@cdc.gov</a> so that the paire rectal swab of a positive Cepheid test can be cultured without delay. Culturebased methods for surveillance screening may take up to 21 days for TAT.
CDC Points of Contact	Sarah Malik Kamile Rasheed (404) 718-3393 (404)639-3247 vgg9@cdc.gov jkr1@cdc.gov  David Lonsway (404) 639-2825 dlonsway@cdc.gov

January 9, 2019 Version: 1.0 Page 84 of 364

### Congo-Crimean Hemorrhagic Fever Identification CDC-10302

Synonym(s)	CCHF
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 85 of 364

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

Synonym(s)	CCHF
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 86 of 364

#### 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

January 9, 2019 Version: 1.0 Page 87 of 364

### 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 μL (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 include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Real Time Polymerase Chain Reaction (RT-PCR)
Turnaround Time	1 Week
Interferences & Limitations	Prior antibiotic treatment will adversely affect results. Suboptimal volumes of specimens may adversely affect the sensitivity of tests performed therefore it is very important to obtain an acceptable volume and a quality specimen. Clinical specimens collected subsequent to initiation of antimicrobial treatment may not be positive for <i>Corynebacterium</i> species due to reduction of organisms. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with <i>Corynebacterium</i> species.
Additional Information	Diphtheria Antitoxin (DAT) testing should be performed on the patient prior to requesting molecular testing from CDC. <i>Corynebacterium</i> PCR testing is not currently used for diagnostic purposes for diphtheria and is not considered a confirmatory test.
CDC Points of Contact	Pam Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

January 9, 2019 Version: 1.2 Page 88 of 364

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

Synonym(s)	Diphtheria
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Fresh subculture (24–48 hours old) of a pure culture isolate on a suitable agar slant
Minimum Volume Required	Not Applicable
	Use plastic/glass screw-cap, leak-proof vials. Isolates can be refrigerated on an agar slant or common culture medium or frozen in TSB with glycerol or other liquid medium.
Transport Medium	Common transport medium such as blood agar, TSA, nutrient agar, slants/plates, or frozen
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.  Note: Surveillance studies may label specimens according to protocol.
Shipping Instructions which Include Specimen Handling Requirements	Once specimens are collected they should be shipped to the laboratory as soon as possible, between 24–48 hours. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Culture, API Coryne, Elek, Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Isolates passed within 24-48 hours are preferred.
Additional Information	None
CDC Points of Contact	Pam Cassiday (404) 639-1231 pxc1@cdc.gov Maria Tondella (404) 639-1239 mlt5@cdc.gov

January 9, 2019 Version: 1.1 Page 89 of 364

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

Synonym(s)	Diphtheria
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Throat, nasal and wound swabs, pseudo-membrane, and sputum
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Use plastic/glass screw-cap, leak-proof vials. Store refrigerated.
Transport Medium	Common transport media such as Amies or Stuart may be used for swabs. Pseudo-membrane should be sent in leak-proof container with saline, not formalin.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Note: Surveillance studies may label specimens according to protocol.
Shipping Instructions which Include Specimen Handling Requirements	Once specimens are collected they should be shipped to the laboratory as soon as possible, between 24–48 hours. Sender is responsible for shipping charges and when shipping internationally must request CDC's import permit and include this with the Air Waybill. Additionally, the Pertussis/Diphtheria Laboratory requests that the sender contacts the laboratory by email or phone before shipping.
Methodology	Culture, Polymerase Chain Reaction (PCR), API Coryne, Elek
Turnaround Time	2 Weeks
	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 antimicrobia 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

January 9, 2019 Version: 1.1 Page 90 of 364

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

Synonym(s)	Diptheria
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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639–0270 zje8@cdc.gov Anne Whitney (404) 639–1374 amw0@cdc.gov

January 9, 2019 Version: 1.3 Page 91 of 364

#### 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), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; serum; fresh tissue biopsy; swab
Minimum Volume Required	1.0 mL
	Ideally keep specimen at a refrigerated temperature (4°C) within 7 days of draw. If specimen age is over 7 days, then freeze and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline.
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 92 of 364

### 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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 93 of 364

#### Coxiella Special Study

CDC-10306

Synonym(s)	Q fever
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov Zeng, Yan, (404) 639–5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday–Thursday, overnight to avoid weekend deliveries. Specimen shoul be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Cecilia Kato (404) 639–0152 ckato@cdc.gov Yan Zeng (404) 639–5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 94 of 364

### 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

January 9, 2019 Version: 1.3 Page 95 of 364

## Test Order Cyclospora Molecular Detection CDC-10477

Synonym(s)	Cyclospora cayetenensis, parasite
Pre-Approval Needed	
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	14 Days
Interferences & Limitations	Stool specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov

January 9, 2019 Version: 2.1 Page 96 of 364

## **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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lear proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 97 of 364

## **Test Order**Cytomegalovirus (CMV) Detection CDC-10263

Synonym(s)	CMV
Pre-Approval Needed	Dollard, Shelia, (404) 639–2178, sgd5@cdc.gov Schmid, Scott, (404) 639–0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Urine, saliva, and blood
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.
Transport Medium	Not Applicable
Specimen Labeling	Provide a specimen ID. Do not send specimen labeled with patient's name.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday -Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health of management.
CDC Points of Contact	Shelia Dollard (404) 639-2178 sgd5@cdc.gov Scott Schmid (404) 639-0066 dss1@cdc.gov

January 9, 2019 Version: 1.1 Page 98 of 364

### Cytomegalovirus (CMV) Serology CDC-10264

Synonym(s)	CMV
Pre-Approval Needed	Dollard, Sheila, (404) 639–2178, sgd5@cdc.gov Schmid, Scott, (404) 639–0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum or plasma
Minimum Volume Required	500 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen
Transport Medium	Not Applicable
Specimen Labeling	Provide a specimen ID. Do not send specimen labeled with patient's name.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	IgG antibody detected by EIA, IgM antibody detected by EIA
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health of management.
CDC Points of Contact	Sheila Dollard (404) 639–2178 sgd5@cdc.gov Scott Schmid (404) 639–0066 dss1@cdc.gov

January 9, 2019 Version: 1.1 Page 99 of 364

#### 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.pd
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°C or frozen at -20°C (preferred).
	Citrate (collected in yellow top tubes) and heparin plasma (green top tubes) ca 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 ser on dry ice. If dry ice is not available, we recommend that the serum is kept refrigerated and delivered to the CDC Dengue Branch in cold packs.
Transport Medium	Not Applicable
Specimen Labeling	Include complete name, age, and sex of patient, home address, date of onset of symptoms, date sample was obtained, complete name and mailing address of the physician, laboratory, clinic, or hospital
Shipping Instructions which	Ship Monday-Thursday, overnight to avoid weekend deliveries
Include Specimen Handling Requirements	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on ice packs
	Ship To: CDC Dengue Branch and Puerto Rico Department of Health 1324 Calle Cañada, San Juan, P. R. 00920-3860
Methodology	IgM by ELISA, NS1 Antigen Test, Polymerase Chain Reaction (PCR), Viral isolation IgG seroconversion by ELISA
Turnaround Time	7 Days
Interferences & Limitations	Serological tests can cross react with other Flavivirus, such as West Nile Virus. Recent vaccinations for Yellow Fever Virus and Japanese Encephalitis Virus, Tic borne Encephalitis Virus can cause cross reactive test results. Natural infection 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.

January 9, 2019 Version: 1.0 Page 100 of 364

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

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

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

Version: 1.0 Page 101 of 364 January 9, 2019

## Dengue Virus Special Study CDC-10308

Synonym(s)	None
Pre-Approval Needed	Hunsperger, Elizabeth, (787) 706–2472, enh4@cdc.gov Munoz, Jorge, (787) 706–2469, ckq2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Elizabeth Hunsperger (787) 706-2472 enh4@cdc.gov Jorge Munoz (787) 706-2469 ckq2@cdc.gov

January 9, 2019 Version: 1.0 Page 102 of 364

## Detection of *Mycoplasma genitalium* Antimicrobial Resistance Markers Study

CDC-10522

Synonym(s)	Mgen, Antimicrobial Resistance testing
Pre-Approval Needed	Bowden, Katie, (404) 639–2661, wzi1@cdc.goc Danavall, Damien, (404) 639–4964, bpu8@cdc.gov
Supplemental Information Required	Yes. Please indicate the product or medium used for storage and/or transport
Supplemental Form	None
Performed on Specimens From	Human
	Aptima tested, Mycoplasma genitalium-positive oral pharynx swabs, cervical swabs, vaginal swabs, urethral swabs, meatus swabs, and rectal swabs collected on any commercially available product, and urine.
Minimum Volume Required	5 mL (urine)
Storage & Preservation of Specimen Prior to Shipping	Adhere to product insert instructions for swabs
Transport Medium	Adhere to product insert instructions for swabs
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers (e.g. patien name and date of birth) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice if previously frozen, as an etiologic agent.
Methodology	Nucleic Acid Amplification Tests (NAATS), Sanger sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	Adhere to product insert instructions for swabs
Additional Information	None
CDC Points of Contact	Katie Bowden (404) 639-2661 wzil@cdc.goc Damien Danavall (404) 639-4964 bpu8@cdc.gov

January 9, 2019 Version: 1.0 Page 103 of 364

## **Test Order**Ebola Identification CDC-10309

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 104 of 364

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

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 105 of 364

#### Echinococcosis Serology

CDC-10460

Synonym(s)	Hydatid Disease, <i>Echinococcus granulosus</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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
Transport Medium	Not Applicable
Specimen Labeling	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 specimer at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 106 of 364

# **Test Order**Ehrlichia Molecular Detection CDC-10499

Synonym(s)	Human monocytic ehrlichiosis and HME
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), anticoagulant citrate dextrose solution A (ACD-A), or sodium citrate tubes are acceptable; serum; fresh tissue biopsy; swab
Minimum Volume Required	1.0 mL
	Ideally keep specimen at a refrigerated temperature (4°C) within 7 days of draw. If specimen age is over 7 days, then freeze and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline.
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivity after febrile (acute) stage of illness.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 2.0 Page 107 of 364

### *Ehrlichia* Serology

CDC-10311

Synonym(s)	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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 108 of 364

#### **Test Order** Ehrlichia Special Study CDC-10498

Synonym(s)	Human monocytic ehrlichiosis and HME
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov Zeng, Yan, (404) 639–5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with drice.
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.2 Page 109 of 364

### Elizabethkingia species – Special Study CDC–10514

Synonym(s)	None
Pre-Approval Needed	McQuiston, John, (404) 639-0270, zje8@cdc.gov Whitney, Anne, (404) 639-1374, amw0@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.0 Page 110 of 364

### 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 (4 C) or frozen. Stool samples in a PCR-compatible fixative, e.g. TotalFix, UniFix, EcoFix and modified PVA (Zn- or Cu-based), can be kept at room temperature. Alternatively stool specimens can also be mixed in potassium dichromate 2.5% (1:1 dilution) or in absolute ethanol (1:1 dilution).
Transport Medium	If stool specimens are shipped in Cary Blair Transport Medium send these within 3 days of collection
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship fixed/preserved specimens at room temperature. Ship unpreserved specimens of wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if stored frozen.
Methodology	Real-Time PCR
Turnaround Time	21 Days
Interferences & Limitations	Specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.
Additional Information	None
CDC Points of Contact	Ibne Ali (404) 718-4157 xzn5@cdc.gov Jennifer Cope (404) 718-4878 bjt9@cdc.gov

January 9, 2019 Version: 2.2 Page 111 of 364

### Enteric Isolation – Primary Specimen CDC-10106

Synonym(s)	Enteric Pathogen Culture
Pre-Approval Needed	Martin, Haley, (404) 639–1612, hvw0@cdc.gov Strockbine, Nancy, (404) 639–4186, nas6@cdc.gov
	Consult with EDLB contact before sending specimens. Targeted organisms include: Salmonella, Shigella, Campylobacter, STEC and other diarrheagenic Escherichia coli, pathogenic Enterobacteriaceae, Listeria, Vibrio, Cronobacter and related foodborne and waterborne pathogens. Provide any preliminary results available.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	Specimens that are acceptable will be determined upon consultation. Targeted organisms include: <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , STEC and other diarrheagenic <i>Escherichia coli</i> , pathogenic <i>Enterobacteriaceae</i> , <i>Listeria</i> , <i>Vibrio</i> , <i>Cronobacter</i> , and related foodborne and waterborne pathogens.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Storage and preservation are dependent upon consultation.
Transport Medium	Transport medium is dependent upon consultation.
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required.
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries.
	Specifics of shipping will depend upon consultation.  Enrichment, Isolation, Identification, Serotyping, PCR testing for virulence
	markers
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Haley Martin (404) 639-1612 hvw0@cdc.gov Nancy Strockbine (404) 639-4186 nas6@cdc.gov

January 9, 2019 Version: 1.5 Page 112 of 364

#### 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 $-70^{\circ}$ 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.
Include Specimen Handling	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 Igy7@cdc.gov

January 9, 2019 Version: 1.0 Page 113 of 364

## Test Order Enterovirus Detection and Identification CDC-10312

Synonym(s)	Enterovirus (EV), coxsackieviruses (CVA) (CVB), Echovirus
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	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.

January 9, 2019 Version: 1.1 Page 114 of 364

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

## Test Order Enterovirus Detection and Identification CDC-10312

Serum: For each serum specimen, collect (adults and children > 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

January 9, 2019 Version: 1.1 Page 115 of 364

## Test Order Enterovirus-D68 Detection CDC-10524

• • • • •	EV-D68, EV-68
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	Respiratory specimens are acceptable; specifically throat or nasal swabs, or nasopharyngeal (NP)/oropharyngeal (OP) swabs or respiratory aspirates.
Minimum Volume Required	0.20 mL; prefer 0.5–1.0 mL
	For nasal or throat swabs and nasopharyngeal (NP)/oropharyngeal (OP) swabs: Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocked swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays. Place the swab immediately into a sterile viral containing 2mL of viral transport media without antibiotics, if possible. Freeze at $\leq -20^{\circ}$ C as soon as possible.
Transport Medium	Viral transport medium. If you do not have viral transport media, place the swab into a sterile vial without viral transport media. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. For NP/OP swabs, both swabs can be placed in the same vial, if desired.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers (e.g. patient name and date of birth) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice and refrigerated specimen should be shipped on cold packs, as an etiologic agent.
Methodology	Molecular technique
Turnaround Time	14 Days
Interferences & Limitations	Collecting specimens during the first week of illness is ideal although the virus can be shed in the respiratory tract for up to 10 days.
Additional Information	None
CDC Points of Contact	Allan Nix (404) 639-1689 wbn0@cdc.gov Steve Oberste (404) 639-5497 mbo2@cdc.gov

January 9, 2019 Version: 1.0 Page 116 of 364

# **Test Order**Entomology Special Study CDC-10494

Synonym(s)	None
Pre-Approval Needed	Lawrence, Gena, (404) 718–4315, geg7@cdc.gov Sutcliffe, Alice, (404) 718–4326, gok0@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Animal
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Gena Lawrence (404) 718-4315 geg7@cdc.gov Alice Sutcliffe (404) 718-4326 gok0@cc.gov

January 9, 2019 Version: 1.0 Page 117 of 364

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

Synonym(s)	EBV
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Saliva, cerebrospinal fluid (CSF) or blood
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.
	Please ship to the attention of:
	Scott Schmid National VZV Laboratory
	404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.1 Page 118 of 364

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

CDC-10114

None
None
Prior approval is not required for human specimens. Please call for approval prior to sending other specimen types.
Provide any preliminary results available.
None
Human, Animal, and Food/Environmental/Medical Devices/Biologics
Isolates, Sequence Data
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.
Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.
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 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 Identification, Genetic Identification, Serotyping and Virulence Profiling, PCR for STEC and other pathotype-specific virulence genes
8 Weeks
Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors.
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.
outbreak activities or due to limited availability of resources.  Nancy Strockbine Haley Martin (404) 639-4186 (404) 639-1612

January 9, 2019 Version: 1.1 Page 119 of 364

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

CDC-10114

Devon Stripling (404) 639–2251 euo4@cdc.gov

January 9, 2019 Version: 1.1 Page 120 of 364

### Escherichia and Shigella Study

CDC-10115

Synonym(s)	None	
Pre-Approval Needed	Strockbine, Nancy, (404) 63 Stripling, Devon, (404) 639	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human, Animal, and Food/E	nvironmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	As directed by study protoco	ol
Minimum Volume Required	Not Applicable	
		otocol in compliance with Federal and local tive bacteria should be shipped as Category A
Transport Medium	Not Applicable	
Specimen Labeling	Test subject to CLIA regulat specimen container and the	ons and requires two patient identifiers on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements		onselective slant/stab such as TSA, HIA, etc.; screw rected by the study protocol.
Methodology		
Turnaround Time		
Interferences & Limitations	(bacteriophages, plasmids a	ification genes encoded by mobile genetic elements nd pathogenicity islands) may be spontaneously lost Conditions that induce a stress response in the bility of virulence factors.
Additional Information	None	
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Devon Stripling (404) 639-2251 euo4@cdc.gov	Haley Martin (404) 639–1612 hvw0@cdc.gov

January 9, 2019 Version: 1.1 Page 121 of 364

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

Synonym(s)	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Fields, Patricia, (404) 639–1748, pif1@cdc.gov
	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	Two patient identifiers on the specimen container and the test requisition are required
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 Patricia Fields (404) 639–1748 pif1@cdc.gov

January 9, 2019 Version: 1.3 Page 122 of 364

### 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	Two patient identifiers on the specimen container and the test requisition are required.
Shipping Instructions which Include Specimen Handling Requirements	Ship isolates or cultures Monday – Thursday, overnight to avoid weekend deliveries.
	Ship at ambient temperature in compliance with Federal and local guidelines. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances.
	There are no time constraints for submitting sequence data.
Methodology	Phenotypic Serotyping, Genetic Serotyping, Virulence Profiling, AST, PFGE, MLVA, WGS
Turnaround Time	8 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	Specify type of subtyping requested in 'Previous Laboratory Results' on back of form. Epidemiologic metadata, PulseNet cluster code, and PFGE pattern designation requested if available.
	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Nancy Strockbine Haley Martin (404) 639–4186 (404) 639–1612 nas6@cdc.gov hvw0@cdc.gov Devon Stripling (404) 639–2251 euo4@cdc.gov

January 9, 2019 Version: 1.3 Page 123 of 364

### Fascioliasis Serology

CDC-10505

Synonym(s)	Fascioliasis, <i>Fasciola hepatica</i> , liver fluke	
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 or plasma	
Minimum Volume Required	0.5 mL	
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.	
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.	
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 at room temperature or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.	
CDC Points of Contact	Isabel McAuliffe (404) 718-4100 ibm4@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov	

January 9, 2019 Version: 2.0 Page 124 of 364

### Filariasis Serology

#### CDC-10462

Synonym(s)	Brugia malayi, Wuchereria bancrofti, Bancroftian filariasis, 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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.1 Page 125 of 364

### Francisella tularensis Culture and Identification CDC-10313

Synonym(s)	Tularemia
Pre-Approval Needed	None
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address; patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human and Animal
	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
	Refrigerate specimens containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.
Transport Medium	Transport respiratory specimens, aspirates and tissues in a sterile container. Original blood tubes and blood culture bottles are acceptable. If swabs are utilized for transport, Cary-Blair is recommended
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:
·	Centers for Disease Control and Prevention
	Bacterial Diseases Branch Attn: John Young
	3156 Rampart Road
	Fort Collins, CO 80521
	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on ice packs
Methodology	Culture, Direct Fluorescent Antibody (DFA), Biochemical subtyping
Turnaround Time	3 Weeks
Interferences & Limitations	Samples for testing by culture should be taken prior to antibiotic treatment
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.3 Page 126 of 364

### Francisella tularensis Serology

CDC-10314

Synonym(s)	
Pre-Approval Needed	None
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	500 uL
	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
	Microagglutination
Turnaround Time	
	Hemolyzed samples interfere with test results
Additional Information	
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.3 Page 127 of 364

### Francisella tularensis Special Study

CDC-10315

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov Kingry, Luke, (970) 266–3567, vtx8@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.2 Page 128 of 364

# **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.	
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries.	
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	

January 9, 2019 Version: 1.1 Page 129 of 364

### 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.
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries.  Refrigerated specimen at 4°C should be shipped on cold packs. Frozen specime 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

January 9, 2019 Version: 1.1 Page 130 of 364

### 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 specimer 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	

January 9, 2019 Version: 1.3 Page 131 of 364

#### 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

January 9, 2019 Version: 1.1 Page 132 of 364

# **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
	Jan Vinje (404) 639–3721 ahx8@cdc.gov Leslie Barclay (404) 639–1159 gvm3@cdc.gov

January 9, 2019 Version: 1.1 Page 133 of 364

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

CDC-10174

Synonym(s)	GUD
Pre-Approval Needed	Kersh, Ellen, (404) 639–2728, egk6@cdc.gov Pettus, Kevin, (404) 639–4338, kbp9@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Ulcer swabs, FFPE tissues or frozen tissues, and aspirates from ulcer or buboes
Minimum Volume Required	Not Applicable
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 cyc1@cdc.gov Kevin Pettus (404) 639-4338 kbp9@cdc.gov

January 9, 2019 Version: 2.0 Page 134 of 364

## 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	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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 135 of 364

## 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 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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 136 of 364

# **Test Order**Gram Positive Bacillus ID CDC-10137

Synonym(s)	Gram Positive Rod Identification, GPB, GPR
Pre-Approval Needed	None
Supplemental Information Required	Please notify laboratory prior to shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
	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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday - Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 137 of 364

## Haemophilus ducreyi Molecular Detection Study CDC-10511

Synonym(s)	GUD
Pre-Approval Needed	Kersh, Ellen, (404) 639–2728, egk6@cdc.gov Pettus, Kevin, (404) 639–4338, kbp9@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Ulcer swabs, FFPE tissues or frozen tissues, and aspirates from ulcer or buboes
Minimum Volume Required	Not Applicable
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	Ellen Kersh (404) 639–2728 egk6@cdc.gov Kevin Pettus (404) 639–4338 kbp9@cdc.gov

January 9, 2019 Version: 2.0 Page 138 of 364

### 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 or "tests used" column 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. If submitting live cultures, slants should be incubated overnight at 37°C with 5% CO2 and then stored and shipped at ambient temperature.
Transport Medium	Preferred medium includes frozen stocks or chocolate agar slants. When shipping 10 or more specimens, please submit frozen stocks only.
Specimen Labeling	Tests subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries and enclose a shipping spreadsheet or submission form in all shipments. Frozen specimens and stocks should be shipped on dry ice. Whenever possible, email the shipping spreadsheet and tracking number in advance (especially for suspected outbreak specimens or isolates).
Methodology	Real-time PCR, slide agglutination
Turnaround Time	30 Days
Interferences & Limitations	Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Test order results provide or confirm serotype for potential outbreak specimens or isolates. Additional microbiological and/or molecular testing completed as needed. For research purposes only, molecular characterization of <i>H. influenzae</i> isolates will be completed by whole genome sequencing with prior approval from the Bacterial Meningitis Laboratory.
CDC Points of Contact	Melissa Whaley (404) 639-3920 (404) 639-1380 dbq3@cdc.gov Caelin Potts (404) 718-5532 lyi3@cdc.gov

January 9, 2019 Version: 1.6 Page 139 of 364

### Haemophilus influenzae Surveillance

CDC-10222

S (-)	TP Consisting as TP study.
• • •	Hi Surveillance, Hi study
Pre-Approval Needed	None
	If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or "tests used" column of submission form.
Supplemental Form	
Performed on Specimens From	Human
	Pure culture isolate or frozen stock. If no viable isolate is available and bacteria DNA is detected, submit frozen primary specimens.
Minimum Volume Required	N/A
	Primary specimens or stocks should be kept frozen. If submitting live cultures, slants should be incubated overnight at 37°C with 5% CO2 and then stored and shipped at ambient temperature.
Transport Medium	Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.
Specimen Labeling	Tests require at least one patient identifier on the specimen container and the test requisition. Label specimens with the state ID & accession number, and if applicable surveillance (ABCs or Enhanced Surveillance) ID.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday overnight to avoid weekend deliveries. Frozen specimens should be shipped on dry ice. Please include a shipping spreadsheet and email spreadsheet prior to shipment.
Methodology	Real-time PCR
Turnaround Time	
Interferences & Limitations	Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Additional microbiological and/or molecular testing completed as needed.
CDC Points of Contact	Melissa Whaley (404) 639-3920 dbq3@cdc.gov Caelin Potts (404) 718-5532 lyi3@cdc.gov

January 9, 2019 Version: 2.0 Page 140 of 364

### 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	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639–0270 zje8@cdc.gov Anne Whitney (404) 639–1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 141 of 364

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

Synonym(s)	Hanta, HPS, HFRS
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 142 of 364

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

Synonym(s)	Hanta, HPS, HFRS
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 143 of 364

### *Hantavirus* Serology

CDC-10321

Synonym(s)	Hanta, HPS, HFRS, Hantaan
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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	None
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.
CDC Points of Contact	John Klena (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 144 of 364

## Healthcare-associated Outbreak Identification and Typing CDC-10162

Synonym(s)	Healthcare Outbreak or Nosocomial Outbreak
• • • • • • • • • • • • • • • • • • • •	
	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) 639-4000.
	-If healthcare facility will be submitting samples directly to CDC they must receive prior approval from State Health Department. Provide State Health Department contact information.
	-For isolate submission, include the test method that was used to identify the specimen in the "Previous Laboratory Results/Comments" section.
	The identification methods used and the results reported are for investigations or research purposes. These test results may not be used for diagnosis, treatment, or for the assessment of a patient's health.
CDC Points of Contact	Heather Moulton-Meissner (404) 639–4864

January 9, 2019 Version: 1.3 Page 145 of 364

ftw2@cdc.gov Judith Noble-Wang

### Healthcare-associated Outbreak Identification and Typing CDC-10162

(404) 639–2321 cux2@cdc.gov

January 9, 2019 Version: 1.3 Page 146 of 364

## Healthcare-associated Outbreak Isolate Sequencing and Analysis

CDC-10518

Synonym(s)	Whole genome sequencing
Pre-Approval Needed	McAllister, Gillian, (404) 639–2283, kbi5@cdc.gov Laufer Halpin, Alison, (404) 639–1776, vif0@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Pure culture isolates
Minimum Volume Required	N/A
Storage & Preservation of Specimen Prior to Shipping	Keep specimen at a refrigerated temperature until ready for shipping
Transport Medium	Use an agar slant not an agar plate for isolates
Specimen Labeling	No patient identifiers. Please include specimen identifiers on Line List.
Shipping Instructions which Include Specimen Handling Requirements	Ship isolates at ambient temperature. Ship overnight, Monday through Thursda for delivery within 24 hours of collection.
Methodology	Whole genome sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	Isolates not maintained under specific selective pressure may lose mobile antibiotic resistance elements. The methods used and the results reported are for investigational or research purposes. These test results may not be used for diagnosis, treatment, or for the assessment of a patient's health.
Additional Information	Turnaround time for nontuberculosis mycobacteria may take up to 12 weeks
	Criteria for Submission  • Prior consultation with CDC/DHQP Prevention and Response Branch on epidemiological investigation. Contact info: haioutbreak@cdc.gov or 404-639-4000.  • If healthcare facility will be submitting samples directly to CDC, they must receive prior approval from State Health Department. Provide State Health Department contact information.  • For isolate submission, include the test method used to identify the specimen in the "Previous Laboratory Results/Comments" section.
CDC Points of Contact	Gillian McAllister (404) 639–2283 kbi5@cdc.gov Alison Laufer Halpin (404) 639–1776 vif0@cdc.gov

January 9, 2019 Version: 1.1 Page 147 of 364

### Healthcare-associated Outbreak Metagenomic Sequencing and Analysis

CDC-10519

Synonym(s)	Metagenomic sequencing (shotgun, amplicon-based)
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	N/A
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Primary clinical or Food/Environmental/Medical Device/Biologic specimens
Minimum Volume Required	N/A
Storage & Preservation of Specimen Prior to Shipping	Keep specimen at a refrigerated temperature until ready for shipping
Transport Medium	If sending stool specimens, an approved stool preservation collection tube should be used
Specimen Labeling	No patient identifiers. Please include specimen identifiers on Line List.
Shipping Instructions which Include Specimen Handling Requirements	Ship primary specimens on cold-packs. Ship overnight, Monday through Thursday, for delivery within 24 hours of collection
Methodology	Metagenomic sequencing (shotgun, amplicon-based)
Turnaround Time	12 Weeks
Interferences & Limitations	Holding samples at room temperature >1 hour after collection may impact sample microbial composition. The methods used and the results reported are for investigational or research purposes. These test results may not be used fo diagnosis, treatment, or for the assessment of a patient's health.
Additional Information	Criteria for Submission  • Prior consultation with CDC/DHQP Prevention and Response Branch on epidemiological investigation. Contact info: haioutbreak@cdc.gov or 404-639-4000.  • If healthcare facility will be submitting samples directly to CDC, they must receive prior approval from State Health Department. Provide State Health Department contact information.
CDC Points of Contact	_ ·

January 9, 2019 Version: 2.0 Page 148 of 364

## Helicobacter pylori Special Study CDC-10117

Synonym(s)	None
Pre-Approval Needed	Simons-Petrusa, Brenna, (907) 729-3452, imd4@cdc.gov Morris, Julie, (907) 729-3445, zbf2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Gastric biopsy or <i>H. pylori</i> bacterial isolate
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	Store at -70°C.
Transport Medium	Cysteine freeze media-provided by Arctic Investigations Program laboratory
Specimen Labeling	Patient name, date of birth, medical record number, area of stomach (e.g. antrum or fundus) and date of collection
Shipping Instructions which Include Specimen Handling Requirements	Ship on dry ice.
Methodology	culture and susceptibility testing for amoxicillin, tetracycline, and clarithromycir
Turnaround Time	7 Weeks
Interferences & Limitations	To be determined
Additional Information	Please provide shipping information to CDC Points of Contact prior to shipping specimens.
CDC Points of Contact	Brenna Simons-Petrusa (907) 729-3452 imd4@cdc.gov Julie Morris

(907) 729–3445 zbf2@cdc.gov

January 9, 2019 Version: 1.2 Page 149 of 364

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

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 150 of 364

# **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  Frozen specimen should be shipped on dry ice
Methodology	Total anti-HAV by Chemiluminescence, IgM anti-HAV by Chemiluminescence, IgM anti-HAV by Chemiluminescence, HAV RNA by Real Time qRT-PCR, HAV Genotyping
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	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 1.3 Page 151 of 364

# **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
Methodology	HBsAg by Chemiluminescence, IgM anti-HBc by Chemiluminescence, Total anti-HBc by Chemiluminescence, Anti-HBs by Chemiluminescence, HBeAg by ELISA, Anti-HBe by ELISA, HBV DNA by Real Time PCR, HBV Genotyping by PCR S Gene Sequencing
Turnaround Time	1 Week
Interferences & Limitations	Hemolyzed specimen are not accepted
Additional Information	NAT based assays and genotyping may take up to 3 weeks for turn around time
CDC Points of Contact	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 1.4 Page 152 of 364

### **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	1.0 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens should be stored frozen
Transport Medium	None
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specime container and the test requisition
Shipping Instructions which Include Specimen Handling	
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	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 1.4 Page 153 of 364

# **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
Requirements	Frozen specimen should be shipped on dry ice
Methodology	Anti-HCV by Chemiluminescence, HCV RNA by Real Time qRT-PCR, HCV Genotyping
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	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 1.4 Page 154 of 364

# **Test Order**Hepatitis D Serology, NAT and Genotyping CDC-10328

Synonym(s)	HDV, Hepatitis D virus
Pre-Approval Needed	None
Supplemental Information Required	See Supplemental Form
Supplemental Form	Please complete the CDC Specimen Submission (50.34) Form using the following link: <a href="https://www.cdc.gov/hepatitis/hdv/index.htm">https://www.cdc.gov/hepatitis/hdv/index.htm</a>
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	Provide two unique identifiers on the specimen container and the test requisition (original submitter and state PHL).
Shipping Instructions which Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
•	Frozen specimen should be shipped on dry ice
Methodology	Total anti-HDV by ELISA, HDV RNA by Real Time qRT-PCR, HDV Genotyping
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
	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should <b>NOT</b> be used for diagnosis, treatment, or assessment of patient health management.
CDC Points of Contact	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 2.0 Page 155 of 364

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

	HEV Handride Failure
• • • • • • • • • • • • • • • • • • • •	HEV, Hepatitis E virus
Pre-Approval Needed	None
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	Provide two unique identifiers on the specimen container and the test requisition (original submitter and state PHL).
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 ELISA, IgG anti-HEV by ELISA, HEV RNA by Real Time qRT-PCR, HEV Genotyping
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
	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should <b>NOT</b> be used for diagnosis, treatment, or assessment of patient health management.
CDC Points of Contact	Amanda Poe (404) 639-0723 DVHLabTesting@cdc.gov Jan Drobeniuc (404) 639-3790 DVHLabTesting@cdc.gov

January 9, 2019 Version: 2.0 Page 156 of 364

# 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

January 9, 2019 Version: 1.0 Page 157 of 364

## Herpes Simplex Virus 1/2 Detection CDC-10258

6 ()	
. , , , ,	Oral herpes, Genital herpes
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Skin lesion, cerebrospinal fluid (CSF) or saliva
Minimum Volume Required	200 uL (CSF, saliva)
Storage & Preservation of Specimen Prior to Shipping	Skin lesions should be kept dry and saliva can be kept either refrigerated or frozen.
Transport Medium	Not Applicable
Specimen Labeling	Requires two patient identifiers on the specimen container and the test requisition.
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
	Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 2.1 Page 158 of 364

## Herpes Simplex Virus 1/2 Serology CDC-10259

Synonym(s)	Oral herpes, Genital herpes
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum, plasma, or cerebrospinal fluid (CSF)
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen.
Transport Medium	Not Applicable
Specimen Labeling	Requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday-Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	IgG antibody detected by EIA
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health of management.
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 2.1 Page 159 of 364

# **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.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR) for VZV, Polymerase Chain Reaction (PCR) for HSV1, Polymerase Chain Reaction (PCR) for HSV2, Polymerase Chain Reaction (PCR) for EBV, Polymerase Chain Reaction (PCR) for HHV6
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.2 Page 160 of 364

# **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

January 9, 2019 Version: 1.0 Page 161 of 364

# **Test Order**HIV antigen/antibody Combo CDC-10485

C c (-)	Mana
Synonym(s)	
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
•	For best results, specimens should be shipped frozen on dry ice for overnight delivery to the HIV reference laboratory.
Methodology	EIA
Turnaround Time	21 Days
Interferences & Limitations	Do not heat inactivate specimens
Additional Information	None
CDC Points of Contact	Timothy Granade (404) 639-3850 txg1@cdc.gov Bill Switzer (404) 639-0219 bis3@cdc.gov

January 9, 2019 Version: 1.2 Page 162 of 364

### HIV Molecular Surveillance Study (International Only)

CDC-10332

Synonym(s)	HIV subtypes, HIV molecular epidemiology, HIV outbreak
Pre-Approval Needed	Ramos, Arthur, (404) 718–4518, cer9@cdc.gov DeVos, Joshua, (404) 639–5442, ext8@cdc.gov
	Specimens must be accompanied with completed International Laboratory Drug Resistance and Molecular Surveillance Test Requisition Form. Contact CDC Points of Contact for this test order to obtain requisition and approval for testing as well as CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form
Supplemental Form	None
Performed on Specimens From	Human
	Plasma separated from whole blood in the presence of EDTA as anticoagulant, or dried blood spots (DBS) collected from finger/heel prick or venous blood collected on a 903 sample collection card or similar.
Minimum Volume Required	0.5 mL of plasma or at least four (preferably five) DBS of 100 $\mu$ L in each of the 13mm printed circles on blood collection cards
	Freeze plasma and DBS samples as soon as possible at $-80^{\circ}$ C before shipment, 6 month maximum. If a $-80^{\circ}$ C freezer is not available, store samples at $-20^{\circ}$ C before shipment, 1 month maximum. Higher temperatures and longer lengths of time in storage may compromise sample quality and invalidate test results.
	Aliquot plasma samples in 1.5 – 2.0 mL polypropylene tube with screw cap and O-ring.
	Five to 10 DBS cards must be separated or wrapped individually by glassine paper and placed in a laboratory–grade, gas–impermeable ziplock bags, containing five desiccant packs and one humidity indicator. Humidity indicators must visible inside the ziplock bags without opening it. Gently apply pressure to the partially sealed bag to expel the air before sealing it completely. Stabilize ziplock bags to ambient temperature before opening, in case desiccant packs and humidity indicators need to be replaced, to avoid exposure of samples to humidity. Avoid freeze/thaw cycles as much as possible.
	Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.
Transport Medium	Plasma samples and DBS samples must be transported in the 1.5 – 2.0 mL polypropylene tubes with screw cap and O-ring used for preparing aliquots.
	DBS cards must be transported in the properly packaged zip-lock bags.
Specimen Labeling	All primary specimen containers must include two unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form. Surveillance studies and some study protocols require de-linked patient information, which should not accompany samples, or provided to CDC.
Shipping Instructions which Include Specimen Handling Requirements	Transport plasma specimens in frozen conditions using dry ice or liquid nitrogen.  DRS can be transported at ambient temperature (20°, 20°C) for chipments that are
	DBS can be transported at ambient temperature $(20^{\circ}-30^{\circ}C)$ for shipments that are in transit for up to 7 days. Avoid direct exposure to sunlight and use the most

January 9, 2019 Version: 1.2 Page 163 of 364

## **Test Order**HIV Molecular Surveillance Study (International Only)

CDC-10332

	direct shipping route to expedite delivery. For shipments that are in transit more than 7 days, maintain specimens at -20°C or colder with dry ice.
9.	Identification of HIV-1 group M subtypes, determination of transmission clusters of genetically related viruses, phylogenetic analyses of circulating strains from suspected cases, Phylogenetic analysis might be performed in gag, pol, or env HIV-1 gene seq
Turnaround Time	16 Weeks
Interferences & Limitations	To be determined
Additional Information	Do not use heparin as an anticoagulant. Plasma should not be used after more than two freeze-thaw cycles. Plasma and DBS samples will be rejected if improperly labeled or unlabeled, with discrepant documentation, insufficient volume, without documentation, and evidence of leakage or contamination.
CDC Points of Contact	Artur Ramos (404) 718-4518 cer9@cdc.gov Joshua DeVos (404) 639-5442 ext8@cdc.gov

January 9, 2019 Version: 1.2 Page 164 of 364

# Test Order HIV Serology NHANES CDC-10279

HIV ELISA, HIV antibody
None
None
None
Human
Serum and/or plasma. The following anticoagulants are acceptable: EDTA, sodium citrate, CPD, CPDA-1, and ACD. SST and PPT are also acceptable.
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.
Not Applicable
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
Frozen specimen should be shipped on dry ice
Refrigerated specimen should be shipped on cold packs
Enzyme-linked Immunosorbent Assay (ELISA), Western Blot, Rapid Test
21 Days
None
None
Tim Granade
(404) 639–3850
txg1@cdc.gov
Bill Switzer (404) 639–0219
(404) 039-0219

January 9, 2019 Version: 2.1 Page 165 of 364

# **Test Order**HIV Serology Study (International Only) CDC-10333

Synonym(s)	None
Pre-Approval Needed	Parekh, Bharat, (404) 639–3647, bsp1@cdc.gov Kalou, Mireille, (404) 639–2794, chn7@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.  Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Bharat Parekh (404) 639-3647 bsp1@cdc.gov Mireille Kalou (404) 639-2794 chn7@cdc.gov

January 9, 2019 Version: 1.1 Page 166 of 364

#### **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

January 9, 2019 Version: 1.1 Page 167 of 364

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

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	HIV drug resistance (DR), HIV susceptibility to antiretroviral drugs
	Ramos, Artur, (404) 718–4518, cer9@cdc.gov DeVos, Joshua, (404) 639–5442, ext8@cdc.gov
	Specimens must be accompanied with completed International Laboratory Drug Resistance and Molecular Surveillance Test Requisition Form. Contact POCs listed below to obtain requisition and approval for testing as well as CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form
Supplemental Form	None
Performed on Specimens From	Human
	Plasma separated from whole blood in the presence of EDTA as anticoagulant, or dried blood spots (DBS) collected from finger/heel prick or venous blood collected on a 903 sample collection card or similar.
Minimum Volume Required	0.5 mL of plasma, or at least four (preferably five) DBS of 100 $\mu$ L in each of the 13mm printed circles on blood collection cards
	Freeze plasma and DBS samples as soon as possible at $-80^{\circ}$ C (may be stored for a maximum of 6 months). In the event a $-80^{\circ}$ C freezer is not available, samples may be stored at $-20^{\circ}$ C for a maximum of one month prior to shipment. Higher temperatures and longer lengths of time in storage can damage sample quality and invalidate test results.
	Aliquot plasma samples in 1.5 – 2.0 mL polypropylene tube with screw cap and O-ring.
	Five to 10 DBS cards must be separated or wrapped individually by glassine paper and placed in a laboratory-grade, gas-impermeable zip-lock bags, containing five desiccant packs and one humidity indicator. Humidity indicators must visible inside the zip-lock bags without opening it. Gently apply pressure to the partially sealed bag to expel the air before sealing it completely. Stabilize zip-lock bags to ambient temperature before opening, in case desiccant packs and humidity indicators need to be replaced, to avoid exposure of samples to humidity. Avoid freeze/thaw cycles as much as possible.
	Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.
Transport Medium	Plasma samples and DBS samples must be transported in the 1.5 - 2.0 mL polypropylene tubes with screw cap and O-ring used for preparing aliquots.
Specimen Labeling	All primary specimen containers must include two unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form. Surveillance studies and some study protocols require de-linked patient information, which should not accompany samples, or provided to CDC.
Shipping Instructions which Include Specimen Handling Requirements	Transport plasma specimens in frozen conditions using dry ice or liquid nitrogen.
	DBS can be transported at ambient temperature $(20^{\circ}-30^{\circ}C)$ for shipments that are in transit for up to 7 days. Avoid direct exposure to sun light and use the most direct shipping route to expedite delivery. For shipments that are in transit more than 7 days, maintain specimens at $-20^{\circ}C$ or colder with dry ice.

January 9, 2019 Version: 1.2 Page 168 of 364

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

Methodology	Identification of mutations within HIV-1 pol gene region by RNA extraction, PCR amplification, DNA sequencing, and drug resistance analysis
Turnaround Time	16 Weeks
Interferences & Limitations	Do not use heparin as an anticoagulant. Plasma should not be used after more than two freeze-thaw cycles. Plasma and DBS samples will be rejected if improperly labeled or unlabeled, with discrepant documentation, insufficient volume, without documentation, and evidence of leakage or contamination.
	Additionally, DBS samples will be rejected if packaged without humidity indicators and desiccants, demonstrating any indication of humidity in the ziplock bags, containing blood clots or clumps, with a halo around the blood spot indicating hemolysis, if spots are congruent or show evidence of commingling, and collected onto inappropriate filter paper.
Additional Information	The genotyping assay may not detect minor viral species infecting a patient that constitute less than 20% of virus mixtures. Consultation with an expert in HIV drug resistance is encouraged to facilitate interpretation of susceptibility or resistance to antiretroviral drugs and to evaluate antiretroviral treatment options
CDC Points of Contact	Artur Ramos (404) 718-4518 cer9@cdc.gov Joshua DeVos (404) 639-5442 ext8@cdc.gov

January 9, 2019 Version: 1.2 Page 169 of 364

### 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. Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Plasma can be collected using plasma preparation tubes (PPT) or EDTA or ACD. Serum can be collected in serum tubes. Follow sample tube manufacturer's instructions. Whole blood should not be frozen, but can be kept at 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.
Minimum Volume Required	1 ml plasma or serum; 10 ml whole blood
	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 $\leq 25^{\circ}\text{C}$ ; 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 and serum specimens may be stored at $\leq -20^{\circ}\text{C}$ for up to 6 months; however, storage at these temperatures for longer periods has not been fully evaluated. Do not freeze whole blood.
Transport Medium	Not Applicable
Specimen Labeling	Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday –Thursday overnight to avoid weekend deliveries.  Ship unprocessed whole blood specimens overnight at ambient temperature. If serum or plasma is collected, these specimen should be shipped frozen overnight on dry ice.
Methodology	Nucleic acid amplification
Turnaround Time	21 Days
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification
Additional Information	For RNA testing, separate the plasma or serum by centrifugation and transfer serum or plasma to a polypropylene screw-cap tube for shipment. Freeze (-70°C is optimal, -20°C acceptable) sera/plasma as soon as possible after separation (min volume of 1mL of plasma/sera is required, 5 mLs is optimal). For DNA testing, do not process or freeze the whole blood specimen. Ship the whole blood tubes overnight at ambient temperature to CDC Monday -Thursday to avoid weekend deliveries.
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Tim Granade (404) 639-3850 txg1@cdc.gov

January 9, 2019 Version: 2.2 Page 170 of 364

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

Synonym(s)	HIV, EID, PMTCT, Early infant diagnostic, DNA
Pre-Approval Needed	Zeh, Clement, (404) 553-7264, cbz2@cdc.gov Hurlston, Mackenzie, (404) 639-1281, wpd9@cdc.gov
	Supplemental forms will be provided upon consultation: -Fill out the ILB-160-F08E Viral Load-EID Requisition Form CDC Form 0.753: -Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this formInternational Laboratory Branch Test Directory with shipping instructions sent upon request.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Dried Blood Spots (DBS)
Minimum Volume Required	At least 3 saturated 13mm circles (preferably 5) containing $70\mu L$ of whole blood including capillary blood obtained by finger/toe/heel stick which is dropped directly onto the DBS card.
Storage & Preservation of Specimen Prior to Shipping	The appropriate anticoagulant for DBS whole blood collection is EDTA.
	Dried blood spots should be kept at an ambient temperature ( $15^{\circ}-35^{\circ}$ C) for storage and shipment if testing is performed within 14 days or frozen at $-70^{\circ}$ C it testing is not performed within 14 days.
Transport Medium	Please email the contacts listed above for this test in order to receive a job aid with specific packing guidance. Specimens should be transported in a gas impermeable plastic bag with desiccant and humidity indicator card.
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.
	Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.
Shipping Instructions which Include Specimen Handling Requirements	Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact laboratory prior to submission.
	For shipments that are in transit for up to 14 days, maintain at ambient temperature ( $15^{\circ}-35^{\circ}$ C) and shipments that are in transit for greater than 14 days, maintain temperature at $-20^{\circ}$ C or colder with dry ice.
	Qualitative PCR
Turnaround Time	28 Days
Interferences & Limitations	Do not use heparin as an anticoagulant. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot

January 9, 2019 Version: 1.6 Page 171 of 364

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

indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.

Additional Information Turnaround time for batches with less than 100 specimens is within 28 days. The turnaround times listed are reflective of specimens sent for retesting or study purposes. Contact Clement Zeh, cbz2@cdc.gov for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing.

> A test result of "HIV-1 Not Detected" or "Target not detected", does not necessarily rule out the presence of HIV-1 DNA or RNA. Nucleic acid (HIV-1 DNA/RNA) concentrations may be below the limit of detection of the assays. presence of PCR inhibitors in the patient specimen or improper specimen handling can lead to false negative results. HIV-1 may not be detected immediately after exposure. The diagnosis of HIV-1 infection is based on clinical presentation and results from additional diagnostic tests such as DNA PCR. Diagnosis should not be based solely on a single HIV-1 test. False positive test results may be caused by PCR contamination.

> NOTE: If a specific testing platform is required, please contact Clement Zeh (cbz2 @cdc.gov).

#### CDC Points of Contact Clement Zeh

(404)553-7264cbz2@cdc.gov Mackenzie Hurlston (404) 639-1281 wpd9@cdc.gov

Version: 1.6 Page 172 of 364 January 9, 2019

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

Synonym(s)	HIV, VL, RNA
Pre-Approval Needed	Zeh, Clement, (404) 553–7264, cbz2@cdc.gov Hurlston, Mackenzie, (404) 639–1281, wpd9@cdc.gov
	Supplemental forms will be provided upon consultation: -Fill out the ILB-160-F08E Viral Load-EID Requisition Form CDC Form 0.753: -Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this formInternational Laboratory Branch Test Directory with shipping instructions sent upon request.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Plasma or dried blood spots (DBS)
Minimum Volume Required	Plasma: 1.1mL plasma (3mL ideally)
	DBS: At least 3 saturated 13mm circles (preferably 5) containing 70µL of whole blood including capillary blood obtained by venipuncture or finger/toe/heel stick which is dropped directly onto the DBS card
Storage & Preservation of Specimen Prior to Shipping	The appropriate anticoagulant for whole blood collection is EDTA.
	Fresh whole blood may be held at 15-30°C for up to 6 hours or at 2-8°C for up to 24 hours. After centrifugation, plasma may be stored at 15-30°C for up to 24 hours and at 2-8°C for up to 5 days. Plasma may be frozen at -70°C or colder. Freeze-thaw cycles should be avoided and should not exceed 3 cycles.
	Dried blood spots should be kept at an ambient temperature $(15^{\circ}-35^{\circ}C)$ for storage and shipment if testing is performed within 14 days or frozen at -70°C if testing is not performed within 14 days.
Transport Medium	Plasma: Transport specimen in a sterile 1.5–2.0 mL polypropylene tube, screw cap with O-ring.
	DBS: Please email the contacts listed above for this test in order to receive a job aid with specific packing guidance. Specimens should be transported in a gas impermeable plastic bag with desiccant and humidity indicator card.
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.
	Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.
Shipping Instructions which Include Specimen Handling Requirements	Plasma: Refer to Plasma Shipment information on page 4 of International Laboratory Branch Test Directory or contact laboratory prior to submission. To maintain temperature of -20°C or colder, plasma should be shipped on dry ice.

January 9, 2019 Version: 1.5 Page 173 of 364

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

DBS: Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact laboratory prior to submission.

For shipments that are in transit for up to 14 days, maintain at ambient temperature (15°-35°C) and shipments that are in transit for greater than 14 days, maintain temperature at -20°C or colder with dry ice.

#### Methodology Quantitative PCR

#### Turnaround Time 28 Days

Interferences & Limitations Do not use heparin as an anticoagulant. Do not use specimens after more than 5 freeze-thaw cycles for the Roche assays and 3 freeze-thaw cycles for the Abbott m2000 assay. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.

Additional Information Turnaround time for batches with less than 100 specimens is within 28 days. The turnaround times listed are reflective of specimens sent for retesting or study purposes. Contact Clement Zeh, cbz2@cdc.gov for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing.

> An interpretation of "Target Not Detected", "HIV-1 RNA Not Detected", and "Not Detected" does not rule out the presence of PCR inhibitors or HIV-1 RNA concentrations below the level of detection of the assay. Care should be taken in the interpretation of any single viral load determination. The clinical significance of changes in HIV-1 RNA measurements has not been fully established; however, a change of 0.5 log copies/mL may be significant.

The linear range of each assay is as follows:

Plasma:

COBAS® AmpliPrep/COBAS® Tagman® HIV-1 v2.0 is 20-10,000,000 copies/mL  $(1.30-7.00\log)$ 

Abbott Real Time HIV-1 assay is 40-10,000,000 copies/mL(1.60-7.00log)

#### DBS:

COBAS® AmpliPrep/COBAS® Tagman® Free Virus Elution Protocol is 701-10,000,000 copies/mL (2.85-7.00log)

Abbott Real Time HIV-1 assay is 839-10,000,000 copies/mL (2.92-7.00log)

NOTE: If a specific testing platform is required, please contact Clement Zeh (cbz2 @cdc.gov).

#### CDC Points of Contact Clement Zeh

(404) 553-7264 cbz2@cdc.gov Mackenzie Hurlston (404)639-1281wpd9@cdc.gov

Version: 1.5 Page 174 of 364 January 9, 2019

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

Synonym(s)	HIV, EIA, WB, ELISA
	Parekh, Bharat, (404) 639–3647, bsp1@cdc.gov Kalou, Mireille, (404) 639–2794, chn7@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. 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.
Shipping Instructions which Include Specimen Handling Requirements	For shipments that are in transit for up to 7 days, maintain temperature at 2-8 For shipments that are in transit for greater than 7 days, maintain temperature at -20°C or colder with dry ice.

For shipments that are in transit for up to 14 days, maintain at ambient

January 9, 2019 Version: 1.1 Page 175 of 364

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

	temperature (20-30°C). For shipments that are in transit for greater than 14 days, maintain temperature at $-20$ °C or colder with dry ice.
Methodology	Enzyme Immunoassay, Enzyme-linked Immunosorbent Blot Technique (Western Blot)
Turnaround Time	90 Days
Interferences & Limitations	Do not use plasma and serum after more than 5 freeze-thaw cycles. Plasma or serum will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
	Dried blood spots will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot indicating contamination, if specimer 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	Bharat Parekh (404) 639-3647 bsp1@cdc.gov Mireille Kalou (404) 639-2794 chn7@cdc.gov

January 9, 2019 Version: 1.1 Page 176 of 364

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

Synonym(s)	HIV, RT
	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°-35°C if testing will be performed within 48 hours of collection. If testing is to be performed within 7 days keep specimen refrigerated at 2°-8°C. If testing is to be performed after 7 days, keep specimen frozen at -20°C or colder.
Transport Medium	Specimen should be transported in a plastic screw-cap vial
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.
	Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.
Include Specimen Handling	For shipments that are in transit for up to 7 days, maintain temperature at $2-8^\circ$ and for shipments that are in transit for greater than 7 days, maintain temperature at $-20^\circ$ C or colder with dry ice.
Methodology	Immuno-concentration
Turnaround Time	90 Days
Interferences & Limitations	Do not use specimens after more than 5 freeze-thaw cycles. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	Turn around times are dependent on batch specimen:
	Batch with less than 200 specimens - within 50 days Batch with 200-600 - within 70 days Batch with greater than 600 specimens - within 90 days
CDC Points of Contact	Bharat Parekh (404) 639-3647 bsp1@cdc.gov Mireille Kalou

January 9, 2019 Version: 1.1 Page 177 of 364

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

(404) 639–2794 chn7@cdc.gov

January 9, 2019 Version: 1.1 Page 178 of 364

### 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

January 9, 2019 Version: 2.1 Page 179 of 364

### 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
	Whole blood. Specimen should be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Whole blood should not be frozen, but can be kept at 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.
Minimum Volume Required	20 mL
	Whole blood should not be frozen, but can be kept at 4°C or room temperature for short periods (24 hrs. or 6 hrs., respectively) prior to shipping the same day of collection.
Transport Medium	Not Applicable
Specimen Labeling	Specimens and accompanying submission forms require 2 unique patient identifiers. Identifiers that protect the identity of the individual are preferred
Include Specimen Handling	Ship specimen Monday –Thursday overnight to avoid weekend deliveries.  Ship unprocessed whole blood specimens overnight at ambient temperature. If serum or plasma is collected, these specimen should be shipped frozen overnight on dry ice.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	21 Days
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with PCR amplification.
Additional Information	Do not process or freeze the whole blood specimen. Ship the whole blood tubes overnight at ambient temperature to CDC Monday –Thursday to avoid weekend deliveries.
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Tim Granade (404) 639-3850 txg1@cdc.gov

January 9, 2019 Version: 1.3 Page 180 of 364

#### **Test Order** HIV-2 Serology CDC-10273

Synonym(s)	HIV ELISA, HIV antibody
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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
Requirements	Refrigerated specimen should be shipped on cold packs
Methodology	HIV-1/2 Differentiation Assay, HIV-2 Western Blot
Turnaround Time	21 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Tim Granade (404) 639-3850 txg1@cdc.gov
	Bill Switzer
	(404) 639–0219 bis3@cdc.gov
	biso@cuc.gov

January 9, 2019 Version: 2.2 Page 181 of 364

# Test Order HPV Special Study CDC-10131

Synonym(s)	None		
Pre-Approval Needed	Unger, Elizabeth, (404) 639- Panicker, Gitika, (404) 639-2		
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 (P	CR), 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	

January 9, 2019 Version: 1.1 Page 182 of 364

## **Test Order**Human Herpes Virus 6 (HHV6) Detection and Subtyping CDC-10266

Synonym(s)	HHV6
Pre-Approval Needed	
Supplemental Information Required	
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Saliva, cerebrospinal fluid (CSF) or blood
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.
Transport Medium	None
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.
-4-	Please ship to the attention of:
	Scott Schmid National VZV Laboratory
	404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.2 Page 183 of 364

### 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	Requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	If stored at 4 degrees C can be overnighted on cold packs in well-sealed O-ring vials; if frozen can be overnighted on dry ice in well-sealed O-ring vials  Please ship to the attention of:
	Scott Schmid National VZV Laboratory 404–639–0066
Methodology	ELISA
Turnaround Time	7 Days
Interferences & Limitations	False positive results may be obtained if samples are excessively lipemic or contaminated by bacteria. False negative results may be obtained if samples 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 test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should <b>NOT</b> be used for diagnosis, treatment, or assessment of patient health of management.
CDC Points of Contact	Scott Schmid (404) 639–0066 SSchmid@cdc.gov Jennifer Folster (404) 639–3668 JFolster@cdc.gov

January 9, 2019 Version: 1.1 Page 184 of 364

## **Test Order**Human Herpes Virus 7 (HHV7) Detection CDC-10267

Synonym(s)	HHV7
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Saliva, cerebrospinal fluid (CSF) or blood
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.
	Please ship to the attention of:
	Scott Schmid National VZV Laboratory
	404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.1 Page 185 of 364

## **Test Order**Human Herpes Virus 8 (HHV8) Detection CDC-10268

Synonym(s)	Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8
• • • • • • • • • • • • • • • • • • • •	Dollard, Sheila, (404) 639–2178, sgd5@cdc.gov
The Approval Recaca	Schmid, Scott, (404) 639–0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Blood or saliva
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen. Blood should be collected in EDTA or citrate tubes.
Transport Medium	Not Applicable
Specimen Labeling	Provide a specimen ID. Do not send specimen labeled with patient's name.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health of management.
CDC Points of Contact	Sheila Dollard (404) 639–2178 sgd5@cdc.gov Scott Schmid (404) 639–0066 dss1@cdc.gov

January 9, 2019 Version: 1.1 Page 186 of 364

### Human Herpes Virus 8 (HHV8) Serology CDC-10269

Synonym(s)	Kaposi's sarcoma-associated herpesvirus, KSHV, HHV8
Pre-Approval Needed	Dollard, Sheila, (404) 639–2178, sgd5@cdc.gov Schmid, Scott, (404) 639–0066, dss1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum or plasma
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Keep specimen either refrigerated or frozen.
Transport Medium	Not Applicable
Specimen Labeling	Provide a specimen ID. Do not send specimen labeled with patient's name.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	IgG antibody detected by IFA
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health management.
CDC Points of Contact	Sheila Dollard (404) 639–2178 sgd5@cdc.gov Scott Schmid (404) 639–0066 dss1@cdc.gov

January 9, 2019 Version: 1.3 Page 187 of 364

## **Test Order**Influenza Antiviral Resistance Diagnosis CDC-10423

Synonym(s)	Flu, Influenza Drug resistance, Neuraminidase inhibitor, Influenza Resistance testing	
Pre-Approval Needed	None	
	Requires additional WHO submission form that can be obtained with your password	
Supplemental Form	https://www.aphl.org/programs/infectious_disease/influenza/Documents/Iruenza-Specimen-Submission-Form.zip	
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 LGubareva@cdc.gov David Wentworth (404) 639–3387	

January 9, 2019 Version: 1.7 Page 188 of 364

### **Test Order**Influenza Antiviral Resistance Diagnosis CDC-10423

DWentworth@cdc.gov

January 9, 2019 Version: 1.7 Page 189 of 364

## **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	https://www.aphl.org/programs/infectious_disease/influenza/Documents/Influenza-Specimen-Submission-Form.zip	
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.	
	Clinical specimens should be placed at 4°C and transported to the laboratory promptly. Specimens received cold that are to be shipped within 48 hours should be stored refrigerated (2°-8°C); otherwise specimens should be frozen at or below -70°C until shipped.	
Transport Medium	Swabs must be in viral transport medium	
Specimen Labeling	Specimen ID must match the ID on the form	
	Ship Monday-Thursday, overnight to avoid weekend deliveries. Urgent specimen can be shipped any time with prior approval from the laboratory. Prior to shipping, notify CDC Influenza Division that you are sending specimen. Refer to the International Air Transport Association (IATA – <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	7 Days	
Interferences & Limitations	Low virus numbers or co-infections can affect test results. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended because it can cause a false-negative result.	
Additional Information	Specimens requiring additional testing and specimens submitted for surveillance studies will take longer than seven days for results.	
CDC Points of Contact	LaShondra Berman (404) 639–1686 zhj5@cdc.gov John Barnes (404) 639–2434 fzq9@cdc.gov	

January 9, 2019 Version: 1.7 Page 190 of 364

#### **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
	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.
•	Ship Monday-Thursday, overnight to avoid weekend deliveries Frozen specimen should be shipped on dry ice
Markandalan	Obtain approval prior to shipping
Turnaround Time	Hemagglutination inhibition assay, Microneutralization assay
Interferences & Limitations	Whole blood cannot be used for testing. Lipemic or hemolyzed sera will affect test results.
Additional Information	None
CDC Points of Contact	Min Levine (404) 639-3504 mwl2@cdc.gov Jackie Katz (404) 639-4966 jmk9@cdc.gov

January 9, 2019 Version: 1.3 Page 191 of 364

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

Synonym(s)	None	
Pre-Approval Needed	Wentworth, David, (404) 639–3387, gll9@cdc.gov Dugan, Vivien, (404) 718–5399, lny1@cdc.gov	
	Requires additional WHO submission form that can be obtained with your password	
Supplemental Form	https://www.aphl.org/programs/infectious_disease/influenza/Documents/Infuenza-Specimen-Submission-Form.zip	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	To be determined	
Minimum Volume Required	To be determined	
Storage & Preservation of Specimen Prior to Shipping	To be determined	
Transport Medium	To be determined	
Specimen Labeling	To be determined	
Shipping Instructions which Include Specimen Handling Requirements	To be determined	
Methodology		
Turnaround Time		
Interferences & Limitations	To be determined	
Additional Information	To be determined	
CDC Points of Contact	David Wentworth         Larisa Gubareva           (404) 639-3387         (404) 639-3204           gll9@cdc.gov         lqg3@cdc.gov           Xu Xiyan         Vivien Dugan           (404) 639-1657         (404) 718-5399           xxx1@cdc.gov         lny1@cdc.gov	

January 9, 2019 Version: 1.3 Page 192 of 364

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

Symonym(s)	Flu, Influenza Antigen Characterization	
• • • • • • • • • • • • • • • • • • • •		
	Requires additional WHO submission form that can be obtained with your password	
Supplemental Form	https://www.aphl.org/programs/infectious_disease/influenza/Documents/Influenza-Specimen-Submission-Form.zip	
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	
Include Specimen Handling	Ship Monday-Thursday, overnight to avoid weekend deliveries. Urgent specimen can be shipped at any time with prior approval from the laboratory. Refer to the International Air Transport Association (IATA – <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	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.	
Additional Information	Turn around time may take up to a month if the virus needs to be cultured. Turn around time for isolates may be less than 1 month.	
CDC Points of Contact	Xiyan Xu (404) 639-1657 xxx1@cdc.gov Wendy Sessions (404) 639-3211 gra6@cdc.gov	

January 9, 2019 Version: 1.3 Page 193 of 364

## **Test Order**Junin Serology CDC-10340

Synonym(s)	Argentine Hemorrhagic Fever, AHF, arenavirus	
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Blood and serum	
Minimum Volume Required	1 mL	
	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 spec 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 shoul 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	e 10 Days	
Interferences & Limitations	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 194 of 364

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

C. (m. o. m. (m. (a)	KED	
Synonym(s)		
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing		
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 speci 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	odology ELISA	
Turnaround Time	10 Days	
Interferences & Limitations	ons 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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 195 of 364

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

Synonym(s)	HPS. hanta	
• • • • • •	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing		
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 speci 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	on Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.	
CDC Points of Contact	John Klena (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 196 of 364

## Test Order Lassa Fever Identification CDC-10343

6 (-)	A series and desires	
Synonym(s)		
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, and serum	
Minimum Volume Required	1 mL	
	f Specimen must be placed in plastic screw capped vials, frozen to -70°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	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 197 of 364

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

Synonym(s)	Arenavirus	
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov	
Supplemental Information Required	See Supplemental Form	
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing	Blood and serum	
Minimum Volume Required	1 mL	
9	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 should be shipped on cold packs or dry ice if frozen. See supplemental submission forms for further details. Do not ship specimen without prior consultation and approval.	
Methodology	ELISA	
Turnaround Time	10 Days	
Interferences & Limitations	Specimen must remain frozen; warming or freeze thawing reduces sensitivity	
Additional Information	Critical specimens will take less than 4 days to turn around. See link to supplemental submission forms for detailed information.	
CDC Points of Contact	John Klena (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov	

January 9, 2019 Version: 1.3 Page 198 of 364

### Legionella Special Study

CDC-10161

Synonym(s)	None		
Pre-Approval Needed	, legionellalab@cdc.gov, , Raphael, Brian, (404) 639–4292, elx9@cdc.gov		
Supplemental Information Required	None		
Supplemental Form	None		
Performed on Specimens From	Human and Food/Environmental/Medical	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 federal holiday. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf		
Methodology			
Turnaround Time			
Interferences & Limitations	To be determined		
Additional Information	To be determined		
CDC Points of Contact	legionellalab@cdc.gov (Primary Contact)	Jonas Winchell (Emergency) (404)639–4921 jwinchell@cdc.gov	
	Brian Raphael (Emergency) (404) 639–4292 elx9@cdc.gov		

January 9, 2019 Version: 2.0 Page 199 of 364

## **Test Order** *Legionella* species Detection and Identification CDC-10159

Synonym(s)	Legionnaires' disease or LD, Legionellosis,	Pontiac fever	
Pre-Approval Needed	None		
Supplemental Information Required	None		
Supplemental Form	None		
Performed on Specimens From	Human and Food/Environmental/Medical D	Devices / Biologics	
	Human Origin: Isolates or primary specimens for culture. Acceptable clinical specimens are sputum, bronchoalveolar lavage (BAL), lung tissue, endotracheal tube (ETT), tracheal aspirate, and urine Environmental Origin: Isolates only		
Minimum Volume Required	Contingent on specimen type. Please see attached shipping instructions for details. <a href="http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf">http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf</a>		
	Clinical specimens should be frozen immediately. Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast (BCYE)] and shipped at 4°C. Please see attached shipping instructions for details. <a href="http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf">http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf</a>		
Transport Medium	BCYE or equivalent slants for isolates		
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.		
Shipping Instructions which Include Specimen Handling Requirements	Do not ship on Fridays or the day before a federal holiday. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf		
Methodology	Culture, Serogrouping, Sequencing, Real Ti	Culture, Serogrouping, Sequencing, Real Time PCR	
Turnaround Time	4 Weeks		
Interferences & Limitations	Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.		
Additional Information	If only PCR is needed then turn around time will be shorter than 4 weeks.		
CDC Points of Contact	legionellalab@cdc.gov (Primary Contact)	Jonas Winchell (Emergency) (404)639–4921 jwinchell@cdc.gov	
	Brian Raphael (Emergency) (404) 639–4292 elx9@cdc.govv		

January 9, 2019 Version: 2.0 Page 200 of 364

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

Synonym(s)	LD, Legionnaires' disease, Legionellosis, Pontia	c fever
Pre-Approval Needed	None	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human and Food/Environmental/Medical Devic	es/Biologics
	Human Origin: Isolates, purified nucleic acid, or primary specimens. Acceptable clinical specimens are sputum, bronchoalveolar lavage (BAL), lung tissue, endotracheal tube (ETT), and tracheal aspirate. Environmental Origin: Isolates only	
Minimum Volume Required	Contingent on specimen type. Please see attached shipping instructions for details. <a href="http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf">http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf</a>	
	Clinical specimens should be frozen immediately. Isolates should be prepared on appropriate slants [Buffered Charcoal Yeast (BCYE)] and shipped at 4°C. Please see attached shipping instructions for details. http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf	
Transport Medium	BCYE or equivalent slants for isolates	
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.	
Include Specimen Handling	Do not ship on Fridays or the day before a federal holiday. Please see attached shipping instructions for details.  http://www.cdc.gov/legionella/downloads/shipping-instructions.pdf	
Methodology	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	(404	as Winchell (Emergency) 4)639–4921 achell@cdc.gov
	Brian Raphael (Emergency) (404) 639-4292 elx9@cdc.gov	

January 9, 2019 Version: 3.0 Page 201 of 364

### 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 root 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	14 Days
Interferences & Limitations	Formalin fixed specimens are not suitable for culture
Additional Information	None
CDC Points of Contact	Marcos de Almeida (404) 718-4175 bnz0@cdc.gov Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov

January 9, 2019 Version: 3.1 Page 202 of 364

## **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	ns Substances known to interfere with immunoassays include: bilirubin, lipids, a 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	

January 9, 2019 Version: 4.0 Page 203 of 364

### Leptospira species Identification and Genotyping CDC-10199

Synonym(s)	Leptospirosis
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	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 30°C or at room temperature.
Transport Medium	Isolates need to be shipped on Ellinghausen-McCullough-Johnson-Harris (EMJH semisolid media.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship specimen Monday - Thursday, overnight to avoid weekend deliveries.
Requirements	Isolates should be shipped at room temperature.
Methodology	Pulsed field gel electrophoresis (PFGE), Polymerase Chain Reaction (PCR), Microscopy, 165-rRNA sequencing, Whole Genome Sequencing (WGS)
Turnaround Time	24 Weeks
Interferences & Limitations	None
Additional Information	Turnaround time will vary depending on if an isolate is sent for identification or 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

January 9, 2019 Version: 2.0 Page 204 of 364

## 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, serum, and urine). Blood specimens should be collected in EDTA or Sodium Citrate tubes
Minimum Volume Required	250 μL (blood, CSF, and serum) and 10 mL (urine)
Storage & Preservation of Specimen Prior to Shipping	Keep frozen at −20°C.
Transport Medium	Blood specimens transported in EDTA or Sodium Citrate tubes
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.  Specimens should be shipped frozen at –20°C.
<u> </u>	· · · · · · · · · · · · · · · · · · ·
Turnaround Time	Polymerase Chain Reaction (PCR)
	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

January 9, 2019 Version: 1.3 Page 205 of 364

### Leptospira species Serology

CDC-10201

Synonym(s)	Leptospirosis
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Serum (acute and convalescent preferred)
Minimum Volume Required	100 μL
Storage & Preservation of Specimen Prior to Shipping	Store serum at 4°C before shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.  Serum should be shipped at 4°C.
Methodology	MAT-micro agglutination
Turnaround Time	2 Weeks
Interferences & Limitations	
Additional Information	
CDC Points of Contact	Renee Galloway (404) 639-5461 zul0@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

January 9, 2019 Version: 1.1 Page 206 of 364

### 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

January 9, 2019 Version: 1.0 Page 207 of 364

### Test Order Listeria Identification

CDC-10128

C (-)	Plateata.
Synonym(s)	
Pre-Approval Needed	
	Prior approval is not required for human specimens but is required for all other specimen types.
	Provide any preliminary results that are available.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Isolates, Sequence Data
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Ship growth on nonselective slant/stab such as TSA, HIA, etc.; screw cap tubes preferred.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers for all submissions, on the specimen container, and test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship isolates or cultures Monday – Thursday, overnight to avoid weekend deliveries.
Requirements	Ship at ambient temperature in compliance with Federal and local guidelines.
	There are no time constraints for submitting sequence data.
Methodology	Phenotypic Identification, Genetic Identification
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Cheryl Tarr (404) 639-2011 crt6@cdc.gov Zuzana Kucerova (404) 718-4143 zik0@cdc.gov

January 9, 2019 Version: 1.0 Page 208 of 364

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

Synonym(s)	Listeria 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.
Requirements	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

January 9, 2019 Version: 1.1 Page 209 of 364

# **Test Order** *Listeria* Study CDC-10130

Synonym(s)	None
• • •	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

January 9, 2019 Version: 1.0 Page 210 of 364

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

Synonym(s)	Screening for <i>Bacillus anthracis</i> , <i>Brucella spp.</i> , <i>Burkholderia mallei</i> , <i>Burkholderia pseudomallei</i> , <i>Francisella tularensis</i> , <i>Yersinia pestis</i> , Orthopoxvirus, and ricin toxin.
Pre-Approval Needed	Thomas, Jennifer, (404) 639–4259, fsu8@cdc.gov Kamal, Nazia, (404) 639–4733, ird7@cdc.gov
	Please contact Dr. Jennifer Thomas at (404) 639-4259 or fsu8@cdc.gov, for the required supplemental form and packaging and shipping requirements.
Supplemental Form	None
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
	Bulk sampling of visible materials (e.g., powders, liquids, etc.) and/or sampling from contaminated surfaces (e.g., with polyester swabs).
Minimum Volume Required	Dependent on Specimen Type
	Dry swabs or powders can be stored and shipped at room temperature. Liquid samples should be held and shipped at 4°C.
Transport Medium	None
Specimen Labeling	No special requirements
	Ship Monday-Thursday, overnight to avoid weekend deliveries, if possible. If weekend delivery is necessary, please contact laboratory upon shipment.
Methodology	Real Time PCR, Culture Isolation, Time-Resolved Fluorescence
Turnaround Time	
Interferences & Limitations	Dependent on sample time
Additional Information	Turnaround time is dependent on test and sample type.
CDC Points of Contact	Jennifer Thomas (404) 639-4259 fsu8@cdc.gov Nazia Kamal (404) 639-4733 ird7@cdc.gov

January 9, 2019 Version: 3.2 Page 211 of 364

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

Synonym(s)	LCM, Arenavirus
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood, serum, and CSF
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 212 of 364

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

Synonym(s)	LCM, Arenavirus
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	CSF, blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 213 of 364

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

Synonym(s)	Bolivian Hemorrhagic Fever, BHF, <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 214 of 364

#### **Test Order** Machupo Serology CDC-10348

Synonym(s)	Bolivian Hemorrhagic Fever, BHF, <i>Arenavirus</i>
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 215 of 364

## **Test Order**Malaria Drug Resistance 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

January 9, 2019 Version: 3.0 Page 216 of 364

## **Test Order**Malaria Molecular Identification CDC-10480

Synonym(s)	Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale, parasite
Pre-Approval Needed	
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 specimen 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	Conventional PCR, Real-Time PCR
Turnaround Time	14 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Theresa Benedict (404) 718-4124 tgd5@cdc.gov

January 9, 2019 Version: 2.3 Page 217 of 364

# **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 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	Specimens for serology testing should be collected, spun and transfered to leak proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tube for each test requested.
CDC Points of Contact	Hilda Rivera (404) 718-4100 igi2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 218 of 364

### Malaria: Morphologic Identification

CDC-10520

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Whole blood smear and images
Minimum Volume Required	N/A
Storage & Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific and available on consultation
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries Shipping is specimen specific and available on consultation
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Henry Bishop (404) 718-4102 hsb2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 1.0 Page 219 of 364

# **Test Order**Marburg Identification CDC-10349

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 220 of 364

## **Test Order**Marburg Serology CDC-10350

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 221 of 364

### 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: <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>
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.
Requirements	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 production 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>
Additional Information	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

January 9, 2019 Version: 1.1 Page 222 of 364

## **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	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 pricto shipment.
CDC Points of Contact	Carole Hickman (404) 639-3339 cjh3@cdc.gov Joe Icenogle (404) 639-4557 jcil@cdc.gov

January 9, 2019 Version: 1.1 Page 223 of 364

#### **Test Order** Measles Avidity

CDC-10248

Synonym(s)	None
Pre-Approval Needed	Mercader, Sara, (404) 639–4568, sjm7@cdc.gov Hickman, Carole, (404) 639–3339, cjh3@cdc.gov
Supplemental Information Required	See additional information
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	300 uL
Storage & Preservation of Specimen Prior to Shipping	Serum should be kept refrigerated, not frozen
Transport Medium	Not Applicable
Specimen Labeling	Provide a unique identifier on the specimen container and the test requisition
Shipping Instructions which Include Specimen Handling	
Requirements	Refrigerated specimen should be shipped on cold packs
Methodology	Measles avidity
Turnaround Time	30 Days
Interferences & Limitations	None
Additional Information	http://www.cdc.gov/vaccines/pubs/surv-manual/index.html
	The measles avidity assay is a specialized tool that may help with confirmation of suspect cases with RT-PCR-negative results or with questionable IgM results (false positive or false negative results are suspected). However, avidity results cannot rule out cases. Avidity testing can also help in vaccine failure classification. Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with measles vaccine.
	Samples must be measles IgG positive for testing
	The following information is required for result interpretation:  - Records of vaccination status, with the number of doses and dates of administration  - Date of birth  - Date of rash onset  - Date of sample collection  - Clinical symptoms.
	The Viral Vaccine Preventable Diseases Branch reserves the right to determine if testing for measles avidity could be beneficial.

January 9, 2019 Version: 1.4 Page 224 of 364

CDC Points of Contact Sara Mercader

(404) 639–4568 sjm7@cdc.gov

### Test Order Measles Avidity CDC-10248

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

January 9, 2019 Version: 1.4 Page 225 of 364

# Test Order Measles Detection (PCR) and Genotyping CDC-10240

Synonym(s)	
Pre-Approval Needed	
Supplemental Information Required	None
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 informatio 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 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 parl@cdc.gov Rebecca McNall (404) 639-4541 dqo2@cdc.gov

January 9, 2019 Version: 1.2 Page 226 of 364

### 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
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

January 9, 2019 Version: 1.1 Page 227 of 364

## **Test Order**Measles Serology CDC-10244

Synonym(s)	Rubeola
Pre-Approval Needed	
Supplemental Information Required	
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  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	· · · · · · · · · · · · · · · · · · ·
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 price 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

January 9, 2019 Version: 1.2 Page 228 of 364

### 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

January 9, 2019 Version: 1.1 Page 229 of 364

# Test Order MERS-CoV Molecular Detection CDC-10488

Synonym(s)	MERS-CoV PCR, Middle East Respiratory Syndrome Coronavirus PCR
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/coronavirus/mers/downloads/MERS-investigation-short-form.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, 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-clinical-specimens.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.
Shipping Instructions which Include Specimen Handling Requirements	See the following link for additional shipping information: http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html
Methodology	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	2 Days
Interferences & Limitations	Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of MERS-CoV specimens are NOT recommended at this time. However, if done, these activities must be performed in a BSL-3 facility using BSL-3 work practices.
	Use only sterile Dacron or rayon swabs with plastic shafts or if available, flocked swabs. Do NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.
Additional Information	http://www.cdc.gov/coronavirus/mers/index.html, http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html, http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html
CDC Points of Contact	Xiaoyan Lu (404) 639–2745 xal9@cdc.gov

January 9, 2019 Version: 2.1 Page 230 of 364

### Test Order MERS-CoV Molecular Detection CDC-10488

Shifaq Kamili (404) 639–2799 sgk5@cdc.gov

January 9, 2019 Version: 2.1 Page 231 of 364

## Test Order MERS-CoV Serology CDC-10489

Synonym(s)	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) ELISA, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EIA
Pre-Approval Needed	Thornburg, Natalie, (404) 639-3797, nax3@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/coronavirus/mers/downloads/MERS-investigation-short-form.pdf
Performed on Specimens From	Human
	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.
Shipping Instructions which Include Specimen Handling Requirements	http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html
Methodology	ELISA
Turnaround Time	3 Days
Interferences & Limitations	Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of MERS-CoV specimens are NOT recommended at this time. However, if done, these activities must be performed in a BSL-3 facility using BSL-3 work practices.  Do not collect specimen in heparin tubes.
Additional Information	http://www.cdc.gov/coronavirus/mers/index.html, http://www.cdc.gov/coronavirus/mers/guidelines-clinical-specimens.html, http://www.cdc.gov/coronavirus/mers/guidelines-lab-biosafety.html
CDC Points of Contact	

January 9, 2019 Version: 1.4 Page 232 of 364

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

Synonym(s)	Anncaliia, Encephalitozoon cuniculi, Encephalitozoon hellem, Encephalitozoon intestinalis, Septata intestinalis, Tubulinosema, Enterocytozoon bieneusi, Nosema, Pleistophora, Trachipleistophora, Vittaforma corneae, Nosema corneum parasite
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
	Tissue, urine, stool (unpreserved or in a PCR-compatible preservative e.g. EcoFix UniFix, ZN-PVA, TotalFix, ethanol, potassium dichromate). Other specimen types can be accepted after consultation and pre-approval.
Minimum Volume Required	See Additional Information
Storage & Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
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	14 Days
Interferences & Limitations	Stool specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.
Additional Information	Minimum Volume Required: 0.5 g of stool or 1ml of urine or 25 mg tissue
CDC Points of Contact	Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Marcos de Almeida (404) 718-4126 bnz0@cdc.gov

January 9, 2019 Version: 2.1 Page 233 of 364

## **Test Order** *Moraxella* species ID CDC-10140

Synonym(s)	Moraxella, GNDC
Pre-Approval Needed	None
Supplemental Information Required	Please notify laboratory prior to shipment if this is a critical care specimen.
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
	Pure culture isolate on a suitable agar slant medium; consultation required for other sample/specimen types.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Keep specimen refrigerated if unable to ship immediately.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday - Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 234 of 364

#### Test Order MPIR – Study CDC–10428

Synonym(s)	Anthrax TNA
Pre-Approval Needed	Quinn, Conrad, (404) 639–2858, caq7@cdc.gov Schiffer, Jarad, (404) 639–0894, aku3@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Paired acute and convalescent sera
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Serum should be separated from whole blood and kept at -80°C
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition including patient ID, date of collection, submitter information, and specimen ID number.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Contact laboratory prior to shipment.
	Ship paired sera together and all frozen specimen should be shipped on dry ice
Methodology	Cell Based Serological Assay
Turnaround Time	2 Weeks
Interferences & Limitations	Prefer non-hemolyzed specimen and non-lipemic specimen. If they are hemolyzed or lipemic, the specimen will not be tested. Plasma specimen are 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

January 9, 2019 Version: 2.0 Page 235 of 364

# **Test Order**Multipathogen Respiratory Panel CDC-10526

Synonym(s)	TaqMan Array Card, TAC
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.
	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 (e.g. patient name and date of birth) on the specimen container and on 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 microfluidic array
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	The intended use of this test is for investigation of unexplained respiratory disease outbreaks. Prior approval required for submission of specimens. Visit <a href="https://www.cdc.gov/urdo">www.cdc.gov/urdo</a> for CDC assistance with unexplained respiratory disease outbreak investigations.
CDC Points of Contact	Jonas Winchell (404) 639–4921 jwinchell@cdc.gov Maureen Diaz (404) 639–4534 mdiaz1@cdc.gov

January 9, 2019 Version: 1.0 Page 236 of 364

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

Synonym(s)	None
Synonym(s)	
Pre-Approval Needed	
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

January 9, 2019 Version: 1.2 Page 237 of 364

### 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 cjh3@cdc.gov

January 9, 2019 Version: 1.1 Page 238 of 364

#### Test Order Mumps Serology CDC-10245

Synonym(s)	None
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	300 uL
Storage & Preservation of Specimen Prior to Shipping	Serum should be kept refrigerated, not frozen
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
Requirements	Refrigerated specimen should be shipped on cold packs
Methodology	CDC IgM Capture, Commercial indirect IgG
Turnaround Time	7 Days
Interferences & Limitations	Rheumatoid factor, Parainfluenza viruses 1, 2, and 3, Epstein-Barr virus, adenovirus, and Human Herpes Virus 6 have all been noted to interfere with mumps serologic assays.
Additional Information	IgM and IgG assays are qualitative assays
	Please include vaccination history, age, date of onset and sample collection
CDC Points of Contact	Nobia Williams (404) 639–1049 new8@cdc.gov Carole Hickman (404) 639–3339 cjh3@cdc.gov

January 9, 2019 Version: 1.2 Page 239 of 364

# 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

January 9, 2019 Version: 1.1 Page 240 of 364

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

Synonym(s)	Non-TB Mycobacteria, Mycobacteria
Pre-Approval Needed	
Supplemental Information Required	
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
	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

January 9, 2019 Version: 1.0 Page 241 of 364

### *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 no be shipped frozen.
Methodology	Agar proportion, Pyrazinamide (PZA) by MGIT 960
Turnaround Time	40 Days
Interferences & Limitations	Some isolates of MTB (<5% of submitted isolates) do not grow on the media use for testing. Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated; submitting laboratory may submit a pure culture if clinically needed.
Additional Information	On average, TAT times range from 35 to 60 calendar days. Delays may occur du to holidays and unexpected events (e.g., closure of CDC).
CDC Points of Contact	Beverly Metchock (404) 639-2455 TBLab@cdc.gov

January 9, 2019 Version: 1.1 Page 242 of 364

## 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

January 9, 2019 Version: 1.0 Page 243 of 364

#### Mycobacterium TB Complex – Identification and Drug Susceptibility Testing

CDC-10188

Synonym(s)	TB, Tuberculosis
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Pure isolate on solid medium or in broth culture
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Mycobacterium tuberculosis (MTB) Growth Medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Broth should not be shipped frozen.
Methodology	Genetic based testing, Pyrazinamide (PZA) by MGIT 960, Agar Proportion
Turnaround Time	40 Days
Interferences & Limitations	Some isolates of MTB (<5% of submitted isolates) do not grow on the media used for susceptibility testing. Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated; submitting laboratory may submit a pure culture if clinically needed.
Additional Information	On average, TAT times range from 35 to 60 calendar days. Delays may occur due to holidays and unexpected events (e.g., closure of CDC).
CDC Points of Contact	Beverly Metchock (404) 639-2455 TBLab@cdc.gov

January 9, 2019 Version: 1.1 Page 244 of 364

### 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 no 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

January 9, 2019 Version: 1.0 Page 245 of 364

#### 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+) sediment; pure culture isolate on solid medium or in broth culture; Mixed cultures known to contain MTBC; DNA
Minimum Volume Required	0.5 mL (sediment)
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Mycobacterium tuberculosis (MTB) Growth Medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Sediments and broth cultures should not be shipped frozen.
Methodology	Targeted DNA Sequencing (Pyrosequencing or Sanger sequencing based on submission criteria provided by submitter), Agar Proportion DST, MGIT 960 Pyrazinamide (PZA) also performed for sediments and isolates
Turnaround Time	3 Days
Interferences & Limitations	Samples with low numbers of MTBC may not amplify; Heteroresistance may no be detected; the results of MDDR assay should not be used to rule out the presence of MTBC in a sample.
Additional Information	On average, TAT ranges from 1-6 calendar days. Delays may occur due to holidays and unexpected events (e.g., closure of CDC).
CDC Points of Contact	Beverly Metchock (404) 639-2455 TBLab@cdc.gov Jeff Driscoll (404) 639-2455 TBLab@cdc.gov

January 9, 2019 Version: 1.1 Page 246 of 364

### Mycobacterium TB Complex – Pyrazinamide Susceptibility Testing

CDC-10189

Synonym(s)	PZA DST, TB, Tuberculosis
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Pure isolate on solid medium or in broth culture
Minimum Volume Required	Not applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Mycobacterium tuberculosis (MTB) Growth Medium
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Broth should no be shipped frozen.
Methodology	Pyrazinamide (PZA) by MGIT 960
Turnaround Time	30 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Beverly Metchock (404) 639–2455 TBLab@cdc.gov

January 9, 2019 Version: 1.1 Page 247 of 364

## 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

January 9, 2019 Version: 1.0 Page 248 of 364

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

CDC-10352

	656 10332
Synonym(s)	Culture, DST, AST, MTB, MTB complex, TB, MDR TB, ID, Tuberculosis
Pre-Approval Needed	Campbell, Patricia, (404) 718–1440, igg5@cdc.gov DeGruy, Kyle, (404) 639–0875, gsz4@cdc.gov
Supplemental Information Required	Supplemental forms will be provided upon consultation
·	Fill out the ILB-160-F08C TB Requisition Form
	CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease. It is a requirement to complete this form.
Supplemental Form	None
Performed on Specimens From	Human
	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°C indefinitely, but specimen may be stored at -20°C for three months.
Transport Medium	Inoculate Middlebrook 7H9 or MGIT (7H9) liquid media with culture isolate of a suspected <i>Mycobacterium tuberculosis</i> complex microorganism. Transfer culture material to a sterile 2.0 ml screw cap cryovial with o-ring for transport.
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.
	Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.
Shipping Instructions which	Keep specimen frozen at -70°C or lower by using dry ice.
Include Specimen Handling Requirements	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	Phenotypic DST will not be performed on nonviable, contaminated or mixed isolates.
	Specimens may be rejected if improperly labeled, submission of missing or discrepant documentation, insufficient volume for testing, or leaking specimens.
Additional Information	Turnaround time for batches with less than 100 specimens is within 150 days. Contact Patricia Campbell, igg5@cdc.gov for turnaround times for batches with greater than 100 specimens.
	Phenotypic drug susceptibility testing (DST) on <i>Mycobacterium tuberculosis</i> complex for first line drugs is performed using the BD BACTEC MGIT 960 system

January 9, 2019 Version: 1.2 Page 249 of 364

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

CDC-10352

for streptomycin, isoniazid, rifampicin, and ethambutol. Phenotypic DST is performed for second line drugs using the modified agar proportion method (Middlebrook 7H10).

Genotypic DST for *Mycobacterium tuberculosis* is performed using Hain Lifescience GenoType MTBDRplus, Hain Lifescience GenoType MTBDRsl and Cepheid Xpert MTB/RIF assays.

CDC Points of Contact Patricia Campbell

(404) 718–1440 igg5@cdc.gov Kyle DeGruy (404) 639–0875 gsz4@cdc.gov Zilma Rey (404) 639-2345 yzr0@cdc.gov

January 9, 2019 Version: 1.2 Page 250 of 364

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

Synonym(s)	None	
Pre-Approval Needed	l Alexander, Heather, (404) 639–5331, drz5@cdc.gov DeGruy, Kyle, (404) 639–0875, gsz4@cdc.gov	
Supplemental Information Required		
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	To be determined	
Minimum Volume Required	To be determined	
Storage & Preservation of Specimen Prior to Shipping	To be determined	
Transport Medium	To be determined	
Specimen Labeling	All primary specimen containers must include 2 unique identifiers at the time of collection. The identifiers must be clearly labeled on each specimen and correspond to information on the requisition form.  Surveillance studies and some protocols require 1 unique identifier (the ILB recommends 2 identifiers) de-linked from the patient. Do not include the patient's name or any other personally identifiable information. Results are not reported back to patient.	
Shipping Instructions which Include Specimen Handling Requirements	To be determined	
Methodology		
Turnaround Time		
Interferences & Limitations	To be determined	
Additional Information		
CDC Points of Contact	Heather Alexander (404) 639-5331 drz5@cdc.gov Kyle DeGruy (404) 639-0875 gsz4@cdc.gov	Zilma Rey (404) 639–2345 yzr0@cdc.gov

January 9, 2019 Version: 1.0 Page 251 of 364

# *Mycoplasma pneumoniae* Macrolide Susceptibility Genotyping CDC-10513

Synonym(s)	Atypical pneumonia, Community Acquired Pneumonia (CAP), macrolide	
Synonym(s)	resistance, Walking pneumonia	
Pre-Approval Needed	None	
Supplemental Information Required		
Supplemental Form	None	
Performed on Specimens From	Human	
	Nasopharyngeal (NP) and/or Oropharyngeal (OP) swabs, any lower respiratory tract specimen (ie. bronchoalveolar lavage (BAL)), sputum, tissue, cerebrospinal fluid (CSF), isolate, and purified nucleic acid. Upon consultation with CDC laboratory points of contact, other specimen types may be acceptable.	
Minimum Volume Required	Contingent upon specimen type. Please consult with CDC laboratory point of contact.	
	Specimens can be kept refrigerated if shipped within 72 hours of collection; otherwise specimen should be frozen. Store swabs in universal transport medium.	
Transport Medium	Universal transport medium (swabs)	
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.	
Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries. Refrigerated specimens should be packed with cold packs. Frozen specimens should be packed with dry ice.	
Methodology	Real-time PCR with high-resolution melt (HRM)	
Turnaround Time		
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	Sequencing may also be performed. All specimens are tested for the presence of <i>M. pneumoniae</i> using test order Respiratory Agents (Chlamydia, Legionella, Mycoplasma) Molecular Detection (CDC-10157).	
CDC Points of Contact	Jonas Winchell (404) 639-4921 jwinchell@cdc.gov Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov	

January 9, 2019 Version: 1.0 Page 252 of 364

## Mycoplasma pneumoniae Molecular Detection

#### CDC-10155

Synonym(s)	Atypical pneumonia, Community Acquired Pneumonia (CAP), Walking pneumonia
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
	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	Ship Monday - Thursday, overnight to avoid weekend deliveries.
	Refrigerated specimen should be sent on ice packs. Frozen specimen should be sent on dry ice.
Methodology	Real Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Do not use cotton swabs with wooden shafts. Specimen should be acquired prior to antibiotic treatment. Improper specimen storage and handling may result in inconclusive or inaccurate results.
Additional Information	All specimens are tested as part of a multiplex qPCR assay for detection of <i>M. pneumoniae</i> , <i>C. pneumoniae</i> , and <i>Legionella</i> species (CDC-10157). Specimens in which <i>M. pneumoniae</i> is detected will be subjected to <i>M. pneumoniae</i> Macrolide Susceptibility Genotyping (CDC-10513).
CDC Points of Contact	Jonas Winchell (404) 639–4921 Jwinchell@cdc.gov Maureen Diaz (404) 639–4534 mdiaz1@cdc.gov

January 9, 2019 Version: 2.1 Page 253 of 364

# *Mycoplasma species* (Respiratory) 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

January 9, 2019 Version: 2.0 Page 254 of 364

# **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	
Interferences & Limitations	Formalin-fixed specimens are not suitable for molecular studies as formalin fixation may cause DNA degradation. Fresh or frozen specimens, if available, are preferred over the formalin-fixed specimens.	
Additional Information	None	
CDC Points of Contact	Jennifer Cope (404) 718-4878 bjt9@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov	

January 9, 2019 Version: 1.3 Page 255 of 364

# 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. Results are typically reported directly to the surveillance databases.	
CDC Points of Contact	Jean Whichard (404) 639–2000 zyr3@cdc.gov Jason Foster (404) 639–4948 gux8@cdc.gov	

January 9, 2019 Version: 1.1 Page 256 of 364

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

Synonym(s)	Neisseria, GC	
Pre-Approval Needed	Pham, Cau, (404) 718–5642, whi4@cdc.gov Phillips, Christi, (404) 639–2147, div2@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human	
	Genital, pharyngeal, and/or rectal swabs. In addition, bacterial culture or isolat 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 treate with.	
CDC Points of Contact	Cau Pham (404) 718-5642 whi4@cdc.gov Christi Phillips (404) 639-2147 div2@cdc.gov	

January 9, 2019 Version: 2.0 Page 257 of 364

## Neisseria gonorrhoeae Genetic Analysis

CDC-10178

Synonym(s)	Gonorrhea, GC, Neisseria, Neisseria gonorrhoeae, Sexually Transmitted Disease	
Pre-Approval Needed	Gernert, Kim M, (404) 718–5641, nin1@cdc.gov Abrams McLean, Jeanine, (404) 639–2868, xxp7@cdc.gov	
Supplemental Information Required	Provide the following Specimen Information on the 50.34 Form:  Document the "Specimen source (type)": urethral swab, urine, throat (oropharyngeal) swab, oral swab, rectal swab, or swab.	
	Document the "Specimen source site": urethra, throat, oropharynx, rectum, vagina, or cervix.	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing	Neisseria gonorrhoeae bacterial isolate	
Minimum Volume Required	0.5-1.0 mL	
Storage & Preservation of Specimen Prior to Shipping	Store culture at $-70^{\circ}$ C to $-80^{\circ}$ C in trypticase soy broth (TSB) with 20% glycerol medium.	
Transport Medium	TSB with 20% glycerol	
Specimen Labeling	This is not a CLIA regulated test. All submitted specimens must include two unique identifiers; and should not include patient identifiers or personally identifiable information. The identifiers must be clearly labeled on each specimen container, and may include unique laboratory-based identifiers. Identifiers must correspond to the Specimen ID and Alternative Specimen ID fields provided on the requisition form.	
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight (Monday to Thursday) to avoid weekend deliveries. Specimens should be shipped on dry ice. Upon shipment, submitter is requested to send a email to CDC POC providing shipping company, shipped date and package tracking number.	
Methodology	Whole genome sequencing (WGS)	
Turnaround Time	12 Weeks	
	Viable bacterial culture is required for growth prior to DNA extraction. Low bacterial DNA concentration, low specimen volume, extended time between sample collection and culturing, and transport and handling conditions may impact the results. Inability to attain sufficient DNA for WGS sequencing will result in no test being performed or an inconclusive test result.	
Additional Information	None	
CDC Points of Contact	Kim M Gernert       Jeanine Abrams McLean         (404) 718-5641       (404) 639-2868         nin1@cdc.gov       xxp7@cdc.gov         Matthew W Schmerer       (404) 718-5911         nmk7@cdc.gov       nmk7@cdc.gov	

January 9, 2019 Version: 2.0 Page 258 of 364

## *Neisseria gonorrhoeae* Study

CDC-10103

Synonym(s)	None		
Pre-Approval Needed	Pham, Cau, (404) 718–5642, whi4@cdc.gov Nash, Evelyn, (404) 718–5037, lmq5@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	Cau Pham (404) 718-5642 whi4@cdc.gov Samera Sharpe (404) 639-2875 bpu7@cdc.gov	Evelyn Nash (404) 718–5037 Imq5@cdc.gov	

January 9, 2019 Version: 1.1 Page 259 of 364

## Neisseria gonorrhoeae Susceptibility Testing

CDC-10102

Synonym(s)	Neisseria AST, GC Susceptibility	
Pre-Approval Needed	Kersh, Ellen, (404) 639–2728, egk6@cdc.gov Pham, Cau, (404) 718–5642, whi4@cdc.gov	
Supplemental Information Required	None	
Supplemental Form	None	
Performed on Specimens From	Human	
	Genital, pharyngeal, and/or rectal swabs. In addition, bacterial culture or isolat 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	Cau Pham Ellen Kersh (404) 718-5642 (404) 639-2728 whi4@cdc.gov ekg6@cdc.gov Christi Phillips (404) 639-2147 div2@cdc.gov	

January 9, 2019 Version: 2.0 Page 260 of 364

# 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 or "tests used" column 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. If submitting live cultures, slants should be incubated overnight at 37°C with 5% CO2 and then stored and shipped at ambient temperature.	
Transport Medium	Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.	
Specimen Labeling	Tests subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.	
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday overnight to avoid weekend deliveries and enclose a shipping spreadsheet or submission form in all shipments.	
·	Frozen specimens and stocks should be shipped on dry ice. Whenever possible, email the shipping spreadsheet and tracking number in advance (especially for suspected outbreak specimens or isolates).	
Methodology	Slide Agglutination Serogrouping, Real-time PCR	
Turnaround Time	30 Days	
Interferences & Limitations	Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result.	
Additional Information	Test order results provide or confirm serogroup for potential outbreak specimens or isolates. Additional microbiological and/or molecular testing completed as needed. For research purposes only, molecular characterization of <i>N. meningitidis</i> isolates will be completed by whole genome sequencing.	
CDC Points of Contact	Melissa Whaley (404) 639–3920 dbq3@cdc.gov Caelin Potts (404) 718–5532 lyi3@cdc.gov	

January 9, 2019 Version: 1.6 Page 261 of 364

## Neisseria meningitidis Surveillance

CDC-10220

Synonym(s)	Nm surveillance, Nm study	
Pre-Approval Needed	None	
	If tested and known, please include lab results with methods used (including manufacturer of antiserum) in previous lab results section or "tests used" column of submission form.	
Supplemental Form		
Performed on Specimens From	Human	
	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. If submitting live cultures, slants should be incubated overnight at 37°C with 5% CO2 and then stored and shipped at ambient temperature.	
Transport Medium	Preferred medium includes frozen stocks or agar slants. When shipping 10 or more specimens, please submit frozen stocks only.	
Specimen Labeling	Tests require at least one patient identifier on the specimen container and the test requisition. Label specimens with the state ID & accession number, and if applicable surveillance (ABCs, Enhanced Surveillance, or GISP) ID.	
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries.	
Requirements	Frozen stocks and specimens should be shipped on dry ice. Please include shipping spreadsheet in shipment and email spreadsheet prior to shipment.	
Methodology	Isolates: Whole genome sequencing (WGS), Primary specimens: rt-PCR and when applicable, multilocus sequence typing (MLST)	
Turnaround Time		
Interferences & Limitations	Low bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens of particularly low volume and/or bacterial DNA load may result in a false negative result. Primary specimens with particularly low volume or bacterial DNA may not amplify in MLST PCR reactions necessary for multilocus sequence typing and finetyping.	
Additional Information	Additional microbiological and/or molecular testing completed as needed.	
CDC Points of Contact	Melissa Whaley (404) 639–3920 dbq3@cdc.gov Caelin Potts (404) 718–5532 lyi3@cdc.gov	

January 9, 2019 Version: 2.0 Page 262 of 364

# *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
	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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 263 of 364

# **Test Order**Nipah Virus Identification CDC-10354

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 264 of 364

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

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 265 of 364

# 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
	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	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday – Thursday, overnight to avoid weekend deliveries.
Methodology	Primary Culture based on specimen type, MALDI-TOF, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 266 of 364

# 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	None
Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised.
	Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 267 of 364

# 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 gvm3@cdc.gov

January 9, 2019 Version: 1.1 Page 268 of 364

# **Test Order**Norovirus Molecular Detection CDC-10357

Synonym(s)	Norovirus
Pre-Approval Needed	Vinje, Jan, (404) 639-3721, ahx8@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Stool, environmental swab
Minimum Volume Required	0.25 g or 0.25 mL
Storage & Preservation of Specimen Prior to Shipping	Specimen should be stored at 2°-8°C
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Include Specimen Handling	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
·	Refrigerated specimen should be shipped on cold packs
	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

January 9, 2019 Version: 1.2 Page 269 of 364

# **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	None
Required	
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
Willimani Volume Required	0.25 g 01 0.25 IIIL
	Specimen must be stored at 2°-8°C
Specimen Prior to 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	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
	gvm3@cdc.gov

January 9, 2019 Version: 1.1 Page 270 of 364

# **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), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; serum; fresh tissue biopsy; swab
Minimum Volume Required	1.0 mL
	Ideally keep specimen at a refrigerated temperature (4°C) within 7 days of draw If specimen age is over 7 days, then freeze and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline.
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shoul be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycle and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivit after febrile (acute) stage of illness.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 271 of 364

## *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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 272 of 364

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

Synonym(s)	Scrub typhus
• • • • • •	
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov
Consultant and the Comment of	Zeng, Yan, (404) 639-5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with drice.
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.2 Page 273 of 364

## 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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to leal proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
Transport Medium	Not Applicable
Specimen Labeling	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 or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 274 of 364

## 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

January 9, 2019 Version: 1.2 Page 275 of 364

Parasites: Morphologic Identification

CDC-10234

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite, ova and parasite
Pre-Approval Needed	None
Supplemental Information Required	Supplemental form not needed
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Stool specimens, blood, and tissue. Additional specimens are acceptable on consultation
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific and available on consultation
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Ship Monday - Thursday, overnight to avoid weekend deliveries Shipping is specimen specific and available on consultation
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Henry Bishop (404) 718-4102 hsb2@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 2.0 Page 276 of 364

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

January 9, 2019 Version: 1.1 Page 277 of 364

# **Test Order**Parechovirus Detection and Identification CDC-10362

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

CDC Points of Contact Alan Nix

(404) 639–1689 wbn0@cdc.gov Steve Oberste (404) 639–5497 mbo2@cdc.gov

January 9, 2019 Version: 1.1 Page 278 of 364

# **Test Order**Parvovirus B19 Molecular Detection CDC-10363

Synonym(s)	Fifth Disease
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Ellen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum, blood, plasma, and amniotic fluid
Minimum Volume Required	0.25 mL
	Refrigerate all specimens promptly after collection. If specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4°C and shipped on gel ice-packs. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted into properly labeled, leak-proof, unbreakable screw cap vials. Samples should be collected and processed in a manner that prevents cross-contamination between specimens, including changing gloves between specimens.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries  Refrigerated specimen should be shipped on cold packs Frozen specimen should be shipped on dry ice
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Do not use wooden-shafted swabs or calcium alginate swabs
Additional Information	None
CDC Points of Contact	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

January 9, 2019 Version: 1.3 Page 279 of 364

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

Synonym(s)	Fifth Disease
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	0.25 mL
	Refrigerate all specimens promptly after collection. If specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4°C and shipped on gel ice-packs. If specimens must be held for >72 hours, they should be promptly frozen at -70°C and shipped on dry ice. Liquid specimens should be aliquoted into properly labeled, leak-proof, unbreakable screw cap vials. Samples should be collected and processed in a manner that prevents cross-contamination between specimens, including changing gloves between specimens.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	IgG and IgM enzyme immunoassay
Turnaround Time	2 Weeks
Interferences & Limitations	Do not collect in heparin tubes
Additional Information	None
CDC Points of Contact	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

January 9, 2019 Version: 1.3 Page 280 of 364

### Pathologic Evaluation of Tissues for Possible Infectious Etiologies

CDC-10365

Synonym(s)	Autopsy, biopsy, formalin fixed tissues, FFPE, pathology, paraffin blocks, histopathology, electron microscopy, immunohistochemistry, PCR
Pre-Approval Needed	Infectious Diseases Pathology Branch, , , pathology@cdc.gov
Supplemental Information Required	Please include the following information with each submission:
·	- The full name, title, complete mailing address, e-mail address, telephone, and fax numbers of the submitter. This will be the same person to whom the final pathology report is addressed.
	- An electronically completed CDC Form 50.34 (one copy per case)
	<ul> <li>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).</li> </ul>
	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. Paraffin-embedded tissue blocks are preferred if formalin-fixation of the wet tissues has exceeded 2 weeks. Tissue scrolls or unstained slides are not accepted for PCR testing per IDPB's CLIA approved protocols.
	More specific guidelines regarding tissue samples and submission can be found on the IDPB website:
	http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html
Minimum Volume Required	Not Applicable
	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 Infectious Diseases Pathology Branch immediately. During hot weather, tissue blocks should be shipped on ice packs to prevent the melting of paraffin.

January 9, 2019 Version: 2.1 Page 281 of 364

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

CDC-10365

	The full name, title, complete mailing address, e-mail address, telephone and fax numbers are required for each submitted specimen. This will be to whom the final pathology report is addressed.
Methodology	Histopathology (H&E-stained sections), Cytochemistry (special stains), Immunohistochemistry (IHC), Polymerase Chain Reaction (PCR) and Sequencing, Electron Microscopy (EM), Tissue Culture, Nucleic Acid Extraction for transfer to other branches
Turnaround Time	8 Weeks
Interferences & Limitations	Prolonged fixation (>2 weeks) may interfere with some immunohistochemical and molecular diagnostic assays
Additional Information	More specific guidelines regarding tissue sampling and submission can be found on the IDPB website:
	http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html
	Turnaround time varies depending upon the complexity of each case ranging from 2-8 weeks.
	Digital images can be provided to assist in evaluation and guide testing.
CDC Points of Contact	Infectious Diseases Pathology Branch (404) 639–3132 pathology@cdc.gov

January 9, 2019 Version: 2.1 Page 282 of 364

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

Synonym(s)	None
Pre-Approval Needed	Infectious Diseases Pathology Branch, , , pathology@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	To be determined
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Infectious Diseases Pathology Branch (404) 639–3132 pathology@cdc.gov

January 9, 2019 Version: 1.3 Page 283 of 364

## 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	1 7 3
	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 $^2$ .

January 9, 2019 Version: 1.0 Page 284 of 364

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

CDC-10374

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

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

CDC Points of Contact Alan Nix

(404) 639–1689 wbn0@cdc.gov Steve Oberste (404) 639–5497 mbo2@cdc.gov

January 9, 2019 Version: 1.0 Page 285 of 364

# **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

January 9, 2019 Version: 1.0 Page 286 of 364

# **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

January 9, 2019 Version: 1.0 Page 287 of 364

# **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.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Frozen specimen should be shipped on dry ice as an etiologic agent.
Methodology	Neutralization assay
Turnaround Time	4 Weeks
Interferences & Limitations	Red blood cell hemolysis will adversely affect test results
Additional Information	None
CDC Points of Contact	William Weldon (404) 639-5485 wiw4@cdc.gov Steve Oberste (404) 639-5497 mbo2@cdc.gov

January 9, 2019 Version: 1.0 Page 288 of 364

# Test Order Polio Special Study CDC-10378

Synonym(s)	None
	Burns, Cara, (404) 639–5499, zqd1@cdc.gov
Pre-Approval Needed	Oberste, Steve, (404) 639–5499, https://doi.org/10.1000/
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

January 9, 2019 Version: 1.0 Page 289 of 364

# **Test Order**Poxvirus Molecular Detection CDC-10515

Synonym(s)	None
• • • • • • • • • • • • • • • • • • • •	Poxvirus Inquiry Line, , (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.
	Cerebrospinal fluid (CSF) and serum should be collected for patients with encephalitis.
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.
Transport Medium	None
Specimen Labeling	Test requires two patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (name, date of birth/age, etc.), provide specimen type, date of collection and body location.
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries
	Refrigerated specimen should be shipped on cold packs
Methodology	Real-Time PCR, Standard PCR
Turnaround Time	5 Days
Interferences & Limitations	Swabs intended for the collection and transport of bacterial specimens should not be used. Cotton swabs may cause PCR inhibition and should not be used. Do not add viral transport media to swab specimens as this will dilute any viral DNA present.
Additional Information	Can detect the following poxviruses with real-time PCR: variola, monkeypox, vaccinia, cowpox, orf, psuedocowpox, bovine papular stomatitis, sealpox, molluscum contagiosum, and tanapox virus. Can detect new poxviruses and the following genera with standard PCR: Orthopoxvirus, Parapoxvirus, Molluscipoxvirus, Yatapoxvirus, Suipoxvirus, Capripoxvirus, and Leporipoxvirus
	Formalin fixed material is first tested by the Infectious Disease Pathology 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.
	Poxvirus Inquiry Line

January 9, 2019 Version: 1.0 Page 290 of 364

#### **Test Order**Poxvirus Serology

CDC-10516

Synonym(s)	None
Pre-Approval Needed	Poxvirus Inquiry Line, , (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; Cerebrospinal fluid (CSF) and serum should be collected for patients with encephalitis.
Minimum Volume Required	1 mL
	All specimens should be stored at 4°C until shipment. Serum should be collected in a venous blood tube containing a clot activator and/or gel. Blood tubes should be spun prior to shipment or an aliquot of the collected serum can be shipped.
Transport Medium	Not Applicable
Specimen Labeling	Test requires two patient identifiers on the specimen container and the test requisition. In addition to two patient identifiers (name, date of birth/age, etc.), provide specimen type, tube collection type, and date of collection.
Shipping Instructions which Include Specimen Handling	Ship Monday-Thursday overnight to avoid weekend deliveries
<u> </u>	Refrigerated specimen should be shipped on cold packs
Methodology	
Turnaround Time	•
Interferences & Limitations	Collection in either heparin and/or EDTA tubes will interfere with results. Antibody detection is dependent upon the number of days post symptom or rask onset. A previous history of smallpox vaccination may affect result interpretation.
Additional Information	ELISA will detect an antibody response in persons infected with variola, monkeypox, vaccinia, or cowpox virus.
CDC Points of Contact	Poxvirus Inquiry Line (404) 639–4129

January 9, 2019 Version: 1.0 Page 291 of 364

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

Synonym(s)	Hanta, HFRS, Nephropathia epidemica
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 292 of 364

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

Synonym(s)	None
	Rabies Duty Officer, , (404) 639-1050,
Supplemental Information	Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
Performed on Specimens From	Human
	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	Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.
	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
	Form 50.34 is required for each of the 4 samples (serum, CSF, skin biopsy, and saliva)
Methodology	IgG by IFA (Serum and CSF), IgM by IFA (Serum and CSF), Viral Neutralizing Antibodies by RFFIT (Serum and CSF), DFA (Nuchal (skin) biopsy), RT-PCR (Nuchal (skin) biopsy), RT-PCR (Saliva), Sequencing
Turnaround Time	5 Days
Interferences & Limitations	Saliva and CSF specimen should be free of blood because blood may interfere with test results due to the inhibitors present in blood
Additional Information	Sequencing will only be performed if the RT-PCR test is positive. Nuchal (skin) biopsy has to be a full punch (5-6 millimeters). If testing needs to be repeated results may take up to 7 days.
CDC Points of Contact	Rabie Duty Officer (404) 639–1050

January 9, 2019 Version: 1.3 Page 293 of 364

#### **Test Order**

#### Rabies Antibody - Pre/Post-exposure Prophylaxis CDC-10393

Synonym(s)	Serology, Immunization status, Rabies titer
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050,
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	500 uL
Storage & Preservation of Specimen Prior to Shipping	Specimen can be kept refrigerated but prefer frozen
Transport Medium	Not Applicable
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition, sample type and date of collection
Shipping Instructions which Include Specimen Handling Requirements	Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.
•	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	Viral Neutralizing Antibodies RFFIT
Turnaround Time	10 Days
Interferences & Limitations	Hemolyzed samples interfere with test results
Additional Information	If testing needs to be repeated results may take up to 7 days
CDC Points of Contact	Rabies Duty Officer (404) 639–1050

January 9, 2019 Version: 1.2 Page 294 of 364

# 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, sampl 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
Mathadalagy	Frozen specimen should be shipped on dry ice  DFA for rabies virus antigen, Direct Rapid Immunohistochemistry test (DRIT),
Methodology	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

January 9, 2019 Version: 1.3 Page 295 of 364

# **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, Nuchal (skin) biopsy, and saliva. Fresh-frozen brain tissues for postmortem testing: full cross section of brain stem and cerebellum (vermis right and left lateral lobes).
Minimum Volume Required	500 uL (serum, CSF, saliva)
	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
	Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package.
	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs
Methodology	IgM & IgG by IFA (Serum & CSF), DFA for rabies virus antigen (Nuchal skin biopsy), Antigenic Typing (brain), RT-PCR, Sequence Analysis, Isolation, Direct Rapid Immunohistochemistry test (DRIT), IHC, Viral Neutralizing Antibodies by RFFIT (Serum and CSF)
Turnaround Time	3 Days
Interferences & Limitations	Saliva and CSF specimen should be free of blood because blood may interfere with test results due to the inhibitors present in blood. Test is limited by decomposed tissues due to denaturation of viral proteins.
Additional Information	Sequencing will only be performed if the RT-PCR test is positive. Nuchal (skin) biopsy has to be a full punch (5-6 millimeters). If testing needs to be repeated results may take up to 7 days.
CDC Points of Contact	Rabies Duty Officer (404) 639–1050

January 9, 2019 Version: 1.2 Page 296 of 364

# **Test Order**Rabies Field Surveillance CDC-10517

Synonym(s)	Rabies Field Studies (Domestic and International)
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-2693, Rabies@cdc.gov Ellison, James A., (404) 639-2693, Jellison@cdc.gov
Supplemental Information Required	
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	Molecular detection, Serology, Culture, Immunohistochemistry (IHC),, Other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	James A. Ellison (404) 639-2693 Jellison@cdc.gov

January 9, 2019 Version: 1.0 Page 297 of 364

# **Test Order**Rabies Postmortem Human Testing CDC-10396

Synonym(s)	Rabies DFA
Pre-Approval Needed	Rabies Duty Officer, , (404) 639–1050,
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
Performed on Specimens From	Human
	Fresh-frozen brain tissues: full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Stored at -80°C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition, sample type and date of collection
•	Ship all specimens overnight, first AM delivery and provide the CDC Point of Contact with the tracking number of package
	Frozen specimen should be shipped on dry ice
Methodology	DFA for rabies virus antigen, RT-PCR, Direct Rapid Immunohistochemistry test (DRIT), Virus Isolation, Sequence Analysis, Antigenic Typing
Turnaround Time	7 Days
Interferences & Limitations	Tests are limited by decomposed tissues due to denaturation of viral proteins
Additional Information	Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing.
CDC Points of Contact	Rabies Duty Officer (404) 639-1050

January 9, 2019 Version: 1.1 Page 298 of 364

#### Test Order Rabies Special Study CDC-10501

Synonym(s)	None
	Rabies Duty Officer, , (404) 639–1050, Ellison, James, (404) 639–2693, JEllison@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	James Ellison (404) 639-2693 JEllison@cdc.gov Subbian Satheshkumar Panayampalli (404) 639-1594 xdv3@cdc.gov

January 9, 2019 Version: 1.1 Page 299 of 364

# **Test Order**Rabies Virus Genetic Typing CDC-10397

Synonym(s)	Rabies Antigenic Typing, Rabies Monoclonal Antibody Typing, Rabies MAB Typing, Rabies RT-PCR, Rabies Sequence Analysis, Rabies Variant Typing
Pre-Approval Needed	Rabies Duty Officer, , (404) 639-1050,
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/rabies/pdf/rorform.pdf
Performed on Specimens From	Human and Animal
	Fresh-frozen brain tissues: full cross section of brain stem and cerebellum (vermis, right and left lateral lobes) preferred, or a viral isolate. Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Stored at -80°C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Two unique identifiers for human specimen and one unique identifier for animal specimen, date of collection and specimen type
	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	
Interferences & Limitations	Tests are limited by decomposed tissues due to denaturation of viral proteins
Additional Information	Samples for genetic typing may be a single sample, part of a large study or the entire number of annual positive samples from a state for typing. The amount of testing required will depend on the reason for the testing and tests range from antigenic typing to whole genome sequencing and comparison with regional samples. Urgent samples for typing or molecular epidemiology are tested
CDC Points of Contact	Rabies Duty Officer (404) 639–1050

January 9, 2019 Version: 1.2 Page 300 of 364

#### **Test Order**

#### Respiratory Virus (Non-Influenza) Special Study CDC-10400

Synonym(s)	None
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

January 9, 2019 Version: 2.1 Page 301 of 364

#### **Test Order**

#### Respiratory Virus Molecular Detection (Non-Influenza) CDC-10401

Synonym(s)	Non-influenza Respiratory Virus
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Upper or lower respiratory tract specimens; pure culture isolate
Minimum Volume Required	0.25 mL
	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	• · · · · · · · · · · · · · · · · · · ·
	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	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

January 9, 2019 Version: 2.1 Page 302 of 364

#### **Test Order** *Rickettsia* Molecular Detection CDC-10402

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group rickettsiosis, typhus group rickettsiosis
Pre-Approval Needed	7. 2
Supplemental Information	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), citrate dextrose solution A (ACD-A), or sodium citrate treated tubes preferred; serum; fresh tissue biopsy; swab
Minimum Volume Required	1.0 mL
	Ideally keep specimen at a refrigerated temperature (4°C) within 7 days of draw If specimen age is over 7 days, then freeze and ship frozen on dry ice. If previously frozen, then keep specimen frozen, and ship on dry ice.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad slightly moistened with sterile saline.
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Hemolysis of whole blood can interfere with results. Multiple freeze-thaw cycle and sample storage above refrigerated temperatures can interfere with proper nucleic acid extraction. Molecular detection methods have decreasing sensitivit after febrile (acute) stage of illness.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.6 Page 303 of 364

#### **Test Order**

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

Synonym(s)	Spotted fever group rickettsiosis, Rocky Mountain spotted fever (RMSF)
Pre-Approval Needed	None
	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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 2.5 Page 304 of 364

#### 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, but not frozen. If previously frozen, then keep specimen frozen.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, date of birth, and collection date
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries. Specimen should be shipped refrigerated on cold packs.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles may interfere with antigen binding. Use sterile technique to avoid contamination of sample as this may compromise the sample and interfere with the ability to get accurate results. Acute and convalescent serum samples are needed for accurate diagnosis and if unable to collect both please contact laboratory prior to shipping.
Additional Information	The Rickettsial Zoonoses Branch Reference Diagnostic Laboratory aids state laboratories in diagnosis of difficult samples/cases or if specialized tests are needed. In general, routine diagnostic samples should be sent to your state laboratory or a commercial laboratory if the test is available commercially. Additional specimen and shipping information can be found on the following address: <a href="https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html">https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html</a>
CDC Points of Contact	Cecilia Kato (404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177 xcw9@cdc.gov

January 9, 2019 Version: 1.5 Page 305 of 364

# Test Order Rickettsia Special Study CDC-10405

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever (RMSF), spotted fever group
	rickettsiosis, typhus group rickettsiosis
Pre-Approval Needed	Kato, Cecilia, (404) 639–0152, ckato@cdc.gov
	Zeng, Yan, (404) 639–5177, xcw9@cdc.gov
Supplemental Information Required	To be determined
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
	Ship Monday-Thursday, overnight to avoid weekend deliveries. Specimen shoul be shipped refrigerated on cold packs, unless frozen, then ship with dry ice.
Methodology	Molecular detection, serology, culture, other
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	(404) 639-0152 ckato@cdc.gov Yan Zeng (404) 639-5177
	xcw9@cdc.gov

January 9, 2019 Version: 1.6 Page 306 of 364

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

Synonym(s)	RVF
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 307 of 364

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

Synonym(s)	RVF
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 308 of 364

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

Synonym(s)	Rotavirus Antigen EIA, Rotavirus Antigen ELISA
Pre-Approval Needed	None
Supplemental Information Required	Contact laboratory for supplemental forms
Supplemental Form	None
Performed on Specimens From	None
Acceptable Sample/ Specimen Type for Testing	Human stool
Minimum Volume Required	0.25 g or 0.25 mL
	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.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Wednesday, overnight to avoid weekend deliveries  Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on cold packs  Include a hardcopy list of specimens with your shipment. Please notify Mike Bowen (mkb6@cdc.gov) and Charity Perkins (vmf4@cdc.gov) when you are going to send specimens, and include the shipment tracking number if possible.
Methodology	Enzyme immunoassay (EIA)
Turnaround Time	14 Days
Interferences & Limitations	None
Additional Information	Contact laboratory for instructions to recover a limited sample from diaper material
CDC Points of Contact	Mike Bowen (404) 639-4922 mkb6@cdc.gov Charity Perkins (404) 639-4545 vmf4@cdc.gov

January 9, 2019 Version: 2.2 Page 309 of 364

# **Test Order**Rotavirus Genotyping CDC-10409

Synonym(s)	Rotavirus Real Time RT-PCR, Rotavirus RT-PCR, Rotavirus Sequencing
Pre-Approval Needed	None
Supplemental Information Required	Contact laboratory for supplemental forms.
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Human stool
Minimum Volume Required	0.5 g or 0.5 mL
	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	Contact laboratory about testing a stool specimen in Cary-Blair or viral transpo media. Do not send the specimen in a fixative solution.
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
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 goin to send specimens, and include the shipment tracking number if possible.
Methodology	RT-PCR, Sequencing
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	Contact laboratory for instructions to recover a limited sample from diaper material
CDC Points of Contact	Mike Bowen (404) 639-4922 mkb6@cdc.gov Charity Perkins (404) 639-4545 vmf4@cdc.gov

January 9, 2019 Version: 1.3 Page 310 of 364

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

	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, cataract 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 b 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> and <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	Joe Icenogle (404) 639-4557 jci1@cdc.gov Emily Abernathy (404) 639-1249 efa9@cdc.gov

January 9, 2019 Version: 1.3 Page 311 of 364

# **Test Order**Rubella Serology CDC-10246

Synonym(s)	German measles, three day measles
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum and others upon consultation
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Serum should be kept refrigerated or frozen
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Clearly label specimen type.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday -Thursday overnight to avoid weekend deliveries  Refrigerated or frozen specimen should be shipped on cold packs Laboratory will instruct on how to ship for other specimen types
Methodology	Commercial capture IgM, Commercial indirect IgG
Turnaround Time	
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 jci1@cdc.gov Emily Abernathy (404) 639-1249 efa9@cdc.gov

January 9, 2019 Version: 1.1 Page 312 of 364

#### **Test Order**

#### Rubella Serology (IgM and IgG) and Avidity CDC-10249

Synonym(s)	German measles, three day measles
Pre-Approval Needed	None
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Serum should be kept refrigerated or frozen
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Clearly label specimen type.
Shipping Instructions which Include Specimen Handling Requirements	The laboratory requests that the sender contacts the laboratory by email or phone before shipping
	Ship specimen Monday -Thursday overnight to avoid weekend deliveries
	Frozen specimen should be shipped on dry ice
	Refrigerated specimen should be shipped on cold packs
Methodology	CDC IgG avidity assay
Turnaround Time	7 Days
Interferences & Limitations	Date of onset is necessary for accurate interpretation
Additional Information	Date of onset, vaccination status, age, date of collection and pregnancy status applicable.
CDC Points of Contact	Joe Icenogle (404) 639-4557 jci1@cdc.gov Emily Abernathy (404) 639-1249 efa9@cdc.gov

January 9, 2019 Version: 1.1 Page 313 of 364

# **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

January 9, 2019 Version: 1.0 Page 314 of 364

# 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 foodborr outbreak activities or due to limited availability of resources.
CDC Points of Contact	Susan Van Duyne (404) 639-0186 mdv9@cdc.gov Ana Lauer (404) 639-2117 ybp6@cdc.gov

January 9, 2019 Version: 1.4 Page 315 of 364

#### **Test Order**

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

Synonym(s)	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Fields, Patricia, (404) 639–1748, pif1@cdc.gov
	Date of illness onset, date of serum collection, clinical diagnosis. Indicate if patient is currently on antibiotics. Indicate if patient is suspect chronic carrier
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Serum, paired serum preferred. Do not pool specimens.
Minimum Volume Required	200 uL (More preferred)
Storage & Preservation of Specimen Prior to Shipping	Maintain serum at 4°C (preferred); frozen specimens acceptable
Transport Medium	Separate serum from the clot and ship in a sterile labeled tube with the top tightly closed
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required
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 Patricia Fields (404) 639-1748 pif1@cdc.gov

January 9, 2019 Version: 1.3 Page 316 of 364

# Test Order Salmonella Study CDC-10109

Synonym(s)	None
Pre-Approval Needed	Van Duyne, Susan, (404) 639–0186, mdv9@cdc.gov Lauer, Ana, (404) 639–2117, ybp6@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Susan Van Duyne (404) 639-0186 mdv9@cdc.gov Ana Lauer (404) 639-2117 ybp6@cdc.gov

January 9, 2019 Version: 1.2 Page 317 of 364

# **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 other types of specimen.
	Indicate subtyping method(s) requested; provide PulseNet cluster code and PFGE pattern numbers if appropriate.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Isolates
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required.
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries.
	Ship at ambient temperature in compliance with Federal and local guidelines.
	PFGE, MLVA, AST, WGS
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 Ana Lauer (404) 639-2117 ybp6@cdc.gov

January 9, 2019 Version: 1.2 Page 318 of 364

# Test Order SARS Molecular Detection CDC-10412

Synonym(s)	SARS coronavirus
Pre-Approval Needed	Lindstrom, Stephen, (404) 639–1587, SQL5@cdc.gov Schneider, Eileen, (404) 639–5345, ees2@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Nasopharyngeal wash/aspirates, nasopharyngeal swabs, oropharyngeal swabs, 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/guidance/F-lab/app4.htm">http://www.cdc.gov/sars/guidance/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	Ship Monday-Thursday, overnight to avoid weekend deliveries
·	http://www.cdc.gov/sars/lab/specimen.html
	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 they may contain substances that inactivate some viruses and inhibit some molecular assays.
Additional Information	http://www.cdc.gov/sars/about/index.html http://www.cdc.gov/sars/guidance/F-lab/app5.html
CDC Points of Contact	Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Shifaq Kamili (404) 639-2799 sgk5@cdc.gov

January 9, 2019 Version: 1.3 Page 319 of 364

#### Test Order SARS Serology CDC-10413

SARS-CoV, SARS-CoV EIA, SARS-CoV ELISA, SARS ELISA, SARS EIA  Thornburg, Natalie, (404) 639-3797, nax3@cdc.gov
Thornburg Natalie (404) 639–3797 pay3@cdc.gov
inolineary, radanc, (TOT/ 033 3/3/, nax3@cac.gov
None
None
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>
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 and internal O-ring seals. If there is no O-ring seal, then seal tightly with the available cap and secure with Parafilm. Collect whole blood in either EDTA tubes or in a clotting tube. For plasma, collect blood in EDTA tubes and place in vials with external caps and internal O-ring seals. Store plasma and serum at 4°C. Serum may be frozen.
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  Refrigerated specimen should be shipped on cold packs Frozen specimen should be shipped on dry ice <a href="http://www.cdc.gov/sars/lab/specimen.html">http://www.cdc.gov/sars/lab/specimen.html</a>
ELISA
3 Days
Do not collect in heparin tubes
None
Natalie Thornburg (404) 639-3797 nax3@cdc.gov

January 9, 2019 Version: 1.2 Page 320 of 364

#### **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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to leak proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}$ C for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}$ C or lower.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.
	Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship specimen at room temperature or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tube for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.2 Page 321 of 364

# **Test Order**Seoul Virus Serology CDC-10414

Synonym(s)	Hanta, HFRS, HPS
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Blood and serum
Minimum Volume Required	1 mL
	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 322 of 364

### 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	Two patient identifiers on the specimen container and the test requisition are required.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries.  Ship with cold packs in compliance with federal and local guidelines. Shiga toxin-positive broths should be shipped as Category A Infectious Substances.
Methodology	Isolation, Phenotypic Identification Including Serotyping, PCR Testing for Virulence Markers
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	A final report for CDC-10105 will be issued for broths that are not confirmed as positive by PCR for STEC or from broths that are confirmed as positive by PCR but from which an STEC isolate can not be obtained. Broths from which an STEC is isolated will be reflexively assigned test CDC-10114 Escherichia and Shigella identification, serotyping, and virulence profiling, and a final report will be issued when results for CDC-10114 are complete. Consult with Dr. Nancy Strockbine if a preliminary report for CDC-10105 is needed.
CDC Points of Contact	Nancy Strockbine       Haley Martin         (404) 639-4186       (404) 639-1612         nas6@cdc.gov       hvw0@cdc.gov         Nancy Garrett       (404) 639-1964         dgi3@cdc.gov       dgi3@cdc.gov

January 9, 2019 Version: 1.4 Page 323 of 364

## **Test Order**Special Bacterial Pathogen Study CDC-10147

Synonym(s)	None
Pre-Approval Needed	McQuiston, John, (404) 639-0270, zje8@cdc.gov Whitney, Anne, (404) 639-1374, amw0@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Anne Whitney (404) 639-1374 amw0@cdc.gov

January 9, 2019 Version: 1.2 Page 324 of 364

## Staphylococcal Toxic Shock Syndrome Toxin (TSST-1) CDC-10426

Synonym(s)	Staph Toxin, Toxic Shock Syndrome
Pre-Approval Needed	Lonsway, David, (404) 639–2825, lonsway@cdc.gov Rasheed, Kamile, (404) 639–3247, jkr1@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Pure culture isolate on 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	Real-time polymerase chain reaction (PCR)
Turnaround Time	28 Days
Interferences & Limitations	None
Additional Information	TSST-1 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

January 9, 2019 Version: 2.0 Page 325 of 364

### Test Order 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 roor 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

Version: 1.0 Page 326 of 364 January 9, 2019

## **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 room temperature as an etiologic agent.
Methodology	16S Sequencing, MALDI-TOF, Phenotypic Testing, Molecular Strain Typing
Turnaround Time	28 Days
Interferences & Limitations	None
Additional Information	Not CLIA compliant testing; for epidemiologic purposes only
CDC Points of Contact	Kamile Rasheed (404) 639-3247 JRasheed@cdc.gov Valerie Albrecht (404) 639-4552 gpy8@cdc.gov

January 9, 2019 Version: 1.3 Page 327 of 364

## 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 and food. Only specimens from foodborne outbreaks accepted. Consult with Carolina Luquez and Gerry Gomez before sending specimens.
Minimum Volume Required	25 g (food) and 10 g (stool, vomitus)
Storage & Preservation of Specimen Prior to Shipping	Maintain food, stool and vomitus at 4°C.
Transport Medium	Not Applicable
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required.
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 fyr6@cdc.gov Gerry Gomez (404) 639-0537 goe4@cdc.gov

January 9, 2019 Version: 1.3 Page 328 of 364

## STI Panel-*N. gonorrhoeae, C. trachomatis, M. genitalium, T. vaginalis* Study

CDC-10175

Synonym(s)	Sexually Transmitted Infection
Pre-Approval Needed	Phillips, Christi, (404) 639–2147, div2@cdc.gov Morris, Monica, (404) 639–2733, vul8@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 upor consultation with laboratory.
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	Swabs must be kept frozen.
Transport Medium	Should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium.
Specimen Labeling	Please include country of origin, de-linked identifier and date of collection.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday - Thursday, overnight to avoid weekend deliveries. Specimen should be shipped on dry ice, as an etiologic agent.
Methodology	PCR
Turnaround Time	12 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Christi Phillips (404) 639–2147 div2@cdc.gov Monica Morris (404) 639–2733 vul8@cdc.gov

January 9, 2019 Version: 2.0 Page 329 of 364

# **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 frozer 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	Based on consultation
Additional Information	None
CDC Points of Contact	Lesley McGee (404) 639-0455 afi4@cdc.gov Bernard Beall (404) 639-1237 bbeall@cdc.gov

January 9, 2019 Version: 1.1 Page 330 of 364

## Test Order Streptococcus (Beta Hemolytic Strep) Typing CDC-10216

Synonym(s)	GAS typing, GBS typing, other beta hemolytic strep, Group A Strep, Group B Strep
Pre-Approval Needed	Beall, Bernard, (404) 639-1237, bbeall@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/streplab/other-streptococci-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 frozen glycerol stock; additional details and directions will be provided upon consultation.
Transport Medium	Dependent on specimen type to be determined upon consultation
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling	Ship specimen Monday -Thursday, overnight to avoid weekend deliveries
	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

January 9, 2019 Version: 1.1 Page 331 of 364

### 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 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	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

January 9, 2019 Version: 1.1 Page 332 of 364

#### 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 required for other sample/specimen types.
Minimum Volume Required	Not applicable
Storage & Preservation of Specimen Prior to Shipping	Keep refrigerated if cannot ship immediately.
Transport Medium	Suitable agar slant medium (example: blood or chocolate); Frozen glycerol 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 Requirements	Ship specimen Monday –Thursday, overnight to avoid weekend deliveries.  Frozen specimen should be shipped on dry ice. Refrigerated specimen should be
•	shipped on cold packs. At room temperature for any etiologic agents.
Methodology	Phenotypic Testing, Molecular Testing, Broth microdilution MIC
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	Preliminary susceptibility results may be available within 28 days or less. If susceptibility has been performed, indicate the method and results. Date of specimen collection and original submitter.
CDC Points of Contact	Bernard Beall David Lonsway (404) 639–1237 (404) 639– 2825 BBEALL@cdc.gov dul7@cdc.gov Patricia Shewmaker (404) 639–2825 paw3@cdc.gov

January 9, 2019 Version: 1.1 Page 333 of 364

#### Streptococcus pneumoniae Typing

CDC-10215

Synonym(s)	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, 404-639-1237.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Isolates and clinical/environmental specimens and others as approved upon consultation
Minimum Volume Required	Not Applicable
	For isolates, store on blood or chocolate agar, in transport media or as a frozen glycerol stock; additional details and directions will be provided upon consultation.
Transport Medium	Dependent on specimen type to be determined upon consultation
Specimen Labeling	Test subject to CLIA regulations require two patient identifiers on the specimen container and the test requisition.
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 Lesley McGee (404) 639-0455 afi4@cdc.gov

January 9, 2019 Version: 1.2 Page 334 of 364

## 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
	For isolates blood or chocolate agar; transport media or frozen glycerol stock; additional details and directions will be provided upon consultation.
Transport Medium	To be determined
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition.
	Note: surveillance studies may label specimens according to protocol
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	Phenotypic Testing, Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Bernard Beall (404) 639–1237 bbeall@cdc.gov Lesley McGee (404) 639–0455 afi4@cdc.gov

January 9, 2019 Version: 1.0 Page 335 of 364

## **Test Order**Strongyloidiasis Serology CDC-10467

Synonym(s)	Strongyloidiasis, Strongyloides stercoralis, 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 or plasma
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to lea proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 specimer at room temperature or cold ice packs, 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, an hemoglobin
Additional Information	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 2.1 Page 336 of 364

## **Test Order**Syphilis Serology CDC-10173

Synonym(s)	Treponemal and non-treponema	al
Pre-Approval Needed	Fakile, Yetunde, (404) 639–3784, yfakile@cdc.gov Pettus, Kevin, (404) 639–4338, kbp9@cdc.gov	
Supplemental Information Required	Need to supply date of birth.	
Supplemental Form	None	
Performed on Specimens From	Human	
Acceptable Sample/ Specimen Type for Testing		plasma (possible to preform test but not
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 specimen container and the test	and requires two patient identifiers on the 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 Kevin Pettus (404) 639–4338 kbp9@cdc.gov	Yongcheng Sun (404) 639–2905 Yas2@cdc.gov

January 9, 2019 Version: 2.0 Page 337 of 364

# Test Order Tick Borne Encephalitis (TBE) Identification CDC-10415

Synonym(s)	None
	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	Frozen tissue, blood and serum
Minimum Volume Required	1 mL
	Specimen must be placed in plastic screw capped vials, frozen to -70°C, and kept frozen until shipment. See link to supplemental submission form for specific information on various specimen types.
Transport Medium	Not Applicable
Specimen Labeling	Patient name, patient ID #, specimen type, date collected
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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 338 of 364

## Test Order Tick Borne Encephalitis (TBE) Serology CDC-10416

Synonym(s)	None
Pre-Approval Needed	Klena, John, (470) 312–0094, spather@cdc.gov Rollin, Pierre, (470) 312–0094, spather@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	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 (470) 312-0094 spather@cdc.gov Pierre Rollin (470) 312-0094 spather@cdc.gov

January 9, 2019 Version: 1.3 Page 339 of 364

#### Toxocariasis Serology

CDC-10468

Synonym(s)	Larva migrans, Toxocariasis, <i>Toxocara canis</i> , <i>Toxocara cati</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 or plasma.
Minimum Volume Required	0.5 mL
Storage & Preservation of Specimen Prior to Shipping	Specimens for serology testing should be collected, spun and transfered to leal proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tub for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 718–4100 ibm4@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 4.2 Page 340 of 364

### Toxoplasmosis Special Study CDC-10492

Synonym(s)	None
Pre-Approval Needed	Rivera, Hilda, (404) 718–4100, igi2@cdc.gov DPDx, , (404) 718–4120, dpdx@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	None
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Hilda Rivera (404) 718–4100 igi2@cdc.gov DPDx (404) 718–4120 dpdx@cdc.gov

January 9, 2019 Version: 1.2 Page 341 of 364

### *Treponema pallidum* Molecular Detection Study CDC-10176

Synonym(s)	Syphilis
Pre-Approval Needed	Pillay, Allan, (404) 639–2140, apillay@cdc.gov Pereira, Lara, (404) 639–0169, vvg3@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
	Swabs, blood in EDTA tube, body fluids, and fresh biopsy tissue should be stored at -80°C (preferable) or -20°C. Formalin-Fixed Paraffin-Embedded (FFPE) tissue should be stored at room temperature.
Transport Medium	Ulcer/skin lesion swabs should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium.
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	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should <b>NOT</b> be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov Lara Pereira (404) 639-0169 vvg3@cdc.gov

January 9, 2019 Version: 2.0 Page 342 of 364

### **Test Order** *Treponema pallidum* Molecular Typing Study

CDC-10177

Synonym(s)	Treponema pallidum Genotyping, Treponema pallidum Strain Typing, Syphilis Typing	
Pre-Approval Needed	Pillay, Allan, (404) 639–2140, apillay@cdc.gov Pereira, Lara, (404) 639–0169, vvg3@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	
	Swabs, blood in EDTA tube, body fluids, and fresh biopsy tissue should be stored at -80°C (preferable) or -20°C. Formalin-Fixed Paraffin-Embedded (FFPE) tissue should be stored at room temperature.	
Transport Medium	Ulcer/skin lesion swabs should be transported on commercial Nucleic Acid Amplification Test (NAAT) medium.	
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 shipped on cold packs and FFPE can be shipped at room temperature, as an etiologic agent.	
Methodology	PCR, Sequencing, RFLP	
Turnaround Time	4 Weeks	
Interferences & Limitations	None	
Additional Information	None	
CDC Points of Contact	Allan Pillay (404) 639-2140 apillay@cdc.gov Lara Pereira (404) 639-0169 vvg3@cdc.gov	

January 9, 2019 Version: 2.0 Page 343 of 364

#### 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 (consumption or 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	Specimens for serology testing should be collected, spun and transfered to leak proof tubes.
	Serum or plasma specimens should be stored at $4-8^{\circ}\text{C}$ for max. 7 days until shipment takes place. When kept for longer periods, serum samples should be frozen at $-20^{\circ}\text{C}$ or lower.
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 or cold ice packs, 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	Please send one CDC Specimen Submission (50.34) Form and one separate tube for each test requested.
CDC Points of Contact	Isabel McAuliffe (404) 719-4100 ibm4@cdc.gov DPDx (404) 718-4120 dpdx@cdc.gov

January 9, 2019 Version: 2.1 Page 344 of 364

#### *Trichomonas* Susceptibility

CDC-10239

	Trichomonas, trich, parasite	
Pre-Approval Needed		
	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	7 Weeks	

January 9, 2019 Version: 2.2 Page 345 of 364

#### **Trichomonas** Susceptibility

CDC-10239

Interferences & Limitations None

Additional Information None

CDC Points of Contact Evan Secor

(404) 718-4141 was4@cdc.gov

January 9, 2019 Version: 2.2 Page 346 of 364

#### 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 gok0@cdc.gov

January 9, 2019 Version: 1.1 Page 347 of 364

#### Varicella Zoster Virus (VZV) Avidity

CDC-10256

Synonym(s)	Chicken pox, shingles
Pre-Approval Needed	Schmid, Scott, (404) 639–0066, dss1@cdc.gov Radford, Kay, (404) 639–2192, kjr7@cdc.gov
Supplemental Information Required	See Supplemental Form.  Please Note: Persons with disabilities experiencing problems accessing this document should contact CDC-INFO by either completing the form at <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	Requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship overnight Monday - Thursday, with cold packs or dry ice as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	IgG avidity
Turnaround Time	1 Week
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health o management.
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.3 Page 348 of 364

### 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	Requires two patient identifiers on the specimen container and the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday-Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR), DNA sequencing
Turnaround Time	2 Weeks
Interferences & Limitations	None
Additional Information	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Jennifer Folster (404) 639-3668 apz5@cdc.gov

January 9, 2019 Version: 1.4 Page 349 of 364

### Varicella Zoster Virus (VZV) Intrathecal Antibody Detection CDC-10496

Synonym(s)	None
Pre-Approval Needed	Schmid, Scott, (404) 639–0066, SSchmid@cdc.gov Folster, Jennifer, (404) 639–3668, JFolster@cdc.gov
Supplemental Information Required	See Supplemental Form
Supplemental Form	http://www.cdc.gov/shingles/downloads/specimen_collection_form.pdf
Performed on Specimens From	Human
Acceptable Sample/ Specimen Type for Testing	Paired serum sample and cerebrospinal fluid (both samples required)
Minimum Volume Required	200 uL
Storage & Preservation of Specimen Prior to Shipping	Can be stored at 4 degrees C for several days; frozen at -20 degrees C if samples will be held longer.
Transport Medium	No transport medium.
Specimen Labeling	Requires two patient identifiers on the specimen container and the test requisition.
	If stored at 4°C can be overnighted on cold packs in well-sealed O-ring vials; if frozen can be overnighted on dry ice in well-sealed O-ring vials.
·	Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	gpELISA
Turnaround Time	7 Days
Interferences & Limitations	At least one of the specificity controls must be both positive in serum and negative in CSF; if all three specificity controls are negative in both serum and CSF, interpretation is not possible (If specimen volume allows, additional specificity controls could be attempted, e.g., for anti-CMV antibody).
Additional Information	gpELISA VZV antibody detection method used to determine presence of specific antibody in both CSF and serum. HSV-1, HSV-2 and HHV-6 antibody measurements are performed as specificity controls on both samples. A ratio of 1:10 CSF to serum VZV Ab is regarded as positive if and only if at least one of the specificity controls is both Ab positive in serum and negative in CSF.
	This test order is for research or epidemiological purposes only. The test(s) used have not been cleared or approved by the FDA and the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Scott Schmid (404) 639–0066 SSchmid@cdc.gov Jennifer Folster (404) 639–3668 JFolster@cdc.gov

January 9, 2019 Version: 1.2 Page 350 of 364

## **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.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	IgG antibody detected by EIA, IgM antibody detected by EIA
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 1.4 Page 351 of 364

### 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.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimen Monday-Thursday, overnight. Cold packs or dry ice for liquid specimen. Ambient temperature for scabs and lesions. Ship as an etiologic agent.  Please ship to the attention of: Scott Schmid National VZV Laboratory 404-639-0066
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Scott Schmid (404) 639-0066 dss1@cdc.gov Kay Radford (404) 639-2192 kjr7@cdc.gov

January 9, 2019 Version: 2.1 Page 352 of 364

### 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	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.
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries.  Every suspect <i>Vibrio cholerae</i> isolate should be sent to EDLB as soon as possible.
Requirements	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

January 9, 2019 Version: 2.0 Page 353 of 364

#### Vibrio cholerae serology

CDC-10454

Synonym(s)	Enteric Pathogen
Pre-Approval Needed	Aubert, Rachael, (404) 639–3816, vrl7@cdc.gov Fields, Patricia, (404) 639–1748, pif1@cdc.gov
	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	Two patient identifiers on the specimen container and the test requisition are required
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	None
Additional Information	Paired serum specimens always preferred.
	Please send one tube per specimen submission form. Submit multiple forms it needed.
CDC Points of Contact	Rachael Aubert (404) 639–3816 vrl7@cdc.gov Patricia Fields (404) 639–1748 pif1@cdc.gov

January 9, 2019 Version: 1.2 Page 354 of 364

## **Test Order** *Vibrio* Subtyping CDC-10122

Synonym(s)	None
• • • • • • • • • • • • • • • • • • • •	
Pre-Approval Needed	
	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 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
Include Specimen Handling	Ship Monday - Thursday, overnight to avoid weekend deliveries.
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

January 9, 2019 Version: 1.1 Page 355 of 364

## 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.
	Ship Monday - Thursday, overnight to avoid weekend deliveries.
Include Specimen Handling Requirements	Ship at ambient temperature in compliance with Federal and local guidelines.
Methodology	Phenotypic Identification, Genetic Identification
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	Turnaround times for routine isolates may be extended during major 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

January 9, 2019 Version: 1.1 Page 356 of 364

### 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

January 9, 2019 Version: 1.1 Page 357 of 364

## **Test Order**Waterborne Parasite Special Study CDC-10527

Synonym(s)	None
• • • • • • • • • • • • • • • • • • • •	Roellig, Dawn, (404) 718-4134, iyd4@cdc.gov Murphy, Jennifer, (404) 718-4155, iod7@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Two specimen/patient identifiers on the specimen container and test requisition
Include Specimen Handling	Ship Monday – Thursday, overnight to avoid weekend deliveries. Ship fixed/preserved specimens at room temperature. Ship unpreserved specimens or wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if stored frozen.
Methodology	To be determined
Turnaround Time	3 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Dawn Roellig (404) 718-4134 iyd4@cdc.gov Jennifer Murphy (404) 718-4155 iod7@cdc.gov

January 9, 2019 Version: 1.0 Page 358 of 364

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

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Synonym(s)	
Pre-Approval Needed	
	Prior approval is not required for human specimens, but is required for all other specimen types.
	Indicate subtyping method(s) requested on specimen submission form.
Supplemental Form	None
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics
Acceptable Sample/ Specimen Type for Testing	Isolates
Minimum Volume Required	Not Applicable
Storage & Preservation of Specimen Prior to Shipping	No Specific Requirements
Transport Medium	Ship cultures on nonselective nutrient or similar agar (TSA, HIA, etc.) in tubes with leak-proof screw cap closures. Agar plates are not acceptable.
Specimen Labeling	Two patient identifiers on the specimen container and the test requisition are required.
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday – Thursday, overnight to avoid weekend deliveries.  Ship at ambient temperature in compliance with Federal and local guidelines.
Methodology	Serotyping, PFGE, MLST, WGS
Turnaround Time	
Interferences & Limitations	None
Additional Information	Specify type of subtyping requested in 'Previous Laboratory Results' on back of form.
	Turn around time depends on the nature of subtyping performed; and, results are typically not reported directly back to the submitter, but deposited in surveillance databases. If the surveillance database is not accessible to submitters, results are posted on the PulseNet and OutbreakNet discussion board.
CDC Points of Contact	Cheryl Tarr (404) 639-2011 crt6@cdc.gov Monica Santovenia (404) 718-1446 ixi9@cdc.gov

January 9, 2019 Version: 1.2 Page 359 of 364

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

CDC-10123

Synonym(s	) Arsenophonus, Biostraticola, Brenneria, Buchnera, Budvicia, Buttiauxella,		
	Calymmatobacterium, Cedecea, Citrobacter, Cosenzaea, Cronobacter, Dickeya, Edwardsiella, Enterobacter, Erwinia, Ewingella, Gibbsiella, Hafnia, Klebsiella, Kluyvera, Leclercia, Leminorella, Levinea, Lonsdalea, Mangrovibacter, Moellerella, Morganella, Obesumbacterium, Pantoea, Pectobacterium, Phaseolibacter, Photorhabdus, Plesiomonas, Pragia, Proteus, Providencia, Rahnella, Raoultella, Saccharobacter, Samsonia, Serratia, Shimwellia, Sodalis, Tatumella, Thorsellia, Trabulsiella, Wigglesworthia, Xenorhabdus, Yersinia, Yokenella		
Pre-Approval Neede	d 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 Forn	ı None		
Performed on Specimens From	n Human, Animal, and Food/Environmental/Medical Devices/Biologics		
Acceptable Sample/ Specimen Type for Testing			
Minimum Volume Require	Not Applicable		
Storage & Preservation o Specimen Prior to Shipping	f No Specific Requirements g		
Transport Mediun	n 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 Labelin	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.		
Requirement	s Ship at ambient temperature in compliance with Federal and local guidelines.		
Methodolog	y Phenotypic Identification, Genetic Identification		
Turnaround Time	e 8 Weeks		
Interferences & Limitation	s 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 Contac	t Cheryl Tarr (404) 639–2011 crt6@cdc.gov Monica Santovenia (404) 718–1446 ixi9@cdc.gov		

January 9, 2019 Version: 1.4 Page 360 of 364

### Yersinia pestis Culture and Identification

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Synonym(s)			
Pre-Approval Needed	None		
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.		
Supplemental Form	None		
Performed on Specimens From	Human, Animal, and Food/Environmental/Medical Devices/Biologics		
	Human: lymph node aspirate, sputum, bronchial/tracheal wash, pleural fluid, blood, blood culture bottles, biopsy/autopsy tissues (sections of lymph node, lung, liver, spleen, bone marrow)		
	Animal: necropsy tissues (lymph node, lung, liver, spleen, bone marrow)		
	Environmental: fleas		
Minimum Volume Required	Not Applicable		
	Refrigerate specimens containing suspected live bacteria to maintain viability. If processing is delayed, tissue samples can be directly frozen, preferably at -70°C. Anticoagulants such as heparin, citrate and EDTA are acceptable because they do not inhibit the viability of bacteria.		
Transport Medium	Transport respiratory specimens, aspirates and tissues in a sterile container. Original blood tubes and blood culture bottles are acceptable. If swabs are utilized for transport, Cary-Blair is recommended		
Specimen Labeling	Test subject to CLIA regulations and requires two patient identifiers on the specimen container and the test requisition. Commonly used identifiers are the first and last name and date of birth of the patient.		
Shipping Instructions which Include Specimen Handling Requirements	Ship Monday-Thursday, overnight to avoid weekend deliveries. All packages must be addressed to:		
·	Centers for Disease Control and Prevention		
	Bacterial Diseases Branch Attn: John Young		
	3156 Rampart Road Fort Collins, CO 80521		
	Frozen specimen should be shipped on dry ice Refrigerated specimen should be shipped on ice packs		
Methodology	Culture, Direct Fluorescent Antibody (DFA), Bacteriophage Lysis		
Turnaround Time	3 Weeks		
Interferences & Limitations	Samples for testing by culture should be taken prior to antibiotic treatment		
Additional Information	None		
CDC Points of Contact	Jeannine Petersen (970) 266–3524 nzp0@cdc.gov Luke Kingry (970) 266–3567		
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January 9, 2019 Version: 1.1 Page 361 of 364

### Yersinia pestis Culture and Identification CDC-10418

vtx8@cdc.gov

January 9, 2019 Version: 1.1 Page 362 of 364

#### Yersinia pestis Serology

CDC-10419

Synonym(s)	Plague	
Pre-Approval Needed	None	
	In addition to the specimen type and origin, it is required to include the submitting agency, address, contact name, phone number and email address patient name or unique patient identifier; sex and age or date of birth of the patient; tests to be performed and collection date.	
Supplemental Form	None	
Performed on Specimens From	Human and Animal	
Acceptable Sample/ Specimen Type for Testing		
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	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	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	
	Passive Hemagglutination, Passive Hemagglutination Inhibition	
Turnaround Time		
	Hemolyzed samples may interfere with test results	
Additional Information		
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov	

January 9, 2019 Version: 1.1 Page 363 of 364

#### Yersinia pestis Special Study

CDC-10420

Synonym(s)	None
Pre-Approval Needed	Petersen, Jeannine, (970) 266–3524, nzp0@cdc.gov Kingry, Luke, (970) 266–3567, vtx8@cdc.gov
Supplemental Information Required	None
Supplemental Form	None
Performed on Specimens From	Human and Animal
Acceptable Sample/ Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Storage & Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	To be determined
Shipping Instructions which Include Specimen Handling Requirements	To be determined
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Luke Kingry (970) 266-3567 vtx8@cdc.gov

January 9, 2019 Version: 1.2 Page 364 of 364