



MONTANA PUBLIC HEALTH LABORATORY

LABORATORY SERVICES MANUAL

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For most up-to-date contact information and testing information, see our website: http://dphhs.mt.gov/publichealth/LaboratoryServices

WELCOME TO THE MONTANA PUBLIC HEALTH LABORATORY

Servicing Montana since 1917

The Montana Public Health Laboratory (MTPHL) has been in operation since October 1917. The one-person staff at that time analyzed and reported (sometimes by telegraph) about 100 tests per month. Today a staff of 15 clinical laboratory scientists perform and report approximately 3,500 test per month.

Public health laboratories are often an invisible but crucial component of public health efforts. They often play a significant role in the health of communities by providing confirmation of disease outbreaks, population data regarding the health and welfare of citizens, as well as detection of potential biological and chemical threats to public health. Timely identification and/or confirmation of infectious diseases allows for successful investigation and mitigation to prevent further illness and protect the citizens of Montana.

The success of our laboratory is due to the hard work and dedication of our clinical laboratory scientists. Our laboratory professionals are passionate about their work and take pride in providing quality results in a timely manner, as well as providing technical consultation and outreach. Their efforts are rarely visible to the citizens that they serve although their work often contributes to successful public health interventions and outcomes. The MTPHL is proud to provide the most up-to-date technologies and is here to serve you and your community.

In addition to diagnostic and surveillance testing, the MTPHL offers consultation and outreach, which provides information to a multitude of public health partners. The information provided includes:

- tests of public health significance, appropriate test selection, and specimen requirements
- results of specific laboratory tests aggregated for statewide surveillance.
- training and continuing education opportunities, including biosafety and risk assessments.
- state-of-the-art test methods for diagnosing emerging infectious diseases, or bioterrorism threats.

Please contact our program managers and subject matter experts for any assistance you may need. If you need assistance with a topic not listed below, please give one of us a call, and we can find someone to help.

Additional Contact Information:

For assistance with Newborn Screening results: Newborn Screening Short-Term Follow-up Coordinator, Nikki Goosen, 444-5375 or Nikki.Goosen@mt.gov

For assistance with biosafety, and packaging and shipping: **Biosafety Officer, Crystal Fortune, 444-0930 or cfortune@mt.gov**

For assistance with bio- and chemical terrorism preparedness, including rapid toxic screening questions or training, jurisdictional sample transport plans, CAP LPX facility feedback, and sentinel laboratory outreach, contact: Laboratory Preparedness Specialist, Kim Newman, 444-3068 or knewman@mt.gov

For assistance with the laboratory portal contact: HHSLIMS@mt.gov or Data Coordinator, Kim Varvel, 444-4115

For assistance with laboratory safety and quality assurance, contact: Quality Assurance and Safety Specialist, Donna Jo Hosmer, 444-5941 or dhosmer@mt.gov

The Eleven Core Functions of Public Health Laboratories (courtesy of APHL)

- 1. Disease Prevention, Control and Surveillance—Provide accurate and precise analytical data in a timely manner.
- 2. Integrated Data Management—Serve as the conduit for scientific data and information in support of public health programs.
- 3. Reference and Specialized Testing—Serve as centers of excellence using their expertise, reference, and resources in the areas of biological, chemical, and radiologic issues of public health importance.
- 4. Environmental Health and Protection—Collaborate with partners to coordinate and ensure scientific analysis of environmental and human samples to identify, quantify and monitor potential threats to health.
- 5. Food Safety—Collaborate in the detection, monitoring, and response to food safety issues.
- 6. Laboratory Improvement and Regulation—Provide leadership for laboratory improvement in areas of public health importance.
- 7. Policy Development—Play a role in the development of state and federal health policy.
- 8. Public Health Preparedness and Response—Fulfill a key partnership role in local, state, and national disaster preparedness and response.
- 9. Public Health Related Research—Engage in research to improve and expand the scientific and policy bases of public health laboratory practice and assure their optimal application in support of the public health system.
- 10. Training and Education—Facilitate access to training and education.
- 11. Partnerships and Communication—Support their respective state public health laboratory systems.

The Montana Laboratory Services Bureau and its sentinel laboratories are part of the CDC's Laboratory Response Network (LRN)

LRN Mission: The LRN and its partners will maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies.

Sentinel laboratories play a key role in the early detection of biological agents. Sentinel laboratories provide routine diagnostic services, rule-out, and referral steps in the identification process. While these laboratories may not be equipped to perform the same tests as LRN reference laboratories, they can test samples.

Montana Sentinel Laboratories

In the broadest sense, all laboratories capable of analyzing or referring specimens or samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites, or radiological agents function as sentinels in the public health laboratory system. This includes environmental, food, veterinary, agriculture, military, public health, and clinical laboratories. Because of their routine activities, all these laboratories have the potential to encounter samples that may contain agents that threaten the public's health. While all these laboratories are sentinel laboratories, they may have distinct roles within the public health laboratory system.

Role of Sentinel Clinical Laboratories in the Public Health Laboratory System

Clinical laboratories testing human and animal samples are often the first interface with patients and the public health system. These laboratories perform a variety of critical tests, providing timely results to impact patient care. Optimally, these laboratories also work with local and state health departments to provide information on nationally notifiable diseases and other threats. While reporting of nationally notifiable diseases to the Centers for Disease Control and Prevention (CDC) is not federally mandated, it is currently required by legislation or regulation at the state or local levels. As such, the list of reportable diseases varies slightly by jurisdiction. Ongoing communications and trainings from public health staff, including laboratorians and epidemiologists, help to assure that clinical laboratories are integrated into the public health laboratory system. This coordination is vital to the surveillance and responses for endemic and emerging pathogens, including identification of novel threats such as pandemic coronaviruses and influenza and the development of appropriate countermeasures such as vaccines.

Role of Sentinel Clinical Laboratories in the LRN for Biological Threat Preparedness

In addition to their broad role in the public health laboratory system, clinical laboratories work closely with local and state public health and federal laboratories to recognize potential biological threat agents and other emerging threats to public health. Such laboratories are part of the nation's Laboratory Response Network (LRN) founded by the CDC, the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL). The strength of the LRN lies in its standardized approach and its tiered capability construct—with sentinel clinical laboratories serving at the foundation to quickly recognize, rule-out, or refer potential biothreat agents to the LRN Reference Laboratories." (Excerpt taken from "Definition of LRN Sentinel Laboratories" on the ASM website)

Are you a Sentinel Lab?

Refer to the following link for the Association of Public Health Laboratories *Definition of a Sentinel Lab* and the *Responsibilities of the Sentinel Clinical Laboratory*: https://www.aplh.org/about APHL/publications/

For assistance with becoming an officially recognized Sentinel Laboratory and partnering in activities with the MTPHL, contact Kim Newman, Laboratory Preparedness Specialist, 444-3068 or knewman@mt.gov

For more information on sentinel laboratories and rule-out testing, see the American Society for Microbiology website, https://www.asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C

TIPS FOR USING THIS MANUAL

Tests are listed alphabetically under the laboratory section that performs them.

The best way to search this manual is to press CTRL-F and use the search feature.

Ctrl-Click on items in the table of contents to jump to the item.

This manual will be continuously updated online. The last date updated is on the cover page and in the page footer. Note: If you choose to print the manual, it may be difficult to find things and the printed version could be out of date. Always refer to the online version when looking for sample and transport requirements.

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LISTING OF LABORATORY TESTING

NOTE: The following list of tests is not inclusive of all testing available by our partner reference laboratories. Capability exists to test for other pathogens of public health significance in cooperation with the State Communicable Disease Epidemiology Program. Please contact the MTPHL for availability of testing and specific guidance on pathogens not listed. 800-821-7284

For the most up to date information, refer to the manual on our <u>website</u> rather than a printed version.

Summary of most recent Changes:

Changes for microbiology tests transitioning to new LIS:

New Test Name	New Test Abbv	Notes
Autoclave Monitoring	Autoclave Monitoring	
Bacillus Anthracis Culture	Bacillus Anthracis Culture	Order instead of Biothreat screen
Bacterial Culture and Identification,		
Aerobic	Bact Cult/ID	
Bacterial Culture and Identification,		
Anaerobe	Ana Bac Cult/ID	
Brucella Culture	Brucella Culture	Order instead of Biothreat screen
Burkholderia Culture	Burkholderia Culture	Order instead of Biothreat screen
C difficile/NAP1 PCR	Cdiff NAP1 PCR	
Campylobacter Confirmation	Campy Confirm	Order instead of Enteric Surveillance
Campylobacter Screen	Campy Screen	
Carbapenem-resistant Acinetobacter		
Panel	CRAB Panel	Profile will add ID, Gene Testing and AST
Carbapenem-resistant Enterobacteriaceae		
Panel	CRE Panel	Profile will add ID, Gene Testing and AST
Carbapenem-resistant Pseudomonas		
Aeruginosa Panel	CRPA Panel	Profile will add ID, Gene Testing and AST
E coli Confirmation	E coli Confirm	Order instead of Enteric Surveillance
E coli O157 Verification (Rule out O157)	E coli O157 Verify	Order instead of Toxigenic E. coli Screen
E coli Screen (Test of Cure)	E coli Screen	Order instead of Toxigenic E. coli Screen
Enteric Panel	Enteric Panel	
ESBL ID Confirmation	ESBL ID Confirm	Will add ESBL Susceptibility Confirm
	Francisella Tularensis	
Francisella Tularensis Culture	Culture	Order instead of Biothreat screen
Haemophilus influenza Confirm (Sterile		
Site)	Haemophilus Confirm	
Hold for Surveillance	Hold	Order instead of Noro Hold
Legionella Culture	Legionella Culture	
Listeria Confirmation	Listeria Confirm	
MRSA Susceptibility Confirm	MRSA Confirm	
Neisseria gonorrhoeae Confirmation	N. gonorrhoeae Confirm	
Neisseria meningitidis Confirm (Sterile	Neisseria meningitidis	
Site)	Confirm	
Norovirus Testing (NAAT)	Norovirus	

Salmonella Confirmation	Salmonella Confirm	Order instead of Enteric Surveillance
Salmonella Screen (Test of Cure)	Salmonella Screen	Order instead of Salmonella/Shigella Screen
Shigella Confirmation	Shigella Confirm	Order instead of Enteric Surveillance
Shigella Screen (Test of Cure)	Shigella Screen	Order instead of Salmonella/Shigella Screen
Strep pneumo Confirmation (sterile site)	Strep pneumo Confirm	
Vibrio Confirmation	Vibrio Confirm	
Vibrio Screen	Vibrio Screen	
VISA/VRSA Susceptibility Confirm	VISA Confirm	
VRE Susceptibility Confirm	VRE Confirm	
Yersinia enterocolitica Confirmation	Yersinia entero Confirm	
Yersinia enterocolitica Screen	Y entero Screen	
Yersinia pestis Culture	Yersinia pestis Culture	Order instead of Biothreat screen

Removed Listeria Culture/Isolation. Order Bacterial Culture and Identification, Aerobic instead.

Note: To avoid rejection, **all patient specimens should be clearly marked with two identifiers (name, DOB, medical record number, etc.) and collection date.** Additionally, specimens should be submitted, with absorbent material, inside a biohazard transport bag and the corresponding online requisition in the outer pouch of the transport bag. **Identifiers on specimen MUST MATCH online requisition**. Please do not submit more than one patient or more than one specimen type (example, culture and blood) per transport bag or allow requisitions to be in contact with specimens. An online manifest listing all specimens sent must accompany each shipment.

Call the laboratory (800) 821-7284 with any questions regarding safe transport.

Bioterrorism and Laboratory Preparedness

The following section describes tests performed by MTPHL in response to public health threats such as suspicious substance or chemical events or as a reference level response in support of the Laboratory Response Network. Please note that requirements for Brucella and Tularemia serum are in the <u>Serology section</u>.

Facilities requesting the following must ensure they have communicated with the Public Health Laboratory and local or state public health as described.

Bacillus anthracis (Anthrax) Culture Isolation/Identification/Rapid Test Methods

Online Order Name/Abbreviation: Bacillus Anthracis Culture/Bacillus Anthracis Culture

Note: A suspected **B. anthracis** culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. **Please notify the laboratory by telephone at time of shipment.**

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Specimen Requirements: Clinical specimen (lesion swab, Sodium citrate or EDTA whole blood, serum, plasma, pleural fluid, respiratory specimens, fresh or frozen tissue, CSF) or a or pure culture isolate on solid media or in Cary-Blair transport.

Transport Temperature: 2-8°C for clinical specimens; Ambient for isolates

Turn-around Time: Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. A positive or negative PCR result on a clinical specimen is a PRESUMPTIVE result and must be confirmed by culture. A positive or negative PCR result on an <u>isolate</u> is a CONFIRMATORY result. Results are telephoned to the submitter as soon as testing is complete.

CPT Code(s): 87081 (Culture screen) Fee Waived, 87798 (PCR) Fee Waived

Brucella spp. Culture Isolation/Identification/Rapid Test Methods

Online Order Name/Abbreviation: Brucella Culture/Brucella Culture

Note: A suspected <u>Brucella</u> spp. culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Specimen Requirements: Sodium citrate or EDTA whole blood (PCR) or a pure culture isolate on solid medium.

Transport Temperature: Ambient for whole blood and isolates

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

Rapid test methods (PCR) are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. **Culture is considered CONFIRMATORY for specimens that are PCR PRESUMPTIVE Positive**. Further

confirmatory testing at the CDC may be needed.

CPT Codes: 87081 (Culture screen) Fee Waived, 87798 (PCR) Fee Waived

Burkholderia mallei, B. pseudomallei Culture Isolation /ID/Rapid Test Methods

Online Order Name/Abbreviation: Burkholderia Culture/Burkholderia Culture

Note: A suspected <u>Burkholderia mallei</u> or <u>B. pseudomallei</u> culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Specimen Requirements: EDTA whole blood (PCR) or a pure culture isolate submitted on solid medium or in Cary-Blair transport.

Transport Temperature: Ambient for whole blood and isolates

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

Rapid test methods (PCR) are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. **CONFIRMATION** requires a combination of culture, biochemical, and PCR results. Presumptive Positives may need additional testing at the CDC.

CPT Code(s): 87081 (Culture screen) Fee Waived, 87798 (PCR) Fee Waived

Francisella tularensis (Tularemia)Culture Isolation/Identification/Rapid Test Methods

Online Order Name/Abbreviation: Francisella tularensis Culture/Francisella tularensis Culture

Note: A suspected <u>Francisella tularensis</u> culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Specimen Requirements: Clinical specimen in sterile container or pure culture isolate on solid medium.

Transport Temperature: Ambient for whole blood and isolates

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

PCR testing methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. **Culture is considered confirmatory for specimens that are PCR-positive**.

CPT Codes: 87081 (Culture screen) Fee Waived, 87798 (PCR) Fee Waived

Orthopoxvirus, including Variola (Smallpox) Real Time PCR

Online Order Name/Abbreviation: Orthopoxvirus PCR/Orthopox PCR

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the patient meets criteria for testing. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

A suspect Orthopoxvirus requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Specimen Requirements: Lesion swab in Universal Viral Transport Media <u>AND</u> an additional lesion swab transported dry in a sterile container.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code: 87798 Fee Waived

Orthopoxvirus, Other Than Variola (inc. Monkeypox), Real Time PCR

Online Order Name/Abbreviation: Non-variola orthopoxvirus/non-variola orthopoxvirus

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the patient meets criteria for testing. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

A suspect Orthopoxvirus requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Specimen Requirements: Lesion swab in Universal Viral Transport Media <u>AND</u> an additional lesion swab transported dry in a sterile container. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport <u>instructions</u>.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code: 87798 Fee Waived

Rapid Toxic Screen, (for Chemical Exposure)

Online Order Name/Abbreviation: Rapid Toxin Screen for Chemical Exposure/Rapid Tox

Consult with the State Epidemiology Section (406) 444-0273 for pre-approval prior to testing. Arrangements must be made with the Environmental Laboratory (800) 821-7284 regarding proper collection, packaging, and transport of blood and urine specimens.

Specimen Requirements: 3 purple top tubes of whole blood (4 ml/tube minimum or 4 tubes with 3ml/tube), 1 green top or gray top tube of whole blood (3-4 ml/tube), AND 40-60 ml urine (clean catch) in a sterile specimen cup. All three specimen types must be submitted from adult patients; submit urine specimens from pediatric patients. The purple top tubes are drawn first and labelled in order of collection (#1, #2, #3) using indelible ink. In addition to two unique

patient identifiers, the date of collection, time of collection, and the initials of the collector must be on each tube/cup as these specimens are considered evidence. If bar code labels are used, do not obscure the tube or cup lot number, and place the label so that when the tube or cup is upright, the bar code looks like a ladder. Two blank purple top tubes, two blank green top or gray top tubes, and two blank Urine cups must be submitted for each lot of tubes and cups used.

Transport Temperature: 2-8°C for whole blood, -70°C for urine (call for instructions)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 36 hours.

CPT Code: None Fee Waived

Ricin Rapid Tests

Online Order Name/Abbreviation: Ricin TRF Detection/Ricin TRF

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the sample meets criteria for testing. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

Specimen Requirements: Environmental samples only

Transport Temperature: Ambient

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code: None Fee Waived

Yersinia pestis (Plague)Culture Isolation/Identification/Rapid Test Methods

Online Order Name/Abbreviation: Yersinia Pestis Culture/Yersinia Pestis Culture

Note: A suspected <u>Y. pestis</u> culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Specimen Requirements: Clinical respiratory specimens transported cold in sterile saline, or a pure culture isolate submitted on solid medium.

Transport Temperature: 2-8°C for clinical specimens; Ambient for isolates

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter. Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. **Culture is considered confirmatory for specimens that are PCR-positive.**

CPT Codes: 87081 (Culture screen) Fee Waived, 87798 (PCR) Fee Waived

<u>Microbiology – Surveillance</u>

The following section describes tests performed by MTPHL and partner reference laboratories for surveillance purposes. Testing done under this section is fee-waived and specimens must meet surveillance criteria. For diagnostic culture or confirmation testing (not for surveillance), see the category Microbiology – Diagnostic Culture/ID. For non-culture-based testing for diagnostic for diagnostic or confirmation purposes, or autoclave monitoring see Microbiology – Other Testing. For Antibiotic Resistant organisms not meeting criteria for surveillance, see Microbiology – Antibiotic Resistance Detection/ID.

Antimicrobial Resistant Bacteria Surveillance (ARLN - AR Lab Network)

Online Order Name/Abbreviation: Choose order based upon organism:

- Carbapenem-resistant Enterobacteriaceae: CRE Panel
- Carbapenem-resistant Pseudomonas (CRPA) Testing: CRPA Panel
- Carbapenem-resistant Acinetobacter: CRAB Panel
- Vancomycin-resistant Staph: VISA/VRSA Susceptibility Confirm
- Vancomycin-resistant Enterococcus: VRE Susceptibility Confirm

Confirmation testing for an isolate that demonstrates a resistance pattern with high epidemiologic significance. See list above for requested organisms. (For mold/fungi see the Mycology category)

Please see the link below and/or contact the laboratory prior to submission regarding surveillance (fee waived) criteria. Isolates that do not meet the surveillance criteria can be tested for a fee*.

ARLN Organism Surveillance Criteria

*For isolates not meeting CDC criteria, to order fee-based testing:

- Carbapenem-resistant organisms see "Carbapenem-Resistant Organism Direct Detection"
- ESBL organisms see "ESBL"

Specimen Requirements: Pure culture isolate submitted in Cary-Blair transport or on solid media.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days. May be referred to the Centers for Disease Control in Atlanta, Georgia.

CPT Code: 87081 (MRSA, VISA/VRSA, VRE); 87801 (CRE, CRPA, CRAB) \$32.00 (fee may change if isolate does not meet CDC criteria)

Clostridium botulinum (Botulism) Confirmation

Online Order Name/Abbreviation: Clostridium botulinum Culture/ID/C Bot Culture

Call the Montana Public Health Laboratory at (800)821-7284 for consultation on sending specimens; an epidemiologic consultation is also required for preapproval of testing, and for planning to receive antitoxin.

Testing includes culture/ID, toxin, and direct detection techniques.

Specimen Requirements: 10 mL serum, and 25 gm stool. Note: **ONLY stool samples will be accepted for infants** (no serum).

Food and patient testing are not performed at MTPHL. Human testing referred to the Centers for Disease Control in

Atlanta, Georgia.

Transport Temperature: 2-8°C

Turn-around Time: Preliminary results in 2 to 4 working days.

CPT Code: \$32.00

Enteric Surveillance

Online Order Name/Abbreviation: Depends on isolate being submitted:

- Salmonella Confirmation/Salmonella Confirm
- Shigella Confirmation/Shigella Confirm
- E coli Confirmation/E coli Confirm
- Campylobacter Confirmation/Campy Confirm
- Listeria Confirmation/Listeria Confirm
- Vibrio Confirmation/Vibrio Confirm
- Yersinia enterocolitica Confirmation/Yersiniaentero Confirm

The following organisms should be referred for surveillance purposes - *Campylobacter* spp., Shiga-toxin producing *Escherichia coli* (STEC including serotype O157:H7), *Salmonella* spp., *Shigella* spp., *Vibrio* spp., *Yersinia* spp., *Listeria* spp.

For diagnostic culture/ID of enteric organisms, see <u>Enteric Panel</u> or individual spp. Culture/Isolation tests in <u>Microbiology-Diagnostic Culture/ID</u> section

All stools that are positive by Culture-Independent Testing (e.g., PCR, EIA) for the listed organisms should be sent for surveillance purposes.

Confirmation of isolates is performed are reported to submitter. In addition, Whole Genome Sequencing will be performed to determine strain-relatedness on certain organisms of interest; results are compared to other strain patterns in Montana and across the nation using the CDC PulseNet database. Results are communicated to the DPHHS Epidemiology staff for follow up.

Specimen Requirements: Stool specimen in Cary-Blair transport, or other commercial enteric transport media, or pure culture isolate submitted in Cary Blair transport or on solid media.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: Routinely tested each week.

CPT Code: 87081 (Culture Screen), 87077 (ID) Fee Waived

Haemophilus influenzae Surveillance

Online Order Name/Abbreviation: Haemophilus influenza Confirm (Sterile Site)/Haemophilus Confirm

This order is for required surveillance sample submission. For diagnostic ID testing, see "<u>Bacterial Isolate Culture/ID</u>, <u>Aerobic</u>." Be sure to indicate suspected organism in the additional information on the order.

NOTE: Serogrouping is routinely performed on *H. influenzae* isolates from sterile body sites such as blood or cerebral spinal fluid. Please submit all *H. influenzae* isolates from sterile body sites.

Specimen Requirements: Primary specimen or pure culture isolate on chocolate media.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days. Positive H. influenzae results from sterile sites are telephoned to the submitter.

CPT Codes: 87081 (culture), 87185 (beta lactamase) Fee waived.

Neisseria gonorrhoeae Culture Isolation/ Identification

Online Order Name/Abbreviation: Neisseria gonorrhoeae Confirmation/N. gonorrhoeae Confirm

This order is for required surveillance sample submission. For diagnostic ID testing, see "Bacterial Isolate Culture/ID, Aerobic." Be sure to indicate suspected organism in the additional information on the order.

NOTE: For public health surveillance, please submit all *N. gonorrhoeae* isolates to the laboratory. This is at no cost to the submitter.

Specimen Requirements: Primary culture or pure culture isolate on MTM or chocolate media; identification performed by MALDI-TOF.

Transport Temperature: Ambient

Turn-around Time: 2 to 3 working days.

CPT Codes: 87081 (Culture screen), 87185 (Beta-lactamase) Fee-waived

Neisseria spp. (including N. meningitidis) Culture Isolation /Identification/Typing

Online Order Name/Abbreviation: Neisseria meningitidis Confirm (Sterile Site)/Neisseria meningitidis Confirm

This order is for required surveillance sample submission. For diagnostic ID testing, see "Bacterial Isolate Culture/ID, Aerobic." Be sure to indicate suspected organism in the additional information on the order.

NOTE: Serogrouping is routinely performed on *N. meningitidis* isolates from sterile body sites such as blood or cerebral spinal fluid. Please submit all N. meningitidis isolates from sterile body sites to the laboratory for serogrouping and storage for future epidemiologic purposes.

Specimen Requirements: Pure culture isolate on chocolate media.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days.

CPT Codes: 87081 (Culture screen), 87185 (Beta-lactamase) Fee Waived

Norovirus Surveillance

Online Order Name/Abbreviation: Hold for Surveillance/Hold for Surveillance (when placing the order you will be asked to indicate the reason for hold where you will indicate Norovirus hold)

Stool samples to be held at MTHPL for outbreak testing.

Specimen Requirements: 2 mL stool in a sterile container.

Transport Temperature: 2-8°C

Turn-around Time: Samples are held for outbreak testing.

CPT Code: N/A

Streptococcus pneumoniae Surveillance

Online Order Name/Abbreviation: Strep pneumo Confirmation/Strep Pneumo Confirm

This order is for required surveillance sample submission. For diagnostic ID testing, see "Bacterial Isolate Culture/ID, Aerobic." Be sure to indicate suspected organism in the additional information on the order.

Specimen Requirements: Pure culture isolate on SBA or chocolate media from a sterile body site.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days.

NOTE: S. pneumoniae isolates from sterile body sites are referred to Minnesota Public Health Laboratory for serogrouping.

CPT Codes: 87081 (Culture screen) Fee Waived

Microbiology - Diagnostic Culture/ID

The following section describes tests performed by MTPHL for diagnostic or confirmation purposes, not for surveillance. For fee-waived surveillance, see the category Microbiology – Surveillance. For non-culture-based testing for diagnostic or confirmation purposes, or autoclave monitoring see Microbiology - Other Testing. For Antibiotic Resistant organisms not meeting criteria for surveillance, see Microbiology – Antibiotic Resistance Detection/ID.

Bacterial Isolate Culture/ID, Aerobic

Online Order Name/Abbreviation: Bacterial Culture and Identification, Aerobic/Bact Cult/ID

For routine/diagnostic identification of Gram negative or Gram-positive aerobic bacterial isolates. Please indicate suspected organism (if known) in the additional information on the order. For culture/ID of specific organisms or primary samples, see enteric panel or organism-specific test. If not found, call the lab for quidance.

To send isolates for bacterial or antimicrobial resistance surveillance, see "Antimicrobial Resistant Bacteria <u>Surveillance</u>", "<u>Enteric Surveillance</u>", or organism-specific surveillance test.

Specimen Requirements: Pure isolates on solid media or on swab in Cary-Blair, Stuart's, or Amies transport medium. Fastidious or slow growing organisms require careful transport on an enriched agar medium.

Transport Temperature: Ambient

Turn-around Time: Normally 1 to 5 working days, depending on the purity and the growth rate of the isolate.

CPT Codes: 87070 (culture, presumptive ID) \$27.00, 87077 (Each ID confirmation) \$27.00, 87185 (beta lactamase – if

Bacterial Isolate Culture/ID, Anaerobic

Online Order Name/Abbreviation: Bacterial Culture and Identification, Anaerobe/Ana Bac Cult/ID

For routine/diagnostic identification of anaerobic bacterial **isolates**. Please indicate suspected organism (if known) in the additional information on the order. For culture/ID of specific organisms, including primary samples, see organism-specific test. If not found, call the lab for guidance.

Specimen Requirements: Send pure culture isolate in an anaerobic transport system.

Transport Temperature: Ambient

Turn-around Time: Normally 1 to 5 working days, depending on the growth rate of the isolate.

CPT Codes: 87075 (culture, presumptive ID) \$27.00, 87076 (Each ID confirmation) \$27.00

Campylobacter spp. Culture Isolation/Identification

Online Order Name/Abbreviation: Campylobacter Screen/Campy Screen

For routine/diagnostic identification of *Campylobacter* spp. To send campylobacter isolates for **surveillance**, see "Enteric Surveillance".

Specimen Requirements: Stool in submitted in stool transport media or pure culture isolate on solid media sent in a *Campylobacter* transport system.

Transport Temperature: 2-8°C for stool specimens, ambient for isolates

Turn-around Time: 3 to 5 working days. Positive results from a primary culture are telephoned to the submitter.

CPT Codes: 87046 (Culture, presumptive ID) \$20.00, 87077 (Each ID confirmation) \$27.00

Corynebacterium diphtheriae Culture Isolation/ Identification

Online Order Name/Abbreviation: CDC ID by culture/CDC ID by culture

Specimen Requirements: Throat, nasal, and wound swabs, pseudo-membrane, and sputum. Swabs may be placed in Amies or Stuart transport medial. Pseudo-membrane should be sent in leak proof container with saline (not formalin).

Please contact the State Epidemiology Department (406)-444-0273) for consultation prior to submission of specimens.

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Atlanta, Georgia.

Turn-around Time: One week. Positive results are telephoned to the submitter.

CPT Code: 87081 \$32.00

Enteric Panel Culture Isolation/Identification

Online Order Name/Abbreviation: Enteric Panel/Enteric Panel

For diagnostic culture/identification of enteric pathogens in **stool**. Includes screens for Salmonella, Shigella, Campylobacter, E. coli O157, EHEC (STEC), Aeromonas, and Plesiomonas

Escherichia coli Shiga-Like Toxin Assay will be performed on all specimens. Stools with positive toxin tests will be further cultured to isolate and identify the toxin-producing organism.

Specimen Requirements: Stool in Cary-Blair transport, or other commercial enteric transport media. Collect stool directly from patient into a clean specimen container. Do not collect from toilet bowl or use stool contaminated with urine. Use a sterile swab to collect a portion of the stool (collect from bloody or mucous-containing areas if present) and insert swab to the lower part of a Cary-Blair transport tube and break or cut the swab stick. A rectal swab is also acceptable if there is evidence of fecal staining on the swab. Cary-Blair transport tubes are supplied upon request.

Transport Temperature: 2-8°C

Turn-around Time: 2 to 4 working days. Positive test results are telephoned to the submitter.

CPT Codes: 87045 (salm/shig culture/iso), 87046 (other pathogens culture/iso), 87449 (STEC) Total Price: \$90.00; 87077 (Each pathogenic isolate ID) \$27.00

Escherichia coli O157 Culture Isolation/Identification (Rule out O157)

Online Order Name/Abbreviation: E coli O157 Verification (Rule out O157)/E coli Verify (OEL)

For diagnostic identification of Escherichia coli O157 in stool or pure isolates

Note: A suspected E. coli O157 culture requires Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

To send Escherichia coli O157 isolates for surveillance see Enteric Surveillance

For Shiga-toxin testing not specific to Escherichia coli 157 see Escherichia coli Shiga-Like Toxin Assay

Specimen Requirements: Stool specimen in Cary-Blair transport, or other commercial enteric transport media, or pure culture isolate submitted in Cary Blair transport or on solid media.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes: 87046 (Culture ID) \$20.00, 87449 (STEC) \$32.00

Escherichia coli Culture Isolation/Identification (Test of Cure)

Online Order Name/Abbreviation: E coli Screen (Test of Cure)/E coli Screen

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate in Cary Blair transport or on solid media. See Enteric Panel for specific instructions.

For public health surveillance, please submit all isolates of *E coli* spp. to the laboratory. See Enteric Surveillance.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive identification results of primary cultures or test of cure cultures are telephoned to the submitter.

CPT Codes: 87046 (Culture ID) \$20.00, 87449 (STEC) \$32.00

Legionella spp. Culture Isolation/Identification and Groups 1-6 Direct Detection

Online Order Name/Abbreviation: Legionella Culture/Legionella Culture

NOTE: Both a DFA test and culture is performed on each primary specimen received.

Specimen Requirements: Submit fresh or frozen lung tissue, pleural fluid, bronchial washings, trans-tracheal aspirates, chest drainage, BAL, or sputum. Put a minimum of 1 mL specimen in a sterile, leak-proof container, and transport on ice in an insulated container. A suspect pure culture isolate submitted on BCYE medium may be submitted.

Transport Temperature: 2-8°C for specimen, ambient for isolate

Turn-around Time: DFA test performed each working day. Positive test results are telephoned to the submitter. Cultures are monitored for 14 working days before reporting as negative.

CPT Codes: 87081 (Culture screen) \$41.00, 87278 (DFA) \$31.00

<u>Salmonella</u> spp. (including *S. typhi*) or <u>Shigella</u> spp. Culture Isolation/Identification (test of cure)

Online Order Name/Abbreviation: Order based on organism:

- Salmonella Screen (Test of Cure)/Salmonella Screen
- Shigella Screen (Test of Cure)/Shigella Screen

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate in Cary Blair transport or on solid media. See Enteric Panel for specific instructions.

Biochemically confirmed Salmonella spp. will be serotyped for epidemiologic purposes at no additional cost.

For public health surveillance, please submit all isolates of *Salmonella* spp. and *Shigella* spp. to the laboratory. <u>See Enteric Surveillance.</u>

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive identification results of primary cultures or test of cure cultures are telephoned to the submitter.

CPT Codes: 87045 (Culture ID) \$20.00, 87077 (Each add'l ID) \$27.00

Vibrio spp. Culture Isolation/Identification

Online Order Name/Abbreviation: Vibrio Screen/Vibrio Screen

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate submitted in Cary-Blair transport or on solid media. Specify species on request form.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes: 87046 (Culture ID) \$20.00, 87077 (Each add'l ID) \$27.00

Yersinia enterocolitica Culture Isolation/Identification

Online Order Name/Abbreviation: Yersinia enterocolitica Screen/Yersinia entero Screen

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate submitted in Cary-Blair transport or on solid media.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes: 87046 (Culture ID) \$20.00, 87077 (Each add'l ID) \$27.00

<u>Microbiology – Antibiotic Resistance Detection/ID</u>

The following section describes tests performed by MTPHL for antimicrobial resistance that do not meet surveillance criteria. For ARLN surveillance, see the category <u>Microbiology - Surveillance</u>. For diagnostic or confirmation testing (not for surveillance), see the category <u>Microbiology - Diagnostic Culture/ID</u>. For non-culture-based testing for diagnostic or confirmation purposes, or autoclave monitoring see <u>Microbiology - Other Testing</u>.

Carbapenem Resistance Detection

Online Order Name/Abbreviation: Choose order based upon organism:

- Carbapenem-resistant Enterobacteriaceae: CRE Panel
- Carbapenem-resistant Pseudomonas (CRPA) Testing: CRPA Panel
- Carbapenem-resistant Acinetobacter: CRAB Panel
- Vancomycin-resistant Staph: VISA/VRSA Susceptibility Confirm
- Vancomycin-resistant Enterococcus: VRE Susceptibility Confirm

Detects and differentiates KPC, NDM, VIM, OXA-48, and IMP gene sequences associated with Carbapenem non-susceptibility in gram-negative bacteria. This test is reserved for isolates that do not meet CDC requirements for fee-waived surveillance testing. For isolates that do meet CDC requirements, this testing is included in the surveillance panel (see "Antimicrobial Resistant Bacteria Surveillance").

Specimen requirements: Pure culture isolate on solid media.

Transport Temperature: Ambient

Turn-around Time: Routinely tested each working day. All results are telephoned to the submitter.

CPT Code: 87184 (mCIM) \$41.00, 87801 (PCR) \$115.00

ESBL ID Confirm

Online Order Name/Abbreviation: ESBL ID Confirmation/ESBL ID Confirm

Specimen Requirements: Pure culture isolate submitted on MAC or SBA media.

Transport Temperature: Ambient

Turn-around Time: 2-5 working days. ESBL testing is batched and performed twice weekly.

CPT Codes: 87081 \$41.00

Methicillin Resistant Staphylococcus aureus (MRSA)

Online Order Name/Abbreviation: MRSA Susceptibility Confirm/MRSA Confirm

Specimen Requirements: Pure culture isolate submitted in Cary-Blair transport or on solid media.

Transport Temperature: Ambient

Turn-around Time: 2-5 working days.

CPT Codes: 87081 \$41.00

Microbiology – Other Testing

The following section describes non-culture tests performed by MTPHL for diagnostic or confirmation purposes, or autoclave monitoring. For testing on specimens being submitted for surveillance purposes, see the category Microbiology – Surveillance. For culture-based diagnostic or confirmation testing (not for surveillance), see the category Microbiology – Diagnostic Culture/ID. For Antibiotic Resistant organisms not meeting criteria for surveillance, see Microbiology – Antibiotic Resistance Detection/ID.

Autoclave Monitoring

Online Order Name/Abbreviation: Autoclave Monitoring/Autoclave Monitoring

Specimen Requirements: EZ Test vials containing Geob*acillus stearothermophilus* are obtained by contacting the laboratory. Place the EZ Test vial in center of the load to be sterilized, then autoclave using normal procedures.

Transport Temperature: Ambient

Turn-around Time: 2 working days from receipt of specimen.

CPT Code: 10005 \$25.00

Clostridium difficile PCR, including NAP1

Online Order Name/Abbreviation: C difficile/NAP1 PCR/Cdiff NAP1 PCR

Specimen Requirements: Liquid or unformed stool in a sterile container

Transport Temperature: 2-8°C (Stable for up to 5 days when stored at 2-8°C)

Turn-around Time: 1 to 2 working days. All results are telephoned to the submitter.

CPT Code: 87493 \$115.00

Escherichia coli Shiga-Like Toxin Assay (EHEC or STEC) by EIA

Online Order Name/Abbreviation: STEC Toxin Test/STEC

Specimen Requirements: Stool specimen in Cary-Blair transport, or other commercial enteric transport media, or pure culture *Escherichia coli* isolate submitted in Cary Blair transport or on solid media.

EHEC/STEC testing is also performed on all routine enteric panels.

Transport Temperature: 2-8°C

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter. Stools with positive toxin tests will be further cultured to isolate and identify the toxin-producing organism.

CPT Code: 87449 \$32.00

Norovirus Direct Detection by Nucleic Acid Amplification

Online Order Name/Abbreviation: Norovirus Testing (NAAT)/Norovirus

For diagnostic testing on primary samples.

To send specimens for surveillance to be held for outbreak testing, see Norovirus Surveillance

Specimen Requirements: 2 mL stool in a sterile container. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport <u>instructions</u>.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code: 87798 \$115.00

Molecular Diagnostics-Traditional PCR Testing

Bordetella pertussis/B. parapertussis/B. holmesii Direct Detection by Real Time PCR

Online Order Name/Abbreviation: Bordetella spp. Multiplex PCR/Bord Multi PCR

Specimen Requirements: Nasopharyngeal (NP) swab in a sterile container without transport media. Do not submit a throat or nares specimen or a specimen submitted in Regan Lowe Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

NOTE: PCR testing should be performed only on symptomatic patients; a positive PCR in an asymptomatic patient does not meet the standard CDC case definition and cannot be considered a case of pertussis. PCR testing may be able to detect *B. pertussis* 3 to 4 weeks post onset.

Transport Temperature: Ambient or 2-8°C

CPT Code: 87801 \$115.00

Influenza A and B Direct Detection by Real Time PCR

Online Order Name/Abbreviation: Influenza A and B Virus Detection (PCR)/Inf A-B PCR

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

This test detects Influenza B and all subtypes of Influenza A. All specimens positive for Influenza A will be reflexed to real-time PCR subtyping. Specimens positive for Influenza B will be reflexed to real-time PCR genotyping.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code: 87502 \$65.00

Influenza A Sub-typing by Real Time PCR

Online Order Name/Abbreviation: Reflexed from Influenza A and B Virus Detection

Detects Influenza A subtypes H3N2, H1N1 2009 pdm, H5, H7, or variant subtypes.

Note: if H5 or H7 is suspected, call the laboratory for a consultation prior to submission. The individual case must meet Epidemiological testing criteria.

Specimen Requirements: Nucleic acid derived from a PCR specimen screened positive for Influenza A. Reflex testing is performed on all Influenza A positive specimens.

Transport Temperature: 2-8°C

Turn-around Time: Sub-typing is performed each working day. Results are telephoned to the submitter.

CPT Code: 87503 \$38.00

Influenza B Genotyping by Real Time PCR

Online Order Name/Abbreviation: Reflexed from Influenza A and B Virus Detection

Detects Yamagata and Victoria lineage genotypes.

Specimen Requirements: Nucleic acid derived from a PCR specimen screened positive for Influenza B. Reflex testing is performed on all Influenza B positive specimens.

Transport Temperature: 2-8°C

Turn-around Time: Sub-typing is performed each working day. Results are telephoned to the submitter.

CPT Code: 87503 \$38.00

Influenza A and B Surveillance

Online Order Name/Abbreviation: Influenza PCR Surveillance/Inf PCR Surv

Influenza Surveillance is only orderable during influenza season according to guidance provided by the MTPHL. Facilities are allowed a limited number of fee-waived surveillance tests.

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

This test detects Influenza B and all subtypes of Influenza A. All specimens positive for Influenza A will be reflexed to real-time PCR subtyping. Specimens positive for Influenza B will be reflexed to real-time PCR genotyping.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days.

CPT Code: 87798 Fee Waived (\$55.00 if limit of fee waived testing exceeded)

Mumps Direct Detection by Real Time PCR

Online Order Name/Abbreviation: Mumps Real Time RT-PCR/Mumps PCR

Specimen Requirements: Oral/buccal or oropharyngeal Dacron swabs in viral transport media and/or 50 ml minimum of urine. Urine should be centrifuged at 2500xg for 15 min at 4° C. Resuspend sediment in 2 ml viral transport media. Swabs are the preferred specimen.

Note: Urine may not be positive until 4 days after symptom onset.

CSF may be submitted in meningitis/encephalitis-suspect cases with prior consult.

Transport Temperature: 2-8° C within 24 hours or freeze at -70° C and transport on dry ice.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code: 87798 \$115.00

Rabies Detection for Diagnostic Purposes (Animal Testing)

Online Order Name/Abbreviation: Not orderable at MTPHL

MT PHL does not perform Animal testing.

Refer specimens to the Veterinary Diagnostic Laboratory in Bozeman, (406) 994-4885

Rabies Detection for Diagnostic Purposes (Human Testing)

Online Order Name/Abbreviation: Rabies Testing CDC/Rabies

Human Testing for Diagnostic Purposes: Consult with the Epidemiology Section (406) 444-0273 for pre-approval prior to testing. Consult the laboratory for specific sampling requirements and proper handling and transport.

Human Diagnostic Testing is referred to the Centers for Disease Control, Atlanta, Georgia.

Transport Temperature: Call for instructions.

Turn-around Time: Preliminary results (PCR) are available as soon as possible, usually the same day as receipt.

CPT Code: 87798 \$32.00

Rubeola (Measles) Direct Detection by Real Time PCR

Online Order Name/Abbreviation: Measles Real Time RT-PCR/Measles PCR

Specimen Requirements: Throat, nasopharyngeal or nasal Dacron swabs in viral transport media and/or 50 ml minimum of urine. Urine should be centrifuged 2500xg for 15 min at 4° C. Resuspend sediment in 2 ml viral transport media. Swabs are the preferred specimen. *CSF may be submitted in meningitis/encephalitis-suspect cases with prior consult.*

Note: Collect specimens as soon after the rash as possible. Detection is optimum with a collection the day one (1) through 3 (three) of rash onset.

Transport Temperature: 2-8° C within 24 hours or freeze at -70° C and transport on dry ice.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code: 87798 \$115.00

SARS-COV-2 (COVID) Direct Detection by Real Time PCR

Online Order Name/Abbreviation: SARS Coronavirus 2/SARS-CoV-2

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

All specimens positive for SARS-CoV-2 and containing enough genetic material will be sequenced. Whole genome sequence results are for surveillance purposes only. Sequencing results will be reported by county by our state epidemiologists.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days.

CPT Code: 87635 \$95.00

SARS-COV-2 (COVID) Variant Surveillance by Whole Genome Sequencing

Online Order Name/Abbreviation: SARS CoV-2 Variant Surveillance/SARS Variant Surveillance

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media that has tested positive for SARS-COV-2. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

All specimens positive for SARS-CoV-2 and containing enough genetic material will be sequenced. Whole genome sequence results are for surveillance purposes only. Sequencing results will be reported by county by our state epidemiologists.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Submitter will receive report indicating whether sample was adequate for

sequencing.

CPT Code: 87153 Fee Waived

Varicella Zoster Virus (VZV) Direct Detection by Real Time PCR

Online Order Name/Abbreviation: Varicella Zoster Virus (PCR)/VZV PCR

Specimen Requirements: Vesicular lesion swab in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days.

CPT Code: 87798 \$115.00

Molecular Diagnostics-Automated NAAT Testing

(Aptima and Quantitative HIV and HCV Testing)

Chlamydia trachomatis Direct Detection by Nucleic Acid Amplification

Online Order Name/Abbreviation: Chlamydia (Aptima)/CT (Aptima)

NOTE: Can be run in tandem with *Neisseria gonorrhoeae* Direct Detection by APTIMA Amplification (see Combination Amplification Test below)

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal, or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday).

CPT Code: 87491 \$47.00

Chlamydia trachomatis/Neisseria gonorrhoeae Direct Detection by NAAT (Combo Test)

Online Order Name/Abbreviation: CT-GC Combo – APTIMA/CT-GC Combo

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday). These tests can be ordered as a panel but will be billed individually.

CPT Codes: 87491 (Chlamydia) \$47.00, 87591(GC) \$47.00

Hepatitis C (HCV) RNA Quantitation

Online Order Name/Abbreviation: Hepatitis C RNA Quantitation/HCV RNA Quant

This CONFIRMATORY testing is a reflex test for repeat positive HCV specimens.

Specimen Requirements: 2 mL serum. Whole blood can be stored at 2-30°C and must be centrifuged within 6 hours of specimen collection. Separate the serum from the pelleted red blood cells following the manufacturer's instruction for the tube used.

Transport Temperature: 2-8°C. Ship specimen within 2 days of collection.

Turn-around Time: 3-5 days.

CPT Code: 87522 \$115.00

HIV-1 RNA Quantitation

Online Order Name/Abbreviation: HIV-1 RNA Quantitation/HIV1 RNA Quant

This testing is a reflex test for repeat positive HIV specimens with discrepant differentiation results or to quantitate HIV-1 RNA group M, N, and O over the range of 30 to 10,000,000 copies/mL.

Specimen Requirements: 2 mL EDTA Plasma. Whole blood can be stored at 2-30°C and must be centrifuged within 24 hours of specimen collection. Separate the plasma from the pelleted red blood cells following the manufacturer's instruction for the tube used.

Transport Temperature: 2-8°C. Ship specimen within 2 days of collection.

Turn-around Time: 3-5 days.

CPT Code: 87900 \$115.00

Herpes Simplex Virus (HSV), Type 1 and 2, Direct Detection by NAAT

Online Order Name/Abbreviation: Herpes Simplex Virus I/II PCR/HSV I/II PCR

Specimen Requirements: Cervical Swab or Lesion swab in Aptima Multitest Specimen collection tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Note: CSF in a sterile container without transport media is sent to North Dakota Public Health Laboratory for testing.

Transport Temperature: 2-30°C

Turn-around Time: 1 to 3 working days.

CPT Code: 87529 \$115.00

Neisseria gonorrhoeae Direct Detection by Nucleic Acid Amplification

Online Order Name/Abbreviation: Gonorrhea (Aptima)/GC (Aptima)

NOTE: Can be run in tandem with *Chlamydia trachomatis* Direct Detection by Amplification (see Combination Amplification Test).

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal, or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday).

CPT Code: 87591 \$47.00

SARS-COV-2 (COVID) Direct Detection by NAAT (Aptima)

Online Order Name/Abbreviation: SARS-CoV-2 (Panther)/ SARS-CoV-2 (Panther)

Specimen Requirements: Nasal swab in Aptima Multitest Specimen collection tube

All specimens positive for SARS-CoV-2 and containing enough genetic material will be sequenced. Whole genome sequence results are for surveillance purposes only. Sequencing results will be reported by county by our state epidemiologists.

Transport Temperature: 2-8°C

Turn-around Time: Routinely tested daily (Monday through Friday).

CPT Code: 87635 \$95.00

SARS-COV-2 (COVID)/FLU AB/RSV Direct Detection by NAAT

Online Order Name/Abbreviation: SARS-CoV-2 Flu AB RSV Panel/ SARS-CoV-2 FluAB RSV

Specimen Requirements: NP swab in viral transport medium (VTM) or universal transport medium (UTM)

All specimens positive for SARS-CoV-2 and containing enough genetic material will be sequenced. Whole genome sequence results are for surveillance purposes only. Sequencing results will be reported by county by our state epidemiologists.

Transport Temperature: 2-8°C

Turn-around Time: 3 Days

CPT Code: 87637 \$65.00

Trichomonas vaginalis Direct Detection by NAAT (Aptima)

Online Order Name/Abbreviation: Trichomonas vaginalis (Aptima)/Trichomonas

Specimen Requirements: Endocervical swab in APTIMA Uni-Sex Swab Specimen Collection Tube; vaginal swab in

APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday).

CPT Code: 87661 \$44.00

Mycobacteriology

Acid Fast Bacilli (AFB) (see *Mycobacterium* spp. Culture/Identification)

Modified Acid-Fast Stain

Online Order Name/Abbreviation: Modified Acid-Fast Stain/ModAFStn

Specimen Requirements: Send specimens in sterile container. Add 1.0 ml sterile saline or broth to tissues or other non-

liquid specimens. Send isolates on LJ medium.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results will be called to the submitter.

CPT Code: 87206 \$20.00

Mycobacterium spp. (inc. tuberculosis) Culture Isolation/Identification

Online Order Name/Abbreviation: AFB Concentration and Isolation/AFB Cult and Acid-Fast Smear/AFB Smea

Specimen Requirements: Send specimens in sterile container. **Add 1.0 ml sterile saline or broth to tissues or other non-liquid specimens**. See *Mycobacterium* spp. (AFB or TB) Testing Collection and Transport instructions.

Note: The specimen must be received within 5 days of collection.

Transport Temperature: Ambient for Heparinized blood or bone marrow; 2-8°C for all other specimens

Turn-around Time: Smear reports are reported to submitter by 5 p.m. the same day that the specimen is processed. Positive results are telephoned to the submitter; cultures are monitored for 6 weeks prior to issuing a negative report. Cultures positive for Mycobacterium tuberculosis complex will be sent out for <u>Mycobacterium tuberculosis complex</u> Antimicrobial Susceptibility Testing.

NOTE: After a patient has tested positive for *M. tuberculosis*, no more than three specimens per week from the same body site will be processed to determine response to therapy and infectious status, without prior consultation. To determine response to therapy, specimens should be obtained no sooner than 7 days post initiation of therapy.

CPT Codes: 87206 (smear) \$20.00, 87015 (concentration) \$22.00, 87116 (culture) \$41.00, 87176 (tissue digestion) \$13.00

Mycobacterium spp. (inc. tuberculosis) Isolate Culture Isolation/Identification

Online Order Name/Abbreviation: Acid Fast Culture and Isolation/AFBCult No Smear

Specimen Requirements: Isolates on LJ medium or in liquid media vials.

Note: The specimen must be received within 5 days of collection.

Transport Temperature: 2-8°C

Turn-around Time: Positive results are telephoned to the submitter; cultures are monitored for 6 weeks prior to issuing a negative report. Cultures positive for *Mycobacterium tuberculosis* complex will be sent out for *Mycobacterium tuberculosis* complex Antimicrobial Susceptibility Testing.

CPT Codes: 87015 (concentration) \$22.00, 87116 (culture) \$41.00

Mycobacterium spp. (inc. tuberculosis) Identification by MALDI-TOF MS

Online Order Name/Abbreviation: Reflexed from AFB Concentration and Isolation/AFB Cult

Specimen Requirements: Isolates sent on LJ slants or in liquid media vials, or as reflex testing on positive primary specimens submitted for culture.

Transport Temperature: Ambient

Turn-around Time: Depends on growth rate and age of culture. For most submitted isolates 5-14 days.

NOTE: Once AFB has been isolated and adequate growth has been obtained, MALDI-TOF MS Identification will be performed. All Mycobacterium tuberculosis specimens are reported as Mycobacterium tuberculosis complex. California Department of Public Health performs pyrosequencing to confirm M. tuberculosis.

CPT Codes: 83789 (MALDI-TOF MS Identification) \$38.00 MALDI-TOF MS ID

Mycobacterium tuberculosis complex Antimicrobial Susceptibility Testing

Online Order Name/Abbreviation: Reflexed from AFB Concentration and Isolation/AFB Cult

Specimen Requirements: Isolates sent on LJ slants or in liquid media vials, or primary specimens submitted for culture. Reflex testing is performed on *Mycobacterium tuberculosis* complex isolates identified in this laboratory.

Agents tested include Isoniazid, Rifampin, Ethambutol and PZA.

Transport Temperature: Ambient for isolates or liquid media vials; 2-8°C for primary specimens

Turn-around Time: 14 to 21 working days from date susceptibility testing is begun.

NOTE: AST testing performed at California Department of Public Health. Susceptibility testing for *M. tuberculosis* will be performed only on the first isolate from the patient and will be repeated as requested by the MT TB Program director. Other susceptibility testing including molecular drug susceptibility testing or second line drug testing is available upon consultation.

CPT Code: \$32.00

<u>Mycobacterium tuberculosis Nucleic Acid Amplification Testing (NAAT) with Rifampin</u> resistance marker

Online Order Name/Abbreviation: M. tuberculosis/RIF Resistance (PCR)/MTB/RIF GeneXpert

Specimen Requirements: Processed concentrated respiratory specimen or primary respiratory specimen. See *Mycobacterium* spp. (AFB or TB) Testing Collection and Transport <u>instructions</u>.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

NOTE: Nucleic acid amplification testing (NAAT) is recommended on specimens of patients highly suspected or known to have TB.

If NAAT is not ordered and an AFB smear is positive, the laboratory will contact the submitter to offer NAAT testing for *M. tuberculosis* complex.

A Mycobacterium spp. Culture Isolation/ Identification is automatically added with this order.

CPT Code: 87556 \$115.00

Mycology

ARLN (Antimicrobial Resistance Lab Network) Surveillance

Online Order Name/Abbreviation: Misc Micro ARLN/Misc Micro ARLN

For submission of *Candida auris* AND *Aspergillus fumigatus* isolates for surveillance. Referred to the regional ARLN laboratory.

Specimen Requirements: Pure culture isolate on solid medium - Sabouraud's Dextrose, blood, or chocolate agar slants.

Transport Temperature: Ambient

Turn-around Time: 1 to 3 working days for submitted isolates, others dependent on growth rate.

CPT Code: Fee waived.

Fungal Culture Isolation/Identification

Online Order Name/Abbreviation: Fungal Culture (other)/Fungcul1

For isolation/identification of molds and yeasts, including but not limited to *Aspergillus* spp., *Blastomyces* spp., *Candida* spp., *Coccidiodes* spp., dermatophytes, *Histoplasma*, *Sporothrix*

Specimen Requirements: Send original specimens in a sterile container. Send cutaneous specimens dry. Send pure fungal isolates (molds or yeasts) on an agar slant. See Mycology (Fungal) Culture Collection and Transport <u>instructions</u>.

Transport Temperature: Ambient

Turn-around Time: Primary specimen cultures are monitored for 4 weeks prior to a negative report.

CPT Codes: 87101 (culture, skin) 87102 (culture, other) 87103 (culture, blood) \$45.00 Each, 87106 (ID, yeast) \$24.00 Each, 87107 (ID, mold) \$24.00 Each

Newborn Screening

Newborn Screening Panel

Online Order Name/Abbreviation: Newborn Screening Panel 1/Newborn Panel 1

Note: Newborn Screening Panel 2 will be automatically added. Panel 2 is referred to Wisconsin State Laboratory of Hygiene.

Specimen Requirements: Dried Blood Spots, collected between 24 and 48 hours or as required for newborns in the NICU (per Montana Administrative Rule ARM 37.57.3: Infant Screening Tests and Eye Treatment.

See Newborn Screening Collection and Transport instructions for collecting the sample and completing the newborn screening requisition. Transport sample within 24 hours of collection (specimens collected on Saturday can be transported with Sunday courier or on Monday if sent via UPS, FedEx, or US Postal Service).

Transport Temperature: Ambient

Turn-around Time: 3 to 5 working days. Abnormal results are telephoned to the submitter. Contact the laboratory for

further information.

CPT Code: See table below. Total Price: \$145.00

Acylcarnitine Disorders by Tandem Mass Spectrometry (MS/MS) * Fatty Acid Oxidation Disorders Carnitine Uptake Defect Long Chain L-3-Hydroxyacyl CoA Dehydrogenase Deficiency (LCHAD) Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) Trifunctional Protein Deficiency (TFP) Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD) Organic Acidemia Disorders 3-OH 3-CH3 Glutaric Aciduria 3-Methylcrotonyl-CoA Carboxylase Deficiency B-ketothiolase Deficiency Glutaric Acidemia Type I Isovaleric Acidemia Methylmalonic Acidemia (CbI A and B) Methylmalonic Acidemia (mutase deficiency) Multiple CoA Carboxylase Deficiency (MCD) Proprionic Acidemia Amino Acid Disorders by Tandem Mass Spectrometry (MS/MS) * ARGININOSUCCINIC ACIDEMIA CITRULLINEMIA HOMOCYSTINURIA (DUE TO CBS DEFICIENCY) MAPLE SYRUP URINE DISEASE TYROSINEMIA TYPE I Biotinidase* 21 hydroxylase deficiency Congenital Adrenal Hyperplasia (CAH) * 21 hydroxylase deficiency Congenital Hypothyroidism (CH) Thyroxine (T4) testing, TSH reflex testing Cystic Fibrosis (IRT) Confirmatory DNA Mutational Analysis* as warranted Phenylketonuria (PKU) Hemoglobinopathies by Isoelectric Focusing Ha S/B-THALASSEMIA Ha SC DISEASE Ha SS DISEASE (SICKLE CELL ANEMIA) HPLC reflex testing* Spinal Muscular Atrophy (SMM)* TBD Severe Combined Immunodeficiency (SCID Immunodeficiency: TREC) *	Screening Tests	CPT Code
Carnitine Uptake Defect Long Chain L-3-Hydroxyacyl CoA Dehydrogenase Deficiency (LCHAD) Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) Trifunctional Protein Deficiency (TFP) Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD) Organic Acidemia Disorders 3-0-H 3-CH3 Glutaric Aciduria 3-Methylcrotonyl-CoA Carboxylase Deficiency β-ketothiolase Deficiency Glutaric Acidemia Type I Isovaleric Acidemia (CbI A and B) Methylmalonic Acidemia (mutase deficiency) Multiple CoA Carboxylase Deficiency Multiple CoA Carboxylase Deficiency (MCD) Proprionic Acidemia Amino Acid Disorders by Tandem Mass Spectrometry (MS/MS)* ARGININOSUCCINIC ACIDEMIA CITRULLINEMIA HOMOCYSTINUBIA (DUE TO CBS DEFICIENCY) MAPLE SYRUP URINE DISEASE TYROSINEMIA TYPE I Biotinidase* Biotinidase* 21 hydroxylase deficiency Congenital Hyperplasia (CAH)* 21 hydroxylase deficiency Congenital Hypothyroidism (CH) Thyroxine (T4) testing, TSH reflex testing Cystic Fibrosis (IRT) Confirmatory DNA Mutational Analysis* as warranted Phenylketonuria (PKU) Hemoglobinopathies by Isoelectric Focusing HB S/B-THALASSEMIA HB SC DISEASE HB SS DISEASE (SICKLE CELL ANEMIA) HPLC reflex testing* Spinal Muscular Atrophy (SMA)* TBD	Acylcarnitine Disorders by Tandem Mass Spectrometry (MS/MS) *	82017
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	Severe Combined Immunodeficiency (SCID Immunodeficiency: TREC) *	TBD

^{*} Tests referred to the Wisconsin State Newborn Screening Laboratory

The cost of reflex confirmatory testing (TSH, Hemoglobinopathies by HPLC and Cystic Fibrosis DNA Mutational Analysis) has been incorporated into the cost of the Newborn Screening panel, and no additional charges will be assessed.

Phenylalanine (PKU) Monitor by Fluorescent Immunoassay

Online Order Name/Abbreviation: Phenylketonuria Monitor (umol/L)/NBS PKUMonit

Used to monitor levels in patients diagnosed with phenylketonuria (PKU) only (as requested by Shodair)

Specimen Requirements: Dried Blood Spots. See Newborn Screening Collection and Transport instructions.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days.

CPT Code: 84030 Fee Waived. Phone the Newborn Screening supervisor for more information 1-406-444-3040.

Parasitology

Blood Parasite Screen

Online Order Name/Abbreviation: Blood Parasite Screen/Blood Parasite Screen

Analysis includes *Plasmodium* spp. (Malaria), *Babesia* spp., *Trypanosoma* spp., and Filarial nematodes (*Brugia malayi*, *Loa loa*, *Mansonella* spp., *Onchocera* volvulus, and *Wuchereria bancrofti*).

Specimen Requirements: Two sets of thick and thin EDTA Blood smears; one set of thick and thin smears stained with Giemsa or Wright's Stain, and 1-5 ml whole blood in EDTA tube (for PCR testing). See <u>Blood Parasite Screen Thick EDTA Blood Smear Preparation Instructions</u> for correct preparation and RBC lysing of thick blood smears.

Please contact the laboratory prior to submission of specimen. Patient travel history is required. The patient's medication and travel history are required. Please note treatment with any anti-malarial drugs like, fluoroquinolones.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive samples for confirmation and specimens for PCR testing are referred to the Centers for Disease Control, Atlanta, Georgia.

CPT Code: 87207 \$41.00

<u>Cryptosporidium Detection by Fluorescent Stain</u>

Online Order Name/Abbreviation: Cryptosporidium Detection/CryptosD

Specimen Requirements: Stool in Total-Fix preservative or 10% Formalin only. PVA is not acceptable.

Transport Temperature: Ambient

Turn-around Time: Performed each working day. Positive results are telephoned to the submitter.

CPT Code: 87207 \$38.00

Cyclospora/Cystoisospora Detection by Fluorescent Stain

Online Order Name/Abbreviation: Cyclospora Cystoisospora Detection/Cyclo Cystoisospor

Specimen Requirements: Stool in Total-Fix preservative or 10% Formalin only. PVA is not acceptable.

Transport Temperature: Ambient

Turn-around Time: Performed each working day. Positive results are telephoned to the submitter.

CPT Code: 87207 \$38.00

Entamoeba histolytica by Molecular Detection

Online Order Name/Abbreviation: Entamoeba histolytica real-time PCR/Entamoeba histolytica real-time PCR

Specimen Requirements: 0.5 g formed Stool (1.0 g preferred), 0.5 mL liquid stool or Liver aspirate (1.0 mL preferred)

Referred to the Centers for Disease Control, Atlanta, Georgia

Transport Temperature: Frozen

Turn-around Time: 21 days.

CPT Code: 87798 \$32.00

Entamoeba dispar by Molecular Detection

Online Order Name/Abbreviation: Entamoeba dispar real-time PCR/Entamoeba dispar real-time PCR

Specimen Requirements: 0.5 g formed Stool (1.0 g preferred), 0.5 mL liquid stool or Liver aspirate (1.0 mL preferred)

Referred to the Centers for Disease Control, Atlanta, Georgia

Transport Temperature: Frozen

Turn-around Time: 21 days.

CPT Code: 87798 \$32.00

Leishmania Detection

Online Order Name/Abbreviation: Leishmania Species Identification/Leishmania ID

Specimen Requirements: Tissue, 1-5 ml of whole EDTA blood, or bone marrow.

Please contact the laboratory prior to submission regarding proper CDC-provided transport medium for tissue specimens.

Transport Temperature: 2-8°C for whole blood and bone marrow, ambient for inoculated culture medium

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 3 to 6 weeks.

CPT Code: 87207 \$32.00

Ova and Parasite Exam

Online Order Name/Abbreviation: Ova and Parasite Exam/OandP

Analysis includes Amebiasis, Giardia, Strongyloides and other stool-borne parasites.

Specimen Requirements: Stool transported in a vial of Total-Fix preservative or a set of PVA and Formalin vials. Collect stool into a clean specimen container. Using the spoon inside the transport vial, immediately transfer stool to the vial until the liquid level reaches the red fill line. Stool should be emulsified into the transport media with the spoon. Recap the vial tightly and shake the vial until the contents are well mixed. Total-Fix transport kits are available from the laboratory upon request.

For optimal recovery, a series of three (3) specimens should be submitted.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Codes: 87177 (concentration/ID) 87209 (Trichrome stain) \$30.00 (each), Total Price: \$60.00

Pinworm Examination (Enterobius vermicularis)

Online Order Name/Abbreviation: Pinworm Examination/Pinworm

Specimen Requirements: Microscopic identification of eggs collected in the perianal area is the method of choice for diagnosing enterobiasis. In the morning, before defecation and washing, press transparent adhesive tape ("Scotch test") on the perianal skin and then place the tape sticky side down on a slide. Alternatively, the tape can be attached to the glass slide in a loop, and then folded over the glass surface after application to the perianal skin.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code: 87172 (concentration/ID) \$30.00

Tick Identification

Online Order Name/Abbreviation: Miscellaneous Tick Examination/Misc Tick

Specimen Requirements: Tick collected in clean dry screw top container without preservatives. Identification performed

by State Entomologist.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days.

CPT Code: 87168 \$27.00

Worm Identification

Online Order Name/Abbreviation: Miscellaneous Worm Examination/Misc Worm

Specimen Requirements: Worm collected in 10% formalin in screw top container.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days.

CPT Code: 87177 \$25.00

Serologic and Blood Lead Testing

Blood Borne Pathogen Exposure - Exposed Worker (HBsAb, HIV, HCV)

Online Order Name/Abbreviation: Hepatitis B Surface Antibody/Anti-HBs Liaison and HIV Antibody/Antigen Combo Assay/HIV Ab/Ag Combo LI and Hepatitis C Antibody/HCV Ab LI

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Codes: 86706 (HBsAb) \$32.00, 87389 (HIV) \$33.00 86803 (HCV) \$43.00, Total Price: \$108.00

Blood Borne Pathogen Exposure - Source Patient (HBsAg, HIV, HCV)

Online Order Name/Abbreviation: Hepatitis B Surface Antigen/HBSAG_LI and HIV Antibody/Antigen Combo Assay/HIV Ab/Ag Combo LI and Hepatitis C Antibody/HCV Ab LI

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Codes: 87340 (HBsAg) \$27.00, 87389 (HIV) \$33.00, 86803 (HCV) \$43.00, Total Price: \$103.00

Blood Lead Concentration

Online Order Name/Abbreviation: Blood Lead (Venous)/Lead (Venous) OR Blood Lead (Capillary)/Lead (Capillary)

Specimen Requirements: at least 500 uL venous or capillary whole blood, EDTA (purple top) or trace element K2 EDTA royal blue or tan top tubes. See Blood Lead Collection and Transport instructions on the collection and transport of capillary and venous specimens. PLEASE ORDER THE CORRECT TEST BASED ON SAMPLE TYPE.

Transport Temperature: 2-8°C

Turn-around Time: 1 week.

CPT Code: 83655 \$25.00

Borrelia hermsii Serology (Tick Borne Relapsing Fever)

Online Order Name/Abbreviation: Borrelia hermsii Serology/Bhermsii

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum recommended. Supplemental information

required: onset date of symptoms, exposure and travel history, brief clinical summary (signs, symptoms, and underlying illnesses if known), prior antibiotic treatment (type of antibiotic and date administered).

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Fort Collins, Colorado

Turn-around Time: 3 weeks.

CPT Code: 86618 \$32.00.00

Brucella Serology

Online Order Name/Abbreviation: Brucella Serology (BA)/Bruc Ser

NOTE: Tularemia serology will be automatically performed on all requests for Brucella serology due to antigen cross

reactivity.

Specimen Requirements: 2 ml. Serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

CPT Code: 86622 \$27.00

Colorado Tick Fever Virus (CTFV)

Online Order Name/Abbreviation: Colorado Tick Fever/CTFV

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Fort Collins, Colorado

Turn-around Time: 6 weeks.

CPT Codes: 86790 \$32.00

Fungal Serology (Histoplasma, Coccidiodides, Blastomyces) by Immunodiffusion

Online Order Name/Abbreviation: Fungal Serology CDC/FungSero

Specimen Requirements: 1.5 mL serum. Serum cannot be hemolyzed and plasma is not accepted.

Transport Temperature: Frozen

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 4 weeks.

CPT Codes: 86698 (Histoplasma) 86612 (Blastomyces) 86635 (Coccidioides) \$32.00

Hantavirus IgM Serology

Online Order Name/Abbreviation: Hantavirus IgM ELISA/Hanta IgM

Specimen Requirements: 4 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week. STAT testing is available each working day, or on weekends and holidays as needed. *Call ahead to notify the laboratory and to plan*.

Positive and STAT results are telephoned to the submitter. Specimens that yield a positive result are referred to the Centers for Disease Control, Atlanta, Georgia for IgG and IgM testing. Confirmation testing turn-around time is 10 days.

To qualify for STAT testing, all the following criteria must be met:

- 1. The patient is hospitalized with an acute respiratory illness, typical of Hantavirus Pulmonary Syndrome (HPS).
- 2. The patient is critically ill.
- 3. The patient does not have any relevant underlying medical condition that could account for the symptoms (COPD, malignancy, immunosuppression, diabetes)
- 4. The onset of illness (date when prodromal symptoms such as low-grade fever and myalgia were noted) is three (3) or more days prior to serum sample collection. IgM antibody to SNV is usually not detectable until the patient develops shortness of breath.

CPT Codes: 86790 (IgM) \$57.00

Hepatitis A IgM Antibody (HAV IgM)

Online Order Name/Abbreviation: HAV IgM/HAVM LI

Specimen Requirements: 1 mL serum or plasma (EDTA, Sodium citrate, Lithium Heparin, Sodium Heparin, Citrate

Dextrose anticoagulants)

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86709 \$38.00

Hepatitis, Acute Panel (HAV IgM Ab, HBsAg, HBc IgM Ab, HCV)

Online Order Name/Abbreviation: Acute Hepatitis Panel/HepPanelAcute

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Codes: 80074 (entire panel) \$146.00

Hepatitis B Core IgM (HBc IgM) Antibody

Online Order Name/Abbreviation: Hepatitis B Core IgM Antibody/HBcoreM Li

Specimen Requirements: 1 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86705 \$38.00

Hepatitis B Core Total Antibody (HBc Total)

Online Order Name/Abbreviation: Hep B Total Core Antibody/HBcTotal_LI

Specimen Requirements: 1 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86704 \$43.00

<u>Hepatitis B Post-Vaccination Panel with Reflex Confirmation (Infants Only)</u>

Online Order Name/Abbreviation: Hepatitis B surface Antibody/Anti-HBs Liaison and Hepatitis B Surface

Antigen/HBSAG LI

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Testing is routinely batch tested once per week.

NOTE: This test is only for post-vaccination serologic testing for infants born to Hepatitis B-infected women.

Confirmatory Neutralization testing will be automatically performed on all repeat reactive HBsAg.

CPT Code: 86706 (HBsAb) \$32.00, 87340 (HBsAg) \$27.00, Total Price: \$59.00, 87341 (HBsAg Neutralization) \$33.00

Hepatitis B Surface Antibody (HBsAb) (Quantitation)

Online Order Name/Abbreviation: Hepatitis B Surface Antibody/Anti-HBs Liaison

Specimen Requirements: 1 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86706 \$32.00

Hepatitis B Surface Antigen (HBsAg) with Reflex Confirmation

Online Order Name/Abbreviation: Hepatitis B Surface Antigen/HBSAG LI

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

NOTE: Confirmatory Neutralization testing will be automatically performed on all repeat reactive screens.

CPT Code: 87340 (HBsAg) \$27.00, 87341 (HBsAg Neutralization) \$33.00

Hepatitis C (HCV) Antibody Screen

Online Order Name/Abbreviation: Hepatitis C Antibody/HCV Ab LI

NOTE: Reflex supplemental testing is performed on all repeat reactive screens.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86803 (Screen) \$43.00, 87522 (HCV RNA Quant) \$115.00

HIV 1/2 Ab/p24 Ag, with Reflex Confirmation

Online Order Name/Abbreviation: HIV Antibody/Antigen Combo Assay/HIV Ab/Ag Combo_LI

Specimen Requirements: 3 mL serum and/or K_2 EDTA plasma (note that plasma is required for HIV RNA quantitation). Before shipping serum and/or plasma should be removed from clot, red cells, or gel separator.

Transport Temperature: 2-8°C

Turn-around Time: 3 days, Specimens sent for confirmation will be tested the day they are received.

NOTE: Reflex supplemental testing is performed on all repeat reactive screens using the CDC HIV testing algorithm.

HIV-1/HIV-2 Geenius testing will be performed to confirm the presence of HIV antibody and to differentiate HIV-1 and HIV-2.

HIV NAT testing will be performed to confirm the presence of HIV p24 antigen (acute infection) when the HIV Ab/Ag Combo test is repeat reactive and the HIV-1/HIV-2 Geenius test is negative. It will also be performed for any newly detected cases.

CPT Codes: 87389 (Screen) \$33.00, 86703 (Geenius) \$60.00, 87900 (HIV-1 RNA Quant) \$115.00

HIV-1/HIV-2 Geenius

Online Order Name/Abbreviation: HIV-1/HIV-2 Geenius/HIVGeenius

This test is used to differentiate HIV-1 and HIV-2 and is used in an algorithm when the HIV Combo Ag/Ab is repeat-reactive. Repeat reactive screens with inconclusive or conflicting Geenius results are reflexed to HIV RNA Quantitation testing.

Specimen Requirements: 2 mL serum or K₂ EDTA plasma (note that plasma is required for HIV RNA quantitation).

Transport Temperature: 2-8°C

Turn-around Time: Within 1 to 2 working days of repeat reactive HIV Combo Ag/Ab

CPT Code: 86703 \$60.00

Lyme (Borrelia burgdorferi) Total Antibody with confirmation

Online Order Name/Abbreviation: Lyme Disease Total Ab/Lyme_LI

Specimens that test positive or equivocal are reflexed to Lyme Disease Ab Confirm.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86618 (Screen) \$43.00

MMR - (Measles/Mumps/Rubella) IgG Profile

Online Order Name/Abbreviation: MMR

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86765 (Measles) \$27.00, 86735 (Mumps) \$27.00, 86762 (Rubella) \$27.00

Mumps IgG Serology

Online Order Name/Abbreviation: Mumps Virus IgG/MUMPG_LI

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86735 \$27.00

Mumps IgM Serology

Online Order Name/Abbreviation: Mumps IgM Antibody (IFA)/MumpIgM

Specimen Requirements: 1 mL serum; collect acute phase serum only and include an immunization history.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory. Results are available within 2-3 days.

CPT Code: 86735 \$39.00

Q-Fever (Coxiella burnetii) Phase 1 and 2 Serology

Online Order Name/Abbreviation: Q Fever 1&2 IgG Serology (IFA)/Q Fever

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum specimens are recommended.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

CPT Code: 86638 \$27.00

QuantiFERON – Gold (QFT – Gold) In-Tube Testing

Online Order Name/Abbreviation: QuantiFERON-TB Gold PLUS/QFT-TB Gold PLUS

Specimen Requirements: Stimulated plasma, obtained from vacutainer tubes specifically coated with antigens. Requires

access to a 37°C incubator. See QuantiFERON®-TB Gold In-Tube Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86480 (Single Test) \$96.00

Rabies Serology for Immune Status Antibody Testing

Online Order Name/Abbreviation: Not orderable at MTPHL

Testing not available through this laboratory

Testing available from:

Atlanta Health Associates, Alpharetta, Georgia (770) 667-8023

http://www.atlantahealth.net

Kansas State University, Manhattan, KS (785) 532-4483

http://www.ksvdl.org/rabies-laboratory/rffit-test/

Rocky Mountain Spotted Fever/Rickettsia rickettsii (RMSF)

Online Order Name/Abbreviation: RMSF IgG Serology (IFA)/RMSF Ser

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

CPT Codes: 86757 (RMSF) \$27.00

Rubella IgG Serology

Online Order Name/Abbreviation: Rubella Virus IgG/RubIgG_LI

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86762 \$27.00

Rubella IgM Serology by EIA

Online Order Name/Abbreviation: Rubella IgM Serology (EIA)/Rub IgM EIA

Specimen Requirements: 1 mL serum; Collect acute phase serum only and include an immunization history. Collect

specimen at least two (2) days after onset of rash and include date of onset.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory as needed. Results are available within

2-3 days.

CPT Code: 86762 \$39.00

Rubeola (Measles) IgG Serology

Online Order Name/Abbreviation: Measles (Rubeola) Virus IgG/MeasIgG_LI

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86765 \$27.00

Rubeola (Measles) IgM Serology by EIA

Online Order Name/Abbreviation: Rubeola IgM Serology (ND)/MeasM (ND)

Specimen Requirements: 1 mL serum; Collect acute phase serum only and include an immunization history. Collect

specimen at least two (2) days after onset of rash and include date of onset.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory as needed. Results are available within

2-3 days.

CPT Code: 86765 \$39.00

SARS-CoV-2 (COVID-19) Antibody Screen

Online Order Name/Abbreviation: SARS-COV-2 TrimericS IgG/ SARS-COV-2 TrimericS IgG

Specimen Requirements: 1 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86769 \$43.00

Syphilis Total Antibody Screen - Serum

Online Order Name/Abbreviation: Syphilis (T. pallidum) Total Antibody/Syphilis (T. pallidum) Ab

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: 3 days, Positive results are reflexed to a quantitative Syphilis VDRL. A positive Total Antibody screen

with a negative Syphilis VDRL result is reflexed to a *Treponema pallidum* Particle Agglutination Assay.

CPT Code: 86780 \$41.00

Syphilis Serology Screen - CSF (Qualitative) by VDRL

Online Order Name/Abbreviation: Syphilis Serology, CSF/VDRL(CSF)

Specimen Requirements: 1 mL CSF

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested twice per week. Positive results are reflexed to quantitative VDRL.

CPT Code: 86592 \$17.00

Syphilis VDRL Titer Monitor

Online Order Name/Abbreviation: Syphilis VDRL Titer Monitor/VDRL Titer

This test is only performed for known positive Syphilis patients who are currently or recently have received

treatment.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested twice per week.

CPT Code: 86593 \$17.00

Treponema pallidum Particle Agglutination Assay

Online Order Name/Abbreviation: Treponema pallidum by Particle Agg/TP-PA

Please refer to the Syphilis Total Antibody Screen – Serum for the testing algorithm.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

CPT Code: 86780 Price: \$41.00

Tularemia (Francisella tularensis) Serology

Online Order Name/Abbreviation: Tularemia Serology (BA)/Tularemi

NOTE: Brucella serology testing will be automatically performed on all requests for Tularemia serology due to antigen

cross reactivity.

Specimen Requirements: 2 mL serum; Paired acute and convalescent specimens recommended.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week.

CPT Codes: 86668 (Tularemia) \$27.00

Varicella Zoster Virus (VZV) (Herpes Zoster Virus) IgG Serology

Online Order Name/Abbreviation: Varicella Zoster (VZV) IgG/VZV IgG

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-8°C

Turn-around Time: 3 days.

CPT Code: 86787 \$27.00

West Nile Virus (WNV) IgG Serology

Online Order Name/Abbreviation: West Nile Virus IgG Serology/WNV IgG

Specimen Requirements: 1 mL serum. Paired acute and convalescent specimens recommended.

Date of onset is required, and the city or county of patient's residence is requested.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week; during seasonal outbreaks, testing may be performed each working day, depending on workload.

CPT Code: 86789 \$27.00

West Nile Virus (WNV) IgM Serology

Online Order Name/Abbreviation: West Nile Virus IgM/WNV-M

NOTE: Serology is the recommended method of testing for WNV in both serum and cerebral spinal fluid (CSF), because viremia (as detected by PCR) is very transient.

Specimen Requirements: 1 mL serum and/or 1 mL CSF (CSF referred to CDC). Date of onset is required, and the city or county of patient's residence is requested.

NOTE: Negative results on specimens drawn less than 9 days from date of onset should have a convalescent serum tested if active disease is suspected.

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week; during seasonal outbreaks, testing may be performed each working day, depending on workload. Certain specimens (including all CSF samples) may be referred to the Centers for Disease Control in Fort Collins, Colorado for confirmation using more specific Plaque Reduction Neutralization tests, and equivocal (borderline) results may be reflexed to St. Louis Encephalitis IgM Serology.

CPT Code: 86788 \$27.00

Collection and Transport of Specimens

Chlamydia/Gonorrhea Amplified Testing Collection and Transport

The Unisex Swab Specimen Collection Kit, Multitest Swab Specimen Collection Kit, and Urine Specimen Collection Kit are stored at room temperature.

Eye Swab Collection

- 1. Use the Unisex Swab Specimen Collection Kit (white label).
- 2. Gently rotate the blue-shafted collection swab clockwise across the surface of the eye to ensure adequate sampling.
- 3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 4. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 5. Re-cap the swab specimen transport tube tightly.
- 6. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Endocervical Swab Collection

- 1. Use the Unisex Swab Specimen Collection Kit (white label).
- 2. Remove excess mucus from the cervical os and surrounding mucosa using the white shafted cleansing swab. Discard the white shafted swab.
- 3. Insert the blue-shafted specimen collection swab into the endocervical canal.
- 4. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
- 5. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- 6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 8. Re-cap the swab specimen transport tube tightly.
- 9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Vaginal Swab Collection

- 1. Use the Multitest Swab Specimen Collection Kit (orange label).
- 2. Patient can collect own specimen in a health care facility. Vaginal swab collection is preferred over urine collection in women when a pelvic examination is not performed.
- 3. Insert the specimen collection swab into the vagina about two inches inside the opening of the vagina.
- 4. Gently rotate the swab clockwise for 10 to 30 seconds touching the walls of the vaginal to ensure adequate sampling.
- 5. Withdraw the swab carefully; avoid any contact with skin.
- 6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 7. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
- 8. Re-cap the swab specimen transport tube tightly.
- 9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Male Urethral Swab Collection

- 1. Use the Unisex Swab Specimen Collection Kit (white label).
- 2. The patient should not have urinated for at least one hour prior to sample collection.
- 3. Insert the blue-shafted specimen collection swab 2 4 cm into the urethra.
- 4. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.

- 5. Withdraw the swab carefully.
- 6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 8. Re-cap the swab specimen transport tube tightly.
- 9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Penile Meatal Swab Collection

- 1. Use the Multitest Swab Specimen Collection Kit (orange label).
- 2. For uncircumcised males roll the foreskin down before staring collection.
- 3. Roll the swab on the tip of the penis, outside the opening of the urethra, ensuring to roll the swab all the way around the opening to obtain the best sample.
- 4. Withdraw the swab carefully without touching any other area of the skin.
- 5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 6. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 7. Re-cap the swab specimen transport tube tightly.
- 8. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Rectal Swab Collection

- 1. Use the Multitest Swab Specimen Collection Kit (orange label).
- 2. Insert the small, pink-shafted collection swab 3 5 cm into the rectum and rotate against the rectal wall several times (at least 3 times).
- 3. Swabs that are grossly contaminated with feces should be discarded and the collection repeated.
- 4. Withdraw the swab carefully without touching the skin.
- 5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 6. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 7. Re-cap the swab specimen transport tube tightly.
- 8. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Throat Swab Collection

- 1. Use the Multitest Swab Specimen Collection Kit (orange label).
- 2. Using a tongue depressor, insert the small, pink-shafted collection swab and vigorously rub the tonsils and the posterior pharynx.
- 3. Carefully remove the swab, not touching any area of the mouth.
- 4. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- 5. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
- 6. Re-cap the swab specimen transport tube tightly.
- 7. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.
- 8. Complete the online order and print the online requisition form; be sure to record the specimen source.

Urine Collection

- 1. Use the Urine Specimen Collection Kit (yellow label).
- 2. The patient should not have urinated for at least one hour prior to sampling.
- 3. Direct patient to provide a first-catch urine (20 to 30 mL of the initial urine stream) into a urine collection cup. Collection of

- larger volumes of urine may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen. This is NOT a clean-catch urine we want the initial urine stream, which contains sloughed cells.
- 4. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black lines on the urine specimen transport tube label.
- 5. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.
- 6. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Swab and Urine Specimen Transport

After collection, ensure that specimens are properly labeled.

Place the corresponding transport tube in an <u>individual</u> zip lock bag containing absorbent material and seal the bag tightly. Place the online requisition in the sleeve of the zip lock bag; DO NOT put the request form inside the zip lock bag.

Store swab specimen transport tubes and processed urine specimens (those in urine specimen transport tubes) at 2°C to 30°C. Place transport tubes in white mailing canisters and send to the laboratory by mail or courier.

NOTE: Although swab specimens in the specimen transport tube must be tested within 60 days of collection and urine specimens in the specimen transport tube must be tested within 30 days of collection, we advise you to submit specimens in a timely manner so that test results can be obtained as soon as possible.

Utilize the MTPHL courier service if available, or ship specimens to the following address:

Montana Public Health Laboratory
(Street Address)

1400 Broadway

Helena, MT 59601

Or

PO Box 4369 Helena, MT 59604-4369

Result Reporting

Positive GC results are notified electronically to the DPHHS STD Program.

Specimen Rejection

Specimens with unresolved labeling issues, leaking containers, expired containers, or with insufficient volume may be rejected. The provider will be notified and asked to resubmit.

Requests for Additional Information or Specimen Collection Questions:

For additional information or questions, or to order collection kits, contact the laboratory at 800-821-7284 or 406-444-3444.

Molecular (Nucleic Acid Amplification) Testing Collection and Transport

For technical assistance in determining proper specimen selection for specific agents, call the laboratory at 800-821-7284.

Universal Viral Transport Media for Viral Agents is supplied by the laboratory. Store the kits at room temperature.

Specimen Type	Instructions			
Bronchial Alveolar Lavage (BAL)	For Viral Agents, mix an equal portion of the BAL with Universal Viral Transport			
/Bronchial Washings	Media. Store in refrigerator and ship on cold packs.			
	For Bacterial Agents, collect in sterile container. Store in refrigerator and ship on			
	cold packs.			
Cerebral Spinal Fluid (CSF)	Place 1 – 2 mL in sterile container without viral transport media. Store in			
	refrigerator and ship on cold packs.			
Lesion swab (HSV)	Use the Aptima Multitest Swab Specimen Collection Kit (orange label).			
	If needed, expose the base of the lesion to access fluid. Vigorously swab the base of			
	the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab			
	without touching any other site outside the lesion. Remove the cap from the swab			
	specimen transport tube and immediately place the specimen collection swab into			
	the transport tube. Carefully break the swab shaft at the score line; use care to			
	avoid splashing of contents. Re-cap the swab specimen transport tube tightly.			
	Store and transport at ambient temperature.			
Nasopharyngeal Aspirate	Introduce 1-2 mL of sterile saline into the nasopharyngeal cavity, aspirate into			
	sterile vial. Store in refrigerator and ship on cold packs. *Note: If the specimen is			
	also being submitted for viral agents, please submit in Universal Viral Transport			
	Media. Store in refrigerator and ship on cold packs.			
Nasopharyngeal Wash	Use only sterile saline to collect the NP wash. Instruct the patient to sit with head			
	slightly tilted backwards, and to hold the sterile collection cup. Instruct the patient			
	on how to constrict the muscles at the back of the throat by saying the "K" sound			
	rapidly and repetitively. Inform the patient that this process may prevent the saline			
	from draining down the throat. Fill a 5-cc syringe with warm sterile saline. Gently			
	push the tip of the patient's nose back with your thumb, and quickly inject 1 – 2 mL			
	of sterile saline into each nostril. Instruct the patient to contain the saline in the			
	nostrils for approximately 10 seconds while repetitively saying the "K" sound. After			
	10 seconds, ask the patient to tilt their head forward and collect the saline in the			
	sterile cup. Cap the washings tightly. Refrigerate the nasopharyngeal washings until			
Nacanharungaal Swah	transport and ship on cold packs. Store in refrigerator and ship on cold packs. Use a flexible wire Dacron or polyester swab. Do not use Calcium Alginate swabs or			
Nasopharyngeal Swab	swabs with wooden shafts. Instruct the patient to sit with head slightly tilted			
	backwards. Bend the flexible wire in a small arc and insert the swab into the nostril			
	back to the nasopharyngeal cavity. The patient's eyes will momentarily tear. Slowly			
	rotate the swab as it is being withdrawn.			
	For Viral Agents, place swab into Universal Viral Transport Media, trim swab shaft,			
	and tightly cap. Store in refrigerator and ship on cold packs.			
	For Pertussis and other Bacterial Agents, place swab in sterile tube without			
	transport.			
Rectal swabs (for CRE)	Collection of paired rectal swab: Carefully insert both swab tips approximately one			
	(1) cm beyond the anal sphincter and rotate gently. Do not collect highly soiled swabs.			
	Place swab pair back in original transport tube. Swabs in the transport tube can be			
	stored at 15-28°C for up to five days and transported at ambient temperature.			
Serum	Collect 5-10 mL of whole blood in serum separator tube. Allow blood to clot,			
	centrifuge, and aliquot resulting sera. Store in refrigerator and ship on cold packs. If			
	serum has already been frozen, ship on dry ice.			

Stool	Collect at least 2 mL of stool in a leak-proof, clean, dry container. Do not add transport media. Store in refrigerator and ship on cold packs.		
Throat Swab	Use a plastic-shafted Dacron swab. Do not use Calcium Alginate swabs or swabs with wooden shafts. Using a tongue depressor, insert the swab and vigorously rub the tonsils and the posterior pharynx. Carefully remove the swab, not touching any area of the mouth.		
	For Viral Agents, place swab into Universal Viral Transport Media, trim swab shaft, and tightly cap. Store in refrigerator and ship on cold packs.		
	For Bacterial Agents, place swab in sterile tube without transport.		
Tissue Specimens Autopsy or Biopsy	For Viral Agents, place each specimen in separate sterile containers containing a small amount of Universal Viral Transport Media. Store and ship on cold packs or dry ice. <i>Do Not submit formalized tissue</i> .		
	For Bacterial Agents, place each specimen in separate sterile containers containing a small amount of sterile saline or PBS. Store and ship on cold packs. <i>Do Not submit formalized tissue.</i>		
Vesicles/Vesicular Fluid/ Scrapings	Aspirate fluid from multiple fresh unbroken vesicles and place into 1-2 mL of Universal Viral Transport Media. Remove the top of the vesicle and place the skin of the vesicle top into a sterile tube without transport. Store both samples in refrigerator and ship on cold packs.		
Whole Blood	Collect 5 -10 mL whole blood in EDTA anticoagulant. Store in refrigerator and ship on cold packs.		

Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.), collection date and specimen source. Place each specimen container in an <u>individual</u> biohazard zip lock bag containing absorbent material and seal bag tightly.

Place the online requisition form in the outer sleeve of the biohazard zip lock bag. Do not place the request form inside the biohazard zip lock bag.

Ship specimens promptly, maintaining cold temperature from collection until receipt at the laboratory. For those specimens that must be shipped cold, use cold packs and Styrofoam containers. Mailers will be returned for reuse. Transport by UPS, FedEx, mail, or courier.

Mycobacterium spp. (AFB or TB) Testing Collection and Transport

All specimens are potentially infectious; handle carefully.

Specimen Type	Instructions		
Sputum or Nebulized Sputum	Collect three early morning specimens on successive days (within 72 hours) and submit daily in separate containers. Good specimens are material brought up by the lungs after a productive cough or nebulization. Send a minimum of 5 mL in a sterile container.		
Urine	Collect multiple first morning "clean catch" specimens on three successive days. Send a minimum of 40 mL in a sterile container.		
Gastric	Collect three early morning fasting specimens on successive days. Send a minimum of 10 mL in a sterile container. Add 10 mg of sodium bicarbonate to neutralize the acidity. Send promptly after collection; these specimens should be processed as soon as possible.		
Bronchial Washings	Submit first sputum specimen following bronchoscopy as well as the bronchial washings. Send a minimum of 5 mL in a sterile container.		
Tissues	Collect aseptically and place in sterile container. Add 1 mL sterile broth or sterile saline to tissues to prevent dehydration.		
CSF or Other Sterile Body Fluids	Submit in a sterile collection tube; at least 2 mL is needed for an adequate test.		
Blood or Bone Marrow	Collect in heparinized tube or add sterile heparin (0.2 mg/mL) to prevent clotting. Send a minimum of 1 mL in a sterile container.		
Stool	Submit 1 gram of raw stool in a sterile container. Send on ice.		
Swab (Not Optimal)	Specimens submitted on swabs are highly discouraged . Please make every effort to submit tissue or aspirated fluid, as these are preferred sources. If swabs are submitted, add 1 ml of sterile saline or sterile broth to the swab to prevent dehydration.		

Use only sterile materials in the collection of the specimen. Collect the specimen directly into the sterile bottle provided or into a sterile container. Screw the lid onto the specimen container tightly so specimen does not leak. Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal the bag tightly. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

<u>Refrigerate the specimen until transported</u> and send as soon as possible. **Specimens must be received within 5 days of obtaining the specimen.**

Place the online requisition form in outside sleeve of biohazard zip lock bag and put into TB mailing container. Respiratory specimens should be packaged and transported cold by mail or courier. All other specimens may be transported at ambient temperature.

Mycology (Fungal) Culture Collection and Transport

Specimen Type	Instructions	
Tissue	Place tissue in a sterile screw cap container and cover with 1 mL of sterile saline or broth.	
	Refrigerate until time of mailing.	
Blood	Collect blood aseptically an automated blood culture system bottle. If mold or yeast is suspected,	
	submit blood culture bottle for culture identification.	
Bone marrow	Collect approximately 0.3 mL of bone marrow in a heparinized tube. Store specimen at room	
	temperature or incubate until mailing. Ship in sterile screw cap container.	
Bronchial wash, Pleural	Send in sterile screw cap container. May be sent in TB transport container. Refrigerate specimen	
fluid, Joint fluid, Sputum	until mailing.	
CSF	Send a minimum of 1.0 mL in sterile screw cap container. Store specimen at room temperature or	
	incubate until mailing.	
Hair	Remove about 10 hairs with roots using forceps and send in a sterile container. NOTE: Hairs that	
	break off at scalp level when using forceps must be removed with a knife. Scraping the scalp rarely	
	yields infected hairs. Store and transport at room temperature.	
Skin	Wipe lesions well with alcohol sponge (cotton will leave too many fibers on skin). Scrape the entire	
	periphery of the lesion(s) with a sterile scalpel. Send scrapings in a sterile container. Store and	
	transport at room temperature.	
Nails	Clean nail with alcohol sponge. Scrape and discard outer portion of nail. Collect scrapings from	
	inner nail and send in a sterile screwcap container. Send an entire nail, if it has been removed, in a	
	sterile screw cap container. Store and transport at room temperature.	

Please Note: Both a TB culture and a fungal culture can be processed from a single specimen by request. Make certain that the test request form is clearly marked for both tests.

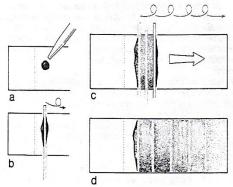
Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal the bag tightly. Specimens should be clearly labeled with **two patient identifiers** (name, DOB, medical record number, etc.) and the collection date.

Place the online requisition form in the outside sleeve of biohazard zip lock bag and put into mailing container. Transport at ambient temperature by mail or courier.

Blood Parasite Screen Thick EDTA Blood Smear Preparation Instructions

- 1. Specimen: an EDTA-preserved tube of peripheral blood that has not cooled to room temperature nor had its lid removed prior to this sampling. **Make two thick smears per specimen** (one to be stained in-house and the other to be stained at MTPHL).
- 2. Wear gloves when performing this procedure.
- 3. Place a pre-cleaned 1 X 3" glass microscope slide on a horizontal surface.
- 4. Place a 30-40 μl drop of blood onto one end of the slide about 0.5 inches from the end.
- 5. Lay an applicator stick across the glass slide and contact the drop of blood. Allow the blood to spread along the applicator stick until it spreads from one side of the slide to the other.
- 6. Keeping the applicator in contact with the blood and glass, rotate (DO NOT "ROLL") the stick in a circular motion while moving the stick down the glass slide to the opposite end. See figure below.

Figure 1: Method of thick-thin combination blood film preparation. (a) Position of drop of EDTA blood; (b) position of applicator stick in contact with blood and glass slide; (c) rotation of applicator stick; and (d) completed thick-thin combination blood film prior to staining. (Illustration by Sharon Belkin)(From reference 2, with permission).



- 7. The appearance of the blood smear should be alternate thick and thin areas of blood that cover the entire slide.
- 8. Immediately place the slide over some small print and be sure that the print is just barely readable through the blood film.
- 9. Allow the film to air dry horizontally and protected from dust for **at least 30 min. to 1 hour**. DO NOT speed the drying process by applying any type of heat as the heat will fix the RBCs and they subsequently will not lyse in the staining process.
- 10. Dip the thick slides twice in acetone and allow them to air dry in a vertical position. This step improves the durability of the blood film and will prevent the blood from flaking off in transit.
- 11. Lyse the RBCs on the thick films by either:
 - a. Dipping each slide in **Buffered Methylene Blue solution (0.65%)** for 1-2 seconds and allow the slides to air dry in a vertical position. **This is the preferred option** as RBCs are hemolyzed, color is introduced into the cytoplasm of the parasites, and prestaining with methylene blue helps to preserve the organisms on the smear. The formula for 0.65% Buffered Methylene Blue solution is as follows:

Methylene Blue 0.65 g. Di-sodium hydrogen phosphate Na_2HPO4 2.0 g. Potassium di-hydrogen phosphate KH_2PO_4 0.65 g. Distilled water 1.0 L Mix and store the solution in a brown stoppered bottle.

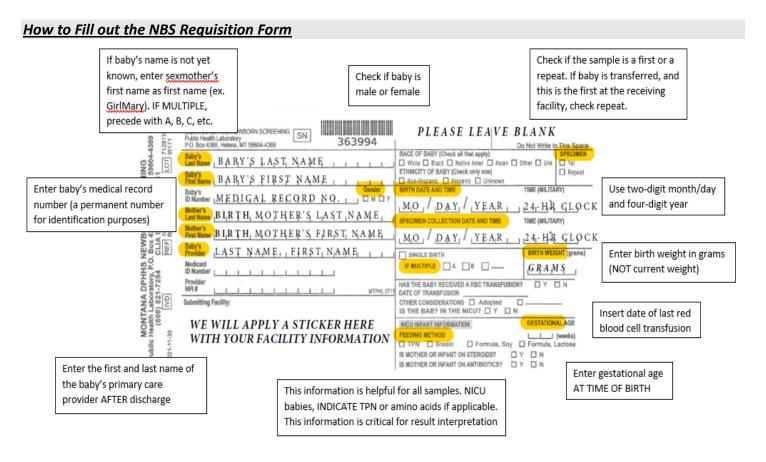
- b. Alternatively, the slides may be placed in Buffered water (pH 7.0 to 7.2) for 10 min. and allow the slides to air dry in a vertical position.
- 12. Stain one thick smear with either Giemsa or Wright's Stain. Submit both slides to MTPHL.
- 13. Note on the online order as to which method the thick smears were lysed.

Newborn Screening Collection and Transport

Newborn screening specimen cards for collection of dried blood spot samples are available from the laboratory. They contain the requisition form along with the attached filter paper collection device. Additional cards can be requested by contacting the laboratory at 406-444-3444 or by placing a supply request online in OEL. When ordering through OEL select "Newborn Screening Cards" under Supply Request.

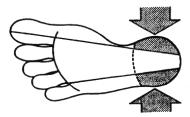
Store specimen cards in a cool dry place **on their sides**; **flat stacking compresses the filter paper fibers**. Do not handle the filter paper portion, as skin oils will prevent saturation.

Completely fill out the information on the requisition form (carbon copy slip) attached to the specimen card. Ensure all information is legibly written using blue or black ink. See section below.



Sample Collection

The usual puncture site is illustrated below (shaded areas). Use of capillary tubes is not recommended because they tend to roughen the filter paper and cause over absorption.



- 1. Wash hands and wear powder-free gloves.
- 2. Warm heel using a heel warmer or warm damp cloth to increase blood flow for easier collection, then position newborn's leg lower than their heart to increase venous pressure.
- 3. Sterilize heel with 70% isopropyl alcohol and allow skin to air dry.
- 4. Puncture heel with sterile lancet.
- 5. Gently wipe away the first drop of blood using sterile gauze then allow a second **large** blood droplet to form.
- 6. **Apply gentle pressure** with thumb around heel, easing intermittently as drop of blood forms. Note: Squeezing the puncture site too hard or "milking" the heel may cause hemolysis and serum separation
- 7. Touch filter paper to blood and fill each printed circle with a single, large drop of blood. **Do not apply blood to both sides**.
- 8. Be certain to properly fill all five (5) circles on the card. Complete saturation of the circles must be evident when the paper is viewed from both sides.
- 9. After collection is complete, elevate the newborn's foot and apply gentle pressure to the puncture site using sterile gauze until the bleeding stops. Do not apply adhesive bandages.
- 10. Allow blood spots to air dry thoroughly in a horizontal position for 2-3 hours at room temperature. **Keep away from direct sunlight and heat.** Do not stack filter papers before thorough drying. Protective cover can be used to hold specimen while drying.
- 11. Cover with end flap only after specimen is completely dry.
- 12. Inspect the dried blood spots for adequacy prior to transport. Do not send unsatisfactory specimens as this will cause delays in testing.
- 13. Transport specimen by UPS, FedEx, or courier at ambient temperature within 24 hours of collection. Samples collected on Saturday can be transported with the next transport day.

The following are considered Unsatisfactory by MTPHL

- All circles are not filled (QNS)
- Filter paper is scuffed or torn.
- Creases through spots
- Blood is layered by application on both sides or by applying multiple drops on the same circle.
- Specimen is contaminated or improperly dried.
- Plasma separation
- Blood clots are present.

Examples of Unsatisfactory Specimens

Problem	Examples	Causes	Prevention
Insufficient quantity: Circles not filled with blood	6 9 9 0	Collector unable to obtain large drops of blood from heel.	Hydrate the baby; warm and lower the heel; puncture again.
Insufficient quantity: Filter paper not saturated (front and back of same card)	*·4 3 3	Blood applied to each circle did not soak through evenly.	Apply one large drop per circle; check reverse for soak through; don't touch sample area.
Filter paper damage: Creases and tears	0000	Wet filter paper is easily damaged.	Do not overload card or touch the wet sample; do not crease.
Filter paper damage: Capillary abrasion	00	Capillary scraped on wet filter paper.	Avoid capillary tubes if possible; never touch capillary to card.
Poor quality: Layered specimen		Collector unable to apply large drops of blood.	Apply one large drop per circle; never add to a partially dry spot.
Poor quality: Contamination	004	Blood contaminated by liquid absorbed on card after blood applied.	Dry the cards flat away from spilled liquids.
Poor quality: Serum rings	900	Serum or tissue fluid separates from blood cells on card.	Dry flat; apply gentle heel pressure rather than "milking".
Poor quality: Clotted specimen		Delayed application of blood to card using capillary or syringe.	Avoid devices; if used, need one per spot; no anticoagulant.
Poor quality: Blood applied to both sides (smearing front and back of same card)		Smeared blood on both sides suggests blood applied to both.	Apply blood to one side only. Dry flat for at least 4 hours before closing flap.

Capillary (Fingerstick Specimens) for Blood Lead Collection and Transport

Performing the Skin Puncture:

- 1. Thoroughly wash hands and don powder free gloves.
- 2. Select the puncture site. Blood can be obtained from:
 - fingertip (for adults and children older than 1 year)
 - the bottom of the big toe (infants only)
 - the heel (infants only)
- 3. Clean the puncture site with alcohol pad. If the site is extremely soiled or very cold, wash with warm soapy water and towel dry. Use the alcohol swab to briskly scrub the puncture site to remove any environmental contamination and to increase blood flow.
- 4. Allow the site to air dry or use sterile gauze to dry the area.
- 5. Puncture the skin with the lancet.

Collection of the Sample:

1. Use gauze to wipe off the first drop of blood, which contains excess tissue fluid. A rounded drop of blood will form over the puncture site. When the tip of the collection device touches this drop, blood will flow by capillary action into the tube. Care should be taken that the tip of the collection device is in contact with the blood only, not skin. Gently apply continuous pressure to the surrounding tissue; avoid milking the site.



Important: The flow of blood must be adequate to fill the capillary rapidly. Do not stop to shake or tap the tube until the capillary is filled. Capillary must be held continuously in a horizontal position during the drawing of the blood.

- 2. After filling, turn the capillary device immediately to a vertical position to allow the blood to flow into the tube. Remove capillary with holder at the same time. Close tube with attached cap.
- 3. Apply pressure to the puncture site with a gauze pad to stop bleeding, while mixing the specimen by inverting a minimum of five times.
- 4. Identify each skin puncture specimen with the patient's name and collection date.

Submitting Specimens to the Laboratory for Testing:

- 1. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date.
- 2. Place the well-mixed blood specimen container into the <u>individual</u> biohazard zip lock transport bag and seal bag tightly. Place the online requisition in the sleeve of the zip lock bag. Store the specimen(s) in the refrigerator until shipped.
- 3. Specimens are transported at ambient temperature by mail or courier.

Results:

Turn-around time is 1 week. Should the initial test be elevated, a venous specimen should be performed for verification.

Venipuncture Specimens for Blood Lead Collection and Transport

Preparation of the Puncture Site:

- 1. Thoroughly wash hands and don powder free gloves.
- 2. Expose the selected antecubital fossa and apply tourniquet to mid-biceps. Scrub the puncture site briskly with the alcohol pad to remove any environmental contamination and to increase blood flow.
- 3. Allow the site to air dry or use sterile gauze to dry the area.

Collection of the Sample:

- 1. Prepare needle assembly, either needle and vacutainer holder, or needle and syringe.
- 2. Perform venipuncture per standard operating procedures. Make sure the vacutainer tube is filled before stopping collection. If using a needle and syringe, obtain a minimum of 2 mL of whole blood.
- 3. Remove tourniquet first, then needle from arm.
- 4. Apply pressure to the puncture site with a gauze pad to stop the patient's bleeding. Parent/guardian or child may continue holding direct pressure on the puncture site.
- 5. If drawn directly into vacutainer tube, immediately mix the specimen manually by inverting a minimum of 10 times.
- 6. If drawn with a needle into the syringe, immediately inject the blood from the syringe into the vacutainer tube, gently mixing while filling. Continue to mix the specimen by inverting 10 times.
- 7. Dispose of used needle and syringe equipment into puncture proof Sharps container.
- 8. Identify each skin puncture specimen with the patient's name, at a minimum, and collection date.

Submitting Specimens to the Laboratory for Testing:

- 1. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date.
- 2. Place the well mixed, unclotted blood specimen in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Place the online requisition in the sleeve of the zip lock bag.
- 3. Store the specimen(s) in the refrigerator until shipped. Specimens are transported at ambient temperature by mail or courier.

Results:

Turn-around time is 1 week.

QuantiFERON®-TB Gold In-Tube Testing Collection and Transport

The QuantiFERON-TB Gold assay (QFT®) measures the Interferon-gamma (IFN-γ) response in whole blood stimulated with antigen. The kit uses specialized QFT blood collection tubes. The following is a guide for blood collection into these tubes.

Please read and follow the complete directions carefully!

Filling QuantiFERON®-TB Gold blood collection tubes

QuantiFERON®-TB Gold IT uses the following collection tubes; the set will be provided for you free of charge by <u>submitting an online</u> <u>supply request</u>.

- 1. Nil Tube (Grey cap with yellow ring). The yellow ring designates a high-altitude tube.
- 2. TB1 Tube (Green cap with yellow ring).
- 3. TB2 Tube (Yellow cap with yellow ring).
- 4. Mitogen Tube (Purple cap with yellow ring).

These procedures should be followed for optimal results:

- 1. Tubes should be at 17 25°C at the time of blood filling.
- 2. Collect 1 mL of blood by venipuncture directly into each QFT blood collection tube in the order Nil, TB1, TB2, and Mitogen. As 1 mL tubes draw blood slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling to ensure that the correct volume is drawn.
- 3. The black mark on the side of the tubes indicates the 1 mL fill volume. QFT blood collection tubes have been validated for volumes ranging from 0.8 to 1.2 ml. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample.
 - •If a "butterfly needle" is used, prime tubing with a "purge" tube before filling the QFT tubes.

Mixing Tubes

- Antigens have been dried onto the inner wall of the blood collection tubes. It is essential that the tubes' contents be thoroughly
 mixed with the blood. Thorough mixing will dissolve the heparin, preventing clotting, and allow resolubilization of the
 stimulating antigen. Mixing is performed by shaking, not just inverting, the tubes vertically ten (10) times, firmly enough to
 ensure that the entire inner surface of the tube is coated with blood. Over-energetic shaking may cause gel disruption and
 could lead to aberrant results.
- 2. Label tubes appropriately with two patient identifiers. Ensure each tube (Nil, TB1, TB2, Mitogen) is identifiable by its label or other means once the cap is removed.

Incubation of Tubes

- Following filling, shaking, and labeling, the tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation.
- 2. Incubate the tubes **UPRIGHT** at 37°C ± 1°C for 16 to 24 **consecutive** hours. The incubator does not require CO₂ or humidification.
- 3. If tubes are not incubated on site, maintain tubes at room temperature (22°C ± 5°C). Do not refrigerate or freeze the blood samples. Tubes must be received in the Public Health Laboratory within 16 hours of collection for incubation.
- 4. Following 37°C ± 1°C incubation, blood collection tubes may be transported between 2°C and 27°C. Specimens must be received in the Public Health Laboratory within 3 days of incubation. If this is not possible, centrifuge tubes at 3000g for 15 minutes.
- 5. Place the blood tubes in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Place the online requisition with date and TIME of draw, and whether the specimen(s) have been incubated in the sleeve of the zip lock bag.

An illustrated Quick Guide for Blood Collection is available at http://www.cellestis.com/. Click on the links: QuantiFERON Products, QuantiFERON®-TB Gold In-Tube, Technical Resources, Technical Documents, and Blood Collection Quick Guide.

QUESTIONS? Contact the MTPHL at 800-821-7284 or mtphl@mt.gov

Serology Specimens Collection and Transport

Specimen Type	Instructions
Acute serology specimen	The DATE OF ONSET of symptoms or disease is less than 7 days from the date serum is obtained, usually the first few days of the illness. IgG antibody titers are not elevated. Exceptions: Rubeola, Rubella, and Colorado Tick Fever and Rocky Mountain Spotted Fever may have a significant IgG titer in 7-10 days.
Convalescent serology specimen	The DATE OF ONSET of symptoms or disease is 2 weeks or greater from the date serum is obtained. IgG antibody levels should be at a significant level. Exception: Legionella sp. antibody levels may not be significant for 4-6 weeks.
Serology screen only	The patient has a chronic condition (the DATE OF ONSET of symptoms or disease being a period of months to years); OR the patient is being screened for antibodies to a certain
Post-convalescent serology specimen	infectious agent (HIV, Hepatitis B, Rubella, VZV, etc. Otherwise, consider IgM testing.
	Single specimen test results may be difficult to interpret, and an additional specimen may be requested if results warrant.

Submit 2 - 4 mL of clear non-hemolyzed serum for testing. Contact the laboratory for exact volumes needed if serum is difficult to obtain. Serum separator tubes can be used. Spin the SST tubes well to separate the serum and cells and submit the whole tube. Serum does not have to be poured off. DO NOT submit unspun SST tubes. If serum is not submitted in the original SST tube, place in a leakproof container.

Cerebral Spinal Fluid (CSF) may also be submitted for serological testing in certain instances. A serum sample should also be submitted with the CSF for comparison testing.

Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date. Identifiers must match online requisition.

Place each specimen container in an <u>individual</u> biohazard zip lock bag containing absorbent material and seal bag tightly. Place the online requisition form in the outer sleeve of the biohazard zip lock bag. Do not place the form inside the zip lock bag.

If specimen is stored prior to shipment, store at 4°C. If storage is longer than 1 week, freeze the specimen. Specimens may be shipped at room temperature. Labeled pre-addressed mailing canisters are available from the laboratory. Transport by mail or courier.

Ordering Clinical Laboratory Testing

Facilities sending testing to MTPHL must have an account. To request an account for your facility contact us at 1-800-821-7284 or 406-444-3444. You may also e-mail us at HHSLIMS@mt.gov.

The MTPHL no longer accepts paper requisition forms. All orders must be placed in our online Laboratory Portal

Find instructions for online ordering and result retrieval on our website: Online Ordering and Result Retrieval

Each user must have their own portal credentials. Forms required for accessing the portal are located on our website: User Authorization Forms

Ordering Testing Supplies

The MTPHL no longer provides paper supply order forms. Supply requests for established accounts can be placed in our online <u>Laboratory Portal</u>

Find instructions for creating supply requests on our website: Creating Supply Requests

Each user must have their own portal credentials. Forms required for accessing the portal are located on our website: <u>User Authorization Forms</u>

Packaging and Shipping Guidelines

It is the responsibility of the facility to ensure proper packaging and shipping of all potentially infectious and biological substances. Listed below are some general guidelines and links to websites that will provide more detailed information.

Category A (UN2814 "Infectious Substance Affecting Humans"): "An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses more risk than Category B." Anyone involved in the shipment of Category A infectious substances must be trained per regulation, and their employer must certify that all training requirements have been met. Training records should be available for auditing purposes. (49 CFR 172, Subpart H)

Category B (UN 3373 "Biological Substance, Category B"): "An infectious substance NOT in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes."

NOTE: **Dried blood spots for newborn screening** require triple packaging (the filter paper card, the yellow flap with the biohazard symbol, and the outer packaging). However, these samples are not regulated and do not require special marking on the outer packaging. Please be aware of weather conditions to avoid samples getting wet during transport.

For more information, please visit the following sites:

US Department of Transportation Hazardous Materials Regulations https://www.ecfr.gov/current/title-49/subtitle-B/chapter-I/subchapter-C

DOT: Transporting Infectious Substances Safely

https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely

ASM SENTINEL LEVEL CLINICAL LABORATORY GUIDELINES FOR SUSPECTED AGENTS OF BIOTERRORISM AND EMERGING INFECTIOUS DISEASES: Packing and Shipping Infectious Substances

https://asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C

WHO Guidance on regulations for transport of infectious substances, 2021-2022 https://www.who.int/publications/i/item/9789240019720

International Air Transport Association (IATA) Dangerous Good Regulations:

https://store.iata.org/IEC SearchResults?site-search=dangerous+goods+regulations

CDC Packaging and Shipping Training Course

https://www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html