2025

CDC

INFECTIOUS DISEASES LABORATORY TEST DIRECTORY

2025, Version 40.0

This document was created under National Center for Emerging and Zoonotic Diseases / Office of Infectious Diseases (NCEZID/OD). The printed version of CDC's Infectious Diseases Laboratory Test Directory contains information that is current as of July 23, 2025. All information contained herein is subject to change.

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

Test Order
Acanthamoeba Molecular Detection- CLIA
CDC-10471

Synonym(s)	Free-living ameba, parasite, *Acanthamoeba*, granulomatous amebic encephalitis (GAE), keratitis
CDC Pre-Approval Needed	**Julia Haston** **(404)-718-1230** **qdx2@cdc.gov** **Ibne Ali** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis, prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**Not Applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For suspected cases of granulomatous amebic encephalitis (GAE) due to *Acanthamoeba* species by *Acanthamoeba* molecular detection, brain tissue is the preferred specimen type; however, these amebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of *Acanthamoeba* keratitis (AK), deep corneal scraping is an acceptable specimen. For suspected cases of *Acanthamoeba* skin lesion, skin tissue is an acceptable specimen.
Minimum Volume Required	0.2 g tissue; 1 mL fluids; 5 mm corneal scraping
Collection, Storage, and Preservation of Specimen Prior to Shipping	Tissue or corneal scraping (in 0.5x phosphate-buffered saline (PBS)), or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days or frozen (-20°C or lower, in absence of PBS buffer), for up to 60 days.
Transport Medium	Small piece of tissue or corneal scraping should be transported in small amount (e.g., 1 mL) of 0.5x phosphate-buffered saline (PBS) to prevent dryness.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Additionally, CSF is NOT the preferred specimen type for *Acanthamoeba* or *Balamuthia* detection, because a negative CSF test result does not completely rule out infections with these amebae. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404)-718-1230 qdx2@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov
Version	3.1

Test Order
Acanthamoeba Molecular Detection- Non-CLIA
CDC-10611

Synonym(s)	Free-living ameba, parasite, Acanthamoeba, granulomatous amebic encephalitis (GAE), keratitis
CDC Pre-Approval Needed	**Julia Haston** **(404) 718-1230** **qdx2@cdc.gov** **Ali Ibne** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis, prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	For suspected cases of granulomatous amebic encephalitis (GAE) due to Acanthamoeba species by Acanthamoeba molecular detection, brain tissue is the preferred specimen type; however, these amebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of Acanthamoeba keratitis (AK), deep corneal scraping is an acceptable specimen. For suspected cases of Acanthamoeba skin lesion, skin tissue is an acceptable specimen.
Minimum Volume Required	0.2 g tissue; 1 mL fluids; 5 mm corneal scraping
Collection, Storage, and Preservation of Specimen Prior to Shipping	Tissue or corneal scraping (in 0.5x phosphate-buffered saline (PBS)), or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days or frozen (-20°C or lower, in absence of PBS buffer), for up to 60 days.
Transport Medium	Small piece of tissue or corneal scraping should be transported in small amount (e.g., 1 mL) of 0.5x phosphate-buffered saline (PBS) to prevent dryness.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	30 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Additionally, CSF is NOT the preferred specimen type for Acanthamoeba or Balamuthia detection, because a negative CSF test result does not completely rule out infections with these amebae. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404) 718-1230 qdx2@cdc.gov Ali Ibne (404) 718-4157 xzn5@cdc.gov
Version	2.0

Test Order
Adenovirus Molecular Detection- CLIA
CDC-10401

Synonym(s)	Human adenovirus, HAdV
CDC Pre-Approval Needed	**David Lowe** **(404) 718-6814** **nqu9@cdc.gov** **Lijuan Wang** **(404) 639-4384** **ynx2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swab (NP) in viral transport media (VTM), oropharyngeal swab (OP) in VTM, combined NP/OP in VTM, nasal aspirate, nasal wash, nasopharyngeal aspirate, bronchial wash, sputum, bronchoalveolar lavage (BAL), tracheal aspirate (TA), plasma, serum, blood, tissue, eye swab in VTM, and urine.
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be collected as soon as possible in the course of the illness and within 72 hours of symptom onset, prior to treatment, if possible. Prior to shipment, specimens can be stored refrigerated at 2-8°C for up to 7 days after collection; specimens stored for longer than 7 days should be stored frozen at -20°C or lower for up to 2 months. Liquid specimens should be aliquoted into properly labeled, leak-proof, unbreakable screw cap vials.
Transport Medium	Viral transport medium (VTM) should be used with specimen types: nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), and eye swabs.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen, overnight on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 84 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests. Whole blood or plasma specimens should be collected in a purple top EDTA tube or a yellow top Acid Citrate Dextrose (ACD) tube. Other acceptable collection tubes include pearl top Plasma Preparation Tube (PPT) and tiger top serum separator tube (SST). Heparin tubes are not recommended for molecular testing as heparin can interfere with PCR reactions.
Additional Information	None
CDC Points of Contact	Lijuan Wang (404) 639-4384 ynx2@cdc.gov Stacey Gonder (404) 639-8739 urv6@cdc.gov David Lowe (404) 718-6814 nqu9@cdc.gov
Version	3.9

Test Order
Adenovirus Molecular Detection- Non-CLIA
CDC-10581

Synonym(s)	Human adenovirus, HAdV
CDC Pre-Approval Needed	**David Lowe** **(404) 718-6814** **nqu9@cdc.gov** **Lijuan Wang** **(404) 639-4384** **ynx2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swab (NP) in viral transport media (VTM), oropharyngeal swab (OP) in VTM, combined NP/OP in VTM, nasal aspirate, nasal wash, nasopharyngeal aspirate, bronchial wash, sputum, bronchoalveolar lavage (BAL), tracheal aspirate (TA), plasma, serum, blood, tissue, eye swab in VTM, and urine.
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be collected as soon as possible in the course of the illness and within 72 hours of symptom onset, prior to treatment, if possible. Prior to shipment, specimens can be stored refrigerated at 2-8°C for up to 7 days after collection; specimens stored for longer than 7 days should be stored frozen at -20°C or lower for up to 2 months. Liquid specimens should be aliquoted into properly labeled, leak-proof, unbreakable screw cap vials.
Transport Medium	Viral transport medium (VTM) should be used with specimen types: nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), and eye swabs.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen, overnight on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 84 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests. Whole blood or plasma specimens should be collected in a purple top EDTA tube or a yellow top Acid Citrate Dextrose (ACD) tube. Other acceptable collection tubes include pearl top Plasma Preparation Tube (PPT) and tiger top serum separator tube (SST). Heparin tubes are not recommended for molecular testing as heparin can interfere with PCR reactions.
Additional Information	None
CDC Points of Contact	Lijuan Wang (404) 639-4384 ynx2@cdc.gov Stacey Gonder (404) 639-8739 urv6@cdc.gov
Version	2.0

Test Order
Aerobic Actinomycetes - Identification and Antimicrobial Susceptibility Testing- CLIA CDC-10149

Synonym(s)	Nocardia, Tsukamurella, Gordonia, Rhodococcus, Streptomyces, Actinomadura
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please provide as much information as possible on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Antimicrobial Susceptibility Testing by broth microdilution, Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	John McQuiston (404) 639-0270 zje8@cdc.gov Melissa Bell (404) 639-1348 jqv7@cdc.gov
Version	2.2

Test Order
Aerobic Actinomycetes - Identification- CLIA
CDC-10148

Synonym(s)	Nocardia, Streptomyces, Tsukamurella, Gordonia, Rhodococcus, Williamsia, Dietzia, Nocardiopsis, Actinomadura, Pseudonocardia, Dermatophilus, Kroppenstedtia, and other related genera
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.3

Test Order
Alkhurma Hemorrhagic Fever Testing- Non-CLIA
CDC-10274

Synonym(s)	AHFV
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.4

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

Synonym(s)	Free-living ameba, *Acanthamoeba*, *Balamuthia*, *Naegleria fowleri*, primary amebic meningoencephalitis (PAM), granulomatous amebic encephalitis (GAE), *Acanthamoeba* keratitis (AK), brain-eating ameba
CDC Pre-Approval Needed	**Julia Haston** **(404)-718-1230** **qdx2@cdc.gov** **Ibne Ali** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**Not Applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Fresh, unfixed tissue, cerebrospinal fluid (CSF), biopsy specimen, and deep corneal scrapings.
Minimum Volume Required	<0.2 mL fluids (preferred 1 mL); 0.1 g tissue (preferred 0.2 g); 5-10 mm corneal scraping.
Collection, Storage, and Preservation of Specimen Prior to Shipping	CSF and fresh, unfixed tissue, and corneal scraping should be kept and shipped at (a) refrigerated temperature (2-8°C) within 7 days, or (b) frozen (-20°C or lower, in absence of PBS buffer) within 60 days.
Transport Medium	For deep scraping and brain or skin biopsy materials, transport in a small volume of 0.5x phosphate-buffered saline (PBS) to prevent dryness for refrigerated temperature shipment with ice-packs. However, addition of 0.5x PBS is not needed if specimen is stored and shipped frozen Unfixed deep corneal scraping and brain or skin biopsy materials for identification of free-living ameba are usually very small and may dry if they are not stored in proper fluid such as 0.5x PBS. However, frozen tissue can be shipped frozen on dry-ice without adding 0.5x PBS.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR).
Turnaround Time	7 Days
Interferences & Limitations	For molecular detection, CSF is the preferred specimen type for *N. fowleri* only, and it is NOT the preferred specimen type for *Acanthamoeba* or *Balamuthia* detection. A negative CSF test result does not completely rule out infection with *Acanthamoeba* or *Balamuthia*. Fresh or frozen (unfixed) tissue specimens are preferred for *Balamuthia* or *Acanthamoeba* detection. Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404)-718-1230 qdx2@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov If calling outside of regular please call the CDC Emergency (770) 488-7100
Version	2.8

Test Order
Ameba Identification (Acanthamoeba, Balamuthia, Naegleria)- Non-CLIA
CDC-10613

Synonym(s)	Free-living ameba, Acanthamoeba, Balamuthia, Naegleria fowleri, primary amebic meningoencephalitis (PAM), granulomatous amebic encephalitis (GAE), Acanthamoeba keratitis (AK), brain-eating ameba
CDC Pre-Approval Needed	**Julia Haston** **(404) 718-1230** **qdx2@cdc.gov** **Ali Ibne** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Fresh, unfixed tissue, cerebrospinal fluid (CSF), biopsy specimen, and deep corneal scrapings
Minimum Volume Required	<0.2 mL fluids (preferred 1 mL); 0.1 g tissue (preferred 0.2 g); 5-10 mm corneal scraping.
Collection, Storage, and Preservation of Specimen Prior to Shipping	CSF and fresh, unfixed tissue, and corneal scraping should be kept and shipped at (a) refrigerated temperature (2-8°C) within 7 days, or (b) frozen (-20°C or lower, in absence of PBS buffer) within 60 days.
Transport Medium	For deep scraping and brain or skin biopsy materials, transport in a small volume of 0.5x phosphate-buffered saline (PBS) to prevent dryness for refrigerated temperature shipment with icepacks. However, addition of 0.5x PBS is not needed if specimen is stored and shipped frozen.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	30 Days
Interferences & Limitations	For molecular detection, CSF is the preferred specimen type for N. fowleri only, and it is NOT the preferred specimen type for Acanthamoeba or Balamuthia detection. A negative CSF test result does not completely rule out infection with Acanthamoeba or Balamuthia. Fresh or frozen (unfixed) tissue specimens are preferred for Balamuthia or Acanthamoeba detection. Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404) 718-1230 qdx2@cdc.gov Ali Ibne (404) 718-4157 xzn5@cdc.gov
Version	2.0

Test Order
Anaplasma Molecular Detection- CLIA
CDC-10290

Synonym(s)	Human granulocytic anaplasmosis (HGA), Anaplasma phagocytophilum anaplasmosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute whole blood. Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): EDTA-treated, or ACD A treated. Acute serum Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): Serum separator tube, or cryo-tubes. Tissue must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): sterile specimen container in saline-moistened gauze.
Minimum Volume Required	1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days prior to arriving at CDC, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood, and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For eschar swabs, place the specimen in a dry sterile specimen container without any medium.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad lightly moistened with sterile saline. Do not immerse the sample in saline.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Molecular detection methods have decreasing sensitivity after resolution of the febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures (2-8°C) can interfere with nucleic acid extraction.

Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Molecular testing for other pathogens including *Rickettsia* spp., *Coxiella*, *Orientia*, *and Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov
Version	3.1

Test Order
Anaplasma Serology- CLIA
CDC-10292

Synonym(s)	Human granulocytic anaplasmosis (HGA), Anaplasma phagocytophilum anaplasmosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of anaplasmosis can only be established by demonstrating a four-fold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including typhus group *Rickettsia*, spotted fever group *Rickettsia*, *Coxiella*, *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Test Order
Angiostrongylus cantonensis Molecular Detection- CLIA
CDC-10472

Synonym(s)	Angiostrongyliasis, Rat lungworm, parasite
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Cerebrospinal fluid (CSF)
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored in sterile leak-proof tubes. Specimens must be stored refrigerated (2-8°C) for up to 7 days or frozen (-20 °C or lower) for up to 30 days after collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped to CDC by same- or next-day courier as etiologic agent. Ship specimens frozen on dry ice. Specimens not meeting these conditions will not be accepted for testing and a new specimen will be required. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks

Interferences & Limitations	Formalin-fixed specimens are not suitable for this test order. Please see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov regarding testing of formalin-fixed specimens.
Additional Information	None
CDC Points of Contact	Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov
Version	2.9

Test Order
Antimicrobial Resistant Bacteria - Colonization Screening- CLIA
CDC-10521

Synonym(s)	point prevalence survey (PPS), carbapenemase-producing organism (CPO) surveillance, processing of surveillance swabs, surveillance screening for antimicrobial resistant (AR) bacteria, Cepheid Xpert Carba-R assay, infection prevention and control (IPC) surveillance
CDC Pre-Approval Needed	**Stephen LaVoie** **(404) 718-4747** **qea5@cdc.gov** **Cynthia Longo** **(404) 718-7568** **own7@cdc.gov**
Supplemental Information Required	**The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information, previous testing results that identify the isolated or suspected microorganism as *Enterobacterales*, *Acinetobacter baumannii* or *Pseudomonas aeruginosa* and demonstrate evidence of carbapenem-non-susceptibility.** **Swab submissions: document the date the swab was collected.** **Pure culture isolate submissions: document the date the submitted culture was inoculated into transport media**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Cepheid Xpert Carba-R assay: rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370) or pure culture isolate of Enterobacterales, *Acinetobacter baumannii* or *Pseudomonas aeruginosa* which are carbapenem non-susceptible. Culture-based methods: rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370) and/or tracheal, axilla, groin or composite axilla/groin swabs on Elution Swab (ESwab) with liquid Amies swab collection and transport system.
Minimum Volume Required	Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping	Rectal swabs on Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370): store at room temperature (15-25 °C) and ship within 24 hours of collection. Do not refrigerate or freeze. Non-rectal swabs on Elution Swab (ESwab) with liquid Amies swab collection and transport system should be stored and shipped in accordance with the manufacturer's instructions for use. Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability and to avoid loss of antimicrobial resistance mechanisms.
Transport Medium	Transport rectal swabs using Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370). Transport non-rectal swabs using elution swab (ESwab) with liquid Amies swab collection and transport system. Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Transport frozen (-20 °C or lower) submissions in trypticase soy broth (TSB) plus 15% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Rectal swabs (Copan Dual-Swab Collection and Transport System (Cepheid catalog #900-0370): ship at room-temperature with room-temperature cold packs within 24 hours of swab collection to arrive at CDC overnight. Do not refrigerate or freeze swab specimens. Non-rectal swabs (Elution Swab (ESwab) with liquid Amies swab collection and transport system): ship refrigerated with refrigerated or frozen cold packs or at room-temperature with room-temperature cold packs within 24 hours of swab collection to arrive at CDC overnight. Do not freeze swab specimens. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	**Cepheid Carba-R Assay:** real-time polymerase chain reaction (PCR)-based detection of blaKPC, blaNDM, blaVIM, blaOXA-48-like, and blaIMP genes. **Culture-based method**: broth enrichment and subsequent characterization by phenotypic testing, polymerase chain reaction (PCR)-based detection of carbapenemase genes, and organism identification by matrix-assisted laser desorption ionization – time of flight mass spectrometry (MALDI-ToF MS).
Turnaround Time	5 Days
Interferences & Limitations	Cepheid Carba-R assay: interfering substances include barium sulfate at >0.1% w/v, Pepto-Bismol at >0.01% w/v; or fecal fat at 0.25% w/v (for blaVIM detection). Level of detection (LOD) of targets for Cepheid system (per package insert) ranged from 74-815 cfu/swab (specificity reported as 100%). If more than one PCR target is present in the sample, one target may not be detected. Pure culture isolates must be viable for testing.

Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Prior epidemiologic consultation with CDC/DHQP Prevention and Response Branch (haioutbreak@cdc.gov) is also required. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed. **Note: Turnaround times differ by methodology** Cepheid Carba-R Assay: 5 days Culture-based method: 3 weeks
CDC Points of Contact	Stephen LaVoie (404) 718-4747 qea5@cdc.gov Cynthia Longo (404) 718-7568 own7@cdc.gov
Version	3.2

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

Synonym(s)	Antimicrobial Susceptibility Testing (AST), sensitivity, resistance, Minimum Inhibitory Concentration (MIC) testing
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, previous results and testing method, as well as the date the submitted culture was inoculated onto transport media.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of bacteria demonstrating unusual resistance or unusual isolates on which the submitter cannot perform susceptibility testing.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability and to avoid loss of antimicrobial resistance mechanisms.
Transport Medium	Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Transport frozen (-20 °C or lower) submissions in trypticase soy broth (TSB) plus 15% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship submissions overnight. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	broth microdilution (BMD), disk diffusion, molecular detection of antimicrobial resistance markers, additional phenotypic testing
Turnaround Time	3 Weeks
Interferences & Limitations	Pure culture isolates must be viable for testing. It is recommended that *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* be stored at room temperature (15-25 °C) to ensure isolate viability.
Additional Information	If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
CDC Points of Contact	Stephen LaVoie (404) 718-4747 qea5@cdc.gov Cynthia Longo (404) 718-7568 own7@cdc.gov
Version	3.5

Test Order
Arbovirus Molecular Detection- CLIA
CDC-10280

Synonym(s)	Arbovirus, RT-PCR, Colorado tick fever virus (CTFV), Oropouche virus (OROV)
CDC Pre-Approval Needed	**Amanda Panella** **(970) 225-4237** **ahf6@cdc.gov** **Holly Hughes** **(970) 266-3536** **ltr8@cdc.gov**
Supplemental Information Required	**Onset date, specimen collected date, brief clinical summary, suspected agent, travel dates, and travel location(s). Please provide dengue testing results for OROV RT-PCR requests.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum and cerebrospinal fluid (CSF) must be acute (0-7 days post onset date) for OROV RT-PCR. For CTFV RT-PCR, acute serum samples only (0-14 days post onset date) will be acceptable.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect blood in a serum-separator tube and separate the serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal. Promptly refrigerate (2-8°C) or freeze (-20°C or lower) serum specimen. For CSF, collect each specimen in a clean, dry, leak-proof container and immediately refrigerate (2-8°C) or freeze (-20°C or lower) specimen. Specimen may be stored at refrigerated temperature (2-8°C) for up to 30 days and frozen (-20°C or lower) for up to 90 days post-collection. If serum or CSF is not shipped to CDC within ≤ 2 weeks of collection, storing and shipping specimen frozen (-20°C or lower) is preferred. Specimen must not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be submitted to CDC through state health departments and not submitted directly to CDC. Ship frozen specimens on dry ice. Ship refrigerated specimens with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Reverse transcriptase (RT)-Polymerase Chain Reaction (PCR); real-time RT-PCR (rRT-PCR)
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolysis can affect the test results.
Additional Information	RT-PCR testing currently offline for most arboviruses (except OROV and CTFV). Testing is available commercially and/or through Wadsworth Center Virology NYS Department of Health. Please contact CDC for assistance if needed. For additional information regarding the fields above, please see this link: "http://www.cdc.gov/vector-borne-diseases/php/laboratories/submitting-arboviral-specimens.html" Turnaround Time: Molecular testing is typically performed once a week but will take longer to have results interpreted and reported to state health department.
CDC Points of Contact	Amanda Panella (970) 225-4237 ahf6@cdc.gov Holly Hughes (970) 266-3536 ltr8@cdc.gov

Test Order
Arbovirus Neutralization Antibody- CLIA
CDC-10283

Synonym(s)	Arbovirus, Arbo plaque reduction neutralization test (PRNT), Chikungunya virus (CHIKV), Dengue virus (DENV), Eastern equine encephalitis virus (EEEV), Jamestown Canyon virus (JCV), Japanese encephalitis virus (JEV), La Crosse virus (LACV), Oropouche virus (OROV), Powassan virus (POWV), St. Louis encephalitis virus (SLEV), West Nile virus (WNV), Yellow fever virus (YFV), Zika virus (ZIKV)
CDC Pre-Approval Needed	**Amanda Panella** **(970) 225-4237** **ahf6@cdc.gov** **Holly Hughes** **(970) 266-3536** **ltr8@cdc.gov**
Supplemental Information Required	**Onset date, specimen collected date, brief clinical summary, suspected agent, travel dates, travel location(s), and IgM test results for requested virus**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	**Serum** and **cerebrospinal fluid (CSF)** are acceptable sample types for WNV, EEEV, SLEV, POWV, JCV and LACV PRNTs. **Only serum** is acceptable for OROV, CHIKV, JEV, YFV, ZIKV, and DENV PRNTs.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect blood in a serum-separator tube and separate the serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal. Promptly refrigerate (2-8 °C) or freeze (-20 °C or lower) serum specimen. For CSF, collect each specimen in a clean, dry, leak-proof container and immediately refrigerate (2-8 °C) or freeze (-20 °C or lower) specimen. Specimen may be stored at refrigerated temperature (2-8°C) for up to 120 days and frozen (-20°C or lower) for up to 1 year post-collection. Specimen must not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC. Ship frozen specimens on dry ice. Ship refrigerated specimens with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Plaque reduction neutralization test (PRNT)
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolysis can cause non-specific binding in serological tests and can have an effect on laboratory results.
Additional Information	PRNT testing is currently offline for many arboviruses (unless listed above in the test order synonym). Diagnostic testing is available through Wadsworth Center Virology NYS Department of Health. Please contact CDC for assistance if needed. For additional information regarding the fields above, please see this link: https://www.cdc.gov/vector-borne-diseases/php/laboratories/submitting-arboviral-specimens.html.
CDC Points of Contact	Amanda Panella (970) 225-4237 ahf6@cdc.gov Holly Hughes (970) 266-3536 ltr8@cdc.gov
Version	2.7

Test Order
Arbovirus Serology- CLIA
CDC-10282

Synonym(s)	Arbovirus, Arbo serology, Arbovirus immunoglobulin M (IgM), Eastern equine encephalitis virus (EEEV), Jamestown Canyon virus (JCV), La Crosse virus (LACV), Powassan virus (POWV), St. Louis encephalitis virus (SLEV), West Nile virus (WNV), Yellow fever virus (YFV), Zika virus (ZIKV)
CDC Pre-Approval Needed	**Amanda Panella** **(970) 225-4237** **ahf6@cdc.gov** **Holly Hughes** **(970) 266-3536** **ltr8@cdc.gov**
Supplemental Information Required	**Onset date, specimen collected date, brief clinical summary, suspected agent, travel dates, and travel location(s)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	**Serum and cerebrospinal fluid (CSF)** are acceptable sample types for WNV, EEEV, SLEV, POWV, JCV and LACV IgM testing. **Only serum** is acceptable for YFV IgM testing.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect blood in a serum-separator tube and separate the serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o-ring seal. Promptly refrigerate (2-8°C) or freeze (-20°C or lower) serum specimen. For CSF, collect each specimen in a clean, dry, leak-proof container and immediately refrigerate (2-8°C) or freeze (-20°C or lower) specimen. Specimen may be stored at refrigerated temperature (2-8°C) for up to 120 days and frozen (-20°C or lower) for up to 1 year post-collection. Specimen must not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be submitted to CDC through state health departments and NOT submitted directly to CDC. Ship frozen specimens on dry ice. Ship refrigerated specimens with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Arbovirus Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Enzyme-linked immunosorbent assay (ELISA) immunoglobulin (Ig) M, Microsphere immunoassay (MIA) IgM
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolysis can cause non-specific binding in serological tests and can have an effect on laboratory results.
Additional Information	IgM serology testing currently offline for many arboviruses (unless listed above in test order synonym). Diagnostic testing is available commercially and/or through Wadsworth Center Virology NYS Department of Health. Please contact CDC for assistance if needed. For additional information regarding the fields above, please see this link: https://www.cdc.gov/vector-borne-diseases/php/laboratories/submitting-arboviral-specimens.html Turnaround time is impacted by whether the specimen tests positive for immunoglobulin (Ig) M antibodies, IgM positive samples may have plaque reduction neutralization tests performed (see CDC-10283 Arbovirus Neutralization Antibodies).
CDC Points of Contact	Amanda Panella (970) 225-4237 ahf6@cdc.gov Holly Hughes (970) 266-3536 ltr8@cdc.gov

Test Order
Arenavirus (New World) Testing- Non-CLIA
CDC-10293

Synonym(s)	New World *Arenavirus,* South American hemorrhagic fever viruses
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.4

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

Synonym(s)	Anthrax PCR
CDC Pre-Approval Needed	**Zoonoses and Select Agent Laboratory ZSAL** **(404) 639-1711** **zsal@cdc.gov** **Bacterial Special Pathogens Branch CDC** **(770) 488-7100** **bzb@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood, serum, cerebral spinal fluid (CSF)
Minimum Volume Required	0.10 mL (prefer 0.5-1.0 mL)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens may be stored at 2-8°C for up to 14 days post-collection and -20°C or lower for up to 28 days and not to exceed 3 freeze/thaw cycles.
Transport Medium	Dependent on specimen type submitted. For more information, reference the Additional Information field.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Varies depending on tests used. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin).

Additional Information	Turnaround time will vary depending on methods selected for detection at CDC. Some methods may require up to 2 weeks. Information on specimens, storage, and shipping can be found at: http://www.cdc.gov/anthrax/labs/recommended_specimen.html Pre-approval required from state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at 770-488-7100 Call: 770-488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at 770-488-7100 Call: 770-488-7100 for additional guidance. Study or research samples should be submitted under test code CDC-10205, *Bacillus anthracis* Study
CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Chung Marston (404) 639-4057 cdk5@cdc.gov Zachary Weiner (404) 639-0507 xxd7@cdc.gov
Version	3.5

Test Order
Bacillus anthracis Identification- CLIA
CDC-10203

Synonym(s)	Anthrax, Anthrax Gamma phage, Anthrax PCR, Anthrax typing
CDC Pre-Approval Needed	**Zoonoses and Select Agent Laboratory ZSAL** **(404) 639-1711** **zsal@cdc.gov** **Bacterial Special Pathogens Branch CDC** **(770) 488-7100** **bzb@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).** **https://www.selectagents.gov/forms.html**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	*B. anthracis* isolates
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates should be kept at room temperature (15-25°C) prior to shipping.
Transport Medium	Agar slants preferred for isolates.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Isolates should be shipped at room temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state, and federal regulations.
Methodology	Polymerase chain reaction (PCR), gamma phage, capsule staining

Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Pre-approval required from state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at 770-488-7100 Call: 770-488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at 770-488-7100 Call: 770-488-7100 for additional guidance. Study or research samples should be submitted under test code CDC-10205, *Bacillus anthracis* Study.
CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Chung Marston (404) 639-4057 cdk5@cdc.gov Cari Kolton (404) 639-2065 fts3@cdc.gov
Version	3.5

Test Order
Bacillus anthracis Lethal Factor Detection (Qualitative)- CLIA
CDC-10568

Synonym(s)	InBios Active Anthrax Detect (AAD) Plus Rapid Test
CDC Pre-Approval Needed	**ZSAL Zoonoses and Select Agent Laboratory** **(404) 639-1711** **zsal@cdc.gov** **CDC Bacterial Special Pathogens Branch** **(770) 488-7100** **bzb@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form:** **• History of present illness** **• Exposure history** **• Travel history** **• Past medical history** **• Treatment history** **• Preliminary results**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	serum; whole blood
Minimum Volume Required	0.10 mL; 0.5-1.0 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at 15-30°C for up to 8 hours post collection, 2-8°C for up to 7 days post collection, or -20°C or lower for up to 2 months post collection and not to exceed 5 freeze/thaw cycles. Whole blood may be stored at 15-30°C for up to 8 hours post collection or 2-8°C for up to 24 hours. Whole blood should not be frozen.
Transport Medium	Ship serum frozen with dry ice. Ship whole blood refrigerated with refrigerated or frozen ice packs.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	None
Methodology	Lateral flow
Turnaround Time	5 Days
Interferences & Limitations	This test is indicated for diagnosis of suspect inhalation anthrax (i.e., presumptively diagnostic for *Bacillus anthracis* infection) from individuals who have signs and symptoms consistent with inhalation anthrax and a likelihood of exposure. The definitive identification of *B. anthracis* from samples requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

Additional Information	Turnaround time will vary depending on methods selected for detection at CDC. Some methods may require up to 2 weeks. Information on specimens, storage, and shipping can be found at: http://www.cdc.gov/anthrax/labs/recommended_specimen.html. Pre-approval is required from the state/territorial health department or laboratory. If you are a state or local health department, please contact the CDC Emergency Operations Center at (770) 488-7100 for additional guidance. If you are an LRN laboratory, please follow the LRN protocol or contact the CDC Emergency Operations Center at (770) 488-7100 for additional guidance. Study or research samples should be submitted under test code CDC-10205, *Bacillus anthracis* Study.
CDC Points of Contact	ZSAL Zoonoses and Select Agent Laboratory (404) 639-1711 zsal@cdc.gov Zachary Weiner (404) 639-0507 xxd7@cdc.gov
Version	2.0

Test Order
Bacillus anthracis Study- Non-CLIA
CDC-10205

Synonym(s)	
CDC Pre-Approval Needed	**Zachary Weiner** **(404) 639-0507** **xxd7@cdc.gov** **Chung Marston** **(404) 639-4057** **cdk5@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/forms.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state, and federal regulations
Methodology	
Turnaround Time	
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	To be determined
CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Chung Marston (404) 639-4057 cdk5@cdc.gov
Version	2.2

Test Order
Bacillus cereus Genotyping- Non-CLIA
CDC-10206

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

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

Version	2.3

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

Synonym(s)	Gram-positive bacilli
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, 16S sequence based identification, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

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

Synonym(s)	Bacterial Identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
Balamuthia Molecular Detection- CLIA
CDC-10474

Synonym(s)	Free-living ameba, parasite, granulomatous amebic encephalitis (GAE), *B. mandrillaris*
CDC Pre-Approval Needed	**Julia Haston** **(404)-718-1230** **qdx2@cdc.gov** **Ibne Ali** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**Not Applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For suspected cases of granulomatous amebic encephalitis (GAE) due to *Balamuthia mandrillaris* detected by *Balamuthia* molecular detection, brain tissue is the preferred specimen type; however, these amebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of *Balamuthia* skin lesion, skin tissue is an acceptable specimen.
Minimum Volume Required	0.2 g tissue; 1 mL fluids
Collection, Storage, and Preservation of Specimen Prior to Shipping	Tissue (in 0.5x PBS) or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower, in absence of PBS buffer) for up to 60 days.
Transport Medium	Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Additionally, CSF is NOT the preferred specimen type for *Acanthamoeba* or *Balamuthia* detection, because a negative CSF test result does not completely rule out infections with these amebae. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404)-718-1230 qdx2@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov
Version	3.0

Test Order
Balamuthia Molecular Detection- Non-CLIA
CDC-10612

Synonym(s)	Free-living ameba, parasite, granulomatous amebic encephalitis (GAE), B. mandrillaris
CDC Pre-Approval Needed	**Julia Haston** **(404) 718-1230** **qdx2@cdc.gov** **Ali Ibne** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	For suspected cases of granulomatous amebic encephalitis (GAE) due to Acanthamoeba species by Acanthamoeba molecular detection, brain tissue is the preferred specimen type; however, these amebae can occasionally be detected in cerebrospinal fluid (CSF; see 'Interference & Limitations' below). For suspected cases of Acanthamoeba keratitis (AK), deep corneal scraping is an acceptable specimen. For suspected cases of Acanthamoeba skin lesion, skin tissue is an acceptable specimen.
Minimum Volume Required	0.2 g tissue; 1 mL fluids
Collection, Storage, and Preservation of Specimen Prior to Shipping	Tissue (in 0.5x PBS) or CSF should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower, in absence of PBS buffer) for up to 60 days.
Transport Medium	Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should only be sent with dry ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	30 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Additionally, CSF is NOT the preferred specimen type for Acanthamoeba or Balamuthia detection, because a negative CSF test result does not completely rule out infections with these amebae. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404) 718-1230 qdx2@cdc.gov Ali Ibne (404) 718-4157 xzn5@cdc.gov
Version	2.0

Test Order
Bartonella Special Study- Non-CLIA
CDC-10297

Synonym(s)	*B. henselae*, *B. quintana*
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.

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

Version	0.0

Test Order
Baylisascariasis Serology- CLIA
CDC-10457

Synonym(s)	Baylisascariasis, Raccoon roundworm, parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors (raccoon) clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum; cerebrospinal fluid (CSF) when paired with serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and CSF for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum and CSF can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera and CSF specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Known interfering substances: hemolysis, hyperlipemia or other causes of turbidity may cause erroneous results.

Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	5.0

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

Synonym(s)	BRAI, Recency assay
CDC Pre-Approval Needed	**Jeff Johnson** **(404) 639-4976** **jlj6@cdc.gov** **Bill Switzer** **(404) 639-0219** **bis3@cdc.gov**
Supplemental Information Required	**Additional information will be requested after the specimen is approved for testing at CDC.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, plasma or whole blood
Minimum Volume Required	10 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen stability is affected by elevated humidity temperature. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping. Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Plasma can be collected using plasma preparation tubes (PPT) or EDTA or ACD. Serum can be collected in serum tubes. Follow sample tube manufacturer's instructions. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Shipping of specimens the same day of collection is preferred. Shipment of specimens plasma or serum specimens stored at 2-8 °C within 7 days of collection should be sent with cold packs, and frozen specimens sent on dry-ice. For EDTA whole blood, tube must be shipped overnight on the date of collection at ambient temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday (overnight shipping preferred). Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 74 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	2 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimens that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	This test order is Research Use Only (RUO). The results reported should NOT be used for diagnosis, treatment, assessment of health, management of the individual patient nor recorded in patient medical records.
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Jeff Johnson (404) 639-4976 jlj6@cdc.gov
Version	1.0

Test Order
Biodefense R&D Study- CLIA
CDC-10487

Synonym(s)	Biodefense Research and Development Laboratory Study
CDC Pre-Approval Needed	**David Sue** **(404) 639-4027** **btx6@cdc.gov** **Julia Bugrysheva** **(404) 639-4892** **vol5@cdc.gov**
Supplemental Information Required	**For isolates from human specimens, prior approval is required. Consult with the lab for details.** **Select Agent Form 2 required for submission of all confirmed Select Agents. The Form 2 can be found at http://www.selectagents.gov/forms.html**
Supplemental Form	**http://www.selectagents.gov/forms.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates on agar plate or slant, consult with lab for details.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Consult with lab for details
Transport Medium	Pure culture isolates (only) on sheep blood or Mueller-Hinton agar
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Select agents that have been identified need form 2 approval prior to shipping. Form 2 may be found at: http://www.selectagents.gov/forms.html CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 206 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Modified Broth Microdilution

Turnaround Time	2 Days
Interferences & Limitations	Isolates from human specimens may be tested only under Emergency Use Authorization.
Additional Information	Turnaround time can vary depending on age/purity of isolate received
CDC Points of Contact	David Sue (404) 639-4027 btx6@cdc.gov Julia Bugrysheva (404) 639-4892 vol5@cdc.gov
Version	2.5

Test Order
Biofire FilmArray NGDS Warrior Panel- Non-CLIA
CDC-10565

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Human specimens stored refrigerated (2-8°C) must be received within 7 days of specimen collection date. Human specimens stored at room temperature (15-25°C) must be received within 1 day of specimen collection date. Contact the CDC POC for approval prior to sending any specimens.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens must be shipped refrigerated with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Biofire FilmArray NGDS Warrior Panel is used to detect Ebola and Marburg
Turnaround Time	

Interferences & Limitations	None
Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	3.2

Test Order
BioFire Respiratory Panel- Non-CLIA
CDC-10556

Synonym(s)	Respiratory 2.1 Panel
CDC Pre-Approval Needed	**David Lowe** **(404) 718-6814** **nqu9@cdc.gov** **Lijuan Wang** **(404) 639-4384** **ynx2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swab collected in viral transport medium.
Minimum Volume Required	0.3 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	• At room temperature (15 - 25° C) for up to 4 hours • Refrigerated (2 - 8° C) up to 3 days • Frozen (-70 °C or lower preferred) for up to 30 days
Transport Medium	Specimens must be in viral transport medium.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen, overnight on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 84 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	This Respiratory Pathogen PCR Panel is used to detect: Adenovirus, coronavirus (HKU1, NL63, 229E, OC43, SARS-CoV-2), human metapneumovirus, human rhinovirus/enterovirus, influenza A (A, A/H1, A/H3, A/H1-2009), influenza B, parainfluenza (1-4), human respiratory syncytial virus, Bordetella (*Bordetella parapertussis*, *Bordetella pertussis*), *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*
Turnaround Time	2 Weeks
Interferences & Limitations	None
Additional Information	Nasopharyngeal swabs should not be spun down.
CDC Points of Contact	Lijuan Wang (404) 639-4384 ynx2@cdc.gov Stacey Gonder (404) 639-8739 urv6@cdc.gov David Lowe (404) 718-6814 nqu9@cdc.gov
Version	0.1

Test Order
Bordetella pertussis Serology- Non-CLIA
CDC-10166

Synonym(s)	IgG against pertussis toxin, Pertussis ELISA, whooping cough
CDC Pre-Approval Needed	**Lucia Pawloski** **(404) 639-4506** **ecz6@cdc.gov** **Hong Ju** **(404) 639-0571** **lkn0@cdc.gov**
Supplemental Information Required	**Specimens are for research or surveillance testing only. Provide the following limited patient information on the CDC 50.34 Specimen Submission Form: patient age, duration of cough, recent pertussis-containing vaccination status. Do not include Personally Identifiable Information (PII).**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	The following are criteria for serum submission: - Adolescent and adult individuals - Cough of at least 2 weeks, up to 12 weeks - Not vaccinated with a pertussis-containing vaccine in the previous 6 months The age cut-off is designed to exclude children who are still receiving their primary pertussis vaccination series. Vaccination with a pertussis-containing vaccine within 6 months of serology test may confound results. Cough of at least 2 weeks and up to 12 weeks is required for IgG antibody detection in this test.
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood should be collected using a serum separation tube with no additives. Centrifuge the tube of blood at 1100-1300 x g for approximately 10 minutes to separate the cells from the serum. Serum specimens may be stored refrigerated (2-8 °C) for up to 7 days. If greater than 7 days, serum must be kept frozen (-20 °C or colder). For long-term storage, the serum should be frozen (-20 °C or colder).
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Serum specimens may be stored refrigerated and shipped on gel ice-packs if they will be received at CDC within 7 days of collection. Specimens that will not be received at CDC within 7 days of collection should be kept frozen and sent with dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday-Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 12 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number. Sender is responsible for shipping charges. International submitters must request CDC's import permit and include this with the Air Waybill.
Methodology	Enzyme-linked Immunosorbent Assay (ELISA)
Turnaround Time	2 Weeks
Interferences & Limitations	Sera collected from patients with less than 2 weeks or greater than 12 weeks of cough or from patients vaccinated with a pertussis-containing vaccine in the previous 6 months are not appropriate for this test. Sera should not be sent if they have incurred more than 5 freeze-thaw cycles. Sera with preservatives such as anti-coagulants will invalidate results. Hemolyzed and lipemic sera are considered suboptimal for this assay.
Additional Information	None
CDC Points of Contact	Lucia Pawloski (404) 639-4506 ecz6@cdc.gov Hong Ju (404) 639-0571 lkn0@cdc.gov
Version	4.1

Test Order
Bordetella species Study- Non-CLIA
CDC-10167

Synonym(s)	*Bordetella pertussis, B. parapertussis, B. holmesii, B. bronchiseptica,* whooping cough, pertussis
CDC Pre-Approval Needed	**Hong Ju** **(404) 639-0571** **lkn0@cdc.gov** **Lucia Pawloski** **(404) 639-4506** **ecz6@cdc.gov**
Supplemental Information Required	**Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of cough, recent antibiotic history and pertussis-containing vaccine status.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For isolation and/or PCR: Nasopharyngeal swabs or nasopharyngeal aspirates; calcium alginate and cotton swabs are not acceptable. For isolate confirmation: Pure culture isolates or cryopreserved isolates. For PCR only: Extracted DNA.
Minimum Volume Required	0.5 mL nasopharyngeal aspirates; 0.2 mL DNA; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swabs for culture and PCR: Nasopharyngeal swabs should be polyester, rayon or nylon. Swabs should be placed in tubes of Regan-Lowe transport medium and kept refrigerated at 4 °C until shipment. Nasopharyngeal aspirates for culture and PCR: Nasopharyngeal aspirates should be in leak-proof plastic tubes. Aspirates should be kept refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, aspirates should be kept frozen at -20 °C. Swabs for PCR only: Nasopharyngeal swabs should be polyester, rayon or nylon. Swabs should be placed in dry, sterile tubes. Swabs in universal transport medium are also acceptable. All swabs should be kept refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, swabs should be kept frozen at -20 °C. Isolates: Isolates can be frozen at -70 °C in cryopreservation medium or kept refrigerated at 4 °C on Regan-Lowe, Bordet-Gengou, charcoal agar or blood agar (B. parapertussis, B. holmesii, or B. bronchiseptica only) slants. DNA: DNA extracted from nasopharyngeal specimens should be in leak-proof plastic tubes. DNA should be kept frozen at -20 °C.

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

CDC Points of Contact	Hong Ju (404) 639-0571 lkn0@cdc.gov Lucia Pawloski (404) 639-4506 ecz6@cdc.gov

Version	3.2

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

Synonym(s)	*Bordetella* Identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.5

Test Order
Borrelia Molecular Detection - Relapsing Fever- Non-CLIA
CDC-10532

Synonym(s)	Relapsing fever, Tickborne relapsing fever, Borrelia miyamotoi disease, Louse-borne relapsing fever, Borrelia hermsii, Borrelia turicatae, Borrelia miyamotoi, Borrelia recurrentis
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated whole blood is preferred; acute serum or plasma is also acceptable.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separate and aliquot serum and plasma prior to storage and transport. Specimens may be held at refrigerated temperature (2-8°C) for up to 14 days post-collection. Specimens may be held frozen (-20°C or lower) for up to 60 days post-collection or may be held frozen (-70°C or lower) for up to 9 months post-collection. Specimens must not exceed 2 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs and frozen specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Prior antibiotic treatment may reduce sensitivity by decreasing the amount of bacterial DNA present in specimens. Detection in serum or plasma is less sensitive than detection in EDTA-treated whole blood.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Borrelia Serology - Soft Tick Relapsing Fever- Non-CLIA
CDC-10399

Synonym(s)	Relapsing Fever, *Borrelia hermsii*, *Borrelia turicatae*
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separate and aliquot serum prior to storage and transport. Specimens may be held at refrigerated temperature (2-8°C) for up to 14 days and frozen (-20°C or lower) for up to 60 days post-collection. Specimens must not exceed 2 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs and frozen specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by Western Blot

Turnaround Time	3 Weeks
Interferences & Limitations	This test detects IgG seroconversion only. Sensitivity of this test is limited in serum samples collected from patients with < 10 days of illness. Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.
Additional Information	This test is not intended for Borrelia miyamotoi (Borrelia miyamotoi disease, hard tick relapsing fever) serology.
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Borrelia Special Study- Non-CLIA
CDC-10300

Synonym(s)	
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.

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

Version	0.0

Test Order
Botulism Laboratory Confirmation- CLIA
CDC-10132

Synonym(s)	Botulinum toxin, Clostridium botulinum
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**For clinical samples, provide patient name, date of birth, history of present illness, and treatment history, including date of BabyBIG or BAT administration. If not submitting through CSTOR, complete one CDC Specimen Submission Form (50.34) per specimen and include in shipment. Include the following information within the CDC 50.34 Specimen Submission Form: point of contact name, phone number and email address for State Department of Health and Hospital.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Contact CDC POC prior to specimen submission for specimen acceptance, collection, storage and preservation requirements.
Minimum Volume Required	Adult patients: 5 mL serum, 10 g of stool. Infant patients: 10 g of stool. Note: Smaller quantities of stool (up to 0.5 - 1 g) may be tested; if needed, enema can be obtained with sterile non-bacteriostatic water. Minimum volume for serum is 1 mL.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum must be collected before antitoxin treatment. Use tubes with noadditive and no anti-coagulant for serum collection. Collect raw stool in a sterile container. If enema is needed, use sterile non-bacteriostatic water. Refrigerate all specimens promptly after collection. Maintain specimen refrigerated (2-8°C) until shipment. Ship stool specimens to CDC within 2 days of collection. Note: serum can be shipped within 20 days of collection date.
Transport Medium	Submit cultures of suspected botulinum neurotoxin producing species of *Clostridium* in Chopped Meat Glucose Starch broth or Chopped Meat Glucose broth
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated (refrigerated or frozen cold packs). Package must have proper labeling for biological hazards: UN3373 biological substance, Category B. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 26 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Mass Spectrometry (MS)
Turnaround Time	12 Weeks
Interferences & Limitations	N/A
Additional Information	CDC pre-approval is not needed; however, hospitals must obtain approval from their state health department prior to submitting specimens to CDC. Turnaround Time: Preliminary results may be available within 48 hours of specimen receipt.
CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov
Version	3.4

Test Order
Botulism Special Study- Non-CLIA
CDC-10133

Synonym(s)	Botulinum toxin, Clostridium botulinum
CDC Pre-Approval Needed	**Carolina Luquez** **(404) 639-0896** **fry6@cdc.gov** **Janet Dykes** **(404) 639-3625** **jkd1@cdc.gov**
Supplemental Information Required	**For clinical samples, provide patient name, date of birth, history of present illness, and treatment history, including date of BabyBIG or BAT administration. If not submitting through CSTOR, complete one CDC Specimen Submission Form (50.34) per specimen and include in shipment. Include the following information within the CDC 50.34 Specimen Submission Form: point of contact name, phone number and email address for State Department of Health and Hospital.**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf**
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Food, environmental, isolates
Minimum Volume Required	N/A
Collection, Storage, and Preservation of Specimen Prior to Shipping	Foods should be left in their original containers or placed in sterile unbreakable containers. Empty containers with remnants of foods can also be recovered and submitted for testing. Refrigerate all specimens promptly after collection. Maintain specimen refrigerated (2-8°C) until shipment.
Transport Medium	For isolates: Chopped Meat Glucose Starch
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Ship refrigerated specimens (2-8 °C) with cold packs. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 26 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Mouse Bioassay, Mass Spectrometry (MS), Polymerase Chain Reaction (PCR), Whole Genome Sequencing
Turnaround Time	24 Weeks
Interferences & Limitations	To be determined
Additional Information	None
CDC Points of Contact	Carolina Luquez (404) 639-0896 fry6@cdc.gov Janet Dykes (404) 639-3625 jkd1@cdc.gov
Version	3.0

Test Order
Brucella species Identification- CLIA
CDC-10207

Synonym(s)	Brucellosis, Brucella
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results. For select agents please consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Suspected or presumptive *Brucella* Isolates
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates should be kept at room temperature (15-25°C) prior to shipping
Transport Medium	Agar slants preferred for shipping isolates.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Isolates should be shipped at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR), Biochemicals, Phage Susceptibility
Turnaround Time	2 Weeks
Interferences & Limitations	None
Additional Information	Study or research samples should be submitted under test code CDC-10209, *Brucella* species Study.

CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Rebekah Tiller (404) 639-4507 eto3@cdc.gov Elke Saile (404) 639-0716 csx2@cdc.gov David Lonsway (404) 639-2825 dul7@cdc.gov
Version	3.3

Test Order
Brucella species Serology- CLIA
CDC-10197

Synonym(s)	BMAT
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Paired serum samples are preferred (acute: during active stage of illness; convalescent: 2-4 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 14 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Brucella microagglutination test (BMAT)
Turnaround Time	2 Weeks
Interferences & Limitations	Acute and convalescent sera are preferred for confirming diagnosis. Plasma is not an acceptable specimen. Hemolysis can interfere with testing. No serology test is available for *B. canis* or vaccine strain RB51. May have poor sensitivity for chronic or complicated brucellosis.
Additional Information	Study or research samples should be submitted under test code CDC-10209, *Brucella* species Study

CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

Version	1.7

Test Order
Brucella species Study- Non-CLIA
CDC-10209

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined

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

Version	2.5

Test Order
Burkholderia mallei/pseudomallei Identification- CLIA
CDC-10210

Synonym(s)	Glanders, Melioidosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form. For select agents, consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2). https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Suspected or presumptive *Burkholderia mallei/pseudomallei* isolates
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates should be kept at room temperature (15-25°C) prior to shipping.
Transport Medium	Agar slants preferred for isolates
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Isolates should be shipped at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Biochemicals, polymerase chain reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Study or research samples should be submitted under test code CDC-10212, *Burkholderia mallei/pseudomallei* Study.

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

Version	3.5

Test Order
Burkholderia mallei/pseudomallei Study- Non-CLIA
CDC-10212

Synonym(s)	
CDC Pre-Approval Needed	**Zoonoses and Select Agent Laboratory ZSAL** **(404) 639-1711** **zsal@cdc.gov** **Bacterial Special Pathogens Branch CDC** **(770) 488-7100** **bzb@cdc.gov**
Supplemental Information Required	**Please provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form. For select agents please consult for completion of APHIS/CDC FORM 2 (Request to Transfer Select Agents and Toxins).**
Supplemental Form	**Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2).** **https://www.selectagents.gov/resources/APHIS-CDC_Form_2_English_Fillable.pdf**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state, and federal regulations.
Methodology	
Turnaround Time	

Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	To be determined
CDC Points of Contact	Zoonoses and Select Agent Laboratory (ZSAL) (404) 639-1711 ZSAL@cdc.gov Jay Gee (404) 639-4936 xzg4@cdc.gov Mindy Elrod (404) 639-4055 wzg0@cdc.gov
Version	2.3

Test Order
Burkholderia pseudomallei Serology- CLIA
CDC-10198

Synonym(s)	Melioidosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please provide the following information: history of present illness, exposure history, travel history, past medical history, treatment history, preliminary results on the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum (acute: during active stage of illness; convalescent: 2 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 7 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Indirect Hemagglutination (IHA)
Turnaround Time	2 Weeks
Interferences & Limitations	Acute and convalescent are required.
Additional Information	Turnaround time may be longer to account for testing of paired specimens. Processing time may be expedited depending on risk and need. Study or research samples should be submitted under test code CDC-10212, *Burkholderia mallei/pseudomallei* Study

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

Version	2.4

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

Synonym(s)	*Burkholderia* Identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

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

Synonym(s)	*Campylobacter, Helicobacter* species
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Campylobacter*, *Helicobacter*, and related organisms; Sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	*Campylobacter*, *Helicobacter*, and related organisms are sensitive to oxygen and may lose viability quickly. Prior to shipping, organisms should be stored in a microaerobic environment between 37-42°C and subbed every 2-4 days. Storage at 25°C may be optimal for some Campylobacter species. Prepared isolates can also be stored long-term frozen at -70 °C or lower (i.e., more than one month). Shipping conditions that maximize viability include: - Solid agar transport media slants (HIA or chocolate agar, or Wang's transport semisolid media) that should be inoculated with fresh bacterial growth and incubated in a microaerobic environment for 18-24 hours prior to shipment. - Semisolid or liquid transport media (Cary Blair or Amies) that should be inoculated heavily with fresh bacterial growth. - Trypticase soy broth (TSB) supplemented with 20% glycerol with bacterial suspension that has been frozen for at least 18-24 hours prior to shipment and shipped with sufficient dry ice to prevent thawing. Isolates should be prepared for shipment and shipped within 4 hours of preparation. Shipping fresh bacterial growth and shipping quickly help ensure isolate viability upon arrival.
Transport Medium	If isolates are shipped refrigerated, inoculate preferred solid or semisolid/liquid media. If isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol. Preferred solid agar transport media includes heart infusion agar (HIA), Wang's medium, blood agar, Columbia agar, or chocolate agar. Screw cap tubes are preferred. Preferred semisolid or liquid transport media includes modified Cary Blair, or Amies transport medium (with or without charcoal).

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship isolates refrigerated overnight with refrigerated or frozen cold packs ensuring that the specimen tube does not come into direct contact with the cold packs to prevent freezing, or ship frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 18 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic Identification, Genetic Identification
Turnaround Time	13 Weeks
Interferences & Limitations	Specimens that are not shipped overnight or are exposed to temperatures above or below refrigeration temperatures (2-8 °C) may be at risk for reduced/lost viability of the specimen. Frozen specimens (less than or equal to -70 °C) should be shipped with sufficient dry ice to maintain frozen state. Thawed specimens may be at risk for reduced/lost viability.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Charlotte Lane (404) 718-4789 koe7@cdc.gov Yang Gao (404) 718-3404 nrj0@cdc.gov
Version	3.7

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

Synonym(s)	*Campy, Helicobacter* species
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Campylobacter*, *Helicobacter*, and related organisms; Sequence data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Campylobacter, Helicobacter, and related organisms are sensitive to oxygen and may lose viability quickly. Prior to shipping, organisms should be stored in a microaerobic environment between 37-42°C and subbed every 2-4 days. Storage at 25°C may be optimal for some Campylobacter species. Prepared isolates can also be stored long-term frozen at -70 °C or lower (i.e., more than one month). Shipping conditions that maximize viability include: - Solid agar transport media slants (HIA or chocolate agar, or Wang's transport semisolid media) that should be inoculated with fresh bacterial growth and incubated in a microaerobic environment for 18-24 hours prior to shipment. - Semisolid or liquid transport media (Cary Blair or Amies) that should be inoculated heavily with fresh bacterial growth. - Trypticase soy broth (TSB) supplemented with 20% glycerol with bacterial suspension that has been frozen for at least 18-24 hours prior to shipment and shipped with sufficient dry ice to prevent thawing. Isolates should be prepared for shipment and shipped within 4 hours of preparation. Shipping fresh bacterial growth and shipping quickly help ensure isolate viability upon arrival.
Transport Medium	If isolates are shipped refrigerated, inoculate preferred solid or semisolid/liquid media. If isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol. Preferred solid agar transport media includes heart infusion agar (HIA), Wang's medium, blood agar, Columbia agar, or chocolate agar. Screw cap tubes are preferred. Preferred semisolid or liquid transport media includes modified Cary Blair, or Amies transport medium (with or without charcoal).

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship isolates refrigerated overnight with refrigerated or frozen cold packs ensuring that the specimen tube does not come into direct contact with the cold packs to prevent freezing, or ship frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 18 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Antimicrobial susceptibility testing (AST), whole genome sequencing (WGS)
Turnaround Time	13 Weeks
Interferences & Limitations	Specimens that are not shipped overnight or are exposed to temperatures above or below refrigeration temperatures (2-8 °C) may be at risk for reduced/lost viability of the specimen. Frozen specimens (less than or equal to -70 °C) should be shipped with sufficient dry ice to maintain frozen state. Thawed specimens may be at risk for reduced/lost viability.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Charlotte Lane (404) 718-4789 koe7@cdc.gov Yang Gao (404) 718-3404 nrj0@cdc.gov
Version	4.6

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

Synonym(s)	"Microbiology, cell culture, tissue culture, autopsy, pathology"
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Hannah Bullock** **(404) 718-6434** **ocr3@cdc.gov**
Supplemental Information Required	**Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order code** **• Test order name** **• Patient full name** **• Patient birth date** **• Date of death (if applicable)** **• Patient ID (e.g., medical record number or autopsy number)** **• Specimen ID (e.g., surgical pathology accession number)** **• State public health laboratory (PHL) point of contact** **• Original submitter contact information** **One electronically completed copy of the CDC 50.34 Specimen Submission Form per case is sufficient, unless specimens are being submitted from multiple specimen collection dates in one package.** **Requested additional information:** **• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information** **• A copy of: (a) the autopsy report (preliminary or final), or (b) surgical pathology report** **• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)** **• Relevant clinical, gross pathology, or microscopic pathology images, as available** **• A key listing the tissues submitted for evaluation**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal

Acceptable Sample / Specimen Type for Testing	Frozen (un-fixed) autopsy, or necropsy tissues from any organ or site are acceptable. However, tissue specimens should be submitted from the site(s) of the patient's disease process. If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process. Tissue specimens submitted for infectious agent isolation must be fresh and not in formalin. The tissues must be kept on ice and be frozen as quickly as possible after removal from the body. Specimens suspected of infection with Category A pathogens will not be accepted. For list of agents, see https://emergency.cdc.gov/agent/agentlist-category.asp
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Freeze specimens (-20°C or lower) immediately and ship within 24 to 48 hours of collection. Do not add any media to specimens. If specimens must be stored for more than 48 hours, freeze immediately at -70°C or lower and ship within 4 weeks of collection.
Transport Medium	No transport media necessary.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, contact IDPB (pathology@cdc.gov) immediately. Ship tissue specimens frozen on dry ice in leak proof plastic containers. Do not ship specimens in glass containers. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship for overnight delivery. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Microbiology (cell culture)
Turnaround Time	12 Weeks
Interferences & Limitations	Clinical treatment with antivirals, antibiotics, and antiparasitics may minimize growth potential of cultures. Long term refrigeration may minimize growth potential of cultures.

Additional Information	CDC Pre-Approval Needed: • Contact Pre-approval POC • Infectious Diseases Pathology Branch Mailbox More specific guidelines regarding tissue sampling and submission can be found on the IDPB website: http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html Turnaround Time is case-dependent: • For routine human autopsy cases and animal cases turnaround time is 12 weeks.
CDC Points of Contact	Infectious Diseases Pathology Mailbox (404) 639-3132 pathology@cdc.gov Hannah Bullock (404) 718-6434 ocr3@cdc.gov Roosecelis Martines (404) 639-3886 xgn7@cdc.gov
Version	1.2

Test Order
Chagas Disease Molecular Detection- CLIA
CDC-10475

Synonym(s)	*Trypanosoma cruzi*; American trypanosomiasis, parasite
CDC Pre-Approval Needed	**Susan Montgomery** **(404) 718-4731** **zqu6@cdc.gov** **Yvonne Qvarnstrom** **(404) 718-4123** **bvp2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated whole blood
Minimum Volume Required	2.2 mL (infant 0.2 mL)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored in sterile leak-proof containers. EDTA-treated whole blood must be stored refrigerated (2-8°C) and shipped to CDC within 7 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens must be shipped to CDC by same or next-day courier as an etiologic agent. EDTA whole blood must be shipped in insulated shipping containers with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	1. This test should only be used in clinically indicated situations such as acute or congenital infections, post-transplant from a donor with confirmed T. cruzi infection, or risk of reactivation due to immunocompromise in patients with chronic Chagas disease. Diagnosis of chronic Chagas Disease in an immunocompetent patient should be performed by serology. 2. This test may cross-react with other Trypanosoma species.
Additional Information	Shipping Instructions: EDTA whole blood must arrive to CDC at 2-8°C within 7 days of collection. Specimens not meeting these conditions will not be accepted for testing and new specimen will be required.
CDC Points of Contact	Susan Montgomery (404) 718-4731 zqu6@cdc.gov Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov
Version	2.5

Test Order
Chagas Disease Serology- CLIA
CDC-10458

Synonym(s)	*Trypanosoma cruzi*; American trypanosomiasis, parasite
CDC Pre-Approval Needed	**Sue Montgomery** **(404) 718-4731** **zqu6@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include previous positive serology result on an LDT or FDA cleared/approved test for chronic Chagas disease, exposure and travel history, and other relevant risk factors that include clinical symptoms, and treatment.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Antibody Detection, Western blot, Immunoblot, T. cruzi trypomastigote excretory secretory antigens (TESA)
Turnaround Time	3 Weeks
Interferences & Limitations	Due to the nature of this antibody detection assay, it cannot determine whether a positive result is a current or previous infection.
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Sue Montgomery (404) 718-4731 zqu6@cdc.gov
Version	5.0

Test Order
Chlamydia pneumoniae Molecular Detection- Non-CLIA
CDC-10152

Synonym(s)	*C. pneumoniae, Chlamydophila pneumoniae,* Atypical pneumonia, Community acquired pneumonia, CAP, *Chlamydia, Chlamydophila*
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum
Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Refrigerate (2–8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection. Specimens should be kept frozen and shipped within 40 days.
Transport Medium	Viral transport medium (VTM) for NP and OP swabs
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days

Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	All specimens are tested using test order "Chlamydia Species (Respiratory) Molecular Detection (CDC-10525)." Laboratory test results will also include results for *Chlamydia psittaci*.
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov
Version	2.7

Test Order
Chlamydia psittaci Molecular Detection- Non-CLIA
CDC-10153

Synonym(s)	*C. psittaci, Chlamydophila psittaci,* Atypical pneumonia, Community acquired pneumonia, CAP, *Chlamydia, Chlamydophila,* Parrot fever, Psittacosis
CDC Pre-Approval Needed	**Jonas Winchell** **(404) 639-4921** **Jwinchell@cdc.gov** **Maureen Diaz** **(404) 639-4534** **mdiaz1@cdc.gov**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen.** **Required fields on CDC 50.34:** **-Test order name** **-Date of onset** **-Specimen source (type)** **-Specimen collection date** **-Specimen handling (e.g. frozen)** **-State of illness** **-Brief clinical summary, including signs and symptoms compatible with psittacosis, pertinent comorbidities, and response to treatment.** **-Therapeutic agent and dates (specific antibiotic therapy and initiation date).** **-Exposure history (e.g. avian exposure), including type or extent (if known). Please include any available information about status of bird health in Comment field.** **-Previous laboratory results, specifically other testing performed for Chlamydia psittaci and/or other potential infectious etiologies of respiratory illness.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum

Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Refrigerate (2–8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection. Specimens should be kept frozen and shipped within 40 days.
Transport Medium	Viral transport medium (VTM) for NP and OP swabs
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	All specimens are tested using "Chlamydia Species (Respiratory) Molecular Detection (CDC-10525)." Laboratory test results will also include results for *Chlamydia pneumoniae*.

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

Version	4.7

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

Synonym(s)	*C. pneumoniae, Chlamydophila pneumoniae, C. psittaci, Chlamydophila psittaci,* Atypical pneumonia, Community acquired pneumonia, CAP, *Chlamydia, Chlamydophila,* Parrot fever, Psittacosis
CDC Pre-Approval Needed	**Jonas Winchell** **(404) 639-4921** **jwinchell@cdc.gov** **Maureen Diaz** **(404) 639-4534** **mdiaz1@cdc.gov**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen.** **Required fields on CDC 50.34:** **-Test order name** **-Date of onset** **-Specimen source (type)** **-Specimen collection date** **-Specimen handling (e.g. frozen)** **-State of illness** **-Brief clinical summary, including signs and symptoms compatible with psittacosis, pertinent comorbidities, and response to treatment.** **-Therapeutic agent and dates (specific antibiotic therapy and initiation date).** **-Exposure history (e.g. avian exposure), including type or extent (if known). Please include any available information about status of bird health in Comment field.** **-Previous laboratory results, specifically other testing performed for Chlamydia psittaci and/or other potential infectious etiologies of respiratory illness.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum

Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Refrigerate (2–8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection. Specimens should be kept frozen and shipped within 40 days.
Transport Medium	Viral transport medium (VTM) for NP and OP swabs
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	None
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov

Test Order
Corynebacterium diphtheriae Study- Non-CLIA
CDC-10172

Synonym(s)	*Corynebacterium diphtheriae, C.ulcerans, C. pseudotuberculosis,* diphtheria
CDC Pre-Approval Needed	**Hong Ju** **(404) 639-0571** **lkn0@cdc.gov** **Lucia Pawloski** **(404) 639-4506** **ecz6@cdc.gov**
Supplemental Information Required	**Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of symptoms, specimen source, recent antibiotic history.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	For isolation and/or PCR: Throat, nasal and wound swabs, pseudo-membrane, and sputum. For isolate confirmation: Pure culture isolates or cryopreserved isolates. For PCR only: Extracted DNA.
Minimum Volume Required	0.1 mL DNA; 0.2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat, nasal, or wound swabs should placed in tubes of transport medium and kept refrigerated at 4 °C until shipment. Sputum should be placed in a leak-proof plastic tube and refrigerated at 4 °C until shipment. Pseudo-membrane should be placed in a leak-proof plastic container with physiological saline and kept refrigerated at 4 °C until shipment. Pseudo-membrane in formalin is not acceptable. Isolates should be refrigerated at 4 °C on an agar slants or frozen in cryopreservative and stored at -70 °C until shipment. DNA extracted from specimens should placed be in leak-proof plastic tubes and kept frozen at -20 °C until shipment.
Transport Medium	Common transport media such as Amies or Stuart may be used for swabs. Isolates can be frozen at -70 °C in cryopreservation medium; for best results a 24-48 hour subculture on common agar slants such as blood, trypticase soy, or nutrient is recommended. Pieces of pseudo-membrane for culture and PCR must be in physiological saline; formalin is not acceptable.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	For best results, specimens should be shipped within 24-48 hours of collection. Specimens refrigerated (isolates on slants, swabs in transport media, pseudo-membrane in saline, sputum) should be shipped overnight on gel ice-packs. Specimens frozen (cryopreserved isolates, extracted DNA) should be shipped overnight on dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 12 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number. Sender is responsible for shipping charges. International submitters must request CDC's import permit and include this with the Air Waybill.
Methodology	Culture, Multi-target Polymerase Chain Reaction (PCR), Whole Genome Sequencing, Multi-Locus Sequence Typing, Antibiotic Susceptibility
Turnaround Time	
Interferences & Limitations	PCR is not a confirmatory test for diphtheria toxin production. PCR detects the presence of the diphtheria toxin gene but does not show diphtheria toxin production. Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with *Corynebacterium* spp.
Additional Information	None
CDC Points of Contact	Hong Ju (404) 639-0571 lkn0@cdc.gov Lucia Pawloski (404) 639-4506 ecz6@cdc.gov
Version	3.2

Test Order

Corynebacterium diphtheriae/ulcerans/pseudotuberculosis and tox PCR Detection and Diphtheria Toxin Testing- CLIA

CDC-10168

Synonym(s)	*Corynebacterium diphtheriae, C.ulcerans, C. pseudotuberculosis,* diphtheria
CDC Pre-Approval Needed	**Hong Ju** **(404) 639-0571** **lkn0@cdc.gov** **Lucia Pawloski** **(404) 639-4506** **ecz6@cdc.gov**
Supplemental Information Required	**Provide the following Patient and Specimen Information on the CDC 50.34 Specimen Submission Form: patient age, onset of symptoms, specimen source, recent antibiotic history.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Submit drafted 50.34 form into CSTOR for CDC review and approval before shipping specimen.
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat, nasal, or wound swab for PCR only (non-viable specimen; no toxin testing can occur): collect from patient and immediately place in a dry, sterile tube. Freeze at (-20°C or lower) within 30 minutes of collection. Throat, nasal, or wound swab for PCR and toxin testing (toxin testing only if viable Corynebacterium species is recovered): collect from patient and immediately place in an Amies clear gel transport tube and store within 30 minutes of collection refrigerated (2-8°C) until shipment. Ship within 24-72 hours of collection. Pseudomembrane or heart tissue for testing if viable Corynebacterium species is recovered: collect from patient and place in physiological saline without formalin in a leak-proof plastic container and store within 30 minutes of collection refrigerated (2-8°C) until shipment. Ship within 24-48 hours of collection. Pure culture isolate: maintain isolate on any agar or transport medium that supports the growth of Corynebacterium species.
Transport Medium	Throat, nasal, or wound swab for PCR only: dry in sterile tube without transport medium. Throat, nasal, or wound swab for PCR and toxin testing: Amies clear gel transport medium. Pseudomembrane or heart tissue (if viable Corynebacterium species is recovered): physiological saline without formalin. Pure culture isolate: any agar or transport medium that supports the growth of Corynebacterium species, for example blood (any type), chocolate, trypticase soy, nutrient, brain heart infusion, heart infusion, Amies clear gel, etc.

Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Throat, nasal, or wound swab for PCR only: ship frozen overnight with dry ice within 1 week of collection. Once frozen, do not allow swab to thaw. Throat, nasal, or wound swab for PCR and toxin testing: ship refrigerated overnight with refrigerated or frozen cold packs within 24-72 hours of collection. Ensure enough refrigerated/frozen cold packs are included in shipment to have specimens arrive to CDC at 2-8°C. Specimens not meeting these conditions will be rejected for testing and new specimens will be required. Pseudomembrane or heart tissue (if viable Corynebacterium species is recovered): ship refrigerated overnight with refrigerated or frozen cold packs within 24-48 hours of collection. Pure culture isolate: ship refrigerated overnight with refrigerated or frozen cold packs OR ship ambient overnight with room temperature cold packs. Note: The original isolate should be retained by the submitter for the duration of testing at CDC. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 12 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Multi-target Polymerase Chain Reaction (PCR) and Elek (for diphtheria toxin testing)
Turnaround Time	2 Weeks
Interferences & Limitations	PCR is not a confirmatory test for diphtheria toxin production. PCR detects the presence of the diphtheria toxin gene but does not show diphtheria toxin production. Prior antibiotic treatment will adversely affect culture and PCR results. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with *Corynebacterium* spp.

Additional Information	Additional Information Should an isolate be confirmed as toxigenic/toxin-producing, a subculture plate will be transferred to Division of Healthcare Quality Promotion (DHQP) for antibiotic susceptibility testing. Turnaround time: 2 weeks from receipt of specimens in the testing laboratory. Interferences & Limitations PCR is not a confirmatory test for diphtheria toxin production. PCR detects the presence of the diphtheria toxin gene but does not show diphtheria toxin production. Prior antibiotic treatment will adversely affect viability of bacteria from specimen. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with Corynebacterium species.
CDC Points of Contact	Hong Ju (404) 639-0571 lkn0@cdc.gov Lucia Pawloski (404) 639-4506 pdlab@cdc.gov
Version	3.8

Test Order
Corynebacterium species Identification (not C. diptheriae)- CLIA
CDC-10136

Synonym(s)	Coryneform gram-positive rods
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
Coxiella burnetii Molecular Detection- CLIA
CDC-10304

Synonym(s)	Q fever
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood: EDTA-treated, or ACD A treated. Serum: Serum separator tube, or cryo-tubes. Tissue specimens, including surgically excised prosthetic and native heart valves, vascular aneurysms and grafts, and tissues obtained at autopsy.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days prior to arriving at CDC, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood, and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad lightly moistened with sterile saline. Do not immerse the sample in saline.

Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Molecular detection methods have decreasing sensitivity after resolution of the febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures (2-8°C) can interfere with nucleic acid extraction.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Molecular testing for other pathogens including *Anaplasma*, *Rickettsia* spp, *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html

CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Version	2.3

Test Order
Coxiella burnetii Serology- CLIA
CDC-10305

Synonym(s)	Q fever
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of acute Q fever disease by serology can only be established by demonstrating a fourfold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness. In some cases, serologic confirmation of chronic Q fever can be achieved with a single serum titer to phase I antigen.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including *Anaplasma*, *Rickettsia* spp., *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html

CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Version	2.3

Test Order
Crimean-Congo Hemorrhagic Fever Testing- CLIA
CDC-10302

Synonym(s)	CCHF
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	**Recommended method**: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 60 days of collection. **Alternative method (not recommended)**: Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.3

Test Order
Crimean-Congo Hemorrhagic Fever Testing- Non-CLIA
CDC-10602

Synonym(s)	CCHF
CDC Pre-Approval Needed	**Trevor Shoemaker** **470) 312-009** **spather@cdc.gov** **Schuh Amy** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum for PCR Whole blood (EDTA) or serum for serology
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	2.0

Test Order

Cronobacter, Yersinia (non-Y.pestis), and Other Enterobacterales Identification and Characterization- Non-CLIA

CDC-10123

Synonym(s)	*Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae, Yersiniaceae, Budvicia, Buttiauxella, Citrobacter, Cronobacter, Enterobacter, Erwinia, Hafnia, Klebsiella, Kluyvera, Morganella, Pantoea, Proteus, Providencia, Rahnella, Raoultella, Serratia, Yersinia, Yokenella*
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Cronobacter*, *Yersinia* (non-*Y. pestis*), and *Enterobacterales*; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) or refrigerated (2-8°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 16 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification
Turnaround Time	13 Weeks
Interferences & Limitations	Repeat freeze/thaw cycles can lower test sensitivity.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Christine Lee (404) 498-2295 pfx6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov
Version	3.7

Test Order

Cronobacter, Yersinia (non-Y.pestis), and Other Enterobacterales Subtyping- Non-CLIA

CDC-10124

Synonym(s)	*Budviciaceae, Enterobacteriaceae, Erwiniaceae, Hafniaceae, Morganellaceae, Pectobacteriaceae, Yersiniaceae, Budvicia, Buttiauxella, Citrobacter, Cronobacter, Enterobacter, Erwinia, Hafnia, Klebsiella, Kluyvera, Morganella, Pantoea, Proteus, Providencia, Rahnella, Raoultella, Serratia, Yersinia, Yokenella*
CDC Pre-Approval Needed	**Christine Lee** **(404) 498-2295** **pfx6@cdc.gov** **Monica Im** **(404) 718-1446** **ixi9@cdc.gov**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Cronobacter*, *Yersinia* (non-*Y. pestis*), and *Enterobacterales*; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 16 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping
Turnaround Time	10 Weeks
Interferences & Limitations	Repeat freeze/thaw cycles can lower test sensitivity.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Christine Lee (404) 498-2295 pfx6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov
Version	3.4

Test Order
Cryptosporidium Special Study- Non-CLIA
CDC-10491

Synonym(s)	
CDC Pre-Approval Needed	**Shatavia Morrison** **(404) 639-3395** **xxh5@cdc.gov** **Brooke OConnell** **(404) 639-0069** **ryo6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	None
Acceptable Sample / Specimen Type for Testing	Stools must be collected in a non-formalin based fixative, preservative, or storage medium. For additional information about acceptable preservatives, contact the CDC POC.
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship fixed/preserved specimens at room temperature. Ship unpreserved specimens on wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if stored frozen. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 53 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Shatavia Morrison (404) 639-3395 xxh5@cdc.gov Brooke OConnell (404) 639-0069 ryo6@cdc.gov
Version	1.9

Test Order
Cyclospora genotyping- Non-CLIA
CDC-10567

Synonym(s)	None
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please provide the following specimen information on the CDC Global File Accessioning Template (GFAT): Case ID.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store specimens following the suggested storage instructions for the transport media or fixative used. If no media/fixative used, store specimens refrigerated (2-8°C) prior to shipping. Preferably ship within 7 days of collection, but specimens within 6 months of collection < 6 months old may also be sent.
Transport Medium	Any fixative or transport media except for formalin. Specimens in no media/fixatives are also accepted.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	None
Methodology	Polymerase chain reaction (PCR), DNA Sequencing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Research or surveillance specimens should be labelled with a state laboratory ID only. Please do not include patient personally identifiable information on labels for research or surveillance specimens. Ensure completion of the Cyclospora Global File Accessioning Template (GFAT), which can be obtained by contacting cyclosporaAMD@cdc.gov.
CDC Points of Contact	Cyclospora Laboratory (404) 718-8212 cyclosporaAMD@cdc.gov Joel Barratt (404) 718-1027 nsk9@cdc.gov

Test Order
Cysticercosis Serology- CLIA
CDC-10459

Synonym(s)	Neurocysticercosis, *Taenia solium*, cysitcercus, EITB, LLGP-EITB, parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum; cerebrospinal fluid (CSF) when paired with serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and CSF for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum and CSF can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera and CSF specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Known interfering substances: hemolysis, hyperlipemia or other causes of turbidity may cause erroneous results.

Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	5.0

Test Order
Cytomegalovirus (CMV) Detection- Non-CLIA
CDC-10263

Synonym(s)	CMV
CDC Pre-Approval Needed	**Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov** **Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Urine, saliva, or whole blood
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen at -20 °C. Whole blood should be collected in EDTA or citrate tubes.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimens with cold packs or dry ice as an etiologic agent. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	2.4

Test Order
Cytomegalovirus (CMV) Serology- Non-CLIA
CDC-10264

Synonym(s)	CMV
CDC Pre-Approval Needed	**Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov** **Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum or plasma
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen at -20 °C.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimens with cold packs or dry ice as an etiologic agent. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by Enzyme Immunoassay (EIA)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	2.4

Test Order
Dengue Virus Detection and Serology- CLIA
CDC-10307

Synonym(s)	Dengue fever, severe dengue
CDC Pre-Approval Needed	**Rafael Tosado** **(787) 706-3449** **npp0@cdc.gov** **Gilberto Santiago** **(787) 706-4311** **fbz3@cdc.gov**
Supplemental Information Required	**Provide the following information on the form: complete name, age, date of birth and sex of patient, home address, sample collection date, date of onset of symptoms, pregnancy status, complete name and mailing address of the provider (physician, laboratory, clinic, or hospital). Specimen identification must match the identification on the form. One form must be completed for each sample sent.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute serum, collected during the first 7 days of illness is suitable for molecular and serological tests, and convalescent serum, collected after the first 7 days of illness is suitable for serological tests. Other specimen types such as whole blood, plasma and cerebrospinal fluid may be acceptable upon consultation with the laboratory.
Minimum Volume Required	0.5 mL (1.0 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	The blood should be collected in a red-top or tiger-top tube. After blood is allowed to clot, separate serum by centrifugation and keep refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, specimen should be kept frozen at -20 °C. Citrate (collected in yellow top tubes) and heparin plasma (collected in green top tubes) can be tested by real-time plymerase chain reaction (RT-PCR). Refer to collection devices manufacturer instructions for more details. If specimens can be shipped to the CDC Dengue Branch Lab within 72 hours of collection, they should be kept refrigerated at 4 °C and shipped on cold packs. If specimens must be held for more than 72 hours before shipping, they should be promptly frozen at -20 °C and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	Frozen specimens should be shipped on dry ice and refrigerated specimens on frozen gel packs. Serum must remain frozen if specimens are to be held for more than 72 hours before shipping. If dry ice is not available for shipping, we recommend that the serum be stored refrigerated and shipped on cold packs. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Dengue Branch 1324 Calle Cañada Puerto Nuevo San Juan, P. R. 00920-3860 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the Laboratory POC providing information on the shipping company, shipped date, expected delivery date and package tracking number.
Methodology	Real-Time Polymerase Chain Reaction (RT-PCR), Enzyme Linked Immunosorbent Assay (ELISA)
Turnaround Time	10 Days
Interferences & Limitations	Dengue antibody detection (serological testing) can be affected by cross reactivity with other Flaviviruses, including recent vaccinations (dengue, yellow fever, Japanese encephalitis, tickborne encephalitis), and natural infections (Zika, St. Louis encephalitis, West Nile viruses). Serum with evidence of hemolysis or contaminated samples are not acceptable for serological testing. EDTA may cause interference with PCR testing and should be avoided. Warming or freeze-thawing affects stability of viral nucleic acid and antibodies in serum reducing the sensitivity of molecular and serological testing. The use of lavender/violet-top collection tubes with EDTA is not recommended for PCR testing. Convalescent serum samples from blood collected in Lavender/violet or green-top tubes should not be used for serological testing.

Additional Information	To diagnose dengue infection, an acute serum sample obtained during the first 7 days of illness is required for molecular diagnosis by direct detection of the virus nucleic acid. The 4 dengue serotypes can be identified through real-time polymerase chain reaction (RT-PCR) testing. If the acute sample is negative, a convalescent serum sample is required for case confirmation by serological testing. The convalescent serum should be collected after the first 7 days of illness. The case is confirmed by antibody seroconversion through the detection of dengue-specific Immunoglobulin M antibodies (IgM) in the convalescent serum. Informing the patient about the importance of returning for a second sample and providing an appointment for a specific day and time, will increase the probability of obtaining the second sample. If the patient makes the first visit to the physician after the 7th day of illness, a serum sample collected then would be sufficient. In that case, the patient would not need to return for collection of a second sample. Sample rejection criteria include: 1. Samples sent without the appropriate documentation (CDC form 50.34) 2. Specimen submission forms sent without a sample 3. Illegible or incomplete sample submission forms (especially lacking the date of onset of symptoms and/or the date of sample collection) 4. Samples delivered at suboptimal temperatures (over 25 °C) 5. Spilled samples or damaged samples containers 6. Samples received more than 90 days after the onset of symptoms 7. Serum hemolysis would be a rejection criterion for convalescent samples only More information available at: https://www.cdc.gov/dengue/index.html Reporting times for test results may be longer when arbovirus activity increases.
CDC Points of Contact	Rafael Tosado (787) 706-4339 npp0@cdc.gov Candimar Colon (787) 706-2473 fbz3@cdc.gov
Version	3.2

Test Order
Ebola Hemorrhagic Fever Testing- CLIA
CDC-10309

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	"Recommended method: Whole blood (EDTA) specimens must be frozen (<-70°C) and shipped on dry ice within 365 days of collection. Alternative method: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 365 days of collection. Alternative method (not recommended): Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection."
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)

Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.4

Test Order
Echinococcosis Serology- CLIA
CDC-10460

Synonym(s)	Hydatid Disease, *Echinococcus granulosus*, parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include exposure and travel history,and other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody detection
Turnaround Time	3 Weeks

Interferences & Limitations	Cross-reactivity with various species of *Echinococcus* such as *E. multiocularis* and *E. vogeli*, has been observed.
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	4.9

Test Order
Ehrlichia Molecular Detection- CLIA
CDC-10499

Synonym(s)	Ehrlichia chaffeensis ehrlichiosis, human monocytic ehrlichiosis (HME), Ehrlichia ewingii ehrlichiosis, Ehrlichia muris euclairensis ehrlichiosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute whole blood. Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): EDTA-treated, or ACD A treated. Acute serum Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): Serum separator tube, or cryo-tubes. Tissue must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): sterile specimen container in saline-moistened gauze.
Minimum Volume Required	1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days prior to arriving at CDC, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood, and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in a cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For eschar swabs, place the specimen in a dry sterile specimen container without any medium.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad lightly moistened with sterile saline. Do not immerse the sample in saline.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Molecular detection methods have decreasing sensitivity after resolution of the febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures (2-8°C) can interfere with nucleic acid extraction.

Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Molecular testing for other pathogens including *Anaplasma*, *Coxiella*, *Orientia*, and *Rickettsia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov
Version	2.9

Test Order
Ehrlichia Serology- CLIA
CDC-10311

Synonym(s)	Ehrlichia chaffeensis ehrlichiosis, human monocytic ehrlichiosis (HME)
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of an ehrlichiosis can only be established by demonstrating a four-fold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including typhus group *Rickettsia*, *Anaplasma*, *Coxiella*, *Orientia*, and spotted fever group *Rickettsia*. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Test Order
Elizabethkingia species - Special Study- Non-CLIA
CDC-10514

Synonym(s)	None
CDC Pre-Approval Needed	**John McQuiston** **(404) 639-0270** **zje8@cdc.gov** **Melissa Bell** **(404) 639-1348** **jqv7@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined

CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov

Version	2.2

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

Synonym(s)	Amebiasis, *Entameba histolytica*, *Entameba dispar,* parasite
CDC Pre-Approval Needed	**Ibne Ali** **(404) 718-4157** **xzn5@cdc.gov** **Julia Haston** **(404)-718-1230** **qdx2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool, liver aspirate or other abscess fluid
Minimum Volume Required	0.5 g formed stool; 1.0 g preferred. 0.5 mL liquid stool, liver aspirate or other abscess fluid; 1.0 mL preferred.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stool, liver aspirate or other abscess fluid specimens should be collected in the absence of preservatives, and must be kept frozen (-20°C or lower) and shipped with dry-ice within 60 days of collection.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship frozen stool, liver aspirate or other abscess fluid specimens on dry ice within 60 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-Time PCR

Turnaround Time	21 Days
Interferences & Limitations	Specimens fixed in formalin-containing preservatives or LV-PVA are not suitable for molecular studies.
Additional Information	None
CDC Points of Contact	Ibne Ali (404) 718-4157 xzn5@cdc.gov Julia Haston (404)-718-1230 qdx2@cdc.gov
Version	4.8

Test Order
Enteric Isolation - Primary Specimen- Non-CLIA
CDC-10106

Synonym(s)	Enteric Pathogen Culture, Stool Culture
CDC Pre-Approval Needed	**Haley McKeel** **(404) 639-1612** **hvw0@cdc.gov** **Nancy Strockbine** **(404) 639-4186** **nas6@cdc.gov**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Acceptable specimen will be determined upon consultation.
Minimum Volume Required	Acceptable minimum volumes will be determined upon consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Acceptable storage and preservation conditions will be determined upon consultation.
Transport Medium	Transport medium requirements will be determined upon consultation.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimen shipping conditions will be determined upon consultation. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 129 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Enrichment, Detection and Isolation, and Subtyping

Turnaround Time	13 Weeks
Interferences & Limitations	Inferences and limitations will be discussed upon consultation.
Additional Information	Targeted organisms include: *Salmonella, Shigella, Campylobacter*, Shiga toxin-producing *Escherichia coli* (STEC) and other diarrheagenic *Escherichia coli*, pathogenic *Enterobacteriaceae, Listeria, Vibrio, Cronobacter*, and related foodborne and waterborne pathogens.
CDC Points of Contact	Haley McKeel (404) 639-1612 hvw0@cdc.gov Nancy Strockbine (404) 639-4186 nas6@cdc.gov Christine Lee (404) 498-2295 pfx6@cdc.gov
Version	1.9

Test Order
Enteric Special Study- Non-CLIA
CDC-10512

Synonym(s)	none
CDC Pre-Approval Needed	**Andrew Huang** **(404) 639-1545** **wwm8@cdc.gov** **A Jo Williams Newkirk** **(404) 639-1087** **igy7@cdc.gov**
Supplemental Information Required	**Notify POCs before sending specimens and send study-specific datasheet.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool or pathogen isolate
Minimum Volume Required	Stool: 4 mL unless lower volume preapproved; pathogen isoloate: n/a
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stool specimens must be frozen at -70 °C or lower upon receipt by the submitting laboratory and held at that temperature until shipment to CDC
Transport Medium	Stool: none or Cary Blair; Pathogen isolate: pathogen-appropriate agar in tubes with leak-proof screw cap closures. Agar plates are not acceptable.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Stool samples must be shipped on dry ice. Ship pathogen isolates at ambient temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 129 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	
Turnaround Time	

Interferences & Limitations	n/a
Additional Information	This test is for the submission of samples to participate in an enteric pathogen special study. No results of testing will be reported back to submitters.
CDC Points of Contact	Andrew Huang (404) 639-1545 wwm8@cdc.gov A Jo Williams Newkirk (404) 639-1087 igy7@cdc.gov
Version	1.2

Test Order

Enterovirus and Parechovirus Detection and Identification, including Enterovirus-D68 (EV-D68)- CLIA

CDC-10312

Synonym(s)	Enterovirus (EV), coxsackieviruses (CVA) (CVB), Echovirus, Parechovirus, Enterovirus-D68 (EV-D68)
CDC Pre-Approval Needed	**Shannon Rogers** **(404) 639-2677** **boo9@cdc.gov** **Terry Fei Fan Ng** **(404) 639-4880** **ylz9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool, Cerebrospinal fluid (CSF), Serum, Respiratory swab specimens in virus transport media (VTM), including nasopharyngeal swab (NP), oropharyngeal swab (OP), nasopharyngeal/oropharyngeal swab (NP/OP), nasal swab (NS), throat swab (TS)
Minimum Volume Required	Stool: 1 gram; 10 - 20 grams preferred Cerebrospinal fluid (CSF): 0.15 mL; 0.5-2 mL preferred Serum: 0.15 mL; 0.5 - 2 mL preferred Respiratory swab specimens in virus transport media: 0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample. For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media. For stool and CSF, collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Send only original, unprocessed stool. Do not add transport medium. For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes, centrifuge, remove serum from the separator tube and send an aliquot in a sterile container. After collection, freeze (-20°C or lower) all specimens and ship to CDC within 2 months. Please note: If necessary, CSF, may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing. If necessary, stools, serum and respiratory swabs may be kept at 2-8°C for no more than 14 days after collection and prior to freezing.

Transport Medium	Viral transport medium (VTM) should be used with these specimen types: nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), nasal swabs (NS), throat swabs (TS)
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.
Additional Information	Not Applicable
CDC Points of Contact	Picornavirus Laboratory PicornaLab@cdc.gov Shannon Rogers (404) 639-2677 boo9@cdc.gov Terry Fei Fan Ng (404) 639-4880 ylz9@cdc.gov
Version	0.2

Test Order
Entomology Special Study- Non-CLIA
CDC-10494

Synonym(s)	Insect
CDC Pre-Approval Needed	**Gena Lawrence** **(404) 718-4315** **geg7@cdc.gov** **Alice Sutcliffe** **(404) 718-4326** **gok0@cdc.gov**
Supplemental Information Required	**To be determined**
Supplemental Form	**None**
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Insects, insect DNA, and other types to be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 222 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	To be determined
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	Turnaround time is to be determined based on the tests performed.

CDC Points of Contact	Gena Lawrence (404) 718-4315 geg7@cdc.gov Alice Sutcliffe (404) 718-4326 gok0@cc.gov

Version	1.1

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

Synonym(s)	EBV
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL (saliva, cerebrospinal fluid (CSF), whole blood)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours. Whole blood should be collected in anticoagulant blood collection tubes (EDTA). Refrigerate whole blood (2-8°C) within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower). All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-4812 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	1.9

Test Order
Escherichia and Shigella Identification and Characterization- Non-CLIA
CDC-10114

Synonym(s)	*Escherichia,* STEC, *Shigella, E. coli,* serotyping, virulence, profiling
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Escherichia* and *Shigella*; Sequence Data
Minimum Volume Required	No miminum volume required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 07 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling
Turnaround Time	13 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Haley McKeel (404) 639-1612 hvw0@cdc.gov
Version	3.7

Test Order
Escherichia and Shigella Subtyping- Non-CLIA
CDC-10116

Synonym(s)	*Escherichia,* STEC, *Shigella, E. coli,* subtyping
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Escherichia* and *Shigella*; Sequence Data
Minimum Volume Required	No minimum volume required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25 °C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. Shiga toxin-positive bacteria should be shipped as Category A Infectious Substances. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 07 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	20 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Nancy Strockbine (404) 639-4186 nas6@cdc.gov Haley McKeel (404) 639-1612 hvw0@cdc.gov
Version	2.7

Test Order
Fascioliasis Serology- CLIA
CDC-10505

Synonym(s)	Fascioliasis, *Fasciola hepatica*, liver fluke
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include exposure and travel history, and other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western blot, Antibody detection
Turnaround Time	3 Weeks
Interferences & Limitations	Known interfering substances: hemolysis, hyperlipemia or other causes of turbidity may cause erroneous results.

Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	4.7

Test Order
Filariasis Serology- CLIA
CDC-10462

Synonym(s)	*Brugia malayi*, *Wuchereria bancrofi*, *Onchocerca volvulus*, *Loa loa*; parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks

Interferences & Limitations	This assay may yield positive results in individuals infected with hookworm and *Strongyloides* spp.
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	4.8

Test Order
Filovirus Testing (Non-human Primates)- Non-CLIA
CDC-10603

Synonym(s)	None
CDC Pre-Approval Needed	**Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov** **Shannon Whitmer** **(404) 639-4930** **evk3@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**https://www.cdc.gov/viral-hemorrhagic-fevers/media/pdfs/2024/05/primate-form-508.pdf**
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Liver for antigen detection Serum for serology
Minimum Volume Required	Antigen detection: Collect two pieces of liver tissue at least 1cm3 each and place them in two separate containers. Antibody detection (collected from live non-human primates): 4 mL serum
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens must be shipped on dry ice or frozen cold packs.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	10 Days

Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Pre-approval must be obtained in advance by contacting CDC Points of Contact.
CDC Points of Contact	Amy Schuh (404) 639-1756 wuc2@cdc.gov Shannon Whitmer (404) 639-4930 evk3@cdc.gov
Version	2.0

Test Order
Francisella tularensis Culture and Identification- Non-CLIA
CDC-10313

Synonym(s)	Tularemia
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label. For transfer of a select agent, a completed Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2) is required.**
Supplemental Form	**For transfer of a select agent: Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2)** **https://www.selectagents.gov/forms.html**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Bacterial isolates
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates can be refrigerated (2-8°C) or kept at room temperature (15-25°C). Isolates should be maintained to ensure viability.
Transport Medium	Isolates should be transported on chocolate or cysteine containing agar.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs. Ship room temperature specimens with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic and genotypic methods
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Francisella tularensis Serology- Non-CLIA
CDC-10314

Synonym(s)	Tularemia
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL (serum)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separate and aliquot serum prior to storage and transport. Specimens may be held at refrigerated temperature (2-8°C) for up to 14 days post-collection. Specimens may be held frozen (-20°C or lower) for up to 60 days post-collection or may be held frozen (-70°C or lower) for up to 9 months post-collection. Specimens must not exceed 2 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs and frozen specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Microagglutination
Turnaround Time	2 Weeks
Interferences & Limitations	Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Francisella tularensis Special Study- Non-CLIA
CDC-10315

Synonym(s)	
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.

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

Version	0.0

Test Order
Fungal Identification- CLIA
CDC-10179

Synonym(s)	Fungal identification, mold identification, yeast identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates can be refrigerated (2-8°C) or kept at an room temperature (15-25°C). Isolate should be maintained to ensure viability.
Transport Medium	Isolates should be on a suitable agar slant.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimen should be shipped at ambient temperature. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 40 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic Testing, DNA sequencing, MALDI-ToF
Turnaround Time	6 Weeks
Interferences & Limitations	None
Additional Information	Turnaround Time: Turnaround time for yeast identification is 6 weeks or less and mold identification is 6 weeks or less.

CDC Points of Contact	Shawn Lockhart (404) 639-2569 gyi2@cdc.gov Lalitha Gade (404) 639-5471 hvr0@cdc.gov

Version	1.9

Test Order
Fungal Study- CLIA
CDC-10181

Synonym(s)	None
CDC Pre-Approval Needed	**Shawn Lockhart** **(404) 639-2569** **gyi2@cdc.gov** **Lalitha Gade** **(404) 639-5471** **hvr0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Contact your CDC POC.
Minimum Volume Required	Contact your CDC POC.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact your CDC POC.
Transport Medium	Contact your CDC POC.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 40 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact your CDC POC.
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	For Fungal Studies not covered under CDC-10179 and CDC-10180.

CDC Points of Contact	Shawn Lockhart (404) 639-2569 gyi2@cdc.gov Lalitha Gade (404) 639-5471 hvr0@cdc.gov

Version	1.9

Test Order
Fungal Study- Non-CLIA
CDC-10576

Synonym(s)	None
CDC Pre-Approval Needed	**Shawn Lockhart** **(404) 639-2569** **gyi2@cdc.gov** **Lalitha Gade** **(404) 639-5471** **hvr0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Contact your CDC POC.
Minimum Volume Required	Contact your CDC POC.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact your CDC POC.
Transport Medium	Contact your CDC POC.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 40 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact your CDC POC.
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	For Fungal Studies not covered under CDC-10179 and CDC-10180.

CDC Points of Contact	Shawn Lockhart (404) 639-2569 gyi2@cdc.gov Lalitha Gade (404) 639-5471 hvr0@cdc.gov

Version	2.0

Test Order
Gastroenteritis Virus Special Study- Non-CLIA
CDC-10316

Synonym(s)	
CDC Pre-Approval Needed	**Jan Vinje** **(404) 639-3721** **ahx8@cdc.gov** **Leslie Barclay** **(404) 639-1159** **gvm3@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool
Minimum Volume Required	0.25 g or 0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen must be refrigerated at 2-8°C for up to 7 days, or frozen at <-20°C for up to 60 days or ≤-70°C for up to 90 days.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 186 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	To be determined
Additional Information	None

CDC Points of Contact	Jan Vinje (404) 639-3721 ahx8@cdc.gov Leslie Barclay (404) 639-1159 gvm3@cdc.gov

Version	1.4

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

Synonym(s)	Gram-negative rod/bacillus
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
Gram Positive Bacillus Identification- CLIA
CDC-10137

Synonym(s)	Gram-positive rod identification, gram-positive bacillus identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay..
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order

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

CDC-10138

Synonym(s)	*Neisseria* Identification, GNC
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
Haemophilus influenzae Surveillance- Non-CLIA
CDC-10222

Synonym(s)	*H. influenzae* Surveillance, Hi study
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form or on the surveillance submission form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Bacterial isolates: viable bacterial culture at room temperature or frozen stocks Primary specimens: cerebrospinal fluid (CSF), serum, and other sterile site specimen types
Minimum Volume Required	0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens
Collection, Storage, and Preservation of Specimen Prior to Shipping	Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping. When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates. Primary specimens (CSF, serum and other sterile site specimen types) should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.
Transport Medium	When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF and serum) should be shipped on dry ice and received frozen. Enclose CDC 50.34 Specimen Submission Form in shipment. Email the tracking number in advance, particularly if prioritized testing is requested. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 44 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time Polymerase Chain Reaction (rt-PCR) and/or slide agglutination serotyping (SAST)
Turnaround Time	
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result.
Additional Information	Additional microbiological and/or molecular testing can be completed as needed.
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Matthew Keller (404) 718-3359 meningitislab@cdc.gov
Version	4.0

Test Order
Haemophilus species (not H. influenza/ H. ducrey) Identification- CLIA
CDC-10141

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Biochemical analysis, Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
Healthcare-Associated Infections (HAI) - Outbreak Investigation- Non-CLIA
CDC-10162

Synonym(s)	Healthcare Outbreak, Nosocomial Outbreak, Healthcare-Associated Infection (HAI) Outbreak
CDC Pre-Approval Needed	**Paige Gable** **(404) 718-5815** **woz8@cdc.gov** **Heather Moulton-Meissner** **(404) 639-4864** **ftw2@cdc.gov**
Supplemental Information Required	**Contact the CDC POC for instructions on completing a Supplemental Line List.** **The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) or Supplemental Line List must include the date the submitted culture was inoculated onto transport media and/or the date environmental samples were collected.**
Supplemental Form	**Contact the CDC POC regarding contents of the required Supplemental Line List.**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Acceptable samples include pure culture isolates and primary environmental specimen types (e.g. swabs, wipes, water and other fluids, medical devices, products), however, additional sample types may be accepted for testing upon consultation.
Minimum Volume Required	Not applicable for pure culture isolates. Minimum volumes may be required for certain types of environmental samples. Please confirm volume requirements with the CDC POC before collecting samples.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store all aerobic bacterial isolates at room temperature (15-25°C). If isolates cannot be shipped within 24 hours, refrigerate only non-fastidious organisms (2-8°C) for shipping. Primary environmental specimens should be refrigerated (2-8°C) within 1 hour. Samples of healthcare or outbreak related products (e.g. compounded medications, lotions, medical devices) should be stored in accordance with manufacturer's instructions if relevant. Special storage and preservation requirements for anaerobic isolates and other unlisted environmental or product samples are available upon request.

Transport Medium	Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on suitable agar slant (not an agar plate or broth culture media). Transport frozen (-20 °C or lower) submissions in trypticase soy broth (TSB) plus 15% glycerol. Transport refrigerated (2-8 °C) environmental specimens in suitable buffers or media if necessary (e.g. swabs). Transport conditions for anaerobic isolates available upon request.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship submissions overnight. Room-temperature samples should be shipped with room-temperature cold packs. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 154 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Primary Processing of non-clinical specimens (e.g., culture and isolation, species identification, membrane filtration, sterility testing), Molecular Identification and Typing of non-clinical specimens (e.g., MALDI-ToF, 16S, Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS))
Turnaround Time	
Interferences & Limitations	Primary environmental samples should not be held at room temperature for >1 hour. Doing so may decrease recovery of microorganisms or otherwise adversely affect the results obtained from testing recovered organisms. Neutralization of chlorine residual in potable water is necessary during collection. Samples that arrive containing personally identifiable information under this test code will be rejected for testing. Pure culture isolates must be viable for testing.

Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a Healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Prior epidemiologic consultation with CDC/DHQP Prevention and Response Branch [haioutbreak@cdc.gov] also required. Turnaround Times vary based on target organism and sample type. The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
CDC Points of Contact	Paige Gable (404) 718-5815 woz8@cdc.gov Heather Moulton-Meissner (404) 639-4864 ftw2@cdc.gov
Version	3.4

Test Order
Healthcare-Associated Infections (HAI) and Antimicrobial Resistance (AR) Surveillance and Research- Non-CLIA
CDC-10583

Synonym(s)	Nosocomial, Healthcare Associated, Healthcare Associated Infections (HAI), Surveillance, Research, Antimicrobial Resistance, Aerobic Bacteria, Anaerobic Bacteria, Nontuberculous Mycobacteria (NTM)
CDC Pre-Approval Needed	**Stephen LaVoie** **(404) 718-4747** **qea5@cdc.gov** **Amy Gargis** **(404) 639-8850** **uvg0@cdc.gov**
Supplemental Information Required	**Surveillance Submittals: Submit line listing of isolates and information relevant to your surveillance activity.** **Research Submittals: Contact the CDC POC for instructions on completing a specimen submission form or line list. The CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) or Supplemental Line List must include specimen origin, suspect agent, material submitted, submitter contact information, specimen ID, and the date the submitted culture was inoculated onto transport media and/or the date sample(s) were collected. Additional documentation requirements for anaerobes and NTM are below.** **Anaerobic Bacteria: If the suspect agent is Clostridium species, include documented confirmation that the isolate is not Clostridium botulinum.** **Nontuberculous Mycobacteria (NTM): Previous testing results demonstrating that the isolate is pure and is not a part of the Mycobacterium tuberculosis complex (MTC), as well as the date visible growth was observed for the submitted isolate. For isolates from wounds or surgical sites, document that nontuberculous mycobacteria (NTM) was abundant on primary culture (3+ to 4+) or was the only organism isolated. For isolates from sputum, document that NTM was from two or more sputum cultures, collected on different days; was the only mycobacterial species present and that there was abundant growth on primary culture.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	**Aerobic Bacteria:** Pure culture isolates. **Anaerobic Bacteria:** Pure culture isolates of anaerobic bacteria from clinically relevant sources. **Nontuberculous Mycobacteria (NTM):** Pure cultural isolates of NTMs demonstrated to not be part of the Mycobacterium tuberculosis complex (MTC) from the following sources: Sterile sites (e.g. Whole blood, cerebral spinal fluid (CSF), other body fluids); Abscess, exudate or skin lesion; Wounds or surgical sites (see Supplemental Information); Bronchoalveolar lavage (BAL)/bronchial wash; Sputum (see Supplemental Information); Gastric lavage (pediatric). Other sample types may be accepted for testing upon consultation.

Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	**Aerobic Bacteria:** Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability and to avoid loss of antimicrobial resistance mechanisms. **Anaerobic Bacteria:** Inoculate pure culture isolate in chopped meat broth and incubate anaerobically for 36-48 hours. Store anaerobically sealed vial at room temperature (15-25°C) or refrigerated temperature (2-8°C) and ship within 3 days of inoculation to transport media. For pure culture isolate on commercial semi-solid media, store according to temperature recommendations outlined in manufacturer's instructions and ship room temperature vials (15-25°C) or refrigerated temperature vials (2-8°C) within 3 days of inoculation to transport media. Alternatively, freeze culture following 36-48 hour anaerobic incubation and store frozen (-20°C or lower) until shipped. Anaerobe isolates submitted frozen in tryptic soy broth (TSB) plus glycerol (or preferably sterile skim milk media plus glycerol to enhance viability) must be inoculated very heavily (half to all the colonial mass from a 48-hour anaerobe culture plate). Ship isolates as soon as possible to ensure viability. **Nontuberculous Mycobacteria (NTM):** Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability.
Transport Medium	**Aerobic Bacteria:** Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Transport frozen (-20 °C or lower) submissions in trypticase soy broth (TSB) plus 15% glycerol. **Anaerobic Bacteria:** Transport pure culture isolates in chopped meat broth at room temperature (15-25°C) or refrigerated (2-8°C). Transport pure culture isolates in commercial anaerobic semi-solid agar tube transport media (e.g. Anaerobe Systems Transport Media) in accordance with manufacturer's instructions. Transport pure culture isolates frozen (-20°C or lower) in sterile skim milk media plus glycerol (preferred) or tryptic soy broth (TSB) plus glycerol. **Nontuberculous Mycobacteria (NTM):** Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on Lowenstein-Jensen agar, Middlebrook 7H10/7H11 agar or Middlebrook 7H9 broth. Transport frozen isolates in Middlebrook 7H9 broth. NOTE: The Mycobacteria Growth Indicator tube (MGIT) is not acceptable transport media. BacT/ALERT and VersaTREK culture media bottles are also not acceptable transport media.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship submissions overnight. Room-temperature samples should be shipped with room-temperature cold packs. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Broth microdilution (BMD), disk diffusion, agar dilution, agar gradient diffusion, additional phenotypic characterization, matrix assisted laser desorption ionization time of flight mass spectrometry (MALDI-TOF MS), 16S ribosomal ribonucleic acid (16S rRNA) and ß subunit of bacterial RNA polymerase (rpoB) gene sequencing, whole genome sequencing (WGS), real-time polymerase chain reaction (PCR), molecular detection of antimicrobial resistance genes, molecular detection of Staphylococcus toxin genes, Clostridioides toxin profiling and ribotyping, broth enrichment and bacterial isolation
Turnaround Time	
Interferences & Limitations	**All submissions:** Pure culture isolates must be viable for testing. **Aerobic Bacteria:** It is recommended that Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae be stored at room temperature (15-25 °C) to ensure isolate viability. **Anaerobic Bacteria:** Specimens from respiratory, vaginal, and fecal sources are not acceptable.
Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a healthcare facility will be submitting samples directly to CDC, they must receive prior approval from the State Health Department. Submissions require specific documentation as outlined in the Supplemental Information Required section. Turnaround Time varies based on organism and selected testing

CDC Points of Contact	Maria Machado (404) 718-1644 llx6@cdc.gov Davina Campbell (404) 639-4185 xew9@cdc.gov Michelle Adamczyk (404) 639-2276 wqp1@cdc.gov Porscha Bumpus White (404) 718-6203 ofu1@cdc.gov
Version	2.0

Test Order
Hendra Hemorrhagic Fever Testing- Non-CLIA
CDC-10324

Synonym(s)	
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.3

Test Order
Hepatitis A NAT and Genotyping- Non-CLIA
CDC-10621

Synonym(s)	HAV NAT and Genotyping
CDC Pre-Approval Needed	**Saleem Kamili** **(404) 639-4431** **sek6@cdc.gov** **Jan Drobeniuc** **(404) 639-3790** **jqd6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	500 µL; 1 mL - 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Qualitative real-time polymerase chain reaction (PCR) and genotyping by sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolyzed specimens are not acceptable.

Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Lili Punkova (404) 639-2355 vof6@cdc.gov Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov
Version	2.0

Test Order
Hepatitis A Serology- CLIA
CDC-10619

Synonym(s)	Serological markers of HAV infection
CDC 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	0.5 mL or greater for pediatric samples; 1.5 mL or greater for adults
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20°C. Frozen specimens should undergo no more than one freeze-thaw cycle.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Total antibody to Hepatitis A virus (total anti-HAV) and IgM antibody to Hepatitis A virus (IgM anti-HAV) by chemiluminescence immunoassay
Turnaround Time	3 Weeks
Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.
Additional Information	None

CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov

Version	2.0

Test Order
Hepatitis B Genotyping- Non-CLIA
CDC-10622

Synonym(s)	HBV Genotyping
CDC Pre-Approval Needed	**Saleem Kamili** **(404) 639-4431** **sek6@cdc.gov** **Jan Drobeniuc** **(404) 639-3790** **jqd6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL or greater for pediatric samples; 1.5 mL or greater for adults
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Hepatitis B genotyping through DNA sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	Hemolyzed specimens are not acceptable.

Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov
Version	2.0

Test Order
Hepatitis B Serology and Quantitative PCR- CLIA
CDC-10624

Synonym(s)	HBV Serology and Quantitative PCR
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	None
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	Serology: 0.5 mL or greater for pediatric samples; 1.5 mL or greater for adults / Quantitative PCR: 1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C. Frozen specimens should undergo no more than one freeze-thaw cycle.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Hepatitis B surface antigen (HBsAg), quantitative antibody to hepatitis B surface gene (quantitative anti-HBs), Immunoglobulin M (IgM) and total hepatitis B core antibody (anti-HBc) by chemiluminescence immunoassay; and Hepatitis B virus (HBV) deoxyribonucleic acid (DNA) by real-time PCR
Turnaround Time	3 Weeks
Interferences & Limitations	Hemolyzed specimens are not acceptable.
Additional Information	Currently, Hepatitis B Quantitative PCR is unavailable.

CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov

Version	2.0

Test Order
Hepatitis C Serology and Quantitative PCR- CLIA
CDC-10625

Synonym(s)	HCV Serology and Quantitative PCR
CDC 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	Serology: 0.5 mL or greater for pediatric samples; 1.5 mL or greater for adults / Quantitative PCR: 1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at -20 °C or lower. Frozen specimens should undergo no more than one freeze-thaw cycle.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All samples should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Antibody to Hepatitis C Virus (Anti-HCV) by Chemiluminescence, Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) by Real Time qualitative Real Time Polymerase Chain Reaction (qRT-PCR)
Turnaround Time	3 Weeks
Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.
Additional Information	None

CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov

Version	2.0

Test Order
Hepatitis D NAT- Non-CLIA
CDC-10627

Synonym(s)	HDV NAT
CDC Pre-Approval Needed	**Saleem Kamili** **(404) 639-4431** **sek6@cdc.gov** **Jan Drobeniuc** **(404) 639-3790** **jqd6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Hepatitis D ribonucleic acid testing (HDV NAT)
Turnaround Time	3 Weeks
Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.

Additional Information	The tests used have not been cleared and approved by the FDA. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov
Version	2.0

Test Order
Hepatitis D Serology- CLIA
CDC-10626

Synonym(s)	HDV Serology
CDC 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	1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4°C if shipped in less than 72 hours of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	ELISA to detect Total antibodies to hepatitis D virus (total anti-HDV)
Turnaround Time	3 Weeks
Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.
Additional Information	Disclaimer: This test has not been cleared or approved by the FDA. The anti-HDV test used is a commercially available test that has been validated for CLIA testing in the Diagnostic Reference Team at the CDC Division of Viral Hepatitis Laboratory Branch

CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov

Version	2.0

Test Order
Hepatitis E Serology, NAT and Genotyping- Non-CLIA
CDC-10628

Synonym(s)	HEV Serology, NAT and Genotyping
CDC Pre-Approval Needed	**Saleem Kamili** **(404) 639-4431** **sek6@cdc.gov** **Jan Drobeniuc** **(404) 639-3790** **jqd6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at or below -20 °C.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Immunoglobulin G (IgG) Anti-HEV and Immunoglobulin M (IgM) antibody to hepatitis E virus (anti-HEV) by enzyme-linked immunosorbent assay (ELISA); Hepatitis E Virus (HEV) Ribonucleic Acid (RNA) by Real Time qualitative Real Time Polymerase Chain Reaction (PCR), HEV Genotyping by nucleic acid sequencing
Turnaround Time	3 Weeks

Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.
Additional Information	The tests used have not been cleared and approved by the FDA. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. Temporarily, HEV NAT and Genotyping tests are not available.
CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov
Version	2.0

Test Order
Hepatitis Surveillance- Non-CLIA
CDC-10629

Synonym(s)	Global Hepatitis Outbreak and Surveillance Technology (GHOST), Hepatitis A, Hepatitis B, and Hepatitis C outbreaks
CDC Pre-Approval Needed	**Jan Drobeniuc** **(404) 639-3790** **jqd6@cdc.gov** **Saleem Kamili** **(404) 639-4431** **sek6@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form:** **Indicate the following code for test criteria in the Patient History Section of CDC 50.34 Specimen Submission Form:** **1 - Specimen from a case in a county that has yet reported a hepatitis A case in an at-risk population** **2 - Specimen from a case patient who does not report any known risk factors or contact with at-risk populations (e.g., household or sexual contact, volunteering at a homeless shelter)** **3 - Specimen from a case patient suspected to be associated with foodborne transmission** **4 - Archived/stored specimen from a patient who has died and whose classification as an out-break related death requires nucleic acid testing beyond anti-HAV IgM-positivity** **5 - Other patient specimens not meeting the above criteria that require nucleic acid testing or molecular characterization (to be discussed on a case-by-case basis).**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	1.5 mL or greater
Collection, Storage, and Preservation of Specimen Prior to Shipping	After collection, specimens may be stored at room temperature (15-25°C) for up to 8 hours or refrigerated (2–8°C) for up to 48 hours. Specimens stored beyond these time points must be frozen at -20 °C or lower.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 90 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Next Generation Amplicon Sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	Whole blood and hemolyzed specimens are not acceptable.
Additional Information	The tests used have not been cleared and approved by the FDA. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. Temporarily, HEV NAT and Genotyping tests are not available.
CDC Points of Contact	Jan Drobeniuc (404) 639-3790 jqd6@cdc.gov Lili Punkova (404) 639-2355 vof6@cdc.gov
Version	2.0

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

Synonym(s)	Oral herpes, Genital herpes
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	Cerebrospinal fluid (CSF): 0.5 mL Whole blood: 1 mL Viral transport media (VTM) inoculated with swabs from vesicular or pustular fluid: 1 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping	For the collection of skin lesion specimens, unroof the scab and place it directly into a breakage resistant tube. For swab collections of vesicular/pustular fluid from lesions, use a sterile needle to unroof the top of the vesicle. Use a sterile synthetic swab, e.g. polyester swab, to vigorously swab the base of the lesion, applying enough pressure to collect epithelial cells. Swabs may be placed directly into a storage tube. Swabs without VTM and skin lesion specimens should be kept dry, stored at room temperature (15-25°C), and shipped at room temperature within 1 week after collection. Swabs can also be placed in viral transport media. Refrigerate (2-8°C) viral transport medium (VTM) inoculated with swabs from vesicular or pustular fluid. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower. Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and stored in a leak proof container. CSF should be stored at -20°C or lower after collection but if needed, it can be stored at 2-8°C for no more than 72 hours. CSF specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. CSF can be stored at -20°C or lower for a maximum of 1 week prior to shipping. Anticoagulant blood collection tubes (EDTA) should be used for the collection of whole blood. Refrigerate whole blood within 1 hour of collection. These specimen types should not be stored at room temperature (15-25°C) for longer than 1 hour after collection. If these specimens will be stored for longer than 72 hours, they should be frozen at -20°C or lower. All viral transport medium inoculated with swabs from vesicular or pustular fluid, CSF, and whole blood specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.
Transport Medium	Viral transport medium (VTM) inoculated with swabs from vesicular or pustular fluid.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Swabs from vesicular or pustular fluid without viral transport media and skin lesion samples should be shipped overnight at room temperature with room-temperature cold packs. Cerebrospinal fluid (CSF), viral transport media inoculated with swabs from vesicular or pustular fluid and whole blood specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	2.9

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

Synonym(s)	Oral herpes, Genital herpes
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, plasma, or cerebrospinal fluid (CSF)
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen at -20°C.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship specimens with cold packs or dry ice as an etiologic agent. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by Enzyme Immunoassay (EIA)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	The test(s) used have been cleared and approved by the FDA but the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov

Version	2.7

Test Order
Herpesvirus Encephalitis Panel- CLIA
CDC-10262

Synonym(s)	
CDC Pre-Approval Needed	**Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov** **Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours. CSF should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) for VZV, Polymerase Chain Reaction (PCR) for HSV1, Polymerase Chain Reaction (PCR) for HSV2, Polymerase Chain Reaction (PCR) for EBV, Polymerase Chain Reaction (PCR) for HHV6

Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	3.5

Test Order
HIV Special Study- Non-CLIA
CDC-10278

Synonym(s)	
CDC Pre-Approval Needed	**Vickie Sullivan** **(404) 639-3963** **vst5@cdc.gov** **Jeffrey Johnson** **(404) 639-4976** **jlj6@cdc.gov**
Supplemental Information Required	**Contact the CDC POC for supplemental information**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.

CDC Points of Contact	Vickie Sullivan (404) 639-3963 vst5@cdc.gov Jeffrey Johnson (404) 639-4976 jlj6@cdc.gov

Version	2.4

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

Synonym(s)	HIV drug resistance (DR), HIVDR, HIV susceptibility to antiretroviral drugs (ARV), PI, NRTI, NNRTI, INSTI
CDC Pre-Approval Needed	**Joshua DeVos** **(404) 639-5442** **ext8@cdc.gov** **Guoqing Zhang** **(404) 718-4268** **uwz2@cdc.gov**
Supplemental Information Required	**Contact the CDC POCs to obtain the appropriate forms and supplemental information/materials to assist in completing the laboratory specific forms and packaging guidance for DBS.**
Supplemental Form	**Supplemental forms will be provided after pre-approval for specimen submission. Contact the CDC Point of Contacts for: 1) ILB-160-F08D Drug Resistance Requisition Form 2) CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma prepared from EDTA whole blood (centrifuged within 6 hours of collection). Dried blood spots (DBS) prepared from EDTA whole blood (venous whole blood preferred) on a 903 sample collection card or similar.
Minimum Volume Required	Plasma: 0.2 mL (0.5mL preferred) of EDTA plasma. DBS: 4 DBS of 100 µL (5 DBS preferred) in each 13mm printed circle on a blood collection card.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma: EDTA whole blood centrifuged within 6 hours of collection and aliquoted in 1.5 - 2.0 mL polypropylene tube with screw cap and O-ring. Freeze plasma aliquots at -70 °C or colder within 24 hours. DBS: Prepared DBS specimens must be labeled and dried thoroughly prior to packaging. To prevent cross-contamination, separate DBS cards with glassine paper and place in a gas-impermeable bags containing desiccant packs and humidity indicator. Humidity indicators must be visible inside bag without opening. Gently apply pressure to the partially sealed bag to expel the air before completely sealing. If humidity indicator card or dessicant packs must be changed, allow bags to equilibrate to ambient temperature before opening to avoid exposure of samples to humidity. Ensure the specimen identification is clearly visible on both DBS card and plasma tubes. Ideally, use printed barcoded labels or printed information.
Transport Medium	None
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Plasma: Pack plasma specimens per IATA guidelines and ship on dry ice. DBS: Prior to transport, check the dessicants and humidity indicator cards for presence of humidity. Change if necessary. Transport DBS specimens at ambient temperature if to be received within 14 days; otherwise ship DBS on dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 97 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Identification of mutations within HIV-1 pol gene region by ribonucleic acid (RNA) extraction, polymerase chain reaction (PCR) amplification, deoxyribonucleic acid (DNA) sequencing, and Drug Resistance analysis
Turnaround Time	16 Weeks
Interferences & Limitations	Testing will not be performed on the following specimens: - Improperly labeled or unlabeled - Discrepant or missing documentation - Insufficient sample volume - Evidence of leakage or contamination - Use of any anticoagulant other than EDTA - DBS prepared on FTA cards - DBS shipped without dessicant or humidity indicators - Transport time is greater than 14 days Test sensitivity is reduced when specimen undergo multiple freeze thaw cycles.
Additional Information	The genotyping assay may not detect minor viral species infecting a patient that constitute less than 20% of virus mixtures. Consultation with an expert in HIV drug resistance is encouraged to facilitate interpretation of susceptibility or resistance to antiretroviral drugs and to evaluate antiretroviral treatment options.

CDC Points of Contact	Joshua DeVos (404) 639-5442 ext8@cdc.gov Clement Zeh (404) 553-7264 cbz2@cdc.gov Guoqing Zhang (404) 718-4268 uwz2@cdc.gov

Version	1.5

Test Order

HIV-1 Limiting Antigen Avidity Enzyme Immunoassay (International Only)- Non-CLIA CDC-10540

Synonym(s)	LAg
CDC Pre-Approval Needed	**Ernest Yufenyuy** **404-639-1548** **yod0@cdc.gov** **Trudy Dobbs** **404-639-3760** **Tld3@cdc.gov**
Supplemental Information Required	**Supplemental forms will be provided upon Pre-Approval. Following fields are required: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested. All submitted specimens must include two unique specimen identifiers and collection date.**
Supplemental Form	**ILB-160-F08B HIV Serology Requisition Form**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma, Serum, Dried Blood Spots (DBS). DBS are made from fingerstick or venipuncture (EDTA) whole blood on Whatman 903 filter paper.
Minimum Volume Required	Plasma: 0.5 mL (2 mL preferred) Serum: 0.5 mL (2 mL preferred) Dried Blood Spots (DBS): 2 full blood spots (3 full blood spots preferred). DBS should be 13mm circles containing 75 µL of whole blood.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood should be processed into plasma or serum within 24 hours. For plasma whole blood collection, blood can be collected in EDTA anticoagulant tubes. Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at at -20°C or colder. Do not send specimens after more than 5 freeze-thaw cycles. Dried Blood Spots (DBS): DBS must be placed in a airtight zippered bag with 3-5 desiccant packs and 1 humidity indicator card once the blood spot is dried (no more than 24 hours after collection). Up to 10 cards, separated by glassine paper, can be included in 1 zippered bag. Bag may be be stored at 15-30°C for up to 14 days after collection) if shipped within 14 days, or at 2-8°C for up to 2 months or at -20°C or colder.
Transport Medium	Plasma/ Serum: Specimens should be shipped in leak-proof plastic screw-cap vials. For shipments that are in transit for up to 7 days, ship on gel ice-packs. For shipments that are in transit for greater than 7 days, ship on dry ice. DBS: DBS cards should be stored in gas impermeable plastic bag with desiccant bags and humidity indicator card. For shipments that are in transit for up to 14 days, maintain at room temperature (15-35°C). For shipments that are in transit for greater than 14 days, ship on dry ice.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 100 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Limiting antigen avidity enzyme immunoassay
Turnaround Time	8 Weeks
Interferences & Limitations	Classification of individuals as recent seroconverters or long-term infections is based on average development of higher avidity HIV-antibodies calculated from data using a large number of people. As a result, differences among individuals in terms of maturation of HIV antibodies and the rates at which high avidity HIV-antibodies are made may exist. Moreover, while this assay is useful at the population level, its predictive value for individuals has not been determined (especially when levels are close to the cutoff). Therefore, the assay should not be used for individual assessment of recency of infection. Persons with diagnosis of AIDS or low CD4+ T cell counts (<200 cells per µl), recipients of anti-retroviral therapy, and known elite controllers should be excluded from the study as they appear to contribute to the misclassification of long-term infections.
Additional Information	Determination of HIV-1 incidence for surveillance purposes only. Specimen will be rejected for any of the following reasons: improperly labeled, unlabeled, discrepant documentation, no documentation, insufficient quantity, and/or evidence of contamination.
CDC Points of Contact	Ernest Yufenyuy 404-639-1548 yod0@cdc.gov Trudy Dobbs 404-639-3760 Tld3@cdc.gov

Version	1.1

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

Synonym(s)	HIV-1 RNA qualitative, HIV NAAT
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated plasma (preferred) or serum
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	This test can be performed on EDTA-treated plasma (preferred) or serum. Whole blood can be stored refrigerated (2-8°C) or room temperature (15-25°C) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Separated plasma or serum may be stored refrigerated (2-8°C) for up to three days or frozen at -20°C or lower for up to 60 days. Specimen should not have incurred more than two freeze-thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated separated plasma or serum with refrigerated or frozen cold packs. Ship frozen serum or plasma specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Nucleic acid amplification
Turnaround Time	3 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Minimize storage at 18°C to 30°C in order to preserve HIV-1 RNA.
Additional Information	If testing results are inconclusive, additional plasma or serum may be required for subsequent testing.
CDC Points of Contact	Vickie Sullivan (404) 639-3963 vst5@cdc.gov Jeffrey Johnson (404) 639-4976 jlj6@cdc.gov

Version	3.6

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

Synonym(s)	HIV, EID, PMTCT, Early infant diagnostic, DNA
CDC Pre-Approval Needed	**Clement Zeh** **(404) 553-7264** **cbz2@cdc.gov** **Guoqing Zhang** **(404) 718-4268** **uwz2@cdc.gov**
Supplemental Information Required	**Supplemental forms will be provided upon Pre-Approval:** **- Following fields are required to be filled: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested.** **- All submitted specimens must include two unique specimen IDs and collection date.**
Supplemental Form	**FRM-000041-ILB Viral load-EID requisition form. Contact CDC POC to request form.**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Dried Blood Spots (DBS)
Minimum Volume Required	At least 3 fully saturated completely filled 13mm circles (preferably 5) containing 70 microliters of whole blood including capillary blood obtained by finger/toe/heel stick which is dropped directly onto the DBS card
Collection, Storage, and Preservation of Specimen Prior to Shipping	The appropriate anticoagulant for DBS whole blood collection is EDTA. Dried blood spots should be kept at an ambient temperature (15 °-35 °C) for storage and shipment if testing is performed within 14 days or frozen at -70 °C if testing is not performed within 14 days.
Transport Medium	None
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact CDC POC prior to submission. Dried blood spots should be transported in a gas impermeable bag with dessicant and humidity indicator card. For shipments that are in transit for up to 14 days, maintain at ambient temperature (15-35 °C) and shipments that are in transit for greater than 14 days, maintain temperature at -20 °C or colder with dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 96 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Qualitative Polymerase Chain Reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Do not use heparin as an anticoagulant. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.
Additional Information	Contact CDC POC for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing. NOTE: If a specific testing platform is required, please contact CDC POC.
CDC Points of Contact	Clement Zeh (404) 553-7264 cbz2@cdc.gov Katrina Sleeman (404) 639-1886 hhk6@cdc.gov

Version	1.8

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

Synonym(s)	HIV, VL, RNA
CDC Pre-Approval Needed	**Clement Zeh** **(404) 553-7264** **cbz2@cdc.gov** **Guoqing Zhang** **(404) 718-4268** **uwz2@cdc.gov**
Supplemental Information Required	**Supplemental forms will be provided upon Pre-Approval:** **- Following fields are required to be filled: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested.** **- All submitted specimens must include two unique specimen IDs and collection date.**
Supplemental Form	**FRM-000041-ILB Viral load-EID requisition form. Contact CDC POC to request form.**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma or dried blood spots (DBS)
Minimum Volume Required	Plasma: 1.1mL plasma (3mL ideally) DBS: At least 3 saturated 13mm circles (preferably 5) containing 70Î¼L of whole blood including capillary blood obtained by venipuncture or finger/toe/heel stick which is dropped directly onto the DBS card
Collection, Storage, and Preservation of Specimen Prior to Shipping	The appropriate anticoagulant for whole blood collection is EDTA. Fresh whole blood may be held at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours. After centrifugation, plasma may be stored at 15-30 °C for up to 24 hours and at 2-8 °C for up to 5 days. Plasma may be frozen at -70 °C or colder. Freeze-thaw cycles should be avoided and should not exceed 3 cycles. Dried blood spots should be kept at an ambient temperature (15 °-35 °C) for storage and shipment if testing is performed within 14 days or frozen at -70 °C if testing is not performed within 14 days.
Transport Medium	None
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Plasma: Refer to Plasma Shipment information on page 4 of International Laboratory Branch Test Directory or contact CDC POC prior to submission. Plasma specimens should be submitted in 1.5-2.0 mL polypropylene tubes, screw cap with O-ring. To maintain temperature of -20 °C or colder, plasma specimens should be shipped on dry ice. DBS: Refer to Dried Blood Spots for HIV Serology testing, Early Infant Diagnostics or HIV Drug Resistance Shipment information on page 5 of International Laboratory Branch Test Directory or contact CDC POC prior to submission. DBS should be shipped in gas impermeable bags with desiccant and humidity indicator cards. For shipments that are in transit for up to 14 days, maintain at ambient temperature (15-35 °C) and shipments that are in transit for greater than 14 days, maintain temperature at -20 °C or colder with dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 96 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Quantitative Polymerase Chain Reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Do not use heparin as an anticoagulant. Do not use specimens after more than 5 freeze-thaw cycles for the Roche assays and 3 freeze-thaw cycles for the Abbott m2000 assay. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	Contact CDC POC for turnaround times for batches with greater than 100 specimens or for batches being sent for diagnostic testing. NOTE: If a specific testing platform is required, please contact CDC POC.

CDC Points of Contact	Clement Zeh (404) 553-7264 cbz2@cdc.gov Katrina Sleeman (404) 639-1886 hhk6@cdc.gov

Version	1.7

Test Order
HIV-1 Rapid Recency Assay- Non-CLIA
CDC-10541

Synonym(s)	Recent Infection, Rapid Point-of-Care Assay, Immunoassay, Lateral Flow, Incidence, International only
CDC Pre-Approval Needed	**Ernest Yufenyuy** **404-639-1548** **yod0@cdc.gov** **Trudy Dobbs** **404-639-3760** **Tld3@cdc.gov**
Supplemental Information Required	**Supplemental forms will be provided upon Pre-Approval. Following fields are required: Requestor (Sender POC), Address, E-Mail, Phone, Date of shipment, Number of specimens, Specimen type, Tests requested. All submitted specimens must include two unique specimen identifiers and collection date.**
Supplemental Form	**ILB-160-F08B HIV Serology Requisition Form**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma, Serum
Minimum Volume Required	Plasma: 0.5 mL (2 mL preferred) Serum: 0.5 mL (2 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Whole blood should be processed into plasma or serum within 24 hours. Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at -20°C or colder. For plasma whole blood collection, blood can be collected in EDTA anticoagulant tubes.
Transport Medium	Specimens can be kept refrigerated at 2-8°C if shipped within 72 hours of collection; otherwise specimen should be kept frozen at -20°C or colder.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 100 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Lateral flow rapid test
Turnaround Time	8 Weeks
Interferences & Limitations	Determination of HIV-1 incidence for surveillance purposes only. Persons with diagnosis of AIDS or low CD4+ T cell counts (<200 cells per µl), recipients of anti-retroviral therapy, and known elite controllers should be excluded from the study populations to reduce the likelihood of misclassification of recency of infection. The Rapid Test for Recent Infection (RTRI) does not distinguish between HIV-1 and HIV-2. HIV-2 positive specimens should be excluded from recency analysis.
Additional Information	Determination of HIV-1 incidence for surveillance purposes only. Specimen will be rejected for any of the following reasons: improperly labeled, unlabeled, discrepant documentation, no documentation, insufficient quantity, and/or evidence of contamination.
CDC Points of Contact	Ernest Yufenyuy 404-639-1548 yod0@cdc.gov Trudy Dobbs 404-639-3760 Tld3@cdc.gov
Version	1.1

Test Order
HIV-1 Western Blot- CLIA
CDC-10557

Synonym(s)	HIV-1 serology, HIV-1 antibodies
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated plasma (preferred) or serum
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	This test can be performed on EDTA-treated plasma (preferred) or serum. Whole blood can be stored refrigerated (2-8°C) or room temperature (15-25°C) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Separated plasma or serum may be stored refrigerated (2-8°C) for up to three days or frozen at -20°C or lower for up to 60 days. Specimen should not have incurred more than two freeze-thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated separated plasma or serum with refrigerated or frozen cold packs. Ship frozen serum or plasma specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Enzyme immunoassay (EIA), Immunochromatographic assay and Western blot
Turnaround Time	3 Weeks
Interferences & Limitations	Extensive hemolysis may affect test performance. Minimize storage at 18°C to 30°C to preserve p24 antigen reactivity.
Additional Information	The HIV-1/2 antigen/antibody combination immunoassay, if reactive, is followed by the HIV-1/2 differentiation supplemental assay and the HIV-1 Western Blot. If testing results are inconclusive, additional plasma or serum may be required for subsequent testing.
CDC Points of Contact	Vickie Sullivan (404) 639-3963 vst5@cdc.gov Jeffrey Johnson (404) 639-4976 jlj6@cdc.gov
Version	1.4

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

Synonym(s)	HIV, RT
CDC Pre-Approval Needed	**Ernest Yufenyuy** **(404) 639-1548** **yod0@cdc.gov** **Keisha Jackson** **(404) 639-2547** **iqz5@cdc.gov**
Supplemental Information Required	**Specimens must be accompanied with complete requisition form(s).** **CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma and serum
Minimum Volume Required	Plasma and serum 0.5 mL (2.0 mL recommended)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma: The appropriate anticoagulant for whole blood collection is EDTA. If testing is to be performed within 7 days keep specimen refrigerated at 2-8 °C. If testing is to be performed after 7 days, keep specimen frozen at -20 °C or colder.
Transport Medium	Specimen should be transported in a plastic screw-cap vial
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 100 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Immuno-chromatography
Turnaround Time	13 Weeks

Interferences & Limitations	Do not use specimens after more than 5 freeze-thaw cycles. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	Turn around times are dependent on batch specimen: Batch with less than 200 specimens - within 50 days Batch with 200-600 - within 70 days Batch with greater than 600 specimens - within 90 days
CDC Points of Contact	Ernest Yufenyuy (404) 639-1548 yod0@cdc.gov Keisha Jackson (404) 639-2547 iqz5@cdc.gov
Version	1.3

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

Synonym(s)	CDC/APHL HIV Diagnostic Algorithm, HIV Serology Testing with reflex to NAT
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Include patient clinical history and previous lab results within the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated plasma (preferred) or serum
Minimum Volume Required	2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	This test can be performed on EDTA-treated plasma (preferred) or serum. Whole blood can be stored refrigerated (2-8°C) or room temperature (15-25°C) and must be separated within 24 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Separated plasma or serum may be stored refrigerated (2-8°C) for up to three days or frozen at -20°C or lower for up to 60 days. Specimen should not have incurred more than two freeze-thaw cycles.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated separated plasma or serum with refrigerated or frozen cold packs. Ship frozen serum or plasma specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 77 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Enzyme immunoassay (EIA), immunochromatographic assay, nucleic acid amplification (NAT)
Turnaround Time	3 Weeks
Interferences & Limitations	Extensive hemolysis may affect test performance. Do not exceed 48 hours storage at 18°C to 30°C to preserve p24 antigen reactivity.
Additional Information	HIV-1/2 antigen/antibody immunoassay is followed by an HIV-1/2 differentiation supplemental assay, which may be followed by an HIV-1 RNA amplification (qualitative - CDC-10275). If testing results are inconclusive, additional plasma or serum may be required for subsequent testing.
CDC Points of Contact	Vickie Sullivan (404) 639-3963 vst5@cdc.gov Jeffrey Johnson (404) 639-4976 jlj6@cdc.gov
Version	3.7

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

Synonym(s)	HIV, EIA, WB, ELISA
CDC Pre-Approval Needed	**Ernest Yufenyuy** **(404) 639-1548** **yod0@cdc.gov** **Keisha Jackson** **(404) 639-2547** **iqz5@cdc.gov**
Supplemental Information Required	**Specimens must be accompanied with complete requisition form(s).** **Plasma or serum: CDC Form 0.753: Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease and Requisition Form** **Dried Blood Spots: Requisition Form**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma, serum and dried blood spots
Minimum Volume Required	Plasma or serum: 0.5 mL (2.0 mL recommended). Dried Blood Spots: 4 saturated paper circles (13 mm filter) (5 recommended) containing 75 µL of whole blood.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma and Dried Blood Spots (DBS): Prepare from EDTA whole blood. Plasma and Serum storage: Store and ship plasma and serum specimens at -20 °C or colder. Dried Blood Spot storage: Separate individual dried blood spot specimen cards using glassine paper and package them into gas impermeable bags with desiccants and humidity indicator card. Store and ship dried blood spots at -20 °C or colder. Contact CDC POC for DBS filter paper card requirements. For shipping, organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID. For shipping, organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID.
Transport Medium	Transport plasma and/or serum in plastic screw-cap vial with O-ring. Dried blood spots should be in gas impermeable plastic bag with desiccant and humidity indicator card and packaged separately.

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Organize serum, plasma and/or DBS specimens in ascending order according to their specimen ID prior to shipping. For serum and plasma shipments that are in transit for up to 7 days, maintain refrigerated temperature. If the serum and plasma shipments are in transit for greater than 7 days, maintain frozen temperature with dry ice. For DBS shipments that are in transit for up to 14 days, maintain at refrigerated temperature. If the DBS shipments that are in transit for greater than 14 days, maintain frozen temperatures with dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 100 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All specimens must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Enzyme Immunoassay, Immunochromatography (Supplemental/Confirmatory Assay), Enzyme-linked Immunosorbent Blot Technique (Western Blot)
Turnaround Time	23 Weeks
Interferences & Limitations	Do not use plasma and serum after more than 5 freeze-thaw cycles. Plasma or serum will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination. Dried blood spots will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, without humidity indicators and desiccants, demonstrating any indication of humidity in the zip lock bags, insufficient volume for testing, improperly collected, containing blood clots or clumps, with a halo around the blood spot indicating contamination, if specimen are congruent or show evidence of commingling and collected onto inappropriate filter paper.

Additional Information	Positive results are confirmed by the Supplemental Assay and/or Western Blot. Western Blot with an EIA-positivity has combined specificity of greater than 99.9%. Testing for EIA, Supplemental Assay and Western Blot is performed in batches and the turnaround times are the following: - Batch with less than 200 specimens - within 8 weeks - Batch with 200-600 - within 11 weeks - Batch with 600 - 1,000 specimens - within 13 weeks - Batch with greater than 1,000 specimens - within 23 weeks Contact CDC POC for batches greater than 2,000 specimens.
CDC Points of Contact	Ernest Yufenyuy (404) 639-1548 yod0@cdc.gov Keisha Jackson (404) 639-2547 iqz5@cdc.gov
Version	2.1

Test Order
Human Herpesvirus 6 Detection and Subtyping- CLIA
CDC-10266

Synonym(s)	HHV6
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours. Whole blood should be collected in anticoagulant blood collection tubes (EDTA). Refrigerate (2-8°C) whole blood within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower). All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.
Transport Medium	Not applicable.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	2.7

Test Order
Human Herpesvirus 6 Serology- Non-CLIA
CDC-10497

Synonym(s)	HHV6
CDC Pre-Approval Needed	**Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov** **Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum and plasma
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum or plasma samples may be stored at 4 °C for up to one week and can be shipped overnight on cold packs in well-sealed O-ring vials. If more than a week, store at -20 °C and can be shipped overnight on dry ice in well-sealed O-ring vials.
Transport Medium	Transport medium is not required.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Enzyme Linked Immunosorbent Assay (ELISA)
Turnaround Time	7 Days

Interferences & Limitations	False positive results may be obtained if samples are excessively lipemic or contaminated by bacteria. False negative results may be obtained if samples are not properly stored after collection.
Additional Information	HHV-6 antibody detection method (HHV-6 ELISA) used to detect HHV-6 IgG specific antibodies in human serum or plasma. The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results reported should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	3.5

Test Order
Human Herpesvirus 7 Detection- CLIA
CDC-10267

Synonym(s)	HHV7
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Cerebrospinal fluid (CSF) should be collected under sterile conditions and stored in a leak proof container, then stored frozen (-20°C or lower) or, if needed, refrigerated (2-8°C) up to 72 hours. Whole blood should be collected in anticoagulant blood collection tubes (EDTA or citrate). Refrigerate (2-8°C) whole blood within 1 hour of collection. If these specimens will be stored for longer than 72 hours, they should be frozen (-20°C or lower). All specimens submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped on dry ice overnight. Specimens can be stored at -20°C or lower for a maximum of 1 week prior to shipping.
Transport Medium	Not applicable.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Cerebrospinal fluid (CSF) and whole blood specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.

Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	2.7

Test Order

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

CDC-10533

Synonym(s)	HIV-1
CDC Pre-Approval Needed	**Bill Switzer** **(404) 639-0219** **bis3@cdc.gov** **Hao Zheng** **(404) 639-2421** **hxz2@cdc.gov**
Supplemental Information Required	**A separate form for additional information will be provided after the test request is approved.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, plasma or whole blood
Minimum Volume Required	1 mL plasma or serum; 10 mL whole blood
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen stability is affected by elevated temperature. Whole blood should not be frozen but can be kept at 15-30 °C for up to 6 hours or at 2-8 °C for up to 24 hours prior to shipping. Plasma and serum specimens may be stored an additional five days at 2 °C to 8 °C following centrifugation. Plasma and serum specimens may be stored at less than or equal to -20 °C for up to 6 months; however, storage at these temperatures for longer periods has not been fully evaluated. Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) or Acid Citrate Dextrose (ACD) tubes. Plasma can be collected using plasma preparation tubes (PPT) or EDTA or ACD. Serum can be collected in serum tubes. Follow sample tube manufacturer's instructions. Shipping of specimens the same day of collection is preferred.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Ship unprocessed whole blood specimens overnight for next morning delivery at ambient temperature. Shipping of whole blood specimens overnight on wet ice packs is acceptable during periods of high environmental tempartures. If serum or plasma is collected, these specimens should be shipped frozen overnight on dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 227 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Nucleic acid (DNA and RNA) amplification and sequence analysis
Turnaround Time	3 Weeks
Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	For RNA testing, separate the plasma or serum by centrifugation and transfer serum or plasma to a polypropylene screw-cap tube with an O-ring for shipment. Freeze (-70 °C is optimal, -20 °C acceptable) sera/plasma as soon as possible after separation (min volume of 1mL of plasma/sera is required, 5 mLs is optimal).
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov Hao Zheng (404) 639-2421 hxz2@cdc.gov Anupama Shankar (404) 639-1484 ikb6@cdc.gov
Version	1.3

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

Synonym(s)	
CDC Pre-Approval Needed	**Elizabeth Unger** **(404) 639-3533** **eru0@cdc.gov** **Gitika Panicker** **(404) 639-2269** **dhv1@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 178 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	To be determined
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	HPV testing is for surveillance/research studies and needs to be arranged with CDC POC. Assays include a variety of HPV typing and HPV serology platforms.

CDC Points of Contact	Elizabeth Unger (404) 639-3533 eru0@cdc.gov Gitika Panicker (404) 639-2269 dhv1@cdc.gov Troy Querec (404)639-2864 hep0@cdc.gov

Version	2.0

Test Order
Influenza Molecular Detection in Clinical Specimens- CLIA
CDC-10421

Synonym(s)	Influenza Real Time PCR, Influenza Diagnostics, Flu
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Include patient's name and second identifier on the specimen vial. The two identifiers on the specimen vial label must match what is on the CDC 50.34 Specimen Submission form or in CSTOR.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For qualitative detection of influenza virus type A or B viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW] and dual nasopharyngeal/throat swabs [NPS/TS]) and lower respiratory tract specimens (including bronchoalveolar lavage [BAL], bronchial wash [BW], tracheal aspirate [TA], sputum, and lung tissue) and H5 conjunctival swabs.
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron ®, and an aluminum or plastic shaft. Clinical specimens should be transported to the laboratory within less than or equal to 2 hours. Specimens that are to be shipped to CDC should be stored frozen (-20°C or lower) until shipped. May be held for up to 7 days prior to shipping.
Transport Medium	Respiratory specimens must be in viral transport medium (VTM) or universal transport medium (UTM). Lavage specimens in phosphate buffered saline (PBS) are accepted.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship frozen specimens on dry ice. Urgent specimens can be shipped any time with prior approval from the laboratory. Prior to shipping, notify CDC Influenza Division that you are sending a specimen. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 198 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Real-time reverse transcriptions - polymerase chain reactions (rRT-PCR)
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 will take longer than seven days for results.
CDC Points of Contact	Kai Hui Wu (404) 639-4508 ckq8@cdc.gov Marie Kirby (404) 718-7689 pbi0@cdc.gov
Version	3.5

Test Order
Influenza Serology- Non-CLIA
CDC-10424

Synonym(s)	Influenza Hemagglutination inhibition assay, Influenza microneutralization assay
CDC Pre-Approval Needed	**Min Levine** **(404) 639-3504** **mwl2@cdc.gov** **James Stevens** **(404) 639-5008** **fwb4@cdc.gov**
Supplemental Information Required	**Supplemental form will be supplied upon consultation with laboratory**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Paired Serum; Acute (less than 7 days post symptoms onset) and convalescent (at least 14 days after acute serum collection)
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Should be collected and immediately frozen. Specifics around storage and preservation are supplied on the supplemental form and upon consultation with laboratory.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 82s 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Hemagglutination inhibition assay, Microneutralization assay
Turnaround Time	6 Weeks
Interferences & Limitations	Whole blood cannot be used for testing. Lipemic or hemolyzed sera will affect test results.
Additional Information	None

CDC Points of Contact	Min Levine (404) 639-3504 mwl2@cdc.gov James Stevens (404) 639-5008 fwb4@cdc.gov

Version	2.4

Test Order
Influenza Special Study- Non-CLIA
CDC-10425

Synonym(s)	
CDC Pre-Approval Needed	**Rebecca Kondor** **(404) 639-1371** **dqy5@cdc.gov** **Todd Davis** **(404) 639-1428** **ctdavis@cdc.gov**
Supplemental Information Required	**Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password)**
Supplemental Form	**Influenza Specimen Submission Form.** **https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. ATTN: Angie Foust Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 198 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	
Turnaround Time	

Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	Rebecca Kondor (404) 639-1371 dqy5@cdc.gov Larisa Gubareva (404) 639-3204 lqg3@cdc.gov Todd Davis (404) 639-1428 dqy5@cdc.gov
Version	1.6

Test Order
Influenza Surveillance- Non-CLIA
CDC-10422

Synonym(s)	Flu, Influenza Antigen Characterization
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Requires completed Influenza Specimen Submission Form (Can be obtained from APHL with your password)**
Supplemental Form	**Influenza Specimen Submission Form. https://www.aphl.org/programs/infectious_disease/influenza/Pages/Specimen_Submission.aspx**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Respiratory specimens (nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes, dual nasopharyngeal/throat swabs, bronchoalveolar lavage, sputum, tracheal aspirate, etc.), virus cultures, and others upon consultation with the laboratory.
Minimum Volume Required	1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron ®, and an aluminum or plastic shaft. Ensure that, when transporting human respiratory specimens, all applicable regulations for the transport of etiologic agents are met. Specimens received cold should be stored refrigerated (2-8 °C) for up to 72 hours before processing. Store any residual specimens at or below -70 °C. Although optimal performance is met when testing fresh specimens within 72 hours of collection, performance has been demonstrated with frozen specimens. If testing of a fresh specimen is not possible within 72 hours storage at 2-8 °C, the specimen may be frozen at or below -70 °C and tested at a later time. Specimens received frozen should be stored at or below -70 °C until processing. Store any residual specimens at or below -70 °C.
Transport Medium	Swabs must be in viral transport medium
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Ship extracted RNA and frozen specimen on dry ice. Refrigerated specimen should be shipped on cold packs. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Urgent specimen can be shipped any time with prior approval from the laboratory. Refer to the International Air Transport Association (IATA - www.iata.org) for requirements for shipment of human or potentially infectious biological specimens. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 200 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Hemagglutination Inhibition (HI) test, Virus Culture
Turnaround Time	4 Weeks
Interferences & Limitations	Low virus numbers or co-infections can affect test results. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended because it can cause a false-negative result.
Additional Information	None
CDC Points of Contact	Wendy Sessions (404) 639-3211 gra6@cdc.gov Rebecca Kondor (404) 639-1371 dqy5@cdc.gov
Version	1.5

Test Order
International Infection Control Branch (IICB) Special Studies (International Only)-Non-CLIA
CDC-10558

Synonym(s)	International Infection Control Branch (IICB), Antimicrobial Resistance in Communities and Hospitals (ARCH), Global Action in Healthcare Network (GAIHN), Global Antimicrobial Laboratory & Response Network (GARLRN); Healthcare Associated Infections (HAI)
CDC Pre-Approval Needed	**Kara Moser** **(989) 600-8918** **qsy5@cdc.gov** **Natashia Reese** **(404) 718-5584** **nfu2@cdc.gov**
Supplemental Information Required	**Contact the CDC POC for instructions on completing appropriate forms for submittal. For pure culture isolate submittals, the CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) must include the date the submitted culture was inoculated onto transport media. For nucleic acid, the CDC 50.34 Specimen Submission Form or GFAT must include the date of initial sample collection.**
Supplemental Form	**The following supplemental forms will be provided after pre-approval for submission: Study-Specific Requisition Form(s) and CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease.**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates: pure culture isolates of bacteria DNA: extracted nucleic acid in elution buffer
Minimum Volume Required	Isolates: Not Applicable DNA: Contact CDC POC
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability and to avoid loss of antimicrobial resistance mechanisms. Store extracts frozen (-20 °C or lower) and protect from repeated freeze thaws.
Transport Medium	For Isolates: Transport refrigerated (2-8 °C) specimens on suitable agar medium. Transport frozen (-20 °C or lower) specimens in TSB plus glycerol. For DNA: Transport frozen (-20 °C or lower) in elution buffer

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship submissions overnight. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 154 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Amplification and next generation sequencing, phenotypic testing, Disk Diffusion, E-test, Molecular Detection of Antimicrobial Resistance Markers, Broth Microdilution (BMD), Antimicrobial Susceptibility Testing (AST)
Turnaround Time	52 Weeks
Interferences & Limitations	The ability to generate sequences relies primarily on nucleic acid quantity and specimen quality. Pure culture isolates must be viable for testing.
Additional Information	The test(s) used have not been cleared and approved by the FDA or the performance characteristics have not been fully established by CDC. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management.
CDC Points of Contact	Kara Moser (989) 600-8918 qsy5@cdc.gov Natashia Reese (404) 718-5584 nfu2@cdc.gov Gillian McAllister (404) 639-2283 HAISeq@cdc.gov
Version	2.3

Test Order
Kyasanur Forest Disease Testing- Non-CLIA
CDC-10341

Synonym(s)	KFD
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.5

Test Order
Laguna Hemorrhagic Fever Testing- Non-CLIA
CDC-10342

Synonym(s)	HPS, hanta
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For molecular and serology testing, specimens should be shipped frozen on dry ice. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.3

Test Order
Lassa Fever Testing- CLIA
CDC-10343

Synonym(s)	*Arenavirus*
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	**Recommended method**: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 30 days of collection. **Alternative method (not recommended)**: Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.6

Test Order
Lassa Fever Testing- Non-CLIA
CDC-10605

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) for PCR, Whole blood (EDTA) or serum for serology
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	2.0

Test Order

Legionella species Detection and Identification from Clinical Specimens or Isolates-Non-CLIA

CDC-10159

Synonym(s)	*Legionella pneumophila, L. pneumophila, Legionella,* Legionnaires' disease, LD, Legionellosis, Pontiac fever
CDC Pre-Approval Needed	**Melisa Willby** **(404) 639-5479** **mwillby@cdc.gov** **Maureen Diaz** **(404) 639-4534** **iqs5@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For culture: sputum, bronchoalveolar lavage (BAL), fluid_bronchial, bronchial washings, tracheal aspirate, endotracheal tube washes, microbial isolate and fresh lung tissue will be accepted. For molecular characterization: presumptive Legionella pure culture isolates, sputum, bronchoalveolar lavage (BAL), fluid_bronchial, bronchial washings, tracheal aspirate, endotracheal tube washes, and fresh lung tissue will be accepted. Other specimen types will be rejected.
Minimum Volume Required	Respiratory Specimens for culture: 0.05 mL; 0.1 mL preferred. Respiratory specimens for molecular characterization: 0.2 mL; 0.5 mL preferred. Fresh Lung Tissue: 3 mm3; 5 mm3 preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect specimens prior to antibiotic treatment, if possible. Refrigerate (2-8°C) specimens promptly after collection and freeze (-20°C or lower) within 96 hours. Specimens should be kept frozen and shipped within 40 days. Maintain isolates to ensure viability.
Transport Medium	For pure culture isolates: buffered charcoal yeast extract (BCYE) slants (preferred) or plates.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen on dry ice (next day delivery). Isolates should be shipped refrigerated with refrigerated or frozen cold packs (next day delivery) or at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 33 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Specimens and isolates: culture, sequencing, real-time polymerase chain reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Non-viable isolates will be rejected.
Additional Information	None
CDC Points of Contact	primary contact (404) 639-5479 legionellalab@cdc.gov Melisa Willby (404) 639-5479 ghx9@cdc.gov Maureen Diaz (404) 639-4534 iqs5@cdc.gov
Version	6.0

Test Order
Legionella species Detection and Identification from Environmental Samples and Isolates- Non-CLIA
CDC-10160

Synonym(s)	*Legionella pneumophila, L. pneumophila, Legionella,* Legionnaires' disease, LD, Legionellosis, Pontiac fever
CDC Pre-Approval Needed	**Primary Contact** **legionellalab@cdc.gov** **Melisa Willby** **(404) 639-5479** **ghx9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Samples from environmental and other associated sources and their derived pure culture isolates. Consult with CDC POC prior to sending samples.
Minimum Volume Required	Consult CDC POC for minimum volume required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates should be maintained to ensure viability.
Transport Medium	For pure culture isolates: buffered charcoal yeast extract (BCYE) slants (preferred) or plates.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Isolates should be shipped refrigerated with refrigerated or frozen cold packs (next day delivery) or at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 33 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Culture, Sequencing, Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Samples that are not collected, stored, or transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Non-viable isolates will be rejected.
Additional Information	None
CDC Points of Contact	legionellalab@cdc.gov (Primary Contact) 404-639-5479 legionellalab@cdc.gov Melisa Willby 404-639-5479 ghx9@cdc.gov Jonas Winchell (Emergency) (404)639-4921 jwinchell@cdc.gov
Version	4.5

Test Order
Legionella species Molecular Detection from Clinical Specimens- CLIA
CDC-10573

Synonym(s)	Legionella pneumophila, L. pneumophila, Legionella, Legionnaires' disease, LD, legionellosis, Pontiac fever
CDC Pre-Approval Needed	**Melisa Willby** **404-639-5479** **ghx9@cdc.gov** **Maureen Diaz** **404-639-4534** **iqs5@cdc.gov**
Supplemental Information Required	**Complete one submission form per specimen. Required fields include: test order code, test order name, date specimen collected, material submitted, specimen source (type)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Sputum, bronchoalveolar lavage (BAL), bronchial fluid, bronchial washings, tracheal aspirate, endotracheal tube washes, and fresh lung tissue will be accepted. Other specimen types will be rejected
Minimum Volume Required	Respiratory specimens: 0.2 mL; 0.5 mL preferred. Fresh Lung Tissue: 3 mm3; 5 mm3 preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect specimens prior to antibiotic treatment, if possible. Refrigerate (2-8°C) specimens promptly after collection and freeze (-20°C or lower) within 96 hours. Specimens should be kept frozen and shipped within 40 days.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen on dry ice (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 33 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Multiplex Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Primary Contact 404-639-5479 LegionellaNGS@cdc.gov Melisa Willby 770-868-7167 ghx9@cdc.gov Maureen Diaz 404-639-4534 iqs5@cdc.gov
Version	2.0

Test Order
Leishmania species Identification- CLIA
CDC-10238

Synonym(s)	Parasite
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated whole blood and bone marrow, unpreserved skin tissue
Minimum Volume Required	0.2 mL of blood or bone marrow
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored in sterile leak-proof containers. Tissue specimens should be placed in a small amount of sterile buffered medium (e.g., buffered saline, RPMI, Eagle's growth, Schneider's, Tobie's, etc), kept refrigerated (2-8°C), and shipped to CDC within 7 days of collection. Tissue stored beyond 7 days must be frozen at or below -20°C for up to 30 days. EDTA-treated whole blood and bone marrow specimens must be kept refrigerated (2-8°C) and shipped within 7 days of collection.
Transport Medium	Unpreserved tissue specimens should be transported in a sterile buffered medium (e.g., buffered saline, RPMI, Eagle's growth, Schneider's, Tobie's, etc). EDTA-treated (purple top) whole blood and bone marrow do not require transport medium.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens must be shipped to CDC by same- or next-day courier as an etiologic agent. Samples stored refrigerated must be shipped in insulated shipping containers with refrigerated or frozen cold packs. Frozen samples must be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Conventional and Real-time Polymerase Chain Reaction (PCR) and Sanger sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	Formalin-fixed specimens are not suitable for this test order. Please see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov regarding testing of formalin-fixed specimens.
Additional Information	Acceptable Specimen Type for Testing: Unpreserved skin tissue is the preferred specimen type for cutaneous leishmaniasis. Blood and bone marrow are only suitable to diagnose visceral leishmaniasis. Shipping Instructions: Refrigerated specimens must arrive to CDC at 2-8°C within 7 days of collection. Frozen specimens must arrive to CDC at or below -20°C within 30 days of collection. Specimens not meeting these conditions will not be accepted for testing and new specimen will be required.
CDC Points of Contact	Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov Billy Watson (404) 639-8194 qjs7@cdc.gov
Version	6.1

Test Order
Leptospira species Molecular Detection- CLIA
CDC-10200

Synonym(s)	Leptospirosis, PCR
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood and serum
Minimum Volume Required	0.60 mL for serum and whole blood.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Refrigerated (2-8°C) for up to 14 days post- collection and frozen (-20°C or lower) for up to 28 days. Blood specimens should be collected in EDTA or Sodium Citrate tubes (not heparin). All specimens cannot exceed 3 freeze/thaw cycles.
Transport Medium	Transport medium is not required.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Samples should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Heparin may cause interference with the molecular tests and should be avoided.
Additional Information	Study or research samples should be submitted under test code CDC-10202, *Leptospira* species Study

CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

Version	2.1

Test Order
Leptospira species Serology- CLIA
CDC-10201

Synonym(s)	Leptospirosis serology, MAT, microagglutination test
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Paired serum samples is preferred (acute: during active stage of illness; convalescent: 2-4 weeks after acute stage)
Minimum Volume Required	0.1 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum may be stored at refrigerated temperature (2-8°C) for up to 7 days post-collection and frozen (-20°C or lower) for up to 2 months. Specimens should not exceed 3 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Microagglutination test (MAT)
Turnaround Time	2 Weeks
Interferences & Limitations	Plasma is not an acceptable specimen. Hemolysis can interfere with testing.
Additional Information	Study or research samples should be submitted under test code CDC-10202, *Leptospira* species Study

CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

Version	1.7

Test Order
Leptospira species Study- Non-CLIA
CDC-10202

Synonym(s)	
CDC Pre-Approval Needed	**Zoonoses and Select Agent Laboratory ZSAL** **(404) 639-1711** **zsal@cdc.gov** **Bacterial Special Pathogens Branch CDC** **(770) 488-7100** **bzb@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 91 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined

CDC Points of Contact	Zoonoses and Select Agent Laboratory ZSAL (404) 639-1711 ZSAL@cdc.gov Robyn Stoddard (404) 639-2053 frd8@cdc.gov

Version	1.4

Test Order
Listeria Identification and Characterization- Non-CLIA
CDC-10129

Synonym(s)	*L. innocua, L. ivanovii, L. marthii, L. monocytogenes, L. seeligeri, L. welshimeri*
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Listeria*; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, chocolate agar, etc.). If isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 20 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Genetic Identification
Turnaround Time	13 Weeks
Interferences & Limitations	Repeat freeze/thaw cycles can lower test sensitivity.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Zuzana Kucerova (404) 718-4143 zik0@cdc.gov Christine Lee (404) 498-2295 pfx6@cdc.gov
Version	2.8

Test Order
Listeria Subtyping- Non-CLIA
CDC-10130

Synonym(s)	*Listeria* species
CDC Pre-Approval Needed	**Zuzana Kucerova** **(404) 718-4143** **zik0@cdc.gov** **Christine Lee** **(404) 498-2295** **pfx6@cdc.gov**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of Listeria; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, chocolate agar, etc.). If isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 20 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Genetic Identification
Turnaround Time	
Interferences & Limitations	Repeat freeze/thaw cycles can lower test sensitivity.
Additional Information	Refer to study protocol for specific requirements.
CDC Points of Contact	Zuzana Kucerova (404) 718-4143 zik0@cdc.gov Christine Lee (404) 498-2295 pfx6@cdc.gov

Version	3.3

Test Order
LRN Biothreat Multi-Agent Screening - Environmental- Non-CLIA
CDC-10430

Synonym(s)	Screening for *Bacillus anthracis*, *Brucella spp.*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, *Yersinia pestis*, Orthopoxvirus, and ricin toxin.
CDC Pre-Approval Needed	**Jennifer Folster** **(404) 639-3668** **apz5@cdc.gov** **Melissa Whaley** **(404) 639-3920** **dbq3@cdc.gov**
Supplemental Information Required	**Please contact Dr. Jennifer Folster at (404) 639-3668 or apz5@cdc.gov, for the required supplemental form and packaging and shipping requirements.**
Supplemental Form	**None**
Performed on Specimens From	Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Bulk sampling of visible materials (e.g., powders, liquids, etc.) and/or sampling from contaminated surfaces (e.g., with polyester swabs).
Minimum Volume Required	Dependent on Specimen Type
Collection, Storage, and Preservation of Specimen Prior to Shipping	Dry swabs or powders can be stored and shipped at room temperature. Liquid samples should be held and shipped at 4 °C.
Transport Medium	None
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. If weekend delivery is necessary, please contact laboratory upon shipment. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 49A 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real Time PCR, Culture Isolation, Time-Resolved Fluorescence
Turnaround Time	7 Days
Interferences & Limitations	Dependent on sample type
Additional Information	Turnaround time is dependent on test and sample type.

CDC Points of Contact	Jennifer Folster (404) 639-3668 apz5@cdc.gov Melissa Whaley (404) 639-3920 dbq3@cdc.gov

Version	4.5

Test Order
Lymphocytic Choriomeningitis (LCM) Testing- CLIA
CDC-10345

Synonym(s)	LCM, *Arenavirus*
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Human serological specimens stored refrigerated (2-8°C) must be received within 7 days of specimen collection date, and specimens stored frozen (-20°C or below) must be received within 2 months of specimen collection date. Human specimens for PCR testing stored refrigerated (2- 8°C) must be received within 3 days of specimen collection, and specimens stored frozen (-20°C or below) must be received within 2 months of specimen collection date. Contact the CDC POC for approval prior to sending any specimens.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	serology, polymerase chain reaction (PCR)

Turnaround Time	2 Weeks
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. Please include the EPIID in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form. Critical specimens will take less than 4 days to turn around.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.6

Test Order
Lymphocytic Choriomeningitis (LCM) Testing- Non-CLIA
CDC-10608

Synonym(s)	LCM, *Arenavirus*
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA), serum, and cerebral spinal fluid for PCR Whole blood (EDTA), serum, and cerebral spinal fluid for serology
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	2.0

Test Order
Machupo Hemorrhagic Fever Testing- Non-CLIA
CDC-10347

Synonym(s)	Bolivian Hemorrhagic Fever, BHF, *Arenavirus*
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.4

Test Order
Malaria Molecular Identification- CLIA
CDC-10480

Synonym(s)	Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale, Plasmodium knowlesi, parasites
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Submit the blood smear slides with the whole blood, each with its own CDC 50.34 Specimen Submission Form. Microscopic examination of blood smears is mandatory prior to performing molecular detection. Malaria Molecular Identification will be performed if microscopy cannot provide a species-level diagnosis.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	EDTA-treated whole blood
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored in leak-proof containers and kept refrigerated (2-8°C) or frozen (-20°C or lower) at all times. Ship to CDC within 30 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped to CDC by same or next-day courier as an etiologic agent. Specimens must be shipped in insulated shipping containers with cold packs, or with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks

Interferences & Limitations	1. This test has not been evaluated for detection of Plasmodium species that on rare occasions can infect humans and cause zoonotic malaria (e.g., P. cynomolgi, P. inui, P. simiovale, P. simium). Cases of suspected zoonotic malaria should be further investigated with other genotyping methods. 2. This test cannot distinguish between P. malariae and P. brasilianum.
Additional Information	Provide country of travel on specimen submission form. Shipping Instructions: Specimens must arrive to CDC at 2-8°C (if shipped on cold packs) or -20°C or lower (if shipped on dry ice) within 30 days of collection. Specimens not meeting these conditions will not be accepted for testing and new specimen will be required. For questions about submitting specimens, email parasiteslab@cdc.gov. For malaria diagnostic options and related clinical questions call the Malaria Hotline: (770) 488-7788.
CDC Points of Contact	Parasitology Lab Mailbox (404) 718-4123 parasiteslab@cdc.gov Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov
Version	4.7

Test Order
Malaria Molecular Surveillance and Genotyping- Non-CLIA
CDC-10235

Synonym(s)	Malaria Molecular Typing, Parasite
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please provide the following specimen information on the CDC Global File Accessioning Template (GFAT): the patient's travel and treatment history, if available.**
Supplemental Form	**Please provide a completed GFAT with each submission (will be provided in addition to detailed domestic malaria surveillance specimen submission instructions upon request to malarialab@cdc.gov).**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Anticoagulated whole blood Thin and/or thick smears on glass slides The CDC Malaria Laboratory is also able to accept molecular sequence data generated by partnering public health organizations. Before sequencing a sample, please contact malarialab@cdc.gov for more information about the next-generation sequencing approaches CDC uses for P. falciparum and P. vivax, and to obtain information on sequence data control requirements, data quality requirements, and file naming conventions.
Minimum Volume Required	0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store collected specimen refrigerated at 4 °C until shipped to CDC, preferably within 7 days of collection.
Transport Medium	Transport medium not applicable.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. We prefer to receive unfrozen specimens shipped to CDC at ambient temperature, though we can accept frozen specimens shipped to CDC frozen. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 221 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR), DNA Sequencing, In-vitro culture
Turnaround Time	
Interferences & Limitations	No signs of interference or limitations are currently known.
Additional Information	Research or surveillance specimens should be labeled according to the CDC domestic malaria surveillance specimen submission instructions that will be emailed directly to submitters upon contacting malarialab@cdc.gov. Please do not include patient personally identifiable information on labels for research or surveillance specimens.
CDC Points of Contact	Christina Carlson (404) 718-7923 okq1@cdc.gov Julia Kelley (404) 718-4426 xfi8@cdc.gov Joel Barratt (404) 718-1027 nsk9@cdc.gov Malaria Laboratory (770) 488-7788 malarialab@cdc.gov
Version	6.5

Test Order
Marburg Hemorrhagic Fever Testing- CLIA
CDC-10349

Synonym(s)	Orthomarburgvirus
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Recommended method: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 60 days of collection. Alternative method (not recommended): Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)

Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	*Turnaround time is 10 business days. Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	5.7

Test Order
Marburg Hemorrhagic Fever Testing- Non-CLIA
CDC-10604

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) for PCR. Whole blood (EDTA) or serum for Serology
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.

CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov

Version	2.0

Test Order
Measles Avidity- Non-CLIA
CDC-10248

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**Sara Mercader** **(404) 639-4568** **sjm7@cdc.gov** **Heather Colley** **(404) 718-5822** **ohg1@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum. Samples must be measles IgG positive for testing. IgG status will be confirmed by additional testing at CDC. The following conditions may result in the specimen being rejected for testing: • Specimen is measles IgG negative. • Specimen is not frozen upon receipt at CDC. • Specimen is hemolyzed, lipemic, or bacterially contaminated.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for avidity testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 8 weeks prior to shipping. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Measles IgG avidity Enzyme Linked Immunosorbent Assay (ELISA) and Indirect IgG ELISA.
Turnaround Time	4 Weeks
Interferences & Limitations	Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with measles vaccine. If obtained, intermediate avidity results are not interpretable.
Additional Information	Avidity testing is used for vaccine failure classification. Avidity results cannot rule out measles cases.
CDC Points of Contact	Sara Mercader (404) 639-4568 sjm7@cdc.gov Heather Colley (404) 718-5822 ohg1@cdc.gov
Version	2.0

Test Order
Measles Detection- CLIA
CDC-10543

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, throat swabs, urine
Minimum Volume Required	Urine: 50 mL Nasopharyngeal swabs, throat swabs: 0.2 mL; 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Detection of measles RNA is most successful when samples are collected on the first day of rash through the 3 days following onset of rash. Detection of measles RNA by real-time reverse-transcription polymerase chain reaction (rRT-PCR) may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected. rRT-PCR has the greatest diagnostic sensitivity when samples are collected at first contact with a suspected case. Nasopharyngeal swabs and throat swabs should be collected with commercial swab products designed for the collection of throat/nasopharyngeal specimens or flocked polyester fiber swabs. Cotton swabs are not acceptable. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, throat and nasopharyngeal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Urine: 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen.
Transport Medium	For nasopharyngeal swabs and throat swabs: Standard viral transport medium (VTM). Transport medium is not required for urine.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay
Turnaround Time	7 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. A negative result should not be used to rule out measles infection as many variables can affect specimen quality.
Additional Information	For additional information regarding laboratory testing, please see the laboratory testing section in the measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html. For information about molecular diagnostics, see the CDC Measles Webpage: https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov
Version	1.6

Test Order
Measles Genotyping- Non-CLIA
CDC-10240

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, nasal swabs, throat swabs, urine, and urine sediment, Consult the CDC Point of Contact about suitability of other specimen types.
Minimum Volume Required	Urine: 10mL (50mL preferred)All other specimen types: 0.2 mL (2 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal swabs and throat swabs should be collected with commercial swab products designed for the collection of throat/nasopharyngeal specimens or flocked polyester fiber swabs. Cotton swabs are not acceptable. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, throat and nasopharyngeal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Urine: Up to 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen. Urine sediment: 50mL of urine should be collected in a sterile container and then processed by centrifuging at 1500 rpm for 10 minutes. The sediment should be resuspended in 0.5mL VTM at 2-8°C and shipped to CDC overnight on cold packs. If there is a delay in shipment, the sample is best preserved by freezing at -70C. Frozen samples should be shipped on dry ice. Consult the CDC Point of Contact for information on the collection, storage, and preservation of other specimen types.
Transport Medium	For nasopharyngeal swabs, nasal swabs, throat swabs: Standard viral transport medium (VTM). Transport medium is not required for urine.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat, nasal and nasopharyngeal swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Reverse transcription PCR (RT-PCR), genotyping by nucleic acid sequencing
Turnaround Time	10 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in RT-PCR. Non-Flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently.
Additional Information	The genotyping assay has not been cleared or approved by the FDA. The performance characteristics have not been fully established by VVPDB. The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patient's medical record. For additional information regarding laboratory testing, please see the measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html in the laboratory testing section For information about molecular tests, see the CDC Measles Webpage: https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics
CDC Points of Contact	Gimin Kim (404) 718-6216 ofi6@cdc.gov Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov
Version	3.5

Test Order
Measles Molecular Special Study- Non-CLIA
CDC-10606

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, nasal swabs, throat swabs, urine, and urine sediment. Consult the CDC Point of Contact about suitability of other specimen types.
Minimum Volume Required	Urine: 10mL (50mL preferred) All other specimen types: 0.2 mL (2 mL preferred)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Detection of measles RNA is most successful when samples are collected on the first day of rash through the 3 days following onset of rash. Detection of measles RNA by real-time reverse-transcription polymerase chain reaction (rRT-PCR) may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected. rRT-PCR has the greatest diagnostic sensitivity when samples are collected at first contact with a suspected case. Nasopharyngeal swabs and throat swabs should be collected with commercial swab products designed for the collection of throat/nasopharyngeal specimens or flocked polyester fiber swabs. Cotton swabs are not acceptable. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, throat and nasopharyngeal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Urine: Up to 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen. Urine sediment: 50mL of urine should be collected in a sterile container and then processed by centrifuging at 1500 rpm for 10 minutes. The sediment should be resuspended in 0.5mL VTM at 2-8°C and shipped to CDC overnight on cold packs. If there is a delay in shipment, the sample is best preserved by freezing at -70°C. Frozen samples should be shipped on dry ice. Consult the CDC Point of Contact for information on the collection, storage, and preservation of other specimen types.

Transport Medium	For nasopharyngeal swabs, nasal swabs, throat swabs, and urine sediment: Standard viral transport medium (VTM). Transport medium is not required for urine.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay
Turnaround Time	8 Weeks
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. A negative result should not be used to rule out measles infection as many variables can affect specimen quality.
Additional Information	The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patient's medical record. **Measles vaccine virus detection is available for specimens from patients with potential wild-type exposure or suspected vaccine reaction within 21 days of vaccination. This test can be requested in the comment field of the Global File Accessioning Template (GFAT) or via email. Please include the vaccination date and rash onset date.** For additional information regarding laboratory testing, please see the measles surveillance manual: https://www.cdc.gov/surv-manual/php/table-of-contents/chapter-7-measles.html in the laboratory testing section For information about molecular tests, see the CDC Measles Webpage: https://www.cdc.gov/measles/php/laboratories/genetic-analysis.html

CDC Points of Contact	Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov Gimin Kim (404) 718-6216 ofi6@cdc.gov

Version	2.0

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

Synonym(s)	Rubeola, PRN test, Plaque-reduction neutralization
CDC Pre-Approval Needed	**Sara Mercader** **(404) 639-4568** **sjm7@cdc.gov** **Heather Colley** **(404) 718-5822** **ohg1@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: date of birth, date of onset, date of specimen collection, date(s) of MMR vaccination, clinical symptoms and travel history. Provide any preliminary results available.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen (-20°C or lower) upon receipt at CDC
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Neutralization assay - quantitative serological assay
Turnaround Time	4 Weeks
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	For additional information related to specialized serologic testing at CDC, see https://www.cdc.gov/measles/lab-tools/serology.html.
CDC Points of Contact	Sara Mercader (404) 639-4568 sjm7@cdc.gov Heather Colley (404) 718-5822 ohg1@cdc.gov
Version	2.3

Test Order
Measles Serology Special Study- Non-CLIA
CDC-10251

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**Sara Mercader** **(404) 639-4568** **sjm7@cdc.gov** **Heather Colley** **(404) 718-5822** **ohg1@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 8 weeks prior to shipping. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA, or plaque reduction neutralization assay or IgG avidity
Turnaround Time	4 Weeks
Interferences & Limitations	Capture Measles IgM Enzyme Linked Immunosorbent Assay (ELISA): IgM positive may not occur until 4 days post-rash onset Measles IgG avidity: Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with measles vaccine. If obtained, intermediate avidity results are not interpretable. Plaque reduction neutralization assay: There are no known interferences and limitations.
Additional Information	None
CDC Points of Contact	Sara Mercader (404) 639-4568 sjm7@cdc.gov Heather Colley (404) 718-5822 ohg1@cdc.gov
Version	2.8

Test Order
Measles Serology- CLIA
CDC-10244

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information on CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination (if known) and travel history. Provide any preliminary results available.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum. The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 8 weeks prior to shipping. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA
Turnaround Time	7 Days
Interferences & Limitations	IgM positive may not occur until 4 days post-rash onset
Additional Information	IgM and IgG assays are qualitative assays. Include vaccination history, age, date of onset and sample collection.
CDC Points of Contact	Sara Mercader (404) 639-4568 sjm7@cdc.gov Heather Colley (404) 718-5822 ohg1@cdc.gov
Version	2.5

Test Order
Measles Vaccine Virus Detection- CLIA
CDC-10528

Synonym(s)	Rubeola
CDC Pre-Approval Needed	**Paul Rota** **(404) 639-4181** **par1@cdc.gov** **Jessica Prince Guerra** **(404) 498-4023** **yov0@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form for each individual specimen. Please include date of vaccination and date of rash onset.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, throat swabs, urine
Minimum Volume Required	Urine: 50 mL Nasopharyngeal swabs, throat swabs: 0.2 mL; 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Detection of measles RNA is most successful when samples are collected on the first day of rash through the 3 days following onset of rash. Detection of measles RNA by real-time reverse-transcription polymerase chain reaction (rRT-PCR) may be successful as late as 10-14 days after rash onset. Collect throat or nasopharyngeal swab samples as soon as measles disease is suspected. rRT-PCR has the greatest diagnostic sensitivity when samples are collected at first contact with a suspected case. Nasopharyngeal swabs and throat swabs should be collected with commercial swab products designed for the collection of throat/nasopharyngeal specimens or flocked polyester fiber swabs. Cotton swabs are not acceptable. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, throat and nasopharyngeal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Urine: 50 mL of urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated at 2-8°C immediately after collection and shipped to CDC overnight on cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen
Transport Medium	For nasopharyngeal swabs and throat swabs: Standard viral transport medium (VTM). Transport medium is not required for urine.

Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay
Turnaround Time	7 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. A negative result should not be used to rule out measles infection as many variables can affect specimen quality.
Additional Information	This assay specifically detects measles vaccine strains and must be performed in parallel with the existing Measles Detection (CDC-10543). It should only be performed on specimens collected from patients who have potentially been exposed to wild-type virus OR may have a suspect vaccine reaction due to a recently administered vaccination (i.e., within 21 days of measles containing vaccine). Vaccination history is required. For additional information, please see the measles surveillance manual: http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html and the CDC measles webpage for information about molecular diagnostics https://www.cdc.gov/measles/lab-tools/genetic-analysis.html#diagnostics
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov

Test Order

Measurement of HIV Antiretroviral Drugs in Dried Blood Spots and Plasma Specimens by Liquid Chromatography-Tandem Mass Spectrometry- Non-CLIA CDC-10615

Synonym(s)	None
CDC Pre-Approval Needed	**Hetal Patel** **(404) 639-4156** **byg7@cdc.gov** **Jose Perez** **(770) 488-0179** **awt6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Plasma and DBS
Minimum Volume Required	Plasma: Recommended volume: 2.0 mL; Minimum volume: 0.1 mL DBS: At least 1 saturated 13-mm circle (preferably 3–5) containing 75 µL of whole blood
Collection, Storage, and Preservation of Specimen Prior to Shipping	Plasma: Refrigerated at 2-8 °C: Testing is performed within 7 days. Frozen at -20 °C or colder: Testing is not performed within 7 days. Do not use specimens after more than 5 freeze-thaw cycles. DBS: Ambient temperature (15–35 °C): Testing is performed within 14 days. Frozen at -20 °C or colder: Testing is not performed within 14 days.
Transport Medium	Transport Container Plasma: Plastic screw-cap vial DBS: Gas impermeable plastic bag with desiccant bags and humidity indicator card Transport Temperature Plasma: For shipments that are in transit for up to 7 days, maintain temperature at 2-8 °C. For shipments that are in transit for greater than 7 days, maintain temperature at -20 °C or colder. DBS: For shipments that are in transit for up to 14 days, maintain at ambient temperature (15-35 °C). For shipments that are in transit for greater than 14 days, maintain temperature at -20 °C or colder.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 95 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Liquid chromatography-tandem mass spectrometry (LC-MS/MS)
Turnaround Time	15 Weeks
Interferences & Limitations	Do not use specimens after more than 5 freeze-thaw cycles. Specimen will be rejected if improperly labeled or unlabeled, without documentation or with discrepant documentation, insufficient volume, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	Turnaround times are dependent on batch specimen: Batch with less than 500 specimens – within 6 weeks Batches with 500 to 1000 specimens – within 8 weeks Batches with 1000 to 2000 specimens – within 10 weeks Batches >2000 specimens – within 15 weeks
CDC Points of Contact	Hetal Patel (404) 639-4156 byg7@cdc.gov Jose Perez (770) 488-0179 awt6@cdc.gov
Version	2.0

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

Synonym(s)	MERS-CoV PCR, Middle East Respiratory Syndrome Coronavirus PCR
CDC Pre-Approval Needed	**David Lowe** **(404) 718-6814** **nqu9@cdc.gov** **JB Bertumen** **(470) 957-1347** **rhz5@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal and/or Oropharyngeal swabs, sputum, and lower respiratory tract aspirates/washes.
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	When collecting upper respiratory swabs, place swabs immediately into sterile tubes containing 2-3 ml of viral transport media. • Specimens can be stored at 2-8°C for up to 72 hours after collection. • If a delay in extraction is expected, store specimens at -70°C or lower.
Transport Medium	Swabs should be shipped in either commercial viral transport media or universal transport media.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen, overnight on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 84 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)

Turnaround Time	2 Weeks
Interferences & Limitations	Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.
Additional Information	Current information on MERS-CoV, including case definitions, is available at https://www.cdc.gov/coronavirus/MERS/ Additional information for specimen collection is available at https://www.cdc.gov/mers/php/laboratories/index.html
CDC Points of Contact	Lijuan Wang (404) 639-4384 ynx2@cdc.gov Stacey Gonder (404) 639-8739 urv6@cdc.gov David Lowe (404) 718-6814 nqu9@cdc.gov
Version	5.8

Test Order
Moraxella species Identification- CLIA
CDC-10140

Synonym(s)	*Moraxella*, GNDC
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

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

Synonym(s)	TaqMan ® Array Card, TAC, Community acquired pneumonia, CAP, respiratory pathogens
CDC Pre-Approval Needed	**Jonas Winchell** **(404) 639-4921** **jwinchell@cdc.gov** **Maureen Diaz** **(404) 639-4534** **mdiaz1@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.2 mL (viral or universal transport media (VTM, UTM), aspirate, bronchoalveolar lavage (BAL), or cerebrospinal fluid (CSF)); 0.4 mL preferred 0.1 mL (purified nucleic acid)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Nasopharyngeal (NP) and oropharyngeal (OP) swabs: use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Combine NP and OP swabs in a single sterile vial containing at least 2 mL of viral transport media (VTM). Refrigerate (2–8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection. Specimens should be kept frozen and shipped within 40 days.
Transport Medium	Viral transport medium (VTM) or Universal transport medium (UTM)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time Polymerase Chain Reaction (PCR) microfluidic array
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	The intended use of this test is for investigation of unexplained respiratory disease outbreaks. Visit www.cdc.gov/urdo for additional information or contact URDOutbreaks@cdc.gov.
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov

Version	2.2

Test Order
Mumps Detection- CLIA
CDC-10544

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Buccal swabs
Minimum Volume Required	0.2 mL (buccal swabs); 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect buccal swabs as soon as mumps disease is suspected. Real-time reverse-transcription polymerase chain reaction (rRT-PCR) has the greatest diagnostic sensitivity when samples are collected within 3 days of symptom onset. The buccal swabs specimens are obtained by massaging the parotid gland area for 30 seconds prior to swabbing the area around Stensen's duct. A commercial product designed for the collection of throat specimens, or a flocked polyester fiber swab can be used. Cotton swabs are not acceptable. Buccal swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, buccal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, buccal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Buccal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower.
Transport Medium	Buccal swabs: Standard viral transport medium (VTM).
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay
Turnaround Time	7 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in rRT-PCR. Non-Flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently. A negative result should not be used to rule out mumps infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB).
Additional Information	For additional information, please see the CDC mumps webpages: https://www.cdc.gov/mumps/lab/index.html
CDC Points of Contact	Paul Rota (404) 639-4181 par1@cdc.gov Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov
Version	1.6

Test Order
Mumps Genotyping- Non-CLIA
CDC-10241

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Buccal swabs. Consult the CDC Point of Contact about suitability of other specimen types.
Minimum Volume Required	0.2 mL (buccal swabs); 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	A commercial product designed for the collection of throat specimens, or a flocked polyester fiber swab can be used. Cotton swabs are not acceptable. Buccal swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, buccal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, buccal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Buccal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Consult the CDC Point of Contact for information on the collection, storage, and preservation of other specimen types.
Transport Medium	For buccal swabs: Standard viral transport medium (VTM). For other specimen types, consult the POC.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen swab specimens should be shipped frozen on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Reverse transcription PCR (RT-PCR), genotyping by nucleic acid sequencing
Turnaround Time	10 Days
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in RT-PCR. Non-flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently.
Additional Information	The genotyping assay has not been cleared or approved by the FDA. The performance characteristics have not been fully established by VVPDB. The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patient's medical record. For additional information, please see the CDC mumps webpages: https://www.cdc.gov/mumps/php/laboratories/index.html
CDC Points of Contact	Gimin Kim (404) 718-6216 ofi6@cdc.gov Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov
Version	3.6

Test Order
Mumps Molecular Special Study- Non-CLIA
CDC-10607

Synonym(s)	None
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Buccal swabs. Consult the CDC Point of Contact about suitability of other specimen types.
Minimum Volume Required	0.2 mL (buccal swabs); 2 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect buccal swabs as soon as mumps disease is suspected. Real-time reverse-transcription polymerase chain reaction (rRT-PCR) has the greatest diagnostic sensitivity when samples are collected within 3 days of symptom onset. The buccal swabs specimens are obtained by massaging the parotid gland area for 30 seconds prior to swabbing the area around Stensen's duct. A commercial product designed for the collection of throat specimens, or a flocked polyester fiber swab can be used. Cotton swabs are not acceptable. Buccal swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, buccal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, buccal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Buccal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Consult the CDC Point of Contact for information on the collection, storage, and preservation of other specimen types.
Transport Medium	Buccal swabs: Standard viral transport medium (VTM).
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time reverse-transcription polymerase chain reaction (rRT-PCR) assay
Turnaround Time	8 Weeks
Interferences & Limitations	Specimens must remain frozen; warming or freeze thawing reduces sensitivity. Cotton swabs are not recommended and may contain substances that are inhibitory to enzymes used in rRT-PCR. Non-Flocked synthetic swabs are not preferred and appear to be less absorbent and elute samples less efficiently. A negative result should not be used to rule out mumps infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB).
Additional Information	The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patient's medical record. For additional information, please see the CDC mumps webpages: https://www.cdc.gov/mumps/php/laboratories/index.html
CDC Points of Contact	Jessica Prince Guerra (404) 498-4023 yov0@cdc.gov Gimin Kim (404) 718-6216 ofi6@cdc.gov
Version	2.0

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

Synonym(s)	PRN test, Plaque-reduction neutralization
CDC Pre-Approval Needed	**Heather Colley** **(404) 718-5822** **ohg1@cdc.gov** **Sara Mercader** **(404) 639-4568** **sjm7@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Paired serum specimens: acute-phase serum sample (collected as soon as possible upon suspicion of mumps disease) and a second serum sample (collected 5-10 days after symptom onset). The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen (-20°C or lower) upon receipt at CDC.
Minimum Volume Required	0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Neutralization assay - quantitative serological assay
Turnaround Time	4 Weeks
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	For additional information related to speciman collection, storage and shipment, see https://www.cdc.gov/mumps/lab/specimen-collect.html.
CDC Points of Contact	Heather Colley (404) 718-5822 ohg1@cdc.gov Sara Mercader (404) 639-4568 sjm7@cdc.gov
Version	2.4

Test Order
Mumps Serology Special Study- Non-CLIA
CDC-10252

Synonym(s)	
CDC Pre-Approval Needed	**Sara Mercader** **(404) 639-4568** **sjm7@cdc.gov** **Heather Colley** **(404) 718-5822** **ohg1@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum IgG avidity: Samples must be mumps IgG positive for testing. IgG status will be confirmed by additional testing at CDC. The following conditions may result in the specimen being rejected for testing: • All assays: Specimen is hemolyzed, lipemic, or bacterially contaminated. • All assays: Specimen is not frozen (-20°C or lower) upon receipt at CDC • IgG avidity: Specimen is measles IgG negative.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 8 weeks prior to shipping. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Capture IgM Enzyme Linked Immunosorbant Assay (ELISA) and Indirect IgG ELISA, or plaque reduction neutralization assay or IgG avidity
Turnaround Time	4 Weeks
Interferences & Limitations	CDC IgM capture, commercial indirect IgG and IgG avidity assays: 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. IgG avidity: Assay limitations include difficulty in interpretation of results from infants with potential presence of maternal antibodies or from individuals recently immunized with mumps vaccine. Results are not necessarily representative of the avidity of mumps-neutralizing IgG antibodies nor associated with protection. High-avidity IgG may be detected in unvaccinated individuals with prior asymptomatic mumps. Plaque reduction neutralization assay: There are no known interferences and limitations.
Additional Information	None
CDC Points of Contact	Sara Mercader (404) 639-4568 sjm7@cdc.gov Heather Colley (404) 718-5822 ohg1@cdc.gov
Version	2.8

Test Order
Mumps Serology- CLIA
CDC-10245

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum. The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	If it has been >3 days after symptom onset, blood for serologic testing should be collected by aseptic venipuncture. Do not add anticoagulants or preservatives. Collect blood in a red-top or serum-separator tube (SST). Tubes containing whole blood should not be stored frozen (-20°C or lower). Centrifuge blood collection tubes (10 minutes at 1000 – 1300 g) to separate serum from clot. Gel separation tubes should be centrifuged no more than 2 hours after collection. Aseptically transfer serum to a sterile tube that has an externally threaded cap with an o–ring seal. If the serum sample collected >3 days after parotitis onset is IgM negative, and the case has a negative (or not done) result for RT-PCR, and there is a strong suspicion of mumps a second serum sample collected greater than 5 days after symptom onset is recommended because, in some cases, the IgM response is not detectable until 5 days after symptom onset. Refrigerate serum (2-8°C) within 8 hours of collection. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). All samples submitted for serology testing should be frozen (-20°C or lower) and shipped on dry ice. Serum specimens can be stored frozen (-20°C or lower) for up to 8 weeks prior to shipping. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Freeze serum specimens and ship to CDC frozen on dry ice overnight. Specimens should be shipped in proper secondary containment to prevent exposures due to leaks in primary tubes. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	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	Heather Colley (404) 718-5822 ohg1@cdc.gov Sara Mercader (404) 639-4568 sjm7@cdc.gov
Version	1.9

Test Order

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

CDC-10352

Synonym(s)	Culture, DST, AST, MTB, MDR TB
CDC Pre-Approval Needed	**Subhadra Nandakumar** **(404) 639-3090** **ifd0@cdc.gov** **Kyle DeGruy** **(404) 639-0875** **gsz4@cdc.gov**
Supplemental Information Required	**Contact the CDC POCs 1) for approval to send isolates to CDC for testing, 2) to obtain appropriate forms for submission and 3) to obtain information/ materials to assist with the submission process.**
Supplemental Form	**The following supplemental forms will be provided after pre-approval for isolate submission: ILB-160-F08C TB Requisition Form and CDC Form 0.753 Application for Permit to Import or Transport Etiological Agents, Hosts, or Vectors of human disease.**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure isolates of suspected Mycobacterium tuberculosis complex (MTBC)
Minimum Volume Required	0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store MTBC isolates with or without glycerol in sterile 2.0 mL screw cap cryovials with O-rings. Isolates should be stored at -60 °C to -70 °C until shipped to preserve the viability of MTBC.
Transport Medium	Middlebrook 7H9 or Mycobacterial Growth Indicator Tube (MGIT) liquid media
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Store specimens at -60 °C to -70 °C until packed for shipping. Ship specimens in triple packaging and on dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 99 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an e-mail to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	MGIT 960 SIRE and PZA drug susceptibility testing, GenoType MTBDRplus, GenoType MTBDRsl, GenoType CM, Xpert MTB/RIF, Xpert MTB/RIF Ultra
Turnaround Time	22 Weeks
Interferences & Limitations	Testing will not be performed on nonviable, contaminated or mixed isolates.
Additional Information	22 weeks trunaround time for batches with less than 100 isolates. Contact CDC POC for batches greater than 100 isolates. Isolates may be rejected if improperly labeled, missing or discrepant documentation, insufficient volume for testing or leaking containers.
CDC Points of Contact	Subhadra Nandakumar (404) 639-3090 ifd0@cdc.gov Kyle DeGruy (404) 639-0875 gsz4@cdc.gov Zilma Rey (404) 639-2345 yzr0@cdc.gov Mariela Scarbrough (404) 639-1389 hqz4@cdc.gov
Version	2.5

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

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (bacterial isolate), the specimen source (type), specimen collection date, date sent to CDC, and transport medium/specimen preservative.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure *Mycobacterium tuberculosis* complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 180 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-70°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 15- or 50-mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Agar proportion, DNA sequencing for Pyrazinamide (PZA) susceptibility
Turnaround Time	8 Weeks
Interferences & Limitations	Some isolates of MTB (<5% of submitted isolates) do not grow on the media used for testing. Contaminated samples (i.e., not a pure culture of MTB) are reported as contaminated; submitting laboratory may submit a pure culture if clinically needed.
Additional Information	On average, TAT times range from 35 to 80 calendar days. Delays may occur due to holidays and unexpected events.
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov David Sikes (404) 639-5489 zrg5@cdc.gov
Version	3.0

Test Order

Mycobacterium TB Complex - Molecular Detection of Drug Resistance (MDDR)- CLIA CDC-10186

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	**TB Lab** **(404) 639-2455** **TBLab@cdc.gov** **David Sikes** **(404) 639-5489** **zrg5@cdc.gov**
Supplemental Information Required	**Pre-approval is required for this test using the Molecular Detection of Drug Resistance Request Form. Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (bacterial isolate or sediment (referring to Nucleic Acid Amplification Test Positive (NAAT+) specimen)), the specimen source (type), specimen collection date, date sent to CDC, and transport medium/specimen preservative (isolates only).**
Supplemental Form	**Molecular Detection of Drug Resistance Request Form (CDC-002-00220)** **http://www.cdc.gov/tb/topic/laboratory/MDDRsubmissionform.pdf**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nucleic Acid Amplification Test positive (NAAT+) sediment; Pure *Mycobacterium tuberculosis* complex isolate(s) on solid medium or in broth medium; Mixed cultures known to contain MTBC. Only one sample per patient should be submitted; however, testing of duplicate samples will be considered on a case-by-case basis; contact the CDC POC for approval prior to sending.
Minimum Volume Required	Sediment: 0.5 mL, 1 mL is preferred Liquid medium: 0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Sediments: Store refrigerated (2-8°C) up to 30 days post collection or frozen (-20°C or lower) up to 60 days post collection MTBC Isolates in solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 180 days post collection MTBC Isolates in liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-70°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 15- or 50-mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Agar proportion, DNA sequencing (including sequencing for Pyrazinamide (PZA) susceptibility)
Turnaround Time	10 Days
Interferences & Limitations	Results are reported for the sample as received. Samples with low numbers of MTBC may not amplify; Heteroresistance may not be detected; the results of MDDR assay should not be used to rule out the presence of MTBC in a sample.
Additional Information	On average, turnaround time (TAT) ranges from 6 - 14 calendar days (molecular testing), 35 – 80 calendar days (agar proportion). Delays may occur due to holidays and unexpected events.
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov David Sikes (404) 639-5489 zrg5@cdc.gov
Version	3.3

Test Order
Mycobacterium TB Complex - Pyrazinamide Susceptibility Testing- CLIA
CDC-10189

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	**TB Lab** **(404) 639-2455** **tblab@cdc.gov** **David Sikes** **(404) 639-5489** **zrg5@cdc.gov**
Supplemental Information Required	**Pre-approval is required for this test and is obtained via email to the CDC Pre-Approval Points of Contact. Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted (bacterial isolate), specimen source (type), specimen collection date, date sent to CDC, and transport medium/specimen preservative.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure Mycobacterium tuberculosis complex isolate on solid medium or in broth medium
Minimum Volume Required	0.5 mL, 1 mL is preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Solid media: store refrigerated (2-8°C) or room temperature (15-25°C) up to 180 days post collection Liquid media: store refrigerated (2-8°C), room temperature (15-25°C), frozen (-20°C or lower) up to 120 days post collection. Store in deep freeze (-70°C or lower) up to 5 years post collection
Transport Medium	Solid media (i.e., Middlebrook 7H10 or 7H11 plates, Lowenstein-Jensen (LJ) slants) Liquid media (i.e., 7H9, Mycobacterial Growth Indicator Tube (MGIT), BACT/ALERT, VersaTREK) or MTBC colony growth suspended in saline or water
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. Submit liquid medium in a screwcap cryovial that has been sealed with parafilm; do not send in a 15- or 50-mL conical tube. Broth should not be shipped frozen. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	DNA sequencing
Turnaround Time	5 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov David Sikes (404) 639-5489 zrg5@cdc.gov
Version	3.7

Test Order
Mycobacterium TB Complex - Special Study- CLIA
CDC-10191

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	**TB Lab** **(404) 639-2455** **TBLab@cdc.gov** **David Sikes** **(404) 639-5489** **zrg5@cdc.gov**
Supplemental Information Required	**Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted, specimen source (type), specimen collection date, date sent to CDC, and transport medium/specimen preservative.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Includes different methodologies, inclusive of molecular testing
Turnaround Time	

Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov David Sikes (404) 639-5489 zrg5@cdc.gov
Version	2.7

Test Order
Mycobacterium TB Complex - Special Study- Non-CLIA
CDC-10575

Synonym(s)	MTB DST, TB, Tuberculosis, MTBC
CDC Pre-Approval Needed	**TB Lab** **(404) 639-2455** **TBLab@cdc.gov** **David Sikes** **(404) 639-5489** **zrg5@cdc.gov**
Supplemental Information Required	**Provide the following Specimen Information on the CDC 50.34 Specimen Submission Form: material submitted, specimen source (type), specimen collection date, date sent to CDC, and transport medium/specimen preservative.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs; must be received within 5 days of shipment. MTBC isolates must be shipped as Infectious substances (Div. 6.2, Class Category A). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 29 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Includes different methodologies, inclusive of molecular testing.

Turnaround Time	
Interferences & Limitations	To be determined
Additional Information	To be determined
CDC Points of Contact	TB Lab (404) 639-2455 TBLab@cdc.gov David Sikes (404) 639-5489 zrg5@cdc.gov
Version	2.0

Test Order
Mycoplasma pneumoniae Macrolide Susceptibility Genotyping- Non-CLIA
CDC-10513

Synonym(s)	*M. pneumoniae, Mycoplasma,* Atypical pneumonia, Walking pneumonia, Community acquired pneumonia, CAP, macrolide, macrolide resistance, antimicrobial resistance, AMR
CDC Pre-Approval Needed	**Maureen Diaz** **(404) 639-4534** **mdiaz1@cdc.gov** **Jonas Winchell** **(404) 639-4921** **jwinchell@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal (NP) swab, throat (oropharyngeal (OP)) swab, nasal and throat swab, nasal mid-turbinate swab, nasal swab, NP or tracheal aspirates, bronchial washing, sputum, bronchoalveolar lavage (BAL), endotracheal tube (ETT) washing/aspirate, fresh lung tissue, and cerebrospinal fluid (CSF). NP and OP swabs may be combined in a single collection tube.
Minimum Volume Required	0.4 mL preferred, 0.2 mL minimum
Collection, Storage, and Preservation of Specimen Prior to Shipping	Use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Nasopharyngeal (NP) and oropharyngeal (OP) swabs may be combined in a single collection tube. Refrigerate (2-8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection.
Transport Medium	Viral transport medium (VTM), universal transport medium (UTM), or saline
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time Polymerase Chain Reaction (PCR) with high-resolution melt (HRM)
Turnaround Time	7 Days
Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to "Collection, Storage & Preservation of Specimen Prior to Shipping". Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	All specimens will be tested using test order *Mycoplasma pneumoniae* Molecular Detection (CDC-10155) to confirm the presence of *M. pneumoniae*.
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov
Version	2.5

Test Order
Mycoplasma pneumoniae Molecular Detection- Non-CLIA
CDC-10155

Synonym(s)	*M. pneumoniae, Mycoplasma,* Atypical pneumonia, Community acquired pneumonia, CAP, Walking pneumonia
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Combined nasopharyngeal (NP) and oropharyngeal (OP) swab, nasal and throat swab, nasal mid-turbinate swab, nasal swab.
Minimum Volume Required	0.2 mL; 0.4 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Use only sterile Dacron or rayon swabs with plastic shafts or flocked swabs. Do not use calcium alginate swabs or swabs with wooden sticks. Nasopharyngeal (NP) and oropharyngeal (OP) swabs may be combined in a single collection tube. Refrigerate (2-8°C) all specimens promptly after collection and freeze (-20°C or lower) within 96 hours of collection.
Transport Medium	Viral transport medium (VTM), universal transport medium (UTM), or saline
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All specimens should be shipped frozen on dry ice overnight (next day delivery). Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 23 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time Polymerase Chain Reaction (PCR), sequencing
Turnaround Time	7 Days

Interferences & Limitations	Prior antibiotic treatment may impact results; specimens should be collected prior to antibiotic treatment, if possible. Specimens that are not collected, stored, and transported at specified conditions may be rejected by the laboratory. Refer to Collection, Storage & Preservation of Specimen Prior to Shipping. Specimens collected using calcium alginate swabs or swabs wtih wooden sticks may contain substances that inhibit molecular assays and will be rejected by the laboratory.
Additional Information	None
CDC Points of Contact	Maureen Diaz (404) 639-4534 mdiaz1@cdc.gov Jonas Winchell (404) 639-4921 Jwinchell@cdc.gov
Version	2.8

Test Order
Naegleria Molecular Detection- CLIA
CDC-10482

Synonym(s)	Free-living ameba, parasite, primary amebic meningoencephalitis, PAM, brain-eating ameba
CDC Pre-Approval Needed	**Julia Haston** **(404)-718-1230** **qdx2@cdc.gov** **Ibne Ali** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**Not needed.**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For *Naegleria fowleri* molecular detection, CSF is the preferred specimen type. We also accept fresh or frozen brain tissue for *N. fowleri* molecular detection.
Minimum Volume Required	0.2 mL (CSF); 1 mL preferred. 0.1 g tissue (brain); 0.2 g preferred.
Collection, Storage, and Preservation of Specimen Prior to Shipping	CSF (preferred) or brain tissue (in 0.5x PBS) should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower; in the absence of PBS buffer) for up to 60 days.
Transport Medium	Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-Time PCR
Turnaround Time	7 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404)-718-1230 qdx2@cdc.gov Ibne Ali (404) 718-4157 xzn5@cdc.gov
Version	3.0

Test Order
Naegleria Molecular Detection- Non-CLIA
CDC-10614

Synonym(s)	Free-living ameba, parasite, primary amebic meningoencephalitis, PAM, brain-eating ameba
CDC Pre-Approval Needed	**Julia Haston** **(404) 718-1230** **qdx2@cdc.gov** **Ali Ibne** **(404) 718-4157** **xzn5@cdc.gov**
Supplemental Information Required	**Provide the following information: history of present illness, exposure history, past medical history, treatment history, CSF results, imaging results. Available images can be submitted for preliminary morphological diagnosis prior to submitting specimen for molecular identification. Contact dpdx@cdc.gov for more information about submitting images.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	For Naegleria fowleri molecular detection, CSF is the preferred specimen type. We also accept fresh or frozen brain tissue for N. fowleri molecular detection.
Minimum Volume Required	0.2 mL (CSF); 1 mL preferred. 0.1 g tissue (brain); 0.2 g preferred.
Collection, Storage, and Preservation of Specimen Prior to Shipping	CSF (preferred) or brain tissue (in 0.5x PBS) should be stored refrigerated temperature (2-8°C) for up to 7 days, or frozen (-20°C or lower; in the absence of PBS buffer) for up to 60 days.
Transport Medium	Small piece of tissue should be transported in small amount of 0.5x PBS to prevent dryness.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 54 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	30 Days
Interferences & Limitations	Formalin-fixed specimens are not acceptable for molecular studies as formalin fixation may cause DNA degradation. Regarding testing of formalin-fixed specimens see Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies) and contact pathology@cdc.gov.
Additional Information	For 24/7 diagnostic assistance, specimen collection guidance, shipping instructions, and treatment recommendations, contact the CDC Emergency Operations Center at (770) 488-7100.
CDC Points of Contact	Julia Haston (404) 718-1230 qdx2@cdc.gov Ali Ibne (404) 718-4157 xzn5@cdc.gov
Version	2.0

Test Order
NARMS Susceptibility Testing- Non-CLIA
CDC-10107

Synonym(s)	National Antimicrobial Resistance Monitoring System, NARMS surveillance, AST
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Submitter must be a NARMS participating laboratory. Specimens accepted according to current National Antimicrobial Resistance Monitoring System (NARMS) sampling scheme. NARMS log sheet or entry into NARMS web interface.**
Supplemental Form	**NARMS logsheet https://narms.cdc.gov**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Isolates. Specimens accepted according to NARMS guidelines.
Minimum Volume Required	Minimum volume for microbrial isolates is not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at ambient temperature (15-25 °C) or refrigerate (2-8 °C). Isolates held for more than a month should be frozen at less than or equal to -20 °C.
Transport Medium	Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship at ambient temperature or frozen with dry ice. There are no time contraints for submitting sequence data. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 127 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Broth Microdilution Antimicrobial Susceptibility (AST), E-Test Susceptibility Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	The turnaround time depends on the nature of subtyping performed. Results are typically reported directly to the surveillance databases. For additional information regarding shipment timing and other status updates, please see this link: https://narms.cdc.gov
CDC Points of Contact	Jean Whichard (404) 639-2000 zyr3@cdc.gov Jason Folster (404) 639-4948 gux8@cdc.gov Hayat Caidi (404) 639-0766 foi0@cdc.gov
Version	1.4

Test Order
Neisseria gonorrhoeae Surveillance Study- Non-CLIA
CDC-10623

Synonym(s)	None
CDC Pre-Approval Needed	**Myriam Belanger** **(404) 718-5138** **bjf0@cdc.gov** **Matthew Schmerer** **(404) 718-5911** **nmk7@cdc.gov**
Supplemental Information Required	**All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Viable isolate(s) with confirmed identification of N. gonorrhoeae, or as determined during pre-approval consultation.
Minimum Volume Required	Contact the CDC Points-of-Contact (POC) for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	N. gonorrhoeae isolate should be grown on a non-selective medium (Chocolate II or GC base + 1% growth supplements) and incubated for 16-18 hours at 35-37°C in a 4-6% CO2-enriched atmosphere. For long-term preservation, cultures should be resuspended (at concentration of ≥4 McFarland) in trypticase soy broth (TSB) with 15-20% glycerol and immediately frozen at -70°C or below.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 31 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.

Turnaround Time	4 Weeks
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	None
CDC Points of Contact	Myriam Belanger (404) 718-5138 bjf0@cdc.gov Matthew Schmerer (404) 718-5911 nmk7@cdc.gov
Version	2.0

Test Order
Neisseria meningitidis Surveillance- Non-CLIA
CDC-10220

Synonym(s)	*N. meningitidis* surveillance, Nm study
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide any preliminary results available (including manufacturer of antiserum or PCR methods used if applicable) in the Previous Laboratory Results section on the CDC 50.34 Specimen Submission Form or on the surveillance submission form. If prioritized testing is needed for a public health response, contact CDC POC for approval of expedited testing.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Bacterial isolates (viable bacterial culture at room temperature or frozen stocks) and primary specimens [cerebrospinal fluid (CSF), serum and other sterile site specimen types].
Minimum Volume Required	0.25 mL for frozen bacterial stocks; 0.5 mL or more is preferred for primary specimens
Collection, Storage, and Preservation of Specimen Prior to Shipping	Bacterial isolate stocks should be stored in a cryovial and kept frozen (-20°C or lower) prior to shipping. When submitting viable bacterial isolates, incubate the inoculated chocolate agar slants overnight at 35-39°C with 5% carbon dioxide to ensure viability of the isolates. Primary specimens (CSF, serum and other sterile site specimen types) should be refrigerated (2-8°C) after collection and frozen (-20°C or lower) within 96 hours for up to 60 days.
Transport Medium	When submitting frozen bacterial stocks, use defibrinated sheep blood or trypticase soy broth (TSB) plus 15% glycerol. When submitting viable bacterial cultures at room temperature, use chocolate agar slants.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. If shipping viable bacterial isolates, ship at room temperature with room-temperature cold packs. When shipping 10 or more bacterial isolates, submit frozen stocks only. Frozen bacterial isolate stocks and primary specimens (CSF and serum) should be shipped on dry ice and received frozen. Enclose CDC 50.34 Specimen Submission Form in shipment. Email the tracking number in advance, particularly if prioritized testing is requested. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 10 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Whole genome sequencing (WGS), real-time polymerase chain reaction (rt-PCR), and/or slide agglutination serogrouping.
Turnaround Time	
Interferences & Limitations	Bacterial DNA concentration, low specimen volume, collection time, and transport and handling conditions may impact the results. Primary specimens that were collected after antibiotic treatment, were transported under suboptimal conditions, or have a particularly low volume and/or bacterial DNA load may result in a false negative result. For molecular typing methods, primary specimens with low bacterial DNA load may not be acceptable for testing.
Additional Information	Additional microbiological and/or molecular testing can be completed as needed.
CDC Points of Contact	Daya Marasini (404) 718-3522 pnz9@cdc.gov Rebecca Howie (404) 498-4146 fvu8@cdc.gov Matthew Keller (404) 718-3359 meningitislab@cdc.gov
Version	3.9

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

Synonym(s)	Gram-negative coccus (not GC or meningococcus) identification, Neisseria species identification
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

Test Order
New World Hantavirus Testing- CLIA
CDC-10620

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Recommended method: Serum specimens must be frozen (-20°C or lower) and shipped on dry ice within 30 days of collection. Alternative method (not recommended): Serum specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Specimens should be shipped on dry ice.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	10 Days

Interferences & Limitations	Cross-reactivities with some Old World Hantaviruses were observed during test validations. Negative results do not preclude New World Hantavirus infection and should not be used as the sole basis for treatment or other patient management decisions. A false-negative result may occur if a specimen is improperly collected, transported, or handled. False negative results may occur if amplification inhibitors are present in the specimen or if specimen is below lower limit of detection (LLOD) of test. The method is appropriate as a stand-alone test.
Additional Information	Turnaround Time is 10 business days. Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	2.0

Test Order
Nipah Virus Testing- CLIA
CDC-10354

Synonym(s)	
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Recommended method: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 60 days of collection. Alternative method (not recommended): Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.5

Test Order
Nipah Virus Testing- Non-CLIA
CDC-10601

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) for PCR. Whole blood (EDTA) or serum for Serology
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.

CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov

Version	2.0

Test Order

Nocardia species Identification and Antimicrobial Susceptibility Testing- CLIA CDC-10151

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25 °C) for up to 7 days prior to shipping.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.3

Test Order
Nocardia species Identification- CLIA
CDC-10150

Synonym(s)	Beaded branching gram-positive rod, aerobic actinmycetes
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Actively growing pure culture bacterial isolate on an agar slant, Lowenstein Jensen, trypticase soy agar (with or without sheep blood), heart infusion agar (with or without rabbit blood), chocolate agar, Sabouraud dextrose agar
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C) for up to 7 days prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship at room temperature with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Primary culture based on specimen type, Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometry, 16S sequence based identification
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	If available, please provide patient history including if the patient has used a catheter and/or if the patient is immunocompromised. Some isolates require additional time to accurately characterize the organism which may result in a longer turnaround time. Please contact the laboratory if concerned about a delay.
CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov
Version	2.4

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

Synonym(s)	nontuberculous (Non-TB) mycobacteria (NTM), nontuberculous mycobacteria (NTM), *Mycobacterium*, mycobacteria Identification, mycobacteria other than TB (MOTT)
CDC Pre-Approval Needed	**Nadege Toney** **(404) 639-1282** **ngc6@cdc.gov** **Stephen LaVoie** **(404) 718-4747** **qea5@cdc.gov**
Supplemental Information Required	**The CDC Form 50.34 Specimen Submission Form or GFAT must include the State Public Health Department contact information, previous testing results demonstrating that the isolate is pure and is not a part of the *Mycobacterium tuberculosis* complex (MTC), as well as the date the submitted culture was inoculated onto transport media and the date visible growth was observed for the submitted isolate.** **For isolates from wounds or surgical sites, document that nontuberculous mycobacteria (NTM) was abundant on primary culture (3+ to 4+) or was the only organism isolated.** **For isolates from sputum, document that NTM was from two or more sputum cultures, collected on different days; was the only mycobacterial species present and that there was abundant growth on primary culture.**

Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure cultural isolates of NTMs demonstrated to not be part of the Mycobacterium tuberculosis complex (MTC) from the following sources: Sterile sites (e.g. Whole blood, cerebral spinal fluid (CSF), other body fluids); Abscess, exudate or skin lesion; Wounds or surgical sites (see Supplemental Information); Bronchoalveolar lavage (BAL)/bronchial wash; Sputum (see Supplemental Information); Gastric lavage (pediatric).
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability.

Transport Medium	Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on Lowenstein-Jensen agar, Middlebrook 7H10/7H11 agar or Middlebrook 7H9 broth. Transport frozen isolates in Middlebrook 7H9 broth. **NOTE:** The Mycobacteria Growth Indicator tube (MGIT) is not acceptable transport media. BacT/ALERT and VersaTREK culture media bottles are also not acceptable transport media.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship pure culture isolates overnight at room temperature, refrigerated, or frozen. Room-temperature samples should be shipped with room-temperature cold packs. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Matrix assisted laser desorption ionization-time of flight (MALDI-TOF), additional phenotypic testing
Turnaround Time	8 Weeks
Interferences & Limitations	Pure culture isolates must be viable for testing.
Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. Isolates require specific documentation depending on the site of collection as outlined in the Supplemental Information Required section. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.

CDC Points of Contact	Stephen LaVoie (404) 718-4747 qea5@cdc.gov Nadege Toney (404) 639-1282 ngc6@cdc.gov

Version	4.6

Test Order
Norovirus Genotyping- Non-CLIA
CDC-10356

Synonym(s)	Norovirus
CDC Pre-Approval Needed	**Jan Vinje** **(404) 639-3721** **ahx8@cdc.gov** **Leslie Barclay** **(404) 639-1159** **gvm3@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	stool, vomitus, environmental swab
Minimum Volume Required	0.25 g or 0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen must be stored at 2 °-8 °C
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Refrigerated specimen should be shipped on cold packs. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 186 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None

CDC Points of Contact	Jan Vinje (404) 639-3721 ahx8@cdc.gov Leslie Barclay (404) 639-1159 gvm3@cdc.gov

Version	1.3

Test Order
Norovirus Molecular Detection and Genotyping- Non-CLIA
CDC-10358

Synonym(s)	Norovirus
CDC Pre-Approval Needed	**Jan Vinje** **(404) 639-3721** **ahx8@cdc.gov** **Leslie Barclay** **(404) 639-1159** **gvm3@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	stool, vomitus, environmental swab
Minimum Volume Required	0.25 g or 0.25 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen must be stored at 2 °-8 °C
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Refrigerated specimen should be shipped on cold packs. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 186 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR), Sequencing
Turnaround Time	4 Weeks
Interferences & Limitations	None
Additional Information	None

CDC Points of Contact	Jan Vinje (404) 639-3721 ahx8@cdc.gov Leslie Barclay (404) 639-1159 gvm3@cdc.gov

Version	1.3

Test Order
Orientia Molecular Detection- CLIA
CDC-10359

Synonym(s)	Scrub typhus
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute whole blood. Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): EDTA-treated or ACD A treated. Acute serum Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): Serum separator tube or cryo-tubes. Tissue must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): sterile specimen container in saline-moistened gauze. Swab specimen of eschar obtained before or within 14 days of initiation of a tetracycline-class antibiotic (e.g., doxycycline) AND with a residual eschar scab at the time of collection.
Minimum Volume Required	1.0 mL

Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days prior to arriving at CDC, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood, and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in a cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For eschar swabs, place the specimen in a dry sterile specimen container without any medium.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad lightly moistened with sterile saline. Do not immerse the sample in saline.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Molecular detection methods have decreasing sensitivity after resolution of the febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures (2-8°C) can interfere with nucleic acid extraction.

Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Molecular testing for other pathogens including *Anaplasma*, *Coxiella*, *Rickettsia* spp., and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov
Version	2.4

Test Order
Orientia Serology- CLIA
CDC-10360

Synonym(s)	Scrub typhus
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of a scrub typhus disease can only be established by demonstrating a four-fold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including typhus group *Rickettsia*, *Anaplasma*, *Coxiella*, spotted fever group *Rickettsia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html

CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Version	2.3

Test Order
Paragonimiasis Serology- CLIA
CDC-10465

Synonym(s)	*Paragonimus westermani*; *Paragonimus kellicotti,* parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Immunoblot, Western Blot, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	This assay may yield positive results in individuals infected with *Paragonimus kellicotti*.

Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	4.9

Test Order
Parasite - Special Study- Non-CLIA
CDC-10237

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool specimens (must be preserved), blood, food, and tissue. Contact CDC POC regarding submission of additional specimen types.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Microscopy, culture, PCR, seqeuncing, ELISA, immunoblot, multiplex bead array.
Turnaround Time	4 Weeks
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information

CDC Points of Contact	Katie Bowden (404) 718-4100 wzi1@cdc.gov Yvonne Qvarnstrom (404) 718-4123 bvp2@cdc.gov Parasites Lab (404) 639-4292 parasiteslab@cdc.gov

Version	2.6

Test Order
Parasites: Morphologic Identification- CLIA
CDC-10234

Synonym(s)	Parasitology, Malaria parasite identification, Blood parasite, ova and parasite
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Stool specimens (must be preserved), blood, and tissue. Consult the laboratory regarding submission of additional specimen types.
Minimum Volume Required	Minimum volume requirements are specimen specific; please contact the point of contact listed below.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Storage and preservation is specimen specific and available on consultation
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	Shipping is specimen specific and available on consultation. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	None

CDC Points of Contact	DPDx (404) 718-4120 dpdx@cdc.gov Sarah Sapp (404) 718-5227 xyz6@cdc.gov

Version	2.6

Test Order
Parasites: Telediagnosis- CLIA
CDC-10563

Synonym(s)	Parasitology, ova and parasite, telediagnosis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Image or video files depicting suspected parasitic organisms
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Not Applicable
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	None
Methodology	Microscopy
Turnaround Time	7 Days
Interferences & Limitations	None
Additional Information	Do not submit telediagnosis cases via CSTOR. Contact dpdx@cdc.gov for submission instructions and a secure upload link. Submitted images/videos should be of adequate quality (e.g., sufficient resolution, focus, and magnification) to permit examination. If a definitive identification cannot be reached from telediagnosis submissions, the physical specimen may be requested for direct examination (see CDC-10234).
CDC Points of Contact	DPDx (404) 718-4120 dpdx@cdc.gov Sarah Sapp (404) 718-5227 xyz6@cdc.gov

Test Order
Pathologic or Molecular Evaluation of Fixed Animal Tissues- Non-CLIA
CDC-10599

Synonym(s)	Necropsy, biopsy, resection, excision, formalin-fixed tissues, formalin-fixed paraffin-embedded (FFPE), pathology, paraffin blocks, histopathology, immunohistochemistry, polymerase chain reaction (PCR), electron microscopy (EM)
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Jana M Ritter** **(404) 639-1611** **vtr0@cdc.gov**

Supplemental Information Required	**Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order name** **• Test order code** **• Common name or Scientific name** **• Animal name** **• Birth date** **• Sex, Age, Age Units** **• Fatal status** **• Date of Death (if applicable)** **• Specimen collected date** **• Specimen source (type) = Formalin-fixed paraffin-embedded tissue (for blocks or slides), or Tissue (for wet tissue)** **• State public health laboratory (PHL) institution name** **• Animal ID (e.g., medical record number or necropsy number)** **• Specimen ID (e.g., surgical pathology accession number)** **• Original submitter contact information** **• Comments (bottom of page 2): If unstained slides are submitted, the date that unstained slides were created should be provided here.** **One electronically completed copy of CDC 50.34 Specimen Submission Form per case is acceptable ONLY when specimens are collected on the same day AND have the same surgical biopsy or necropsy number. Additional CDC 50.34 Specimen Submission Forms are required for specimens collected on different days or that have different surgical biopsy numbers (e.g., were from a different surgical procedure on the same day) or necropsy numbers.** **Submission of an unredacted copy of: (a) the necropsy report (preliminary or final), or (b) surgical pathology report is required.** **Requested additional information:** **• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history** **• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)** **• Relevant clinical, gross pathology, or microscopic pathology images, as available** **• If paraffin-embedded tissue blocks or unstained slides are submitted, a block key listing the tissues in each paraffin-embedded tissue block**
Supplemental Form	**None**
Performed on Specimens From	Animal

Acceptable Sample / Specimen Type for Testing	Biopsy tissues and necropsy tissues from any organ or site are acceptable; however, tissue specimens should be submitted from the site(s) of the animal's disease process. If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process. 1. Formalin-fixed paraffin-embedded tissue (FFPE) tissue blocks: Preferred specimen type for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories. FFPE tissue blocks must have been made < 10 years ago. • Biopsy tissue specimens and necropsy tissue specimens (excluding brain): Only acceptable if embedded within 2 weeks after being placed in formalin. • Brain necropsy tissue specimens: Acceptable if embedded within 4 weeks of being placed in formalin. • For necropsy tissue specimens only, specimens in formalin for greater than 2 weeks (greater than 4 weeks for brain tissue) prior to embedding may be acceptable on a case-by-case basis. 2. Formalin-fixed wet tissues: • Only acceptable for necropsy tissue specimens. Acceptable for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories, and electron microscopy. - Necropsy tissue specimens (excluding brain): Acceptable if the duration of formalin-fixation has been within 2 weeks, or if tissues have been transferred to 70% ethanol within 2 weeks after initial placement in formalin. - Brain necropsy tissue specimens: Acceptable if the duration of formalin-fixation has been within 4 weeks, or if tissues have been transferred to 70% ethanol within 4 weeks of initial placement in formalin. - For necropsy tissue specimens only, specimens in formalin greater than 2 weeks (greater than 4 weeks for brain tissue) may be acceptable on a case-by-case basis. 3. Unstained paraffinized tissue slides: • Acceptable for histopathology, histochemistry (special stains), immunohistochemistry. Only acceptable if created within 10 days prior to submission of specimens to CDC from an FFPE tissue block that was embedded within 2 weeks of being placed in formalin (or 4 weeks for brain necropsy tissue specimens). For necropsy tissues only, unstained slides from FFPE tissue blocks in formalin greater than 2 weeks (greater than 4 weeks for brain tissue) prior to embedding may be acceptable on a case-by-case basis. • NOT acceptable for PCR testing and sequencing or nucleic extraction for transfer to other CDC laboratories 4. Formalin-fixed paraffin-embedded (FFPE) tissue scrolls: NOT acceptable for testing For more information, reference the Additional Information field.
Minimum Volume Required	Not Applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping	Formalin-fixed paraffin-embedded (FFPE) tissue blocks: •Process within 2 weeks of formalin-fixation of tissues •Store at room temperature (15-25°C) Necropsy specific, formalin-fixed wet tissue: • The volume of 10% neutral buffered formalin used to fix tissues should be 10 times the volume of tissue • Place thinly-sliced tissue in 10% neutral buffered formalin for 7 days. • For brain tissue, place thinly-sliced tissue in 10% neutral buffered formalin for 2 weeks or longer until fully fixed. After fixation, if not paraffin-embedded, tissues should be transferred to 70% ethanol for long-term storage and stored at room temperature (15-25°C). Unstained paraffinized tissue slides should be stored at room temperature (15-25°C).
Transport Medium	If formalin-fixed wet tissues are submitted, transport medium can include 10% neutral buffered formalin or 70% ethanol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Paraffin-embedded tissue blocks should be shipped refrigerated with frozen cold packs during hot summer months to prevent them from melting. Formalin-fixed wet tissue that is currently in formalin or has been transferred to 70% ethanol: • Should be shipped in leak proof containers at room temperature. • The maximum volume of formalin per primary specimen container cannot exceed 30 mL (excess formalin should be discarded prior to shipping). • The maximum net volume of formalin per shipping package cannot exceed 1 L. • If the specimen is in 70% ethanol, discard most of the ethanol prior to shipping. • Leakproof containers should be placed in double Ziploc style bags and add sufficient absorbent material to the outer bag to absorb any potential leaks. Ship for overnight delivery. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Histopathology (hematoxylin and eosin (H&E)-stained sections), histochemistry (special stains), immunohistochemistry (IHC), conventional and real-time polymerase chain reaction (PCR) and Sanger sequencing, nucleic acid extraction for transfer to other CDC Laboratories, electron microscopy (EM)
Turnaround Time	12 Weeks
Interferences & Limitations	Decalcification may interfere with some PCR assays. Paraffin-embedded cell blocks from body fluids (e.g., pleural, pericardial fluid) and aspirates (e.g., bone marrow) may be acceptable in select circumstances but assay sensitivity may be reduced; immunohistochemical, PCR and sequencing assays have been optimized for performance on FFPE tissue samples. Freezing of formalin-fixed wet tissue can result in distorted histopathology and freezing artifacts (formation of interstitial and intracytoplasmic vacuoles resulting from ice-crystal formation). Specimens should not be frozen; specimens should be kept at room temperature (15-25°C).
Additional Information	CDC Pre-Approval Needed: • Contact Infectious Diseases Pathology Branch Mailbox by email to initiate the pre-approval process Acceptable Sample/ Specimen Type for Testing: • Samples that are damaged or depleted are not acceptable for testing and will be rejected; this includes broken unstained slides, and FFPE tissue blocks that have been depleted due to removal of tissue sections from the block. • In the setting of potentially scant paraffin-embedded tissue block samples, submission of original stained slides (e.g., H&E, Gram) may be requested. • For small biopsies (such as liver), to maintain specimen integrity, we recommend existing FFPE tissue blocks be submitted as is, and not split, which might further reduce available tissue in the block. • Scant specimens are subject to depletion during the course of testing. • For necropsy tissues demonstrating decomposition, consultation with POC is required to determine acceptable specimen type(s) on a case-by-case basis. • Necropsy tissue specimens in formalin greater than 2 weeks (greater than 4 weeks for brain tissue), may be acceptable on a case-by-case basis. Consultation with POC prior to specimen submission is required for this determination. Turnaround Time is 12 weeks. The course of testing will be determined by the clinical history, the histopathology observed, and the availability of specimens.

CDC Points of Contact	Infectious Diseases Pathology Branch Mailbox (404) 639-3132 pathology@cdc.gov Jana M Ritter (404) 639-1611 vtr0@cdc.gov

Version	2.1

Test Order

Pathologic or Molecular Evaluation of Fixed Human Tissues (Fatal or International Cases)- Non-CLIA

CDC-10598

Synonym(s)	Autopsy, biopsy, resection, excision, formalin-fixed tissues, formalin-fixed paraffin-embedded (FFPE), pathology, paraffin blocks, histopathology, immunohistochemistry, polymerase chain reaction (PCR), electron microscopy (EM)
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Julu Bhatnagar** **(404) 639-2826** **zrn1@cdc.gov**

Supplemental Information Required	**Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order name** **• Test order code** **• Patient Name (Last, First)** **• Patient Birth date** **• Sex, Age, Age Units** **• Fatal status** **• Date of death (if applicable)** **• Specimen collected date** **• Specimen source (type) = Formalin-fixed paraffin-embedded tissue (for blocks or slides), or Tissue (for wet tissue)** **• State public health laboratory (PHL) institution name** **• Patient ID (e.g., medical record number or autopsy number)** **• Specimen ID (e.g., surgical pathology accession number)** **• Original submitter contact information** **• Comments (bottom of page 2): If unstained slides are submitted, the date that unstained slides were created should be provided here.** **One electronically completed copy of CDC 50.34 Specimen Submission Form per case is acceptable ONLY when specimens are collected on the same day AND have the same surgical biopsy or autopsy number. Additional CDC 50.34 Specimen Submission Forms are required for specimens collected on different days or that have different surgical biopsy numbers (e.g., were from a different surgical procedure on the same day) or autopsy numbers.** **Submission of an unredacted copy of: (a) the autopsy report (preliminary or final), or (b) surgical pathology report is required.** **Requested additional information:** **• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information** **• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)** **• Relevant clinical, gross pathology, or microscopic pathology images, as available** **• If paraffin-embedded tissue blocks or unstained slides are submitted, a block key listing the tissues in each paraffin-embedded tissue block.**
Supplemental Form	**None**
Performed on Specimens From	Human

Acceptable Sample / Specimen Type for Testing	International human biopsy tissues or any human autopsy tissues from any organ or site are acceptable; however, tissue specimens should be submitted from the site(s) of the patient's disease process. If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process. 1. Formalin-fixed paraffin-embedded tissue (FFPE) tissue blocks: Preferred specimen type for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories. FFPE tissue blocks must have been made < 10 years ago. • International human biopsy tissue specimens or any human autopsy tissue specimens (excluding brain): Only acceptable if embedded within 2 weeks after being placed in formalin. • Brain autopsy tissue specimens: Acceptable if embedded within 4 weeks of being placed in formalin. • For autopsy tissue specimens only, specimens in formalin for greater than 2 weeks (greater than 4 weeks for brain tissue) prior to embedding may be acceptable on a case-by-case basis. 2. Formalin-fixed wet tissues: • Only acceptable for autopsy tissue specimens. Acceptable for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories, and electron microscopy. - Autopsy tissue specimens (excluding brain): Acceptable if the duration of formalin-fixation has been within 2 weeks, or if tissues have been transferred to 70% ethanol within 2 weeks after initial placement in formalin. - Brain autopsy tissue specimens: Acceptable if the duration of formalin-fixation has been within 4 weeks, or if tissues have been transferred to 70% ethanol within 4 weeks of initial placement in formalin. - For autopsy tissue specimens only, specimens in formalin greater than 2 weeks (greater than 4 weeks for brain tissue) may be acceptable on a case-by-case basis. • Biopsy tissue specimens: NOT acceptable for testing 3. Unstained paraffinized tissue slides: • Acceptable for histopathology, histochemistry (special stains), immunohistochemistry. Only acceptable if created within 10 days prior to submission of specimens to CDC from an FFPE tissue block that was embedded within 2 weeks of being placed in formalin (or 4 weeks for brain autopsy tissue specimens). For autopsy tissues only, unstained slides from FFPE tissue blocks in formalin greater than 2 weeks (greater than 4 weeks for brain tissue) prior to embedding may be acceptable on a case-by-case basis. • NOT acceptable for PCR testing and sequencing or nucleic extraction for transfer to other CDC laboratories 4. Formalin-fixed paraffin-embedded (FFPE) tissue scrolls: NOT acceptable for testing For more information, reference the Additional Information field.

Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Formalin-fixed paraffin-embedded (FFPE) tissue blocks: •Process within 2 weeks of formalin-fixation of tissues •Store at room temperature (15-25°C) Autopsy specific, formalin-fixed wet tissue: • The volume of 10% neutral buffered formalin used to fix tissues should be 10 times the volume of tissue. • Place thinly-sliced tissue in 10% neutral buffered formalin for 7 days. • For brain tissue, place thinly-sliced tissue in 10% neutral buffered formalin for 2 weeks or longer until fully fixed. After fixation, if not paraffin-embedded, tissues should be transferred to 70% ethanol for long-term storage and stored at room temperature (15-25°C). Unstained paraffinized tissue slides should be stored at room temperature (15-25°C).
Transport Medium	If formalin-fixed wet tissues are submitted, transport medium can include 10% neutral buffered formalin or 70% ethanol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Paraffin-embedded tissue blocks should be shipped refrigerated with frozen cold packs during hot summer months to prevent them from melting. Formalin-fixed wet tissue that is currently in formalin or has been transferred to 70% ethanol: • Should be shipped in leak proof containers at room temperature. • The maximum volume of formalin per primary specimen container cannot exceed 30 mL (excess formalin should be discarded prior to shipping). • The maximum net volume of formalin per shipping package cannot exceed 1 L. • If the specimen is in 70% ethanol, discard most of the ethanol prior to shipping. • Leakproof containers should be placed in double Ziploc style bags and add sufficient absorbent material to the outer bag to absorb any potential leaks. Ship for overnight delivery. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Histopathology (hematoxylin and eosin (H&E)-stained sections), histochemistry (special stains), immunohistochemistry (IHC), conventional and real-time polymerase chain reaction (PCR) and Sanger sequencing, nucleic acid extraction for transfer to other CDC Laboratories, electron microscopy (EM)
Turnaround Time	8 Weeks
Interferences & Limitations	Decalcification may interfere with some PCR assays. Paraffin-embedded cell blocks from body fluids (e.g., pleural, pericardial fluid) and aspirates (e.g., bone marrow) may be acceptable in select circumstances but assay sensitivity may be reduced; immunohistochemical, PCR and sequencing assays have been optimized for performance on FFPE tissue samples. Freezing of formalin-fixed wet tissue can result in distorted histopathology and freezing artifacts (formation of interstitial and intracytoplasmic vacuoles resulting from ice-crystal formation). Specimens should not be frozen; specimens should be kept at room temperature (15-25°C).

Additional Information	CDC Pre-Approval Needed: • Contact Infectious Diseases Pathology Branch Mailbox by email to initiate the pre-approval process Acceptable Sample/ Specimen Type for Testing: • Samples that are damaged or depleted are not acceptable for testing and will be rejected; this includes broken unstained slides, and FFPE tissue blocks that have been depleted due to removal of tissue sections from the block. • In the setting of potentially scant paraffin-embedded tissue block samples, submission of original stained slides (e.g., H&E, Gram) may be requested. • For small biopsies (such as liver), to maintain specimen integrity, we recommend existing FFPE tissue blocks be submitted as is, and not split, which might further reduce available tissue in the block. • Scant specimens are subject to depletion during the course of testing. • For autopsy tissues demonstrating decomposition, consultation with POC is required to determine acceptable specimen type(s) on a case-by-case basis. •Autopsy tissue specimens in formalin greater than 2 weeks (greater than 4 weeks for brain tissue), may be acceptable on a case-by-case basis. Consultation with POC prior to specimen submission is required for this determination. Turnaround Time is case-dependent: • Human surgical biopsy cases it is 6-8 weeks • Complex cases, routine human autopsy cases, and animal cases it is 12 weeks. The course of testing will be determined by the clinical history, the histopathology observed, and the availability of specimens.
CDC Points of Contact	Infectious Diseases Pathology Branch Mailbox (404) 639-3132 pathology@cdc.gov Julu Bhatnagar (404) 639-2826 zrn1@cdc.gov Julian Villalba (404) 639-8531 puv2@cdc.gov Jennifer Kasten (404) 639-6161 gme0@cdc.gov
Version	2.1

Test Order

Pathologic or Molecular Evaluation of Fixed Human Tissues (Non-Fatal U.S. Cases)-CLIA

CDC-10365

Synonym(s)	Biopsy, resection, excision, formalin-fixed paraffin-embedded (FFPE), pathology, paraffin blocks, histopathology, immunohistochemistry, polymerase chain reaction (PCR), electron microscopy (EM)
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Julu Bhatnagar** **(404) 639-2826** **zrn1@cdc.gov**

Supplemental Information Required	**Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order name** **• Test order code** **• Patient Name (Last, First)** **• Patient Birth date** **• Sex, Age, Age Units** **• Fatal status = No** **• Specimen collected date** **• Specimen source (type) = Formalin-fixed paraffin-embedded tissue (for blocks or slides)** **• State public health laboratory (PHL) institution name** **• Patient ID (e.g., medical record number)** **• Specimen ID (e.g., surgical pathology accession number)** **• Original submitter contact information** **• Comments (bottom of page 2): If unstained slides are submitted, the date that unstained slides were created should be provided here.** **One electronically completed copy of CDC 50.34 Specimen Submission Form per case is acceptable ONLY when specimens are collected on the same day AND have the same surgical biopsy number. Additional CDC 50.34 Specimen Submission Forms are required for specimens collected on different days or that have different surgical biopsy numbers (e.g., were from a different surgical procedure on the same day).** **Submission of unredacted copies of the surgical pathology reports is required.** **Requested additional information:** **• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information** **• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)** **• Relevant clinical, gross pathology, or microscopic pathology images, as available** **• A block key listing the tissues in each paraffin-embedded tissue block.**
Supplemental Form	**None**
Performed on Specimens From	Human

Acceptable Sample / Specimen Type for Testing	Biopsy tissues from any organ or site are acceptable; however, tissue specimens should be submitted from the site(s) of the patient's disease process. If an infectious etiology is suspected, tissues should demonstrate histopathologic evidence of a possible infectious process. 1. Formalin-fixed paraffin-embedded tissue (FFPE) tissue blocks: Preferred specimen type for histopathology, histochemistry (special stains), immunohistochemistry, PCR and sequencing, or nucleic acid extraction for transfer to other CDC laboratories. FFPE tissue blocks must have been made < 10 years ago. • Biopsy tissue specimens: Only acceptable if embedded within 2 weeks after being placed in formalin. 2. Unstained paraffinized tissue slides: • Acceptable for histopathology, histochemistry (special stains), immunohistochemistry. Only acceptable if created within 10 days prior to submission of specimens to CDC from an FFPE tissue block that was embedded within 2 weeks of being placed in formalin • NOT acceptable for PCR testing and sequencing or nucleic extraction for transfer to other CDC laboratories 3. Formalin-fixed paraffin-embedded (FFPE) tissue scrolls: NOT acceptable for testing For more information, reference the Additional Information field.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Formalin-fixed paraffin-embedded (FFPE) tissue blocks: • Process within 2 weeks of formalin-fixation of tissues • Store at room temperature (15-25°C)
Transport Medium	If formalin-fixed wet tissues are submitted, transport medium can include 10% neutral buffered formalin or 70% ethanol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Paraffin-embedded tissue blocks should be shipped refrigerated with frozen cold packs during hot summer months to prevent them from melting. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Histopathology (hematoxylin and eosin (H&E)-stained sections), histochemistry (special stains), immunohistochemistry (IHC), conventional and real-time polymerase chain reaction (PCR) and Sanger sequencing, nucleic acid extraction for transfer to other CDC Laboratories, electron microscopy (EM)
Turnaround Time	8 Weeks
Interferences & Limitations	Decalcification may interfere with some PCR assays. Paraffin-embedded cell blocks from body fluids (e.g., pleural, pericardial fluid) and aspirates (e.g., bone marrow) may be acceptable in select circumstances but assay sensitivity may be reduced; immunohistochemical, PCR and sequencing assays have been optimized for performance on FFPE tissue samples.

Additional Information	CDC Pre-Approval Needed: • Contact Infectious Diseases Pathology Branch Mailbox by email to initiate the pre-approval process Acceptable Sample/ Specimen Type for Testing: • Samples that are damaged or depleted are not acceptable for testing and will be rejected; this includes broken unstained slides, and FFPE tissue blocks that have been depleted due to removal of tissue sections from the block. • In the setting of potentially scant paraffin-embedded tissue block samples, submission of original stained slides (e.g., H&E, Gram) may be requested. • For small biopsies (such as liver), to maintain specimen integrity, we recommend existing FFPE tissue blocks be submitted as is, and not split, which might further reduce available tissue in the block. • Scant specimens are subject to depletion during the course of testing. Turnaround Time is case-dependent: • Human surgical biopsy cases it is 6-8 weeks • Complex cases it is 12 weeks. The course of testing will be determined by the clinical history, the histopathology observed, and the availability of specimens.
CDC Points of Contact	Infectious Diseases Pathology Branch Mailbox (404) 639-3132 pathology@cdc.gov Julu Bhatnagar (404) 639-2826 zrn1@cdc.gov Julian Villalba (404) 639-8531 puv2@cdc.gov Jennifer Kasten (404) 639-6161 gme0@cdc.gov
Version	5.9

Test Order

Picornavirus Detection and Identification (not Hepatitis A, not Rhinovirus)- Non-CLIA CDC-10374

Synonym(s)	Theier's murine encephalomyelitis virus (TMEV), Saffold virus (SAFV), Cosavirus (COSV) (Dekavirus), Salivirus (SALV) (Klassevirus), Kobuvirus, Aichi virus, Encephalomyocarditis virus (EMCV), Vilyuisk virus
CDC Pre-Approval Needed	**Terry Fei Fan Ng** **(404) 639-4880** **ylz9@cdc.gov** **Shannon Rogers** **(404) 639-2677** **boo9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Stool, Cerebrospinal fluid (CSF), Serum, Respiratory swab specimens in virus transport media (VTM), including nasopharyngeal swab (NP), oropharyngeal swab (OP), nasopharyngeal/oropharyngeal swab (NP/OP), nasal swab (NS), Respiratory wash specimens, including bronchoalveolar lavage (BAL), bronchial wash (BW), nasal wash (NW), tracheal aspirate (TA), nasal aspirate (NA), Rectal swab in virus transport media (VTM), Conjunctival swab in VTM, Lesion swab in VTM.
Minimum Volume Required	Stool: 1 gram, 10 - 20 grams preferred Cerebrospinal fluid (CSF): 0.15 mL, 0.5-2 mL preferred Serum: 0.15 mL, 0.5 - 2 mL preferred Respiratory wash specimens and swab specimens in virus transport media: 0.5 mL, 1 mL preferred Rectal, conjunctival, and lesion swab in virus transport media: 0.5 mL, 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping	Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample. For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media. For stool, CSF, and respiratory wash specimens, collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Do not add transport medium. For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes and centrifuge. After collection, freeze (-20°C or lower) all specimens and ship to CDC within 2 months. Please note: If necessary, CSF, conjunctival swabs and lesion swabs may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing. If necessary, stools, serum, respiratory swabs and washes, and rectal swabs may be kept at 2-8°C for no more than 14 days after collection and prior to freezing.
Transport Medium	Viral transport medium (VTM) should be used with these specimen types: nasopharyngeal swabs (NP), oropharyngeal swabs (OP), nasopharyngeal/oropharyngeal swabs (NP/OP), nasal swabs (NS), rectal swabs, conjunctival swab, and lesion swabs.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Molecular techniques
Turnaround Time	
Interferences & Limitations	Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.

Additional Information	Not Applicable
CDC Points of Contact	Shannon Rogers (404) 639-2677 boo9@cdc.gov Terry Fei Fan Ng (404) 639-4880 ylz9@cdc.gov
Version	1.7

Test Order
Picornavirus Special Study- CLIA
CDC-10375

Synonym(s)	
CDC Pre-Approval Needed	**Shannon Rogers** **(404) 639-2677** **boo9@cdc.gov** **Terry Fei Fan Ng** **(404) 639-4880** **ylz9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	Stool: 1 gram, 10 - 20 grams preferred Cerebrospinal fluid (CSF): 0.15 mL, 0.5-2 ml preferred, Serum: 0.15 mL, 0.5-2 ml preferred Respiratory swab specimens in VTM: 0.5 mL; 1 ml preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collecting specimens upon the first week of illness is ideal; if collected the second week, it should include a stool sample. For all swab specimens, use only sterile Dacron or rayon swabs with plastic shafts or, if available, flocked swabs. Place the swab immediately into a sterile vial containing 2 mL of viral transport media. For stool and CSF, collect each specimen in a clean, dry, leak-proof container. Stool should be collected within 14 days of symptom onset. Send only original, unprocessed stool. Do not add transport medium. For serum specimens, collect whole blood into a serum separator tube (marble or tiger top SST). Allow to clot at room temperature (15°C to 25°C) for a minimum of 30 minutes, centrifuge, remove serum from the separator tube and send an aliquot in a sterile container. After collection, freeze (-20°C or lower) all specimens and ship to CDC within 2 months. If necessary, specimens may be kept at 2-8°C for no more than 72 hours after collection and prior to freezing.
Transport Medium	Viral transport medium (VTM) should be used with these specimen types: nasopharyngeal swab (NP), oropharyngeal swab (OP), nasopharyngeal/oropharyngeal swab (NP/OP)
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. All specimens should be shipped frozen on dry ice under UN3373, Category B. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR)
Turnaround Time	2 Weeks
Interferences & Limitations	Frozen specimens must remain frozen; warming or freeze-thaw cycle reduces sensitivity. For serum, heparin may cause interference with the molecular tests and should be avoided. For swab specimens, do not use calcium alginate swabs or swabs with wooden sticks, as they may inactivate some viruses and inhibit some molecular assays.
Additional Information	Not Applicable
CDC Points of Contact	Picornavirus Laboratory AFMLab@cdc.gov Shannon Rogers (404) 639-2677 boo9@cdc.gov Terry Fei Fan Ng (404) 639-4880 ylz9@cdc.gov
Version	1.9

Test Order
Polio Direct Detection and Titration- Non-CLIA
CDC-10549

Synonym(s)	Polio special study, CCID50
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Performed on stool. Contact POC for further guidance and information.
Minimum Volume Required	1 gram (stool); 2-3 grams preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stool should be collected into a sterile container and stored refrigerated (2-8°C) for no more than 48 hours before being processed. Once processed, stools should be frozen (-20°C or lower) until shipped frozen on dry ice.
Transport Medium	Specimens should be shipped frozen on dry ice. Stool: No transport medium needed.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 225 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase chain reaction (PCR); virus titration assay; cell culture
Turnaround Time	2 Weeks
Interferences & Limitations	
Additional Information	For clinical trials, please submit under test order CDC-10549. For surveillance, please submit under test order CDC-10376.

CDC Points of Contact	Cara Burns (404) 639-5499 zqd1@cdc.gov Bernardo Mainou (404) 718-3261 qlk6@cdc.gov Steve Oberste (404) 639-5497 mbo2@cdc.gov

Version	1.2

Test Order
Polio Isolation and Genotyping- Non-CLIA
CDC-10376

Synonym(s)	PV, polio virus, Polio sequencing, AFP, acute flaccid paralysis
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool, cell culture isolate, Fast Technology for Analysis of nucleic acids (FTA) cards, wastewater
Minimum Volume Required	Tissue culture isolate: 0.5 mL Stool: 1 gram; 10 - 20 grams preferred Wastewater: 500mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimens refrigerated (2-8 °C) or frozen (-20 °C or lower). For stool, do not add transport medium. Wastewater should be stored refrigerated (2-8 °C) upon collection and stored frozen (-20 °C or lower) prior to shipping.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. FTA cards should be shipped at ambient temperatures and should include humidity indicator cards and desiccant pouches. When shipping ambient specimens, no temperature-maintaining materials (e.g., cold packs) are required. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Molecular techniques, Cell culture
Turnaround Time	3 Weeks
Interferences & Limitations	None

Additional Information	If case investigation form is readily available, please submit with specimen
CDC Points of Contact	Cara Burns (404) 639-5499 zqd1@cdc.gov Jaume Jorba (404) 639-4296 poliovirusisolation@cdc.gov
Version	1.6

Test Order
Polio Serology- CLIA
CDC-10377

Synonym(s)	Neutralization assay, NT, MNT
CDC Pre-Approval Needed	**Bernardo Mainou** **(404) 718-3261** **qlk6@cdc.gov** **Nicholas Wiese** **(404) 639-2650** **kue6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Sera need to be collected from clotted whole blood or through serum separated tubes (SST). Samples must be refrigerated (2-8°C) after collection for short-term storage, not to exceed 24 hours and frozen (-20°C or lower) until shipment without exceeding 1 month. Document conditions in which sample was maintained (e.g., temperature and time) on CDC 50.34 Specimen Submission Form in the comments section.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. Refrigerated specimens should be shipped with refrigerated or frozen cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 225 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Neutralization assay
Turnaround Time	4 Weeks

Interferences & Limitations	Hemolyzed samples are not accepted.
Additional Information	None
CDC Points of Contact	Bernardo Mainou (404) 718-3261 qlk6@cdc.gov Nicholas Wiese (404) 639-2650 kue6@cdc.gov
Version	1.8

Test Order
Polio Special Study- Non-CLIA
CDC-10378

Synonym(s)	None
CDC Pre-Approval Needed	**Cara Burns** **(404) 639-5499** **zqd1@cdc.gov** **Jaume Jorba** **(404) 639-4296** **poliolabusa@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Stool, cell culture isolate, extracted nucleic acid (total nucleic acid)
Minimum Volume Required	Tissue culture isolate: 0.5 mL. Stool: 1 gram; 10 - 20 grams preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	For stool and cell culture isolates keep specimens refrigerated (2-8 °C) or frozen (-20 °C or lower). For stool, do not add transport medium. Extracted nucleic acid should be shipped on dry ice and be received at temperatures between -10°C and -80°C. If specimens are not within the defined temperature range, accurate testing results cannot be guaranteed.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 76 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Cell Culture, PCR, drug susceptibility testing, or genetic sequencing

Turnaround Time	
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	Prior to shipping environmental nucleic acid extracts for sequencing request authorization using email poliolabusa@cdc.gov and include “CDC Poliovirus Sequencing Request” in the subject line.
CDC Points of Contact	William Davis (404) 639-2829 fwb0@cdc.gov Nancy Gerloff (404) 639-1397 poliolabusa@cdc.gov Jaume Jorba (404) 639-4296 poliosequencing@cdc.gov
Version	1.6

Test Order
Poxvirus Molecular Detection and Serology- Non-CLIA
CDC-10577

Synonym(s)	Monkeypox virus, variola virus (smallpox), vaccinia virus, sore mouth, orthopoxvirus serology
CDC Pre-Approval Needed	**Poxvirus Inquiry Line** **(404) 639-4129** **poxvirus@cdc.gov** **Whitni Davidson** **(404) 639-2933** **wdavidson@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. A brief written clinical summary with pertinent medical information (e.g. rash onset date, rash type, symptoms, smallpox vaccination date if relevant) and exposure history should be included. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Lesion material is required for persons with an active lesion or rash. Acceptable samples are dry swabs, swabs in viral or universal transport media, and crusts from lesions without transport media. Swabs should be nylon, dacron, polyester or rayon. Do not use cotton swabs. Viral culture can also be accepted only if a poxvirus other than monkeypox is suspected. Do not attempt to culture or ship monkeypox virus.
Minimum Volume Required	Polymerase chain reaction -- Viral Cultures: 0.5 mL. Note that monkeypox virus should not be cultured and sent for testing. Transport media: 0.3 mL Serology 0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	For dry swabs: Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly after collection. Store frozen samples for up to 60 days. Freezing is strongly recommended. However, if there is no freezer available, refrigerate samples (2-8°C) and store for up to 7 days. It is strongly recommended to send samples within 7 days of collection. For crusts and swabs in viral transport media:Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly after collection. Store frozen samples for up to 30 days. Freezing is strongly recommended. However, if there is no freezer available, refrigerate samples (2-8°C) and store for up to 7 days. Use blood collection tubes containing a clot activator and/or gel for serum separation. Separate and aliquot serum prior to storage and transport. For serum: Refrigerate (2-8 °C) or freeze (-20 °C or lower) specimens within an hour after collection. Refrigerated samples must arrive at CDC within 7 days and frozen samples within 60 days after collection.
Transport Medium	Transport medium, such as viral or universal transport media, can be added to swabs. Do not add any transport media to crusts. Contact the CDC POC for appropriate guidance/relevant information

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Please email the tracking number of the package to the CDC Point of Contact and poxviruslab@cdc.gov. It is preferred to ship samples frozen on dry ice. If dry ice is not available, specimens may be shipped refrigerated with frozen cold packs. Please include several ice packs to ensure samples arrive at the correct temperature. Upon shipment, submitter should send an email to the CDC POC and poxviruslab@cdc.gov providing the shipping company, the date shipped and the package tracking number. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 47 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real-time polymerase chain reaction; enzyme-linked immunosorbent assay (ELISA)
Turnaround Time	14 Days
Interferences & Limitations	Cotton swabs and swabs in media designed for bacterial preservation and/or transport may cause PCR inhibition and should not be used. Specimens with insufficient human DNA will be resulted as inconclusive. Blood collection in tubes with either heparin and/or ethylenediaminetetraacetic acid (EDTA) may interfere with results. Detection of immunoglobulin M and G antibodies is dependent upon the number of days the specimen was collected post-symptom onset. A previous history of smallpox vaccination or orthopoxvirus exposure may affect result interpretation.
Additional Information	Submitters should contact the Poxvirus Inquiry Line by telephone prior to using email and/or contacting the second POC. Real-time polymerase chain reaction can detect the following poxviruses: variola, monkeypox, vaccinia, orf, pseudocowpox, bovine papular stomatitis virus, cowpox, sealpox, molluscum contagiosum, and tanapox virus. ELISA can detect an antibody response in persons infected with an orthopoxvirus (e.g., variola, monkeypox, vaccinia, or cowpox virus).

CDC Points of Contact	Poxvirus Inquiry Line (404) 639-4129 poxviruslab@cdc.gov Whitni Davidson (404) 639-2933 wdavidson@cdc.gov

Version	2.0

Test Order
Poxvirus Molecular Detection- CLIA
CDC-10515

Synonym(s)	*Monkeypox* virus, *Variola* virus, *Vaccinia* virus, smallpox, sore mouth
CDC Pre-Approval Needed	**Poxvirus Inquiry Line** **(404) 639-4129** **poxvirus@cdc.gov** **Whitni Davidson** **(404) 639-2933** **wdavidson@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. A brief written clinical summary with pertinent medical information (e.g. rash onset date, rash type, symptoms, smallpox vaccination date if relevant) and exposure history should be included. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Swabbed lesion material is required for persons with an active lesion or rash. Acceptable samples are dry swabs, swabs in viral transport media (except for Clade I/Congo Basin Monkeypox virus), and crusts from lesions without transport media. Swabs should be nylon, dacron, polyester or rayon. Do not use cotton swabs. Do not use transport media labeled "Universal transport media" or "M4 transport media." Do not attempt to culture or ship monkeypox virus.
Minimum Volume Required	Viral Cultures: 0.5 mL. Note that monkeypox virus should not be cultured and sent for testing. Transport media: 0.3 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	For dry swabs: Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly after collection. Store frozen samples for up to 60 days. Freezing is strongly recommended. However, if there is no freezer available, refrigerate samples (2-8°C) and store for up to 7 days. It is strongly recommended to send samples within 7 days of collection. For crusts and swabs in viral transport media: Freeze (-20°C or lower) or refrigerate (2-8°C) specimens promptly after collection. Store frozen samples for up to 30 days. Freezing is strongly recommended. However, if there is no freezer available, refrigerate samples (2-8°C) and store for up to 7 days.

Transport Medium	Transport medium can be added to swabs, but it must be viral transport media. Other media such as universal transport medium, M4 viral transport medium, etc. cannot be accepted. Do not add any transport media to crusts. Contact the CDC POC for appropriate guidance/relevant information
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Please email the tracking number of the package to the CDC Point of Contact and poxviruslab@cdc.gov. It is preferred to ship samples frozen on dry ice. If dry ice is not available, specimens may be shipped refrigerated with frozen cold packs. Please include several ice packs to ensure samples arrive at the correct temperature. Upon shipment, submitter should send an email to the CDC POC and poxviruslab@cdc.gov providing the shipping company, the date shipped and the package tracking number. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 47 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Real-time polymerase chain reaction
Turnaround Time	14 Days
Interferences & Limitations	Cotton swabs and swabs in media designed for bacterial preservation and/or transport may cause PCR inhibition and should not be used. Specimens with insufficient human DNA will be resulted as inconclusive.
Additional Information	Submitters should contact the Poxvirus Inquiry Line by telephone prior to using email and/or contacting the second POC. Diagnostic real-time polymerase chain reaction can detect monkeypox virus.

CDC Points of Contact	Poxvirus Inquiry Line (404) 639-4129 poxviruslab@cdc.gov Whitni Davidson (404) 639-2933 wdavidson@cdc.gov

Version	1.8

Test Order
Poxvirus Serology- CLIA
CDC-10516

Synonym(s)	Orthopoxvirus serology
CDC Pre-Approval Needed	**Poxvirus Inquiry Line** **(404) 639-4129** **poxvirus@cdc.gov** **Whitni Davidson** **(404) 639-2933** **wdavidson@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. A brief written clinical summary with pertinent medical information (e.g. rash onset date, rash type, symptoms, smallpox vaccination date if relevant) and exposure history should be included. Information must be documented in written form, discussion during initial phone consultation is not a suitable alternative to a written record.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Use blood collection tubes containing a clot activator and/or gel for serum separation. Separate and aliquot serum prior to storage and transport. Refrigerate (2-8 °C) or freeze (-20 °C or lower) specimens within an hour after collection. Refrigerated samples must arrive at CDC within 7 days and frozen samples within 60 days after collection.
Transport Medium	No transport media is required.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship specimen(s) refrigerated on cold packs, unless frozen, then ship on dry ice. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 47 1600 Clifton Road NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Enzyme-linked immunosorbent assay (ELISA)
Turnaround Time	14 Days
Interferences & Limitations	Blood collection in tubes with either heparin and/or ethylenediaminetetraacetic acid (EDTA) may interfere with results. Detection of immunoglobulin M and G antibodies is dependent upon the number of days the specimen was collected post-symptom onset. A previous history of smallpox vaccination or orthopoxvirus exposure may affect result interpretation.
Additional Information	Submitters should contact the Poxvirus Inquiry Line by telephone prior to using email and/or contacting the second POC. ELISA can detect an antibody response in persons infected with an orthopoxvirus (e.g. variola, monkeypox, vaccinia, or cowpox virus).
CDC Points of Contact	Poxvirus Inquiry Line (404) 639-4129 poxviruslab@cdc.gov Whitni Davidson (404) 639-2933 wdavidson@cdc.gov
Version	1.7

Test Order
Puumala Hemorrhagic Fever Testing- Non-CLIA
CDC-10391

Synonym(s)	Hanta, HFRS, Nephropathia epidemica
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) or serum
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Do not ship specimen without prior consultation and approval. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.

CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov

Version	5.3

Test Order
Rabies Antemortem Human Testing- CLIA
CDC-10392

Synonym(s)	Human Rabies Rule Out Testing
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form (for each specimen) and Possible Human Rabies -"Patient Information (CDC Form 55.30 (E)) before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussions during initial phone consultation is not a suitable alternative to a written record. Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted.**
Supplemental Form	**Possible Human Rabies -"Patient Information (CDC Form 55.30 (E))** **http://www.cdc.gov/rabies/pdf/rorform.pdf**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Four samples listed below are required to provide an antemortem rule out of rabies. A rule out cannot be provided if all samples are not submitted: serum, CSF, nuchal (skin) biopsy, and saliva.
Minimum Volume Required	0.5 mL (Serum, CSF, saliva, greater than 1 ml preferred). Nuchal skin biopsy must be a full punch (5-6 millimeters) contain at minimum 10 hair follicles.

Collection, Storage, and Preservation of Specimen Prior to Shipping	Saliva should be collected prior to mouth cleansing using a sterile eyedropper pipette. Collect saliva sterile container that can be sealed securely. If the saliva is difficult to obtain, please collect an oral swab from the patient prior to mouth cleansing. A nuchal (skin) biopsy should be a full punch of skin 5 to 6 mm in diameter collected from the posterior region of the neck at the hairline. The biopsy specimen should contain a minimum of 10 hair follicles and be of sufficient depth to include the cutaneous nerves at the base of the follicle. Place the biopsy specimen in sterile container. Serum and cerebral spinal fluid (CSF) should also be collected. Do not send whole blood. No preservatives or additional fluids should be added to any specimen type. It is preferred to store samples frozen (-20°C or lower). Frozen samples should be received at CDC within 21 days of collection. Samples can also be stored refrigerated (2-8°C) and received at CDC within 3 days of collection. Please send samples as soon as possible. Please see the supplemental link for specific specimen storage and preservation. https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html
Transport Medium	No samples should be put in a transport medium
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. CDC 50.34 Specimen Submission Form is required for each of the four samples (serum, CSF, skin biopsy, and saliva). Ship all specimens overnight as first AM delivery (before 8:30 AM). Please email the tracking number of the package to the CDC Point of Contact and RabiesLaboratory@cdc.gov. It is preferred to ship samples frozen on dry ice. If dry ice is not available, specimens may be shipped refrigerated with frozen cold packs. Please include several ice packs to ensure samples arrive at the correct temperature. Upon shipment, submitter should send an email to the CDC POC and RabiesLaboratory@cdc.gov providing the shipping company, the date shipped and the package tracking number. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Direct Fluorescent Antibody Test (DFA) (Nuchal (skin) biopsy), Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) on Nuchal (skin) biopsy, RT-PCR on Saliva, IgG and IgM by Indirect Fluorescent Antibody Test (IFA) on Serum and CSF, Viral Neutralizing Antibodies by Rapid Fluorescent Focus Inhibition Test (RFFIT) on Serum and CSF
Turnaround Time	7 Days
Interferences & Limitations	Saliva and CSF specimen should be free of blood because blood may interfere with test results due to the inhibitors present in blood.
Additional Information	Do not ship specimens without prior consultation and approval. Submitters should contact the Rabies Duty Officer by telephone prior to using email and/or contacting the second CDC POC. Please include date of collection for CLIA diagnostic samples. IU/mL cannot be reported for RFFIT results. An end-point titer can be provided. Critical specimens will take less than 3 days to determine results; if testing needs to be repeated, results may take up to 7 days. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.

CDC Points of Contact	Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov

Version	4.0

Test Order
Rabies Antibody Titer (Animal)- Non-CLIA
CDC-10395

Synonym(s)	Rabies vaccination status
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 to 1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen can be kept refrigerated at 4 °C but prefer frozen at -20 °C
Transport Medium	Do not use transport media
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship all specimens overnight and provide the CDC Point of Contact and RabiesLaboratory@cdc.gov with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Rapid Fluorescent Focus Inhibition Test (RFFIT)

Turnaround Time	4 Weeks
Interferences & Limitations	Hemolyzed samples interfere with test results.
Additional Information	If the test needs to be repeated results may take up to an additional 7 days. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Duty Officer (404) 639-1050 Rabies@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov
Version	2.1

Test Order
Rabies Antibody Titer (Human)- CLIA
CDC-10393

Synonym(s)	Serology, Immunization status, Rabies titer
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Lillian Orciari** **(404) 639-1065** **lao0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Samples can be stored refrigerated (2-8°C) for up to 7 days after collection or frozen (-20°C or lower) for up to 1 month. Samples should be received at CDC within 7 days for refrigerated samples and 1 month for frozen samples. Please see the supplemental link for specific specimen storage and preservation. https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. It is preferred to ship samples frozen on dry ice. If dry ice is not available, samples within 7 days of collection can also be shipped with frozen cold packs. Please include several cold packs to ensure samples arrive at the correct temperature. Please send samples as soon as possible. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Rapid Fluorescent Focus Inhibition Test (RFFIT)
Turnaround Time	14 Days
Interferences & Limitations	Hemolyzed samples interfere with test results
Additional Information	Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If the test needs to be repeated results may take up to an additional 7 days. Please include date of collection for CLIA diagnostic samples. IU/mL cannot be reported for RFFIT results. An end-point titer can be provided. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100
CDC Points of Contact	Rabies Laboratory 404-718-1503 rabieslaboratory@cdc.gov Lillian Orciari 404-639-1065 lao0@cdc.gov Rabies Duty Officer 404-639-1050 rabies@cdc.gov
Version	3.5

Test Order
Rabies Antibody Titer (Human)- Non-CLIA
CDC-10582

Synonym(s)	Serology, Immunization status, Rabies titer
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Lillian Orciari** **(404) 639-1065** **lao0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL; 1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Samples can be stored refrigerated (2-8°C) for up to 7 days after collection or frozen (-20°C or lower) for up to 1 month. Samples should be received at CDC within 7 days for refrigerated samples and 1 month for frozen samples. Please see the supplemental link for specific specimen storage and preservation. https://www.cdc.gov/rabies/resources/specimen-submission-guidelines.html
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. It is preferred to ship samples frozen on dry ice. If dry ice is not available, samples within 7 days of collection can also be shipped with frozen cold packs. Please include several cold packs to ensure samples arrive at the correct temperature. Please send samples as soon as possible. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Rapid Fluorescent Focus Inhibition Test (RFFIT)
Turnaround Time	14 Days
Interferences & Limitations	Hemolyzed samples interfere with test results
Additional Information	Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If the test needs to be repeated results may take up to an additional 7 days. Please include date of collection for CLIA diagnostic samples. IU/mL cannot be reported for RFFIT results. An end-point titer can be provided. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Laboratory 404-718-1503 rabieslaboratory@cdc.gov Lillian Orciari 404-639-1065 lao0@cdc.gov Rabies Duty Officer 404-639-1050 rabies@cdc.gov
Version	2.0

Test Order
Rabies Confirmatory Testing (Animal)- Non-CLIA
CDC-10394

Synonym(s)	Rabies Direct Fluorescent Antibody Test (DFA), Rabies Confirmatory DFA, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), LN 34 Real-time Assay
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. Submitter must submit a CDC 50.34 Specimen Submission Form for each specimen before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, initial phone consultation is not a suitable alternative to a written record.**
Supplemental Form	**None**
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stored at -80 °C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship all specimens overnight First AM (before 8:30AM) and provide the CDC Point of Contact and RabiesLaboratory@cdc.gov with the package tracking number. Frozen specimens should be shipped on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Direct fluorescent antibody test (DFA), direct rapid immunohistochemistry test (DRIT), real- time reverse transcription polymerase chain reaction (RT-PCR).
Turnaround Time	3 Days
Interferences & Limitations	Decomposition of tissues will interfere or limit testing results due to denaturation of viral protein and degradation of nucleic acids.
Additional Information	If fresh frozen brain tissues (preferred) are unavailable, then formalin-fixed tissues may be tested by immunohistochemistry (IHC) tests if approved by the Rabies Duty Officer. Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing. Please submit processed and paraffin embedded tissue blocks and unstained slides (5 per block) from the required tissues full cross section of the brain stem and representative aliquots of cerebellum, (vermis, right and left lobes) rather than tissues in 10% percent buffered formalin. Ship tissue blocks and unstained slides at ambient temperature, and do not freeze. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Lillian Orciari (404) 639-1065 Lorciari@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov

Test Order
Rabies Field Surveillance- Non-CLIA
CDC-10517

Synonym(s)	Rabies Field Studies (Domestic and International)
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Serum and (cerebrospinal fluid) CSF. Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required. 0.5 to 1.0 mL for serum and CSF. Other volumes may be considered upon consultation with Rabies Duty Officer.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stored at -80 °C and should be kept on dry ice
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Frozen specimens should be shipped on dry ice. Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Molecular detection, Serology, Culture, Immunohistochemistry (IHC),, Other
Turnaround Time	4 Weeks
Interferences & Limitations	Test is limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
Additional Information	This test is for the submission of samples to participate in a rabies surveillance. No results of testing will be reported back to submitters. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov
Version	2.2

Test Order
Rabies Postmortem Human Testing- Non-CLIA
CDC-10396

Synonym(s)	Rabies Direct Fluorescent Antibody Test (DFA), Direct Fluorescent Antibody Test, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), LN 34 Real-time Assay, Immunohistochemistry Test, Rabies IHC
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**Consultation is required prior to specimen submission. Submitter must submit a complete CDC 50.34 Specimen Submission Form (for each specimen) and Possible Human Rabies -"Patient Information (CDC Form 55.30 (E)) before testing is performed. Include a brief written clinical summary with pertinent medical and exposure history. Information must be documented in written form, discussions during initial phone consultation is not a suitable alternative to a written record. Supplemental form in addition to the CDC Form 50.34 is required for each sample submitted.**
Supplemental Form	**Possible Human Rabies -"Patient Information (CDC Form 55.30 (E))** **http://www.cdc.gov/rabies/pdf/rorform.pdf**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Fresh-frozen brain tissues: full cross section of brain stem and representative aliquots of cerebellum (vermis, right and left lateral lobes). Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Fresh-frozen brain tissues: full cross section of brain stem and representative aliquots of cerebellum (vermis, right and left lateral lobes).
Collection, Storage, and Preservation of Specimen Prior to Shipping	Unfixed tissue should be stored at -80 °C
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	Frozen specimens should be shipped on dry ice. Ship all specimens overnight, first AM delivery (before 8:30 AM) and provide the CDC Point of Contact with the tracking number of package. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Direct fluorescent antibody test (DFA) for rabies virusantigen, real-time reverse transcription polymerase chain reaction (RT-PCR)
Turnaround Time	7 Days
Interferences & Limitations	Tests are limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
Additional Information	If fresh frozen brain tissues (preferred) are unavailable, then formalin-fixed tissues may be tested by immunohistochemistry (IHC) tests if approved by the Rabies Duty Officer. Turnaround time for results from fresh frozen tissue is shorter than from formalin-fixed tissues. Tissues submitted in formalin require additional processing. Please submit processed and paraffin embedded tissue blocks and unstained slides (5 per block) from the required tissues full cross section of the brain stem and representative aliquots of cerebellum, (vermis, right and left lobes) rather than tissues in 10% percent buffered formalin. Ship tissue blocks and unstained slides at ambient temperature, and do not freeze. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov
Version	1.3

Test Order
Rabies Special Study- Non-CLIA
CDC-10501

Synonym(s)	None
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Fresh-frozen brain tissues: a full cross section of brain stem and cerebellum (vermis, right and left lateral lobes). If the cerebellum is unavailable, a cross section of right and left hippocampi may be substituted. Serum and (cerebrospinal fluid) CSF. Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Full cross section of brain stem and cerebellum (vermis, right and left lobes). If the cerebellum is unavailable a cross section of right and left hippocampi may be substituted, but brain stem is required. 0.5 to 1.0 mL for serum and CSF. Other volumes may be considered upon consultation with Rabies Duty Officer.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stored at -80C and should be kept on dry ice.
Transport Medium	To be determined upon consultation with Rabies Duty Officer
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Direct Fluorescent Antibody Test (DFA) for rabies virus antigen, Direct Rapid Immunohistochemistry test (DRIT), Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Virus Isolation, Antigenic Typing, Sequence Analysis
Turnaround Time	6 Weeks
Interferences & Limitations	Test is limited by decomposed tissues, due to denaturation of viral proteins and degradation of nucleic acids.
Additional Information	Do not ship specimens without prior consultation and approval. Critical specimens will take less than 3 days to turn around. If testing needs to be repeated results may take up to 12 weeks. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC.
CDC Points of Contact	Subbian Satheshkumar Panayampalli (404) 639-1594 xdv3@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov
Version	1.4

Test Order
Rabies Virus Genetic Typing- Non-CLIA
CDC-10397

Synonym(s)	Rabies Antigenic Typing, Rabies Monoclonal Antibody Typing, Rabies MAB Typing, Rabies RT-PCR, Rabies Sequence Analysis, Rabies Variant Typing
CDC Pre-Approval Needed	**Rabies Duty Officer** **(404) 639-1050** **Rabies@cdc.gov** **Rabies Laboratory** **(404) 718-1503** **rabieslaboratory@cdc.gov**
Supplemental Information Required	**Please provide the county of origin of the animal in the CDC 50.34 Specimen Submission Form -œEpidemiological Data Section, in Other, specify box -.**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Fresh-frozen brain tissues: full cross section of brain stem and cerebellum (vermis, right and left lateral lobes) preferred, or a viral isolate. Other specimens may be submitted upon consultation with Rabies Duty Officer.
Minimum Volume Required	Full cross section of brainstem is required.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Stored at -80 °C and should be kept on dry ice
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC 50.34 Specimen Submission Form is required for each specimen. Ship all specimens overnight, delivery (before 10:30 AM) and provide the CDC Point of Contact with the tracking number of package. Frozen specimens should be shipped on dry ice. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 89 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Antigenic Typing, Real Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR), Sequencing
Turnaround Time	12 Weeks
Interferences & Limitations	Decomposition of tissues will interfere or limit testing results due to denaturation of viral protein and degradation of nucleic acids.
Additional Information	Samples for genetic typing may be a single sample, part of a large study or part of annual samples from a state for typing. The amount of testing required will depend on the reason for the testing and tests range from antigenic typing to whole genome sequencing and comparison with regional samples. Urgent samples for typing or molecular epidemiology are tested rapidly. The test(s) used have not been cleared and approved by the FDA, the performance characteristics have established by CDC Rabies Laboratory. The results should NOT be used for diagnosis, treatment, or assessment of patient health or management. Submitters should contact the Rabies Duty Officer by telephone prior to using email and contacting the second CDC POC. If you are calling outside of regular business hours, please call the CDC Emergency Operations Center (EOC) (770) 488-7100.
CDC Points of Contact	Rabies Laboratory (404) 718-1503 rabieslaboratory@cdc.gov Cyrstal Gigante (404) 718-2403 lzu1@cdc.gov Lillian Orciari (404) 639-1065 lao0@cdc.gov Rabies Duty Officer (404) 639-1050 rabies@cdc.gov
Version	2.4

Test Order
Real Time RT-PCR Testing for Marburg Virus- CLIA
CDC-10572

Synonym(s)	None
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	For molecular testing the accepted specimen type is whole blood (EDTA). CDC POC contact is required prior to sending any specimens.
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Molecular specimens must be kept refrigerated (2-8°C) for up to 3 days after collection, or frozen (-20°C or below) for up to 2 months after collection. All specimens must be shipped on dry ice. See link to supplemental submission form for specific information on various specimen types. Contact the CDC POC for approval prior to sending any specimens.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase chain reaction (PCR)
Turnaround Time	4 Days

Interferences & Limitations	Do not collect specimens in heparin, as heparin may cause interference with the molecular tests. Avoid thawing frozen specimens, as freeze-thawing may affect sensitivity of assays.
Additional Information	Pre-approval is required. Contact VSPB by email (whz2@cdc.gov) or phone (404) 639-1155 to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. Please include the EPIID in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form. Critical specimens will take less than 4 days to turn around.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	1.0

Test Order
Respiratory Panel (SARS-2, Influenza A/B)- Non-CLIA
CDC-10542

Synonym(s)	SARS-2 and Influenza A/B Respiratory Virus, COVID-19, coronavirus, SARS-CoV-2
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs (NP), throat (oropharyngeal (OP)) swabs, and anterior nares swabs.
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling of the nasopharyngeal mucosa should be used. Respiratory specimens can be stored at 2-8°C for up to 72 hours after collection, using viral transport media. Specimens stored for longer than 72 hours should be stored frozen at ≤-70°C. All specimens submitted to CDC for testing should be frozen at ≤-70°C and shipped on dry ice overnight. Liquid specimen aliquots should be in properly labeled, leak-proof, unbreakable screw cap vials. For more collection details, visit https://www.cdc.gov/covid/hcp/clinical-care/clinical-specimen-guidelines.html
Transport Medium	Respiratory specimens should be collected and placed into viral transport media (VTM).
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 66 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	2 Weeks

Interferences & Limitations	Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests.
Additional Information	None
CDC Points of Contact	David Lowe (404) 718-6814 nqu9@cdc.gov Marie Kirby (404) 718-7689 pbi0@cdc.gov SARS FluAB Mailbox CDCSARS2FluAB@cdc.gov
Version	0.1

Test Order
Respiratory Virus (Non-Influenza) Special Study- Non-CLIA
CDC-10400

Synonym(s)	
CDC Pre-Approval Needed	**Lydia Atherton** **(404) 718-8368** **ibz1@cdc.gov** **David Lowe** **(404) 771-1602** **nqu9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Specimens should be shipped frozen, overnight on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 84 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	
Turnaround Time	
Interferences & Limitations	To be determined

Additional Information	To be determined
CDC Points of Contact	Lijuan Wang (404) 639-4384 ynx2@cdc.gov Stacey Gonder (404) 639-8739 urv6@cdc.gov Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Megha Aggarwal (404) 639-3287 tlz5@cdc.gov
Version	2.6

Test Order
Rickettsia Molecular Detection- CLIA
CDC-10402

Synonym(s)	Rickettsiosis, spotted fever group rickettsiosis, Rocky Mountain spotted fever, Rickettsia parkeri rickettsiosis, African tick bite fever, Pacific coast tick fever, rickettsialpox, typhus group rickettsiosis, flea-borne typhus, epidemic (louse-borne) typhus
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human

Acceptable Sample / Specimen Type for Testing	Acute whole blood (available for *R. rickettsii, R. typhi*, and *R. prowazekii* only). Specimen must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): EDTA-treated, or ACD A treated. Acute serum (available for *R. rickettsii*, *R. typhi*, and *R. prowazekii* only) Specimen Serum separator tube, or cryo-tubes. Tissue (available for all *Rickettsia* species) must be obtained within 14 days of illness onset AND before or within 72 hours after initiation of a tetracycline class antibiotic (e.g., doxycycline): sterile specimen container in saline-moistened gauze. Swab of eschar (for African tick bite fever, rickettsialpox, Pacific Coast tick fever, and *Rickettsia parkeri* rickettsiosis only) obtained before or within 14 days of initiation of a tetracycline-class antibiotic (e.g., doxycycline) AND with a residual eschar scab at the time of collection.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days prior to arriving at CDC, freeze at -20°C or lower up to 2 months (35 days for tissue), or -70°C or lower up to 1 year (for serum, blood, and tissue). For 2-8°C storage, tissue should be placed in a sterile specimen cup with a gauze pad slightly moistened with sterile saline. To freeze tissue, place specimen in a cryogenic container at -20°C or lower. Do not immerse the tissue in saline solution. For eschar swabs, place the specimen in a dry sterile specimen container without any medium.
Transport Medium	For tissue, place in sterile specimen cup with gauze pad lightly moistened with sterile saline. Do not immerse the sample in saline.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR), polymerase chain reaction (PCR), sequencing
Turnaround Time	6 Weeks
Interferences & Limitations	Molecular detection methods have decreasing sensitivity after resolution of the febrile (acute) stage of illness. Hemolysis of whole blood can interfere with results. Other shipping media is not recommended and will be subject to rejection. Multiple freeze-thaw cycles and sample storage above refrigerated temperatures (2-8°C) can interfere with nucleic acid extraction.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Molecular testing for other pathogens including *Anaplasma*, *Coxiella*, *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html

CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Version	2.5

Test Order
Rickettsia Serology Spotted Fever Group (RMSF) Serology- CLIA
CDC-10403

Synonym(s)	Spotted fever group rickettsiosis, Rocky Mountain spotted fever, Rickettsia parkeri rickettsiosis, Pacific coast tick fever, African tick bite fever, rickettsialpox
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep specimen refrigerated (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of a rickettsial disease can only be established by demonstrating a four-fold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including typhus group *Rickettsia*, *Anaplasma*, *Coxiella*, *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html

CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Version	3.3

Test Order
Rickettsia Serology Typhus Group Serology- CLIA
CDC-10404

Synonym(s)	Typhus group rickettsiosis, epidemic (louse-borne) typhus, murine (flea-borne) typhus
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **- Test order name (one per submission form)** **- SPHL point of contact including direct phone number of the person responsible for sample submission and follow-up** **- Patient full name, sex, birth date** **- Date of illness onset** **- Specimen collection date** **- Specimen source (e.g., serum, whole blood, eschar swab, tissue)** **- Therapeutic agent and dates (specific antibiotic therapy and initiation date)** **- State of illness** **- Relevant clinical summary that includes signs and symptoms compatible with a rickettsial illness, as well as any pertinent comorbidities** **Requested additional information:** **- Other laboratory results (e.g., previous serologic or molecular tests, complete blood counts, hepatic transaminase levels or electrolyte values, if available)** **- Travel history (within 2 weeks of symptom onset), denote with "No" or "Unknown" if no travel occurred or travel history is unknown)** **- Exposure history, e.g., ticks, fleas, lice, mites, or relevant animal exposures (denote "None" or "Unknown" if no arthropod or animal exposure occurred or is unknown)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Acute-phase serum (taken within 14 days of illness onset or while symptomatic) paired with convalescent-phase serum (taken 2-10 weeks after initial sample); or single acute-phase or convalescent serum.
Minimum Volume Required	1.0 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Keep refrigerated temperature (2-8°C) if sample will arrive at CDC within 7 days from collection. If the sample requires storage for more than 7 days, freeze at -20°C or lower up to 2 months, or -70°C or lower up to 1 year.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Indirect immunofluorescence antibody assay (IFA)
Turnaround Time	6 Weeks
Interferences & Limitations	Multiple freeze thaw cycles can interfere with antigen binding. A detectable antibody response is often not detected during the first week of illness. Confirmation of a rickettsial disease can only be established by demonstrating a four-fold or greater increase in antibody titer which requires evaluation of paired serum samples collected during acute and convalescent phases of the illness.
Additional Information	Routine diagnostic samples should be sent to your state public health laboratory (SPHL) or a commercial laboratory if the test is available commercially. The Rickettsial Zoonoses Branch (RZB) Reference Diagnostic Laboratory assists state public health laboratories by providing specialized testing for rickettsial agents. Serological testing for other pathogens including spotted fever group *Rickettsia*, *Anaplasma*, *Coxiella*, *Orientia*, and *Ehrlichia* spp. may be included following clinical review in RZB. Results are reported directly to SPHLs. Additional RZB specimen and shipping information can be found at the following address: https://www.cdc.gov/ncezid/dvbd/specimensub/rickettsial-shipping.html
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Carmen Ramos (787) 706-4345 wqt8@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov

Test Order
Rickettsial Diseases and Q Fever Special Study- Non-CLIA
CDC-10405

Synonym(s)	Rickettsiosis, Rocky Mountain spotted fever, spotted fever group rickettsiosis, Rickettsia parkeri rickettsiosis, Pacific Coast tick fever, African tick bite fever, rickettsialpox, typhus group rickettsiosis, flea-borne typhus, epidemic (louse-borne) typhus, human granulocytic anaplasmosis, human monocytic ehrlichiosis, scrub typhus, Q fever
CDC Pre-Approval Needed	**Sandor Karpathy** **(404) 639-1098** **evu2@cdc.gov** **Yan Zeng** **(404) 639-5177** **RZBrefdxlab@cdc.gov**
Supplemental Information Required	**As determined during pre-approval consultation.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	As determined during pre-approval consultation.
Minimum Volume Required	As determined during pre-approval consultation.
Collection, Storage, and Preservation of Specimen Prior to Shipping	As determined during pre-approval consultation.
Transport Medium	As determined during pre-approval consultation.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Shipping frozen is strongly recommended. Frozen specimens should only be sent with dry-ice by overnight priority mail and received within 60 days of collection. Refrigerated specimens should be sent with refrigerated or frozen cold packs and received within 7 days of collection. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 78 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Cell culture isolation, polymerase chain reaction (PCR) assay, real-time PCR assay (RT-PCR), nucleotide sequencing, serology
Turnaround Time	
Interferences & Limitations	As determined during pre-approval consultation.
Additional Information	As determined during pre-approval consultation.
CDC Points of Contact	Yan Zeng (404) 639-5177 RZBrefdxlab@cdc.gov Arlyn N Gleaton (404) 639-4904 iwv7@cdc.gov Sandor Karpathy (404) 639-1098 evu2@cdc.gov
Version	4.2

Test Order
Rift Valley Fever (RVF) Testing- CLIA
CDC-10406

Synonym(s)	RVF
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**Private citizens interested in clinical testing should contact their healthcare providers. Clinicians should contact their local or state health department for consultation.**
Supplemental Form	**Not applicable**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA)
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	**Recommended method**: Whole blood (EDTA) specimens must be frozen (<-20°C) and shipped on dry ice within 60 days of collection. **Alternative method (not recommended)**: Whole blood (EDTA) specimens must be refrigerated (2-8°C) and shipped on cold packs within 3 days of collection.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Do not ship specimen without prior consultation and approval. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	10 Days
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.

Additional Information	Pre-approval is required. Contact CDC's Emergency Operation Center at 770-488-7100 and request VSPB's on-call epidemiologist to provide the clinical and epidemiological history on the patient. If testing is approved, VSPB will provide an approval number (EPIID) by email along with instructions for next steps. After receiving pre-approval and the EPIID number, the CDC specimen submission form can be submitted using one of two ways: 1) For submitters that use CSTOR, submit using the CSTOR Web Portal. The EPIID must be included in the Test Order Request's comments field. If the EPIID is not included, the order will be rejected. 2) For submitters that do not use CSTOR, submit via CDC 50.34 Specimen Submission Form. Enter the EPIID in the "Case ID field" within the "Patient Information" section on CSTOR and/or the CDC 50.34 Specimen Submission Form.
CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov
Version	4.4

Test Order
Rift Valley Fever (RVF) Testing- Non-CLIA
CDC-10600

Synonym(s)	RVF
CDC Pre-Approval Needed	**Trevor Shoemaker** **(470) 312-0094** **spather@cdc.gov** **Amy Schuh** **(404) 639-1756** **wuc2@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Whole blood (EDTA) for PCR. Whole blood (EDTA) or serum for Serology.
Minimum Volume Required	4 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be frozen and shipped on dry ice.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 70 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Polymerase Chain Reaction (PCR) or Serology
Turnaround Time	
Interferences & Limitations	Avoid thawing frozen specimens, as freeze-thawing may reduce assay sensitivity.
Additional Information	Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.

CDC Points of Contact	Trevor Shoemaker (470) 312-0094 spather@cdc.gov Amy Schuh (404) 639-1756 wuc2@cdc.gov

Version	2.0

Test Order
Rotavirus Genotyping- Non-CLIA
CDC-10409

Synonym(s)	Rotavirus Real Time RT-PCR, Rotavirus RT-PCR, Rotavirus Sequencing
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Contact laboratory for supplemental forms.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Human stool, human rectal swabs
Minimum Volume Required	0.5 g or 0.5 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimen should be kept either frozen at -20 °C or colder or refrigerated at 4 °C. Specimen tubes or cups must be packed inside of a leak proof secondary container. The secondary container needs to be packed inside an approved class B specimen shipping container (i.e. Fisher scientific cat# 22-130-431).
Transport Medium	Not applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. The Rotavirus Surveillance and Molecular Epidemiology lab at CDC will accept and test samples received from State public health labs only. Hospitals and care facilities should send outbreak/sporadic rotavirus positive samples to State public health labs, which can then ship the samples to CDC for rotavirus genotyping. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 187 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	RT-PCR, Sequencing
Turnaround Time	8 Weeks
Interferences & Limitations	None

Additional Information	• Sample labels and requisition forms (CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT)) should not include any Personal Identifiable Information (PII) such as patient's name, date of birth, age etc. • Samples must be submitted with only sample ID number on the labels and on the requisition forms. • Samples received with PII information on the labels and on the requisition forms will be rejected. The rotavirus genotyping results should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient. The results are intended for public health/surveillance purposes only and must not be communicated to the patient, their care provider, or placed in the patients' medical record.
CDC Points of Contact	Rashi Gautam (404) 639-1628 ijs0@cdc.gov Slavica Rustempasic (404) 639-0443 hsr7@cdc.gov
Version	2.0

Test Order
Rubella Avidity- CLIA
CDC-10249

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	**Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov** **Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum separated from whole blood by centrifugation The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.1 mL; 0.5-1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Optimum time-point for collection is 5 days after onset of symptoms (fever and rash). For suspected congenital rubella syndrome (CRS), collect sample as soon after birth as possible. If paired sera are to be collected, the second sample should be collected 14 to 21 days after the acute specimen was collected. Collect blood into a serum separation tube (serum-separation tube (STT), red-top, or tiger top. Do not add anticoagulants or preservatives. Do not freeze whole blood prior to separating serum. Aseptically transfer serum to a sterile tube after centrifugation and prior to shipping, preferably into a tube that has an externally threaded cap with an o–ring seal. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. Refrigerate serum (2-8°C) within 8 hours of collection and store for up to 48 hours. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). Serum specimens can be stored frozen (-20°C or lower) prior to shipping for a maximum of two months. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All serum specimens should be frozen prior to shipping to CDC and should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by EIA, IgG avidity is determined by a laboratory-developed assay using EIA
Turnaround Time	10 Days
Interferences & Limitations	If a serum collected less than 5 days after onset is negative, a second sample is necessary to confirm/rule out rubella. The rubella IgG avidity assay has not been cleared or approved by the FDA. The performance characteristics have been established by the Viral Vaccine Preventable Diseases Branch.
Additional Information	For additional information on serology assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the serology section. For additional details on sample collection, storage, and transport, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html.
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov
Version	4.4

Test Order
Rubella Detection- CLIA
CDC-10242

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs are preferred specimen types. Other acceptable specimen types include: throat swabs and urine.
Minimum Volume Required	Urine: 1 mL, not to exceed 50 mL. Throat and nasopharyngeal swabs: 1-3 mL of viral transport medium.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat and nasopharyngeal swabs: detection is most successful when samples are collected the first day of rash through 3 days following rash onset. Detection may be successful as late as 7 days post rash onset. Samples collected from suspected congenital rubella syndrome (CRS) cases, the collection window is from birth to 3 months of age for nasopharyngeal swab, throat swab, and urine specimens. Nasopharyngeal swabs and throat swabs should be collected with commercial swab products designed for the collection of throat/nasopharyngeal specimens or flocked polyester fiber swabs. Cotton swabs are not acceptable. Swabs should be placed in 2 mL of standard viral transport medium (VTM) and should not be allowed to dry out. Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab should be broken off and left in the tube. Immediately after collection, throat and nasopharyngeal swab specimens can be refrigerated at 2-8°C for up to 72 hours. After 72 hours, these specimens should be frozen at -20°C or lower. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen at -20°C or lower and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should arrive at CDC within 30 days of being frozen -20°C or lower. Urine: Up to 50 ml of urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated (2-8°C) immediately after collection and shipped to CDC overnight on cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen.
Transport Medium	Viral transport medium (VTM) for nasopharyngeal or throat swabs. Swabs should be immersed in 1-3 mL of viral transport medium. Transport medium is not required for urine.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swabs specimens should be shipped on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Laboratory developed real-time reverse-transcription polymerase chain reaction (RT-PCR) assay
Turnaround Time	10 Days
Interferences & Limitations	A negative result should not be used to rule out rubella infection as many variables can affect specimen quality. The real-time assay has not been cleared or approved by the FDA. The performance characteristics have been established by Viral Vaccine Preventable Diseases Branch (VVPDB)
Additional Information	For additional information on rubella RNA detection, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the RNA Detection section.
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov
Version	3.4

Test Order
Rubella Genotyping- Non-CLIA
CDC-10550

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.**
Supplemental Form	
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs are preferred sample types. Other acceptable specimen types include: throat swabs and urine.
Minimum Volume Required	Urine: 1 mL, not to exceed 50 mL. Throat and nasopharyngeal swabs: 1-3 mL of viral transport medium.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat and nasopharyngeal swabs: detection is most successful when samples are collected the first day of rash through 3 days following rash onset. Detection may be successful as late as 7 days post rash onset. Samples collected from suspected congenital rubella syndrome (CRS) cases, the collection window is from birth to 3 months of age for nasopharyngeal swab, throat swab, and urine specimens. Throat and nasopharyngeal swabs should be stored immediately in 1-3 mL of viral transport medium and should not be allowed to dry out. Synthetic swabs are recommended. Throat and nasopharyngeal swab specimens should be stored refrigerated (2-8°C) immediately after collection and should preferably be frozen (-20°C or lower) within 1 hour after collection. If laboratories do not have immediate access to a freezer and storage frozen (-20°C or lower) is not feasible within 1 hour of collection, these specimens may be stored for up to 72 hours refrigerated (2-8°C) before freezing. Prior to being shipped to CDC, throat and nasopharyngeal swab specimens should be frozen (-20°C or lower) and shipped overnight to CDC on dry ice. Throat and nasopharyngeal swab specimens should preferably arrive at CDC within 5 days of being frozen at -70°C or -20°C or lower but will still be accepted if they arrive at CDC within 30 days of being frozen at -70°C or -20°C or lower. Urine: Urine should be collected in a sterile, leakproof container. Urine specimens should be stored refrigerated (2-8°C) immediately after collection and shipped to CDC overnight on refrigerated or frozen cold packs. Urine specimens must arrive at CDC within 7 days after specimen collection. Urine cannot be frozen.
Transport Medium	Viral transport medium (VTM) for nasopharyngeal or throat swabs. Swabs should be immersed in 1-3 mL of viral transport medium. Transport medium is not required for urine.

Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen throat and nasopharyngeal swabs specimens should be shipped on dry ice overnight. Refrigerated urine specimens should be shipped with refrigerated or frozen cold packs overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Laboratory developed RT-PCR assays for genotyping and Sanger nucleic acid sequencing
Turnaround Time	2 Weeks
Interferences & Limitations	The genotyping assays have not cleared or approved by the FDA. The performance characteristics have not been fully established by VVPDB. The results are intended for public health purposes only and must not be communicated to the patient, their care provider, or placed in the patients medical record. These results should not be used for diagnosis, treatment, or assessment of patient health or management.
Additional Information	For additional information on rubella genotyping assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the RNA Detection and Genetic Analysis sections. For additional detail on sample collection, storage, and shipment, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 idn1@cdc.gov

Test Order
Rubella Serology- CLIA
CDC-10246

Synonym(s)	German measles, three day measles
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide the following information on the CDC 50.34 Specimen Submission Form: date of onset, date of specimen collection, date(s) of MMR vaccination, and any recent travel history. Provide information on pregnancy status if applicable. Provide any preliminary results available.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum separated from whole blood by centrifugation. The following conditions may result in the specimen being rejected for testing: • Specimen is hemolyzed, lipemic, or bacterially contaminated. • Specimen is not frozen upon receipt at CDC.
Minimum Volume Required	0.1 mL; 0.5-1 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Optimum time-point for collection is 5 days after onset of symptoms (fever and rash). For suspected congenital rubella syndrome (CRS), collect sample as soon after birth as possible. If paired sera are to be collected, the second sample should be collected 14 to 21 days after the acute specimen was collected. Collect blood into a serum separation tube (serum-separation tube (STT), red-top, or tiger top. Do not add anticoagulants or preservatives. Do not freeze whole blood prior to separating serum. Aseptically transfer serum to a sterile tube after centrifugation and prior to shipping, preferably into a tube that has an externally threaded cap with an o–ring seal. Serum samples should not be stored at room temperature (15-25°C) for longer than 8 hours after collection. Refrigerate serum (2-8°C) within 8 hours of collection and store for up to 48 hours. If the samples will be stored for more than 48 hours, freeze specimens (-20°C or lower). Serum specimens can be stored frozen (-20°C or lower) prior to shipping for a maximum of two months. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results.
Transport Medium	Not applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. All serum specimens should be frozen prior to shipping to CDC and should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by Enzyme Immunoassay (EIA), IgM antibody detected by EIA
Turnaround Time	10 Days
Interferences & Limitations	If a serum collected less than 5 days after onset is negative, a second sample is necessary to confirm/rule out rubella.
Additional Information	For additional information on serology assays, see https://www.cdc.gov/rubella/lab/lab-testing-procedures.html and refer to the serology section. For additional details on sample collection, storage, and transport, see https://www.cdc.gov/rubella/lab/specimen-collection-shipment.html
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 ldn1@cdc.gov
Version	2.3

Test Order
Rubella Special Studies- Non-CLIA
CDC-10562

Synonym(s)	None
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Nasopharyngeal swabs, throat swabs, nasal swabs, urine sediment, serum, tissue biopsies
Minimum Volume Required	Throat, nasal, or nasopharyngeal swabs, urine sediment: 1 mL; 3 mL preferred.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Throat, nasal, and nasopharyngeal swabs should be stored immediately in 1-3 mL of viral transport medium and should not be allowed to dry out. Synthetic swabs are recommended. Urine sediment should be collected in a sterile tube by centrifugation and resuspended in 1-3 ml VTM. Tissue biopsy should be placed into sterile container without transport media. Serum should be separated from whole blood by centrifugation. Serum, nasopharyngeal swabs, throat swabs, nasal swabs, tissue biopsies, and urine sediment specimens should be stored refrigerated (2-8°C) immediately after collection and should preferably be frozen (-20°C or lower) within 1 hour after collection. Prior to being shipped to CDC, serum, throat, nasal, and nasopharyngeal swabs, tissue biopsies, and urine sediment specimens should be kept frozen (-20°C or lower) for up to 6 months and shipped overnight to CDC on dry ice.
Transport Medium	Viral transport medium (VTM) for nasopharyngeal, nasal, throat swabs, or urine sediment. Swabs should be immersed in 1-3 mL of viral transport medium. Transport medium is not required for serum and tissue biopsies.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Frozen specimens should be shipped on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 81 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	IgG antibody detected by enzyme immunoassay (EIA), IgM antibody detected by EIA, laboratory developed real-time reverse-transcription polymerase chain reaction (RT-PCR) assays
Turnaround Time	8 Weeks
Interferences & Limitations	None
Additional Information	None
CDC Points of Contact	Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov LiJuan Hao (404) 639-1767 idn1@cdc.gov
Version	1.0

Test Order
Salmonella Identification and Characterization- Non-CLIA
CDC-10110

Synonym(s)	*Salmonella* Typing
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Salmonella*; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature or refrigerated, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants refrigerated with refrigerated or frozen cold packs, or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 27 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic or Genetic Identification and Subtyping
Turnaround Time	13 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Charlotte Lane (404) 718-4789 koe7@cdc.gov Blake Dinsmore (404) 668-9648 ftb4@cdc.gov
Version	3.3

Test Order
Salmonella Subtyping- Non-CLIA
CDC-10108

Synonym(s)	*Salmonella* Typing
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Salmonella*; Sequence Data
Minimum Volume Required	Minimum volume for microbrial isolates is not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at refrigerated (2-8°C) to room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	Ship isolates on nutrient agar or non-selective similar agar (trypticase soy agar, heart infusion agar, etc.)
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at refrigerated with refrigerated or frozen cold packs or room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 27 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Antimicrobial Susceptibility Testing (AST)
Turnaround Time	20 Weeks
Interferences & Limitations	Virulence and serotype modification genes encoded by mobile genetic elements (bacteriophages, plasmids and pathogenicity islands) may be spontaneously lost during transit and storage. Conditions that induce a stress response in the bacterium can affect the stability of virulence factors and may affect the expression of O and H antigens.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Charlotte Lane (404) 718-4789 koe7@cdc.gov Blake Dinsmore (404) 668-9648 ftb4@cdc.gov
Version	2.7

Test Order
SARS-CoV-2 Surveillance Sequencing- Non-CLIA
CDC-10551

Synonym(s)	next generation sequencing, coronavirus, COVID, SARS2
CDC Pre-Approval Needed	**Clint Paden** **(404) 639-4959** **fep2@cdc.gov** **Lydia Atherton** **(404) 718-8368** **ibz1@cdc.gov**
Supplemental Information Required	**Please do not include any PII in the sample submission. Previous real-time PCR results are required. Contact CDC POCs for submission form.**
Supplemental Form	**Supplemental form is required for specimen submission. Contact CDC POC for the Supplemental Specimen Metadata Form**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Upper respiratory specimens, such as nasopharyngeal swabs, oropharyngeal swabs or anterior nasal swabs, nasal wash/aspirate, and virus isolates. Clinical specimens should be collected according to CDC interim guidance: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Minimum Volume Required	0.2 mL; 0.5 mL preferred
Collection, Storage, and Preservation of Specimen Prior to Shipping	Respiratory specimens can be stored at 2-8°C for up to 72 hours after collection, using the appropriate transport medium. Specimens stored for longer than 72 hours should be stored frozen at ≤ -70°C. All specimens submitted to CDC for testing should be frozen at ≤ -70°C and shipped on dry ice overnight. Liquid specimen aliquots should be in properly labeled, leak-proof, unbreakable screw cap vials.
Transport Medium	Respiratory specimens should be collected and placed into appropriate transport media, such as viral transport media (VTM), universal transport media (UTM), or sterile saline.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Please e-mail SARSseq@cdc.gov to notify the CDC POC of the shipment. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB / STATT Unit 66 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Next generation sequencing on various platforms
Turnaround Time	6 Weeks
Interferences & Limitations	The ability to generate whole genome sequences relies primarily on specimen quality and the viral load.
Additional Information	None
CDC Points of Contact	Suxiang Tong (404) 639-1372 sot1@cdc.gov Lydia Atherton (404) 718-8368 ibz1@cdc.gov Xiaoyan Lu (404) 639-2745 xal9@cdc.gov Adam Retchless (404) 639-3862 ymw8@cdc.gov
Version	3.5

Test Order
Schistosomiasis Serology- CLIA
CDC-10466

Synonym(s)	*Schistosoma mansoni*, *Schistosoma haematobium*, *Schistosoma japonicum*; Bilharzia, parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**This test is confirmation only. Requirement for specimen acceptance and testing include:** **1) appropriate exposure/travel history in addition to** **2) previous laboratory tests and/or other clinical indications (e.g. clinical symptoms radiographic, bladder findings) consistent with schistosomiasis** **Both pieces of information need to be included during pre-approval and on the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum for serology testing should be collected, centrifuged and transferred to leak proof tubes. Serum can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	FAST-ELISA, Immunoblot, Western Blot, MAMA, HAMA, JAMA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	Known interfering substances: hemolysis, hyperlipemia or other causes of turbidity may cause erroneous results.
Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Malaria Hotline (770) 488-7788 ncicdpdmalaria@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	5.9

Test Order

Simian Immunodeficiency Virus (SIV) and SIV/Human Immunodeficiency Virus (SHIV) Recombinant Virus Testing- CLIA

CDC-10534

Synonym(s)	SIV, SHIV (SIV/HIV recombinants)
CDC Pre-Approval Needed	**Bill Switzer** **(404) 639-0219** **bis3@cdc.gov** **Hao Zheng** **(404) 639-2421** **hxz2@cdc.gov**
Supplemental Information Required	**All submitted specimens should be accompanied by a completed and printed CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Whole blood specimens may be collected in ethylenediaminetetraacetic acid (EDTA) purple top tubes.
Minimum Volume Required	10 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens should be stored at 2-8°C prior to shipping and shipped at 2-8°C using ice packs. Specimens must be received within 48 hours from time of collection.Specimen stability is affected by elevated temperature. Whole blood should not be frozen.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 227 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	real-time Polymerase Chain Reaction (PCR)
Turnaround Time	3 Weeks

Interferences & Limitations	Collections in heparin coated tubes are unacceptable due to heparin interference with nucleic acid amplification. Specimen will be rejected if improperly labeled or unlabeled, or with discrepant documentation, insufficient volume, without documentation, unacceptable preservatives, and specimen that have leaked in transit or otherwise shown evidence of contamination.
Additional Information	None
CDC Points of Contact	Bill Switzer (404) 639-0219 bis3@cdc.gov HaoQiang Zheng (404) 639-2421 hxz2@cdc.gov
Version	0.0

Test Order
Special Bacteriology Pathogen Study- Non-CLIA
CDC-10147

Synonym(s)	
CDC Pre-Approval Needed	**John McQuiston** **(404) 639-0270** **zje8@cdc.gov** **Melissa Bell** **(404) 639-1348** **jqv7@cdc.gov**
Supplemental Information Required	**Please complete all sections on the CDC 50.34 Specimen Submission Form. Please notify laboratory point of contact listed below of shipment if this is a critical care specimen.**
Supplemental Form	**None**
Performed on Specimens From	Human and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	To be determined after consultation with point of contact listed below.
Minimum Volume Required	To be determined after consultation with point of contact listed below.
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined after consultation with point of contact listed below.
Transport Medium	To be determined after consultation with point of contact listed below.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship at room temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 17 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state, and federal regulations.
Methodology	To be determined after consultation with point of contact listed below.
Turnaround Time	
Interferences & Limitations	To be determined after consultation with point of contact listed below.
Additional Information	To be determined after consultation with point of contact listed below.

CDC Points of Contact	Melissa Bell (404) 639-1348 jqv7@cdc.gov Adam Szewc (404) 718-6167 ogi4@cdc.gov

Version	2.2

Test Order
Staphylococcal Toxic Shock Syndrome Toxin - Identification (ID)- CLIA
CDC-10426

Synonym(s)	Staph Toxin, Toxic Shock Syndrome (TSS), Panton-Valentine leukocidin (PVL), Toxic Shock Syndrome Toxin-1 (TSST-1)
CDC Pre-Approval Needed	**Stephen LaVoie** **(404) 718-4747** **qea5@cdc.gov** **Davina Campbell** **(404) 639-4185** **xew9@cdc.gov**
Supplemental Information Required	**The CDC 50.34 Specimen Submission Form must include the State Public Health Department contact information as well as the date the submitted culture was inoculated onto transport media.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Staphyloccoccus aureus*.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store pure culture isolates at room temperature (15-25 °C) for up to 7 days or at refrigerated temperature (2-8 °C) up to 14 days. Isolates being stored more than 14 days should be frozen (-20 °C or lower). Ship isolates as soon as possible to ensure viability.
Transport Medium	Transport pure culture isolates at room temperature (15-25 °C) or refrigerated (2-8 °C) on trypticase soy agar (TSA); heart or brain-heart infusion agar (HIA or BHIA); blood agar or chocolate agar. Transport frozen (-20 °C or lower) submissions in trypticase soy broth (TSB) plus 15% glycerol.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship pure culture isolates overnight at room temperature, refrigerated, or frozen. Room-temperature samples should be shipped with room-temperature cold packs. Refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 13 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Real-time polymerase chain reaction (PCR)
Turnaround Time	4 Weeks
Interferences & Limitations	Pure culture isolates must be viable for testing.
Additional Information	Contact the CDC POC for approval prior to submitting any specimen. If a Healthcare facility will be submitting samples directly to CDC they must receive prior approval from the State Health Department. If submitting pure culture isolate(s) for testing, the original culture/isolate/inoculum should be maintained by the submitter until results are reported, indicating that CDC testing is completed.
CDC Points of Contact	Stephen LaVoie (404) 718-4747 qea5@cdc.gov Davina Campbell (404) 639-4185 xew9@cdc.gov
Version	3.4

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

Synonym(s)	GAS typing, GBS typing, other beta hemolytic strep, Group A Strep, Group B Strep
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **lmcgee@cdc.gov** **Sopio Chochua** **(404) 639-4401** **schochua@cdc.gov**
Supplemental Information Required	**Supplemental form required for pre-approval: Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form.** **All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, any previous results and testing method, and the date the submitted culture was inoculated onto transport media.** **Research or surveillance specimens should NOT have Personally identifiable information (PII) entered on the 50.34 and must have a specimen ID. Any specimen received without specimen ID entered in 50.34 form and on the specimen label will not be processed for testing.**
Supplemental Form	**Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates of Genus *Streptococcus*; contact the CDC POC for approval prior to sending other specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium. Contact the CDC POC for approval prior to sending other specimen types.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature samples should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 paw3@cdc.gov
Version	1.6

Test Order
Streptococcus (Catalase-Negative, Gram-Positive Coccus) Identification- Non-CLIA CDC-10213

Synonym(s)	Streptococci, viridans streptococci , *Enterococcus, Abiotrophia, Aerococcus, Alloiococcus, Dolosicoccus, Dolosigranulum, Facklamia, Gemella, Globicatella, Granulicatella, Helcococcus, Ignavigranulum, Lactococcus, Leuconostoc, Pediococcus, Tetragenococcus, Globiticatella, Vagococcus, and Weissella*
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **lmcgee@cdc.gov** **Patricia Shewmaker** **(404) 639-4826** **PSHEWMAKER@cdc.gov**
Supplemental Information Required	**Complete the Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form for preapproval. Fill in all fields applicable to your isolate and provide any preliminary test results available. All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, any previous results and testing method, and the date the submitted culture was inoculated onto transport media. Research or surveillance specimens should NOT have Personally identifiable information (PII) entered on the CDC 50.34 and must have a specimen ID. Any specimens received without specimen IDs entered in CDC 50.34 form and on the specimen label or it will not be processed for testing. This testing is for research or surveillance specimens and is NOT performed on diagnostic specimens. Refer to CDC test order CDC-10145 Bacterial Identification of Unknown Isolate (Not Strict Anaerobe) for diagnostic specimen testing.**
Supplemental Form	**Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates of *Streptococcus* and related genera (catalase-negative, Gram-positive cocci)
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media).
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature samples should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.

Methodology	Phenotypic Biochemical and Serological Testing, Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 PSHEWMAKER@cdc.gov

Version	3.4

Test Order
Streptococcus ABCs Surveillance Study- Non-CLIA
CDC-10218

Synonym(s)	
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **LMCGEE@cdc.gov** **Sopio Chochua** **(404) 639-4401** **schochua@cdc.gov**
Supplemental Information Required	**See supplemental form: ACTIVE BACTERIAL CORE SURVEILLANCE (ABCS) CASE REPORT**
Supplemental Form	**ACTIVE BACTERIAL CORE SURVEILLANCE (ABCS) CASE REPORT.** **https://www.cdc.gov/abcs/methodology/data-collect-forms.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Sterile site pure isolates of Group A *Streptococcus* (GAS), Group B *Streptococcus* (GBS) and *S. pneumoniae* that meet the ABCs inclusion criteria
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media).
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature specimens should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen stored specimens should be shipped on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21-ABC 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic Biochemical and Serological Testing, Molecular Testing
Turnaround Time	16 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Active Bacterial Core surveillance (ABCs) website. https://www.cdc.gov/abcs/index.html
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 paw3@cdc.gov
Version	2.3

Test Order

Streptococcus Identification and Antimicrobial Susceptibility Testing- Non-CLIA CDC-10214

Synonym(s)	Streptococci, viridans streptococci, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus agalactiae*, AST, Sensitivity, MIC testing
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **lmcgee@cdc.gov** **Patricia Shewmaker** **(404) 639-4826** **PSHEWMAKER@cdc.gov**
Supplemental Information Required	**Complete the Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form for preapproval. Fill in all fields applicable to your isolate and provide any preliminary test results available. All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, any previous results and testing method, and the date the submitted culture was inoculated onto transport media. Research or surveillance specimens should NOT have Personally identifiable information (PII) entered on the CDC 50.34 and must have a specimen ID. Any specimens received without specimen IDs entered in CDC 50.34 form and on the specimen label or it will not be processed for testing. This testing is for research or surveillance specimens and is NOT performed on diagnostic specimens. Refer to CDC test order CDC-10222 Antimicrobial Susceptibility Testing (AST) for testing for diagnostic specimen testing.**
Supplemental Form	**Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates of Genus *Streptococcus*.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media).
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature samples should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic Biochemical and Serological Testing, Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html Please include senders test results and presumed identificaiton.
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 PSHEWMAKER@cdc.gov
Version	4.4

Test Order
Streptococcus pneumoniae Typing- Non-CLIA
CDC-10215

Synonym(s)	Pneumococcus Serotyping
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **lmcgee@cdc.gov** **Sopio Chochua** **(404) 639-4401** **schochua@cdc.gov**
Supplemental Information Required	**Supplemental form required for pre-approval: Streptococcus pneumoniae Testing Request Form. If you have questions, contact the CDC POC.** **All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, any previous results and testing method, and the date the submitted culture was inoculated onto transport media.** **Research or surveillance specimens should NOT have Personally identifiable information (PII) entered on the 50.34 and must have a specimen ID. Any specimen received without specimen ID entered in 50.34 form and on the specimen label will not be processed for testing.**
Supplemental Form	**Streptococcus pneumoniae Testing Request Form.** **https://www.cdc.gov/streplab/testing-request/index.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	*Streptococcus pneumoniae* bacterial isolates; contact the CDC POC for approval prior to sending other specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium. For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature samples should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 paw3@cdc.gov
Version	1.7

Test Order
Streptococcus Study- Non-CLIA
CDC-10217

Synonym(s)	
CDC Pre-Approval Needed	**Lesley McGee** **(404) 639-0455** **lmcgee@cdc.gov** **Sopio Chochua** **(404) 639-4401** **schochua@cdc.gov**
Supplemental Information Required	**Supplemental form required for pre-approval: Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form.** **All submissions must be accompanied by a CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) which must include the State Public Health Department contact information, specific antibacterial agent(s) of interest, any previous results and testing method, and the date the submitted culture was inoculated onto transport media.** **Research or surveillance specimens should NOT have Personally identifiable information (PII) entered on the 50.34 and must have a specimen ID. The specimens received without specimen IDs entered in 50.34 form and on the specimen label will not be processed for testing.**
Supplemental Form	**Other Streptococci and Catalase-Negative, Gram-Positive Cocci Testing Request Form. https://www.cdc.gov/streplab/testing-request/index.html**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Isolates of Genus *Streptococcus*; contact the CDC POC for approval prior to sending other specimen types.
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Pure bacterial isolates should be stored on an appropriate transport medium (see below). Specimens can be stored at room temperature (15-25°C) if shipped within 24 hours and/or kept refrigerated (2-8°C) if shipped in less than 72 hours. Otherwise, specimens should be stored frozen (-20°C or lower) in a glycerol transport medium. Contact the CDC POC for approval prior to sending other specimen types.
Transport Medium	Pure culture isolates should be transported on an appropriate agar medium (e.g. blood or chocolate), or as a frozen glycerol culture (e.g. Tryptic Soy Broth with 15% glycerol, or skim milk, tryptone, glucose, and glycerin (STGG) media). For other specimen/sample types contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Room-temperature samples should be shipped with room-temperature cold packs and refrigerated samples should be shipped with refrigerated or frozen cold packs. Frozen samples should be shipped frozen with dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 21 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic Biochemical and Serological Testing; Molecular Testing
Turnaround Time	8 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	See Frequently Asked Questions. https://www.cdc.gov/streplab/testing-request/index.html
CDC Points of Contact	Sopio Chochua (404) 639-4401 schochua@cdc.gov Patricia Shewmaker (404) 639-4826 pshewmaker@cdc.gov
Version	2.4

Test Order
Toxocariasis Serology- CLIA
CDC-10468

Synonym(s)	Larva migrans, Toxocariasis, *Toxocara canis*, *Toxocara cati,* parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Xiaojuan Tan** **(404) 718-3434** **xit0@cdc.gov**
Supplemental Information Required	**CDC 50.34 Specimen Submission Form must include travel history and other relevant risk factors; clinical symptoms, treatment and relevant lab results.**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum, vitreous fluid
Minimum Volume Required	0.2 mL
Collection, Storage, and Preservation of Specimen Prior to Shipping	Serum and vitreous fluid or serology testing should be collected, centrifuged, and transferred to leak proof tubes. Serum and vitreous fluid can be stored at refrigerated temperature (2-8°C) for up to 7 days prior to freezing or stored frozen (-20°C or lower) for up to 8 weeks.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Sera or vitreous fluid specimens should be shipped frozen on dry ice. Specimens not received under these conditions will be rejected for testing, and a new specimen must be submitted. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 57 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	EIA, ELISA, Antibody Detection
Turnaround Time	3 Weeks
Interferences & Limitations	This assay detects infections caused by both *T. canis* and *T.cati* but cannot differentiate between the two.

Additional Information	Please send one CDC 50.34 Specimen Submission Form and one separate sample tube for each test requested.
CDC Points of Contact	Xiaojuan Tan (404) 718-3434 xit0@cdc.gov Parasitology Lab Mailbox (404) 718-4175 parasiteslab@cdc.gov
Version	7.0

Test Order

Transmission Electron Microscopy Evaluation for Infectious Etiologies- CLIA

CDC-10559

Synonym(s)	Transmission Electron Microscopy (TEM), Electron Microscopy (EM), thin section, negative stain, biopsy, glutaraldehyde-fixed tissues, paraformaldehyde-fixed tissues, pathology
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Hannah Bullock** **(404) 718-6434** **ocr3@cdc.gov**
Supplemental Information Required	**Supplemental Information Required** **Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order code** **• Test order name** **• Patient full name** **• Patient birth date** **• Patient ID (e.g., medical record number or autopsy number)**

• Specimen ID (e.g., surgical pathology accession number)

• State public health laboratory (PHL) point of contact

• Original submitter contact information

One electronically completed copy of CDC 50.34 Specimen Submission Form per case is acceptable ONLY when specimens are collected on the same day AND have the same surgical biopsy number. Additional CDC 50.34 Specimen Submission Forms are required for specimens collected on different days or that have different surgical biopsy numbers (e.g., were from a different surgical procedure on the same day).

Requested additional information:

• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information

• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical) and surgical pathology report

• Relevant clinical, gross pathology, or microscopic pathology images, as available

• A key listing the tissues submitted for evaluation

Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Glutaraldehyde-fixed biopsy tissues from any organ or site are acceptable. However, tissue specimens should be submitted from the site(s) of the patient's disease process. Thin section EM: glutaraldehyde-fixed wet tissues, epoxy-embedded tissues, and ultrathin sections from epoxy-embedded tissues are acceptable. Negative stain EM: paraformaldehyde-fixed cell culture supernatants and body fluids (e.g., cerebral spinal fluid, saliva, urine, stool samples, and crusts to be evaluated for rash illness) are acceptable. Specimens may be rejected if specimen integrity is found to be compromised.
Minimum Volume Required	Not applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Wet tissue specimens: • Gross in at approximately 1-3 mm^3 and fix in phosphate-buffered 2-4% glutaraldehyde (2.5% preferred). • After fixation (preferably the next day but less than 2 weeks), tissues should be transferred to a container filled to the top with 0.1M phosphate buffer. • Store refrigerated (2-8°C); do not freeze. Epoxy-embedded tissues: • store at room temperature (15-25°C). Specimens for negative stain analysis (cell culture supernatants and body fluids): • Fix in phosphate-buffered 5% paraformaldehyde (preferred) at a 1:1 specimen to fixative ratio for a final concentration of 2.5% paraformaldehyde. • Store refrigerated (2-8°C); do not freeze. Ship to CDC within 3 weeks of collection.

Transport Medium	Glutaraldehyde-fixed tissues: hold in 0.1M phosphate buffer. Epoxy embedded tissues: no transport medium required. Specimens for negative stain analysis (cell culture supernatants and body fluids): hold in phosphate-buffered 2.5% paraformaldehyde.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Glutaraldehyde-fixed tissues can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze. Epoxy-embedded tissues can be shipped at room temperature with room-temperature cold packs. Specimens for negative stain analysis (cell culture supernatants and body fluids) can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Electron Microscopy (EM)
Turnaround Time	8 Weeks
Interferences & Limitations	Prolonged glutaraldehyde fixation (greater than 2 weeks) may result in decreased morphological appearance. When indicated, 0.5-micron sections from the epoxy-embedded blocks (prepared after trimming or ultra-thin sectioning) will be reviewed by the pathologist to ensure that appropriate areas have been selected.
Additional Information	CDC Pre-Approval Needed: • Contact Pre-approval POC • Infectious Diseases Pathology Branch Mailbox More specific guidelines regarding tissue sampling and submission can be found on the IDPB website: http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html Turnaround Time is case-dependent: • Human surgical biopsy cases it is 6-8 weeks • Complex cases, routine human autopsy cases, and animal cases it is 12 weeks.

CDC Points of Contact	Infectious Diseases Pathology Mailbox (404) 639-3132 pathology@cdc.gov Hannah Bullock (404) 718-6434 ocr3@cdc.gov Roosecelis Martines (404) 639-3886 xgn7@cdc.gov

Version	2.1

Test Order

Transmission Electron Microscopy Evaluation for Infectious Etiologies- Non-CLIA

CDC-10593

Synonym(s)	Transmission Electron Microscopy (TEM), Electron Microscopy (EM), thin section, negative stain, autopsy, necropsy, glutaraldehyde-fixed tissues, paraformaldehyde-fixed tissues, pathology
CDC Pre-Approval Needed	**Infectious Diseases Pathology Mailbox** **(404) 639-3132** **pathology@cdc.gov** **Hannah Bullock** **(404) 718-6434** **ocr3@cdc.gov**
Supplemental Information Required	**Supplemental Information Required** **Please include the following information with each submission:** **Omission of information on the CDC 50.34 Specimen Submission Form will lead to a delay in accessioning and testing, and potential rejection of specimen submission. Please include the following:** **• Test order code** **• Test order name** **• Patient full name** **• Patient birth date**

• Date of death (if applicable)

• Patient ID (e.g., medical record number or autopsy number)

• Specimen ID (e.g., surgical pathology accession number)

• State public health laboratory (PHL) point of contact

• Original submitter contact information

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

Requested additional information:

• A cover letter or copies of recent pertinent clinical notes outlining a brief clinical history, including relevant demographic/epidemiologic information

• A copy of the autopsy or necropsy report (preliminary or final)

• Copies of pertinent laboratory results (microbiology, hematology, serology, culture, and/or biochemical)

	• Relevant clinical, gross pathology, or microscopic pathology images, as available **• A key listing the tissues submitted for evaluation**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	Glutaraldehyde-fixed tissues from any organ or site are acceptable. However, tissue specimens should be submitted from the site(s) of the patient's disease process. Thin section EM: glutaraldehyde-fixed wet tissues, epoxy-embedded tissues, and ultrathin sections from epoxy-embedded tissues are acceptable. Negative stain EM: paraformaldehyde-fixed cell culture supernatants and body fluids (e.g., cerebral spinal fluid, saliva, urine, stool samples, and crusts to be evaluated for rash illness) are acceptable. Specimens may be rejected if specimen integrity is found to be compromised.
Minimum Volume Required	Not applicable

Collection, Storage, and Preservation of Specimen Prior to Shipping	**Wet tissue specimens**: • Gross in at approximately 1-3 mm^3 and fix in phosphate-buffered 2-4% glutaraldehyde (2.5% preferred). • After fixation (preferably the next day but less than 2 weeks), tissues should be transferred to a container filled to the top with 0.1M phosphate buffer. • Store refrigerated (2-8°C); do not freeze. **Epoxy-embedded tissues**: • store at room temperature (15-25°C). **Specimens for negative stain analysis (cell culture supernatants and body fluids)**: • Fix in phosphate-buffered 5% paraformaldehyde (preferred) at a 1:1 specimen to fixative ratio for a final concentration of 2.5% paraformaldehyde. • Store refrigerated (2-8°C); do not freeze. Ship to CDC within 3 weeks of collection.
Transport Medium	Glutaraldehyde-fixed tissues: hold in 0.1M phosphate buffer. Epoxy embedded tissues: no transport medium required. Specimens for negative stain analysis (cell culture supernatants and body fluids): hold in phosphate-buffered 2.5% paraformaldehyde.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. For urgent cases, immediately contact IDPB (pathology@cdc.gov). Glutaraldehyde-fixed tissues can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze. Epoxy-embedded tissues can be shipped at room temperature with room-temperature cold packs. Specimens for negative stain analysis (cell culture supernatants and body fluids) can be shipped refrigerated in leak proof containers with refrigerated or frozen cold packs; do not freeze. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 109 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Electron Microscopy (EM)
Turnaround Time	8 Weeks

Interferences & Limitations	Prolonged glutaraldehyde fixation (greater than 2 weeks) may result in decreased morphological appearance. When indicated, 0.5-micron sections from the epoxy-embedded blocks (prepared after trimming or ultra-thin sectioning) will be reviewed by the pathologist to ensure that appropriate areas have been selected.
Additional Information	**CDC Pre-Approval Needed**: • Contact Pre-approval POC • Infectious Diseases Pathology Branch Mailbox More specific guidelines regarding tissue sampling and submission can be found on the IDPB website: http://www.cdc.gov/ncezid/dhcpp/idpb/specimen-submission/index.html **Turnaround Time is case-dependent**: • Human surgical biopsy cases: it is 6-8 weeks • Complex cases, routine human autopsy cases, and animal cases: it is 12 weeks
CDC Points of Contact	Infectious Diseases Pathology Mailbox (404) 639-3132 pathology@cdc.gov Hannah Bullock (404) 718-6434 ocr3@cdc.gov Roosecelis Martines (404) 639-3886 xgn7@cdc.gov
Version	3.0

Test Order
Trichomonas Susceptibility- CLIA
CDC-10239

Synonym(s)	*Trichomonas*, trich, parasite
CDC Pre-Approval Needed	**Parasitology Lab Mailbox** **(404) 718-4175** **parasiteslab@cdc.gov** **Peter Augostini** **(404) 718-4142** **pfa9@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Properly inoculated InPouchTV as described in the instructions for use
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Specimens must be received within 96 hours of collection from patient. Store inoculated InPouchTV at 13-25°C. Do not collect and send specimens on a Friday or the day before a federal holiday.
Transport Medium	InPouch TV (Commercial product). See Additional Information for instructions how to obtain a testing kit prior to specimen collection.
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ensure the InPouch is properly closed. Ship overnight and pack with ambient temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 52 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Antimicrobial susceptibility
Turnaround Time	7 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.

Additional Information	Contact CDC POC to request a testing kit that will include a shipping container and InPouch TV culture media device required for specimen submission. CDC does not pay for return shipment of the inoculated InPouch TV. For clinical guidance with the management of recurrent or persistent trichomoniasis, please contact TVconsultation@cdc.gov. Shipping Instructions: Specimens must arrive to CDC at 18-25°C within 48 hours of collection. Specimens not meeting these conditions will not be accepted for testing and new specimen will be required.
CDC Points of Contact	Parasitic Inquiries (404) 718-4745 parasites@cdc.gov Pete Augostini (678) 860-6128 pfa9@cdc.gov Parasitology lab Mailbox (404) 718-4175 pfa9@cdc.gov
Version	5.7

Test Order
Trypanosoma cruzi Molecular Detection - Insects- Non-CLIA
CDC-10493

Synonym(s)	Chagas, American Trypanosomiasis, trypanosome, parasite, triatomine, kissing bug, *T. cruzi*
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Provide detailed information of the human exposure to the insect and where the insect was found (kitchen, bed, porch, etc.) in the Comments field of the CDC 50.34 Specimen Submission Form.**
Supplemental Form	**None**
Performed on Specimens From	Animal
Acceptable Sample / Specimen Type for Testing	Triatomine insect
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store specimen dry or in 70% ethanol at ambient temperature.
Transport Medium	Not Applicable
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Insects should be shipped in a crush-proof container in a box or shipping tube. Padded envelopes are not accpetable. Ship at ambient temperature. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 222 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Conventional Polymerase Chain Reaction (PCR) and Sanger sequencing
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	None

CDC Points of Contact	Gena Lawrence (404) 718-4315 geg7@cdc.gov Alice Sutcliffe (404) 718-4326 gok0@cdc.gov

Version	2.0

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

Synonym(s)	Chicken pox, shingles
CDC Pre-Approval Needed	**Brian Wakeman** **(404) 639-6403** **mrq9@cdc.gov** **Ludmila Perelygina** **(404) 639-4812** **ifw0@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum and Cerebrospinal Fluid (CSF)
Minimum Volume Required	0.1 mL; 0.5 mL preferred (serum, cerebrospinal fluid (CSF))
Collection, Storage, and Preservation of Specimen Prior to Shipping	Collect whole venous peripheral blood in serum separator vacutainer tube. Allow specimen to clot at room temperature (15-25°C) for at least 30 minutes. After the clot has formed, tube can be centrifuged 1100 - 1300 x g for 10 minutes. The clot must pass to the bottom of the tube, leaving the serum on top of the separator plug. The serum can then be aliquoted aseptically into an o-ring seal freezing tube using a pipette. Serum should be refrigerated (2-8°C) within 8 hours of collection. Serum should not be stored at ambient temperatures (15-25°C) for longer than 8 hours after collection. If serum will be stored refrigerated (2-8°C) for longer than 48 hours, specimens should be frozen (-20°C or lower). Serum submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped within 8 weeks of collection on dry ice by overnight shipment. Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and placed in a leak proof container. CSF specimens may be stored in glass or plastic vials. Vials must be tightly sealed to prevent sample desiccation. CSF should be frozen (-20°C or lower) after collection. If needed, specimens can be stored at 2-8°C for up to 72 hours before being frozen (-20°C or lower). CSF submitted for testing at CDC should be frozen (-20°C or lower) prior to shipping and shipped within 8 weeks of collection on dry ice by overnight shipment.
Transport Medium	Not applicable

Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Serum and cerebrospinal fluid (CSF) specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	CDC developed Enzyme Immunoassay (EIA) for detection of IgG antibodies specific to the glycoproteins of varicella-zoster virus.
Turnaround Time	7 Days
Interferences & Limitations	Potential interference from other members of the herpesvirus family including HSV-1 or HSV-2 may exist. Specimen stability beyond parameters of storage and shipment listed were not evaluated and are therefore unknown. The following conditions may result in the specimen being rejected for testing: •Specimen is hemolyzed, lipemic, or bacterially contaminated. •Specimen is not frozen upon receipt at CDC.
Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	3.7

Test Order

Varicella Zoster Virus Detection (Wild-type vs. Vaccine)- CLIA

CDC-10254

Synonym(s)	Chicken pox, shingles
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	This test order is currently not accepting any specimens until further notice.
Minimum Volume Required	Swabs of skin lesions (papule, macule, or vesicles) in viral transport medium (VTM): 0.5 - 1 mL Cerebrospinal fluid (CSF): 0.5 mL, 1 mL preferred

Collection, Storage, and Preservation of Specimen Prior to Shipping	For the collection of scab specimens, unroof the scab and place it directly into a breakage resistant tube. Scabs should be kept dry and stored at room temperature (15-25°C) after collection. Scabs should be shipped to CDC overnight at room temperature (15-25°C) within three weeks of specimen collection. To collect swabs of skin lesions (papule, macule, or vesicles), use a sterile needle to unroof the top of the skin lesion and use a sterile synthetic swab, e.g. polyester swab, to vigorously swab the base of the lesion, applying enough pressure to collect epithelial cells. Swabs of skin lesions may be placed directly into a storage tube or can be placed in viral transport medium (VTM). Swabs of skin lesions without VTM should be kept dry and stored at room temperature (15-25°C) after collection. Swabs of skin lesions without VTM should be shipped to CDC overnight at room temperature (15-25°C) within three weeks of specimen collection. Refrigerate (2-8°C) swabs of skin lesions in VTM within 1 hour of collection. If swabs of skin lesions in VTM will be stored for longer than 72 hours, they should be frozen (-20°C or lower). Swabs of skin lesions in VTM submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. These specimens can be stored at -20°C or lower for a maximum of 6 weeks prior to shipping. Cerebrospinal fluid (CSF) specimens should be collected under sterile conditions and stored in a leakproof container. CSF should be stored at -20°C or lower after collection, but if needed, specimens can be stored at 2-8°C for no more than 72 hours. CSF specimens submitted for testing at CDC should be frozen at -20°C or lower prior to shipping and shipped on dry ice overnight. CSF can be stored at -20°C or lower for a maximum of 6 weeks prior to shipping.
Transport Medium	Swabs of skin lesions (papule, macule, or vesicles) can be placed in viral transport medium (VTM).
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Scabs and swabs of skin lesions without viral transport medium (VTM) should be shipped overnight at room temperature with room-temperature cold packs. Swabs of skin lesions in VTM and cerebrospinal fluid (CSF) specimens should be shipped frozen on dry ice overnight. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 80 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Polymerase Chain Reaction (PCR)
Turnaround Time	7 Days
Interferences & Limitations	There are no known interferences and limitations.
Additional Information	None
CDC Points of Contact	Brian Wakeman (404) 639-6403 mrq9@cdc.gov Ludmila Perelygina (404) 639-4812 ifw0@cdc.gov
Version	3.7

Test Order

Vibrio, Aeromonas, and Related Organisms Identification and Characterization- Non-CLIA

CDC-10119

Synonym(s)	Cholera, *Vibrionaceae*, *Grimontia*, *Photobacterium*
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of *Vibrio*, *Aeromonas*, and Related Organisms; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 08 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.

Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping and Virulence Profiling
Turnaround Time	13 Weeks
Interferences & Limitations	*Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2-8°C) may lose viability.
Additional Information	The original isolate should be retained by the submitter for the duration of testing at CDC. Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Christine Lee (404) 498-2295 pfx6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov
Version	4.5

Test Order
Vibrio, Aeromonas, and Related Organisms Subtyping- Non-CLIA
CDC-10122

Synonym(s)	
CDC Pre-Approval Needed	**None**
Supplemental Information Required	**Complete one CDC 50.34 Specimen Submission Form per specimen and provide the following specimen information: "Specimen source (type)" and "Transport medium/Specimen preservative." Provide any preliminary results in the "Previous laboratory results" section of the CDC 50.34 Specimen Submission Form. For submissions of sequence data (e.g. molecular sequence data specimen type) the specimen identifier should be the PNUSA number. Specify type of subtyping requested in "Previous Laboratory Results" on back of CDC 50.34 Specimen Submission Form. Epidemiologic metadata and PulseNet cluster code are requested if available.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Pure culture isolates of Vibrio, Aeromonas, and Related Organisms; Sequence Data
Minimum Volume Required	Not Applicable
Collection, Storage, and Preservation of Specimen Prior to Shipping	Store isolates at room temperature (15-25°C). Isolates held for more than a month should be frozen (-20°C or lower).
Transport Medium	If isolates are shipped at room temperature, inoculate on nutrient agar or other similar non-selective agar (trypticase soy agar, heart infusion agar, etc.); if isolates are shipped frozen, suspend bacterial growth in trypticase soy broth (TSB) supplemented with 20% glycerol.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship slants at room temperature with room-temperature cold packs. Ship glycerol stocks frozen with dry ice. There are no time constraints for submitting sequence data. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 08 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Phenotypic or Genetic Identification and Subtyping, including Serotyping, Antimicrobial Susceptibility Testing (AST)
Turnaround Time	10 Weeks
Interferences & Limitations	*Vibrio vulnificus* isolates that are kept at refrigeration temperatures (2-8 °C) may lose viability.
Additional Information	Turnaround times for routine isolates may be extended during major foodborne outbreak activities or due to limited availability of resources.
CDC Points of Contact	Christine Lee (404) 498-2295 pfx6@cdc.gov Monica Im (404) 718-1446 ixi9@cdc.gov
Version	2.4

Test Order
Waterborne Parasite Special Study- Non-CLIA
CDC-10527

Synonym(s)	None
CDC Pre-Approval Needed	**Hunter Seabolt** **(404) 718-4163** **ngr8@cdc.gov** **Brooke OConnell** **(404) 639-0069** **ryo6@cdc.gov**
Supplemental Information Required	**None**
Supplemental Form	**None**
Performed on Specimens From	Human and Animal
Acceptable Sample / Specimen Type for Testing	To be determined
Minimum Volume Required	To be determined
Collection, Storage, and Preservation of Specimen Prior to Shipping	To be determined
Transport Medium	To be determined
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	Ship fixed/preserved specimens at room temperature. Ship unpreserved specimens on wet ice (cold pack) if stored refrigerated or frozen (on dry ice) if stored frozen. CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention RDSB/STATT Unit 53 1600 Clifton Road, NE Atlanta, GA 30329 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	To be determined
Turnaround Time	3 Weeks
Interferences & Limitations	None

Additional Information	None
CDC Points of Contact	Hunter Seabolt (404) 718-4163 ngr8@cdc.gov Brooke OConnell (404) 639-0069 ryo6@cdc.gov
Version	2.3

Test Order

Yersinia pestis Culture and Identification- Non-CLIA

CDC-10418

Synonym(s)	Plague
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.For transfer of a select agent, a completed Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2) is required.**
Supplemental Form	**For transfer of a select agent: Request to Transfer Select Agents and Toxins (APHIS/CDC FORM 2)** **https://www.selectagents.gov/forms.html**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Bacterial isolates
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Isolates can be refrigerated (2-8°C) or kept at room temperature (15-25°C). Isolates should be maintained to ensure viability.
Transport Medium	Isolates should be transported on TSA or blood agar slants.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs. Ship room temperature specimens with room-temperature cold packs. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations. Upon shipment, submitter should send an email to the CDC POC providing shipping company, shipped date and package tracking number.
Methodology	Phenotypic and genotypic methods
Turnaround Time	3 Weeks
Interferences & Limitations	No significant interferences or limitations are currently known.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Yersinia pestis Serology- CLIA
CDC-10419

Synonym(s)	Plague
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**Required information on the CDC 50.34 Specimen Submission Form:** **• Test order name (one per submission form)** **• Patient full name, sex, birth date** **• Date of onset (of symptoms)** **• Specimen collected date** **• Specimen source (type)** **• Submitting agency address, contact name, phone number and email address for each submitter** **• Brief clinical summary (if available)**
Supplemental Form	**None**
Performed on Specimens From	Human
Acceptable Sample / Specimen Type for Testing	Serum
Minimum Volume Required	0.5 mL (serum)
Collection, Storage, and Preservation of Specimen Prior to Shipping	Separate and aliquot serum prior to storage and transport. Specimens may be held at refrigerated temperature (2-8°C) for up to 4 days post-collection. Specimens may be held frozen (-20°C or lower) for up to 45 days post-collection or may be held frozen (-70°C or lower) for up to 9 months post-collection. Specimens must not exceed 2 freeze/thaw cycles.
Transport Medium	Not Applicable
Specimen Labeling	Test subject to CLIA regulations and requires two primary patient identifiers (e.g., patient first and last name, date of birth, unique patient identifier from time of collection, such as medical record number) on the specimen container and on the test requisition.

Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday – Friday. Ship refrigerated specimens with refrigerated or frozen cold packs and frozen specimens on dry ice. Ship To: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Rd Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Passive Hemagglutination, Passive Hemagglutination Inhibition
Turnaround Time	2 Weeks
Interferences & Limitations	Samples with hemolysis, increased lipemia or microbial growth may interfere with test results.
Additional Information	None
CDC Points of Contact	Jeannine Petersen (970) 266-3524 nzp0@cdc.gov Elizabeth Dietrich (970) 494-6618 wul2@cdc.gov
Version	0.0

Test Order
Yersinia pestis Special Study- Non-CLIA
CDC-10420

Synonym(s)	
CDC Pre-Approval Needed	**Jeannine Petersen** **(970) 266-3524** **nzp0@cdc.gov** **Elizabeth Dietrich** **(970) 494-6618** **wul2@cdc.gov**
Supplemental Information Required	**A CDC 50.34 Specimen Submission Form or Global File Accessioning Template (GFAT) is required. Specimen ID on submission form must match specimen label.**
Supplemental Form	**None**
Performed on Specimens From	Human, Animal and Food/Environmental/Medical Devices/Biologics
Acceptable Sample / Specimen Type for Testing	Contact the CDC POC for appropriate guidance/relevant information.
Minimum Volume Required	Contact the CDC POC for appropriate guidance/relevant information.
Collection, Storage, and Preservation of Specimen Prior to Shipping	Contact the CDC POC for appropriate guidance/relevant information.
Transport Medium	Contact the CDC POC for appropriate guidance/relevant information.
Specimen Labeling	Research or surveillance specimens may be labeled according to protocol. Labels should not include personally identifiable information. The results reported should NOT be used for diagnosis, treatment, assessment of health or management of the individual patient.
Shipping Instructions which Include Specimen Handling Requirements	CDC does not accept routine shipments on weekends or holidays. Please make sure packages arrive Monday - Friday. Ship to: [Insert CDC Point of Contact] Centers for Disease Control and Prevention Bacterial Diagnostic and Reference Laboratory 3156 Rampart Road Fort Collins, CO 80521 [Insert CDC Point of Contact's Telephone Number] All samples must be shipped in accordance with all applicable local, state and federal regulations.
Methodology	Contact the CDC POC for appropriate guidance/relevant information.
Turnaround Time	
Interferences & Limitations	Contact the CDC POC for appropriate guidance/relevant information.
Additional Information	Contact the CDC POC for appropriate guidance/relevant information.

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

Version	0.0