Laboratory Services

Directory of Services 2024





Health & Human Services

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Last Revision Date: 4/2024





Health & Human Services

Be Legendary.

LABORATORY SERVICES

Christie Massen, Ph.D., M.S., MLS, Section Director Laurie Linz, MD, CLIA Laboratory Director

GENERAL INFORMATION

CLIA NUMBER: 35DO691722

The *Directory of Services* contains a listing of services and tests provided by Laboratory Services. Each test entry contains a brief explanation of the test, stability, transport temperature, turn around time, type of specimen required, cost and CPT code(s).

All specimens submitted to Laboratory Services should be collected and handled with care. Improperly collected or inadequate specimens may give laboratory results of questionable value. Complete information is essential and should be supplied on the request form accompanying the sample.

Testing may be delayed if all requested information is not submitted with the specimen.

Laboratory Services provides collection kits and mailing containers as described on our website at https://www.hhs.nd.gov/public-health/laboratory-services. Infectious substances must be mailed in containers that meet federal regulations. Please refer to the IATA Guidance Diagrams on our Website for Infectious Substances or contact Laboratory Services for assistance.

FEES AND SERVICES ARE SUBJECT TO CHANGE BY LABORATORY SERVICES

SPECIMEN LABELING/REJECTION POLICY

All clinical primary specimen containers must have a patient name, along with a second unique identifier, such as date of birth, medical record number, or accession number.

Appropriate laboratory orders must accompany each specimen and must contain the following information:

- 1. Patient name (Last, First Name)
 - a. Anonymous testing will not be performed
 - b. Specimens labeled with obvious pseudo-names will not be accepted
- 2. Date of birth
- 3. Health care provider
- 4. Submitting institution name and address
- 5. Identification code
- 6. Type of specimen
- 7. Test requested
- 8. Date of collection

Criteria for specimen rejection:

- 1. Recommended transport/hold time exceeded
- 2. Specimen damaged (ex: leaked or broken)
- 3. Improper specimen (ex: contaminated, inadequate collection, wrong body site or duplicate sample)
- 4. Unsuitable for request
- 5. Specimens of insufficient amount (QNS)
- 6. Unlabeled or mislabeled specimens

CONTACT INFORMATION

North Dakota Department of Health and Human Services

Laboratory Services

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Laboratory Testing and Fee Schedule

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Analytio	a Baye: monaay anough rhaay amood other moo marcatea.	
TEST	EXPLANATION	COST

Arboviral	Acceptable Specimen: 2 ml acute phase serum	
Encephalitis Panel		
IFA and EIA	Stability: Ambient: 5 Days; Refrigerated: 5 Days; Frozen: >5 Days	
CPT CODES:		
86654 - WEE	Normal Value: West Nile Virus EIA - Negative	\$137
86652 - EEE	Western Equine, Eastern Equine, St. Louis, California	
86653 - SLE	Group IFA < 1:16	
86651 - California		
86788 - West Nile	Turn Around Time: 3 days	
	Acceptable Specimen: Pure isolate in appropriate tubed transport	
	medium or Amies (with charcoal) transport medium. Plates not	
Bacterial - Aerobic	accepted.	
Reference		
Culture	Stability: Ambient: 7 days; Refrigerated: 7 days; Frozen: Unacceptable	\$58
CPT CODE:		
87077	Normal Value: Not applicable	
	Turn Around Time: 7 days	
	Acceptable Specimen: Pure isolate in anaerobic tubed medium such	
Bactorial -	as Anaerobic Thio, Amies (with charcoal) transport medium, PORT-A-	
Anaorohic	CUL tubes, etc. Plates not accepted.	
Anderopic Poforopico Culturo		
	Stability: Ambient: 7 days; Refrigerated: 7 days; Frozen: Unacceptable	\$58
07076		
01010	Normal Value: Not applicable	
	Turn Around Time: 7 days	
	Acceptable Specimen: Neceptaryngool apocimen, in universal	
	transport modia, provided in kit	
	This Helicase Dependent Amplification (HDA) assay simultaneously	
	tests for the following nathogens:	
Rordetella species	Rordotolla paraportussis and Bordotolla portussis	
HDA	Dordelena parapertussis and Dordelena pertussis	
CPT CODE	Contact Laboratory Services for transport kits	
87798	Refer to Specimen Collection and Handling Section for instructions	\$63
	Stability: Ambient: 2 days; Refrigerated: 4 days; Frozen: 5 months	
	Normal Value: Negative	
	Turn Around Time: 1 day	

TEST	EXPLANATION	COST
Brucella Antibody Agglutination CPT CODE:	 Acceptable Specimen: 2 ml acute and convalescent sample phase sera recommended (at least 14 days apart) Stability: Ambient: Unacceptable; Refrigerated: 4 hours; Frozen: >4 hours 	\$26
	Normal Value: Negative Turn Around Time: 2 days	
California group Encephalitis Ab IFA	Refer to Arboviral Encephalitis Panel	
Carbapenem	Acceptable Specimen: Rectal swab specimen collected with BD BBL liquid Stuart's dual culture swab	
Resistance Gene Screen	Stability: Ambient: 5 days; Refrigerated: 5 days; Frozen: Unacceptable	\$63
87798 x 5	Normal Value: KPC, NDM, VIM, OXA-48, and IMP Not Detected	
Candida auris Rule Out CPT CODE: 87106	Acceptable Specimen: Sabouraud Dextrose Agar Slant or Aimes swab. Plates will not be accepted. Stability: Ambient: 10 days; Refrigerated: 10 days; Frozen:Unacceptable Normal Value: Not Applicable Turn Around Time: 1 week	No Charge
<i>Chlamydia</i> <i>trachomatis</i> and <i>Neisseria</i> <i>gonorrhoeae</i> TMA CPT CODE: 87491 - Chlamydia 87591 - Gonorrhoeae	 Acceptable Specimen: Endocervical, oral, rectal, urine, throat, vaginal, or male urethral specimen in Hologic multi specimen collection kit Contact the Laboratory Services for collection kits. Refer to Specimen Collection and Handling Section for instructions. Stability: Ambient: 60 days; Refrigerated: 60 days Stability: Urine - Ambient: 30 days; Refrigerated: 30 days Normal Value: Negative Turn Around Time: 1 day *Correctional and Rehabilitation facilities, and Safety Net facilities will be charged \$11 	\$21*

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

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EXPLANATION

COST

Eastern Equine Encephalitis Ab IFA	Refer to Arboviral Encephalitis Panel	
Encephalitis Panel Antibody, IgM CLIA, EIA, and IFA CPT CODES: 86694 -Herpes EIA 86735 -Mumps IFA 86762 -Rubella CLIA 86765 -Measles IFA 86787 -VZV IFA	Acceptable Specimen: 2 ml acute phase serum Stability: Ambient: 8 hours; Refrigerated: 2 days; Frozen: >2 days Normal Value: < 1:8 or Negative Turn Around Time: 1 day	\$217
Enterovirus PCR CPT CODE: 87498	 Acceptable Specimen: Nasopharyngeal, skin lesion material, and throat in viral transport medium. CSF and stool in sterile container. Stability: Refrigerated: 7 days; Frozen: >7 days Normal Value: Negative Turn Around Time: 3 days 	\$63

TEST EXPLANATION COST	Analytica	a Days. Monday through the second terms of ter	
	TEST	EXPLANATION	COST

	Acceptable Specimen: 2 ml serum	
Fluorescent Treponemal	Stability: Ambient: 8 hours; Refrigerated: 2 days; Frozen: >2 days	
	Normal Value: Nonreactive	\$26
86780	Turn Around Time: 2 days	
	Acceptable Speciment 2 ml coute and convelescent (2 weeks past	
Franciacula	onset) phase sera	
<i>Francisella</i> <i>tularensis</i> Antibody		
Serum	Stability: Ambient: Unacceptable; Refrigerated: 4 hours;	\$53
Agglutination	Flozen. >4 hours	ψυυ
CPT CODE:	Normal Value: Negative	
	Turn Around Time: 2 days	
	Acceptable Specimen: Sterile containers or on Sabouraud Dextrose	
	Agar. Plates will not be accepted.	
Fungal Primary	Contract Laboratory Complete for an internet with avertary is included	
Culture	Such as histoplasma, coccidioides and blastomyces	
87101-Skin, Hair, Nails		
87102 -Other Source	Stability: Ambient: 10 days; Refrigerated: 10 days;	¢EQ
87103 -Blood	Frozen: Unacceptable	စ္ဝဝ
87107 -Mold ID	Normal Value: No fungi isolated	
	Turn Around Time: Negative culture - 2 weeks	
	Positive culture - 2 to 6 weeks	
	Acceptable Specimen: Pure isolate in tubed medium such as	
	accepted.	
Fungal Reference	Contact Laboratory Services for assistance with systemic	
	isolates such as histoplasma, coccidioides and blastomyces.	\$58
87106 - Yeast	Stability: Ambient: 10 days; Refrigerated: 10 days;	ΨŪŪ
87107 - Mold	Frozen: Unacceptable	
	Normal Value: Not applicable	
	Turn Around Time: 2 to 6 weeks	

TEST	EXPLANATION	COST
Gastrointestinal (GI) Panel PCR CPT CODE: 87507	 Acceptable Specimen: 1 ml stool in Cary-Blair medium This assay simultaneously tests for the following pathogens: Campylobacter (C. jejuni/C. coli/C. upsaliensis), Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae), including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) It/st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2 (including specific identification of the E. coli O157 serogroup within STEC), Shigella/ Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia (also known as G. intestinalis and G. duodenalis), Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I, II, IV, and V) Stability: Ambient: 4 days; Refrigerated: 4 days; Frozen: Unacceptable 	\$189
	Normal Value: Not Detected	
Handling Fee CPT CODE: 12345	Handling fees are dependent on test requested. Call Laboratory Services for test specific handling fee information.	\$16
Hantavirus Antibody Enzyme Capture-IgM ELISA CPT CODE: 86790	Acceptable Specimen: 2 ml acute phase serum Stability: Refrigerated: 5 days; Frozen: >5 days Normal Value: Negative *Positive results are sent to CDC for Confirmation. Turn Around Time: 2 days	\$63
Hepatitis A IgM Antibody CLIA CPT CODE: 86709	Acceptable Specimen: 2 ml acute phase serum Stability: Ambient: 2 days; Refrigerated: 7 days; Frozen: >7 days Normal Value: Negative Turn Around Time: 1 day	\$27

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

TEST	EXPLANATION	COST
Hepatitis B Core	Acceptable Specimen: 2 ml serum	
Antibody, Total Ig CLIA	Stability: Ambient: 4 days; Refrigerated: 4 days; Frozen: >4 days	\$27
CPT CODE: 86704 - Total Ig	Normal Value: Nonreactive	
	Turn Around Time:1 day	
Henatitis B Core	Acceptable Specimen: 2 ml acute phase serum	
Antibody, IgM CLIA	Stability: Ambient: 4 days; Refrigerated: 7 days; Frozen: >7 days	\$27
CPT CODE: 86705	Normal Value: Nonreactive	
	Turn Around Time:1 day	
Hepatitis B Surface	Acceptable Specimen: 2 ml serum	
Status (Anti-HBs)	Stability: Ambient: 1 day; Refrigerated: 7 days; Frozen: >7 days	\$27
CPT CODE:	Normal Value: Positive	
86706	Turn Around Time: 1 day	
	Acceptable Specimen: 2 ml serum	
Hepatitis B Surface Antigen (HBsAg)	Stability: Ambient: 3 days; Refrigerated: 7 days; Frozen: >7 days Normal Value: Nonreactive	\$27
CPT CODE:	*Confirmatory testing will be performed, at no additional charge, on all reactive specimens	
07540	Turn Around Time: 1 day	
	Acceptable Specimen: 2 ml serum	
Hepatitis C Virus Antibody, Total Ig	Stability: Ambient: 4 days; Refrigerated: 7 days; Frozen: >7 days	\$27
(Anti-HCV) CLIA CPT CODE: 86803	Normal Value: Nonreactive	
	*Positive tests will reflex to Hepatitis C Virus RNA	
	Turn Around Time: 1 day	

TEST	EXPLANATION	COST
	Acceptable Specimen: 3 ml serum or 5 ml whole blood	
Hepatitis C Virus	Stability: Serum - Ambient: 1 day; Refrigerated: 3 days; Frozen: >3 days	
Genotyping CPT CODE: 87902	Stability: Whole Blood - Ambient: 6 hours; Refrigerated: 6 hours; Frozen: Unacceptable	\$163
	Normal Value: Not Applicable	
	Turn Around Time: Weekly	
	Acceptable Specimen: 3 ml serum or 5 ml whole blood	
	Stability: Serum- Ambient: 1 day; Refrigerated: 5 days; Frozen: >5 days	
Hepatitis C Virus RNA (Quantitative) CPT CODE: 87522	Stability: Whole Blood- Ambient: 6 hours; Refrigerated: 6 hours; Frozen: Unacceptable	\$58
	Normal Value: Not Detected	
	Turn Around Time: Weekly	
	Acceptable Specimen: 2 ml acute phase serum	
Herpes Simplex Virus Antibody, IgM	Stability: Ambient: 8 hours; Refrigerated: 2 days; Frozen: >2 days	¢40
CPT CODE:	Normal Value: Negative	⊅ 4∠
00094	Turn Around Time: 1 day	
Herpes Simplex Virus 1 & 2 and	Acceptable Specimen: Swab, in viral transport medium, from any lesion.	
<i>Varicella zoster</i> HDA	Stability: Ambient: 2 days; Refrigerated: 7 days; Frozen: 7 days	\$63
CPT CODE: Herpes – 87529	Normal Value: Negative	
Varicella - 87798	Turn Around Time: 1 day	
HIV 1 2 Antibody/	Acceptable Specimen: 3 ml serum or plasma	
HIV-1 p24 Antigen	Stability: Ambient: 3 days; Refrigerated: 7 days; Frozen: >7 days	
Combo CLIA CPT CODE:	Normal Value: Nonreactive	\$11
87389 - Screen 86689 - Confirmation	*Confirmatory testing will be performed, at no additional charge, on all reactive specimens following current CDC and CLSI guidelines for 4th Generation HIV Ab/Ag Combo tests.	
	Turn Around Time: 1 day	

Clinical Laboratory Testing and Fee Schedule

Analytic	a Days. Monday through theas otherwise indicated.	
TEST	EXPLANATION	COST
HIV-1, 2 Antibody/ HIV-1 p24 Antigen Confirmation CPT CODE: 86689	Acceptable Specimen: 1 ml serum or plasma Stability: Ambient: 1 days; Refrigerated: 7 days; Frozen: >7 days Normal Value: Nonreactive Turn Around Time: 2 days	\$42
HIV-1 RNA Viral Load CPT CODE: 87536	Acceptable Specimen: 2 mL serum (Qualitative) or plasma (Quantitative); tubes containing ETDA or Acid Citrate Dextrose (ACD) anticoagulants or Plasma Preparation Tubes (PPTs) Stability: Primary Tube- Ambient: Unacceptable; Refrigerated: 3 days; Frozen: Unacceptable Stability: Secondary Tube- Ambient: Unacceptable; Refrigerated: 5 days; Frozen: 90 days Normal Value: Not Detected Turn Around Time: Weekly	\$58
	Accontable Speciment 2 ml comm	
Immune Screens CPT CODE: 86765- Measles 86735- Mumps 86318- Rubella 86787- Varicella	Acceptable Specimen: 2 mi serum Stability: Ambient: 1 day; Refrigerated: 7 days; Frozen: >7 days Normal Value: Measles > 1:16 Mumps > 1:16 Rubella Positive Varicella > 1:16	\$128
	Turn Around Time: Tuesday and Thursday	
Influenza A/B/ RSV/SARS CoV-2 PCR CPT CODE: 87631	Acceptable Specimen: Nasopharyngeal swab in viral transport medium or universal transport media. Stability: Ambient: Unacceptable; Refrigerated: 4 days; Frozen: Unacceptable Normal Value: Not Detected Turn Around Time: 3 Days	\$58
Influenza Virus Type A & B PCR and Subtype Confirmation CPT CODE: 87501 87501 x 8	 Acceptable Specimen: Specimen in 1.5mL to 3mL viral transport medium. Refer to Specimen Collection & Handling Section for instructions. Sub-typing: A - H3, 2009 H1N1 B - Yamagata, Victoria Stability: Refrigerated: 7 days; Frozen: >7 days Normal Value: Not Applicable Turn Around Time: 3 days 	No Charge
	Acceptable Specimen: Bronchial, lung, sputum, tissue in sterile	
Legionella Culture CPT CODE: 87081 - Presum Cult 87077-Culture ID	container Stability: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: Unacceptable Normal Value: Negative Turn Around Time: 7 days	\$58

Clinical Laboratory Testing and Fee Schedule

TEST	EXPLANATION	COST
Lyme Antibody IgG, IgM, and Total Ig CLIA CPT CODE: 86618 - Total 86617 - IgG, IgM, Confirmation	Acceptable Specimen: 2 ml of serum Stability: Ambient: 8 hours; Refrigerated: 7 days; Frozen: >7 days Normal Value: Negative *Confirmatory testing will be performed on all positive or equivocal specimens for an additional \$64 charge Turn Around Time: 1 day	\$32*
Measles Virus (Rubeola) Antibody, IgM IFA CPT CODE: 86765	Acceptable Specimen: 2 ml acute phase serum Stability: Ambient: 1 day; Refrigerated: 7 days; Frozen: >7 days Normal Value: < 1:8 Turn Around Time: 1 day	\$32
Measles Virus (Rubeola) Antibody, IgG CLIA CPT CODE: 86765	Acceptable Specimen: 2 ml serum Stability: Refrigerated: 9 days; Frozen: >9 days Normal Value: Positive Turn Around Time: 1 day	\$32
Measles Virus (Rubeola) PCR CPT CODE: 87798	 Acceptable Specimen: Nasopharyngeal swabs (preferred) or aspirates, nasal swabs, throat swabs in viral transport medium. 50 ml urine in sterile container. Stability: Ambient: Unacceptable; Refrigerated: 3 days; Frozen: >3 days Normal Value: Negative Turn Around Time: 2 days 	\$63
Monkeypox PCR	Refer to Orthopox (Monkeypox) Panel PCR	
Mumps Virus Antibody, IgM IFA CPT CODE: 86735	Acceptable Specimen: 2 ml acute phase serum Stability: Ambient: 1 day; Refrigerated: 7 days; Frozen: >7 days Normal Value: < 1:8 Turn Around Time: 1 day	\$32

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

TEST	EXPLANATION	COST
Mumps Virus Antibody, IgG	Stability: Refrigerated: 9 days; Frozen: >9 days	
CLIA CPT CODE: 86735	Normal Value: Positive	\$32
	Turn Around Time: 1 day	
	Acceptable Specimen: Buccal swabs (preferred), throat swabs, and nasopharyngeal swabs or aspirates in viral transport medium. Urine in sterile container.	
Mumps PCR CPT CODE:	*Molecular grade swabs only. Dacron or rayon swabs with plastic or metal shafts only. Calcium alginate swabs and cotton swabs with wooden shafts are unacceptable.	\$63
07790	Stability: Ambient: Unacceptable; Refrigerated: 3 days; Frozen: >3 days	
	Normal Value: Negative	
	Turn Around Time: 2 days	
Mycobacteria Primary Culture CPT CODE: 87206-Direct smear 87015 - Concentration 87116 - Presum Cult	 Acceptable Specimen: Sterile container Contact Laboratory Services for collection and mailing kit. Refer to Specimen Collection and Handling Section for instructions. All new positive mycobacterium direct smears on sputum, bronchial lavage, and bronchial wash samples will automatically reflex to perform the <i>Mycobacterium tuberculosis</i>/Rifampin PCR test. Stability: Whole Blood/Bone Marrow - Ambient: 7 days; Frozen: Unacceptable Stability: Other - Ambient: Unacceptable; Refrigerated: 7 days; Frozen: Unacceptable Normal Value: Mycobacteria Culture - No Mycobacteria isolated AFB Smear - No AFB seen 	No Charge
	Turn Around Time: 2 to 8 weeks	
Mycobacteria Reference Culture CPT CODE: 87118-Mycobacteria ID	 Acceptable Specimen: Isolate on tubed solid medium such as LJ slants, 7H10 slants, etc. Plates or liquid medium not accepted. Stability: Ambient: 4 days; Refrigerated: 7 days fresh growth; Frozen: Unacceptable 	\$58
	Normal Value: Not applicable	
	Turn Around Time: 2 to 6 weeks	

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

TEST		COST
ILUI		0001
	Isolates for susceptibility testing will be referred to a reference laboratory.	
•• • • • •	Susceptibility testing on <i>M</i> .tuberculosis will be submitted on all isolates from patients considered to be a new case as part of the initial culture procedure.	No
Susceptibility	*Susceptibility testing on mycobacteria isolates other than <i>M. tuberculosis</i> will be submitted to a reference laboratory upon request with a handling fee.	Charge*
	Normal Value: Susceptible	
	Turn Around Time: Not applicable	
Mycobacterium	Acceptable Specimen: 1ml Sputum 2 samples per patient in a 3 month period or 12 months after the end of treatment	
Rifampin Nested Real Time PCR CPT CODE:	The PCR test is only intended for use on specimens from patients showing signs and symptoms consistent with active pulmonary tuberculosis. The PCR test must be performed in conjunction with mycobacterial culture.	No Charge
87556	Stability: Ambient: 3 days: Refrigerated: 10 days:	
	Frozen: Unaccentable	
	Normal Value: MTB Not detected	
	Turn Around Time: Test performed as peeded	
	run Alound Time. Test performed as needed	
	Acceptable Specimen: Endocervical, urine, vaginal, penile meatal, male urethral specimen in Hologic specimen collection kit	
Mycoplasma genitalium TMA	Stability: Swab -Ambient: 60 days; Refrigerated: 60 days; Frozen: >60 days	¢16
CPT CODE: 87563	Stability: Urine -Ambient: 30 days; Refrigerated: 30 days; Frozen: >30 days	φιΟ
	Normal Value: Negative	
	Turn Around Time: 3 days	
Neisseria gonorrhoeae TMA	Refer to Chlamydia trachomatis and Neisseria gonorrhoeae PCR	
Orthopox (Monkeypox) Panel	Acceptable Specimen: Two sterile, dry synthetic swabs (including, but not limited to polyester, nylon, or dacron) per lesion labeled per site collected OR in synthetic swabs in VTM	No
PCR CPT CODE:	Includes: Orthopox, Non-Variola Orthopox, Varicella Zoster Virus PCR	Charge
87593	Stability: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: >7 days	
	Normal Value: Negative	
	Turn Around Time: 1 day	

Clinical Laboratory Testing and Fee Schedule nalytical D

Analytical Days: Monday through Friday unless otherwise indicated.		
TEST	EXPLANATION	COST
Parasites, Blood Giemsa Stain CPT CODE: 87207 - Thin 87015 - Thick	Acceptable Specimen: At least two thin blood films and two thick films made from fresh blood are preferred. Stain one slide set (one thin and one thick) with Wright-Giemsa or Giemsa (preferred) and send the second slide set unstained. Blood containing anticoagulant (EDTA) can be used if films are prepared within one hour. Air dry and send in protected container to prevent breakage. The submission of a single blood specimen will not rule out blood parasites. Additional blood specimens are recommended. Include EDTA whole blood and serum tubes for possible referral.	COST \$30
	Pertinent travel history is requested. Stability: Ambient: 7 days; Frozen: Unacceptable Normal Value: No parasites seen Turn Around Time: 2 days	
Parasites, Stool CPT CODE: 87177 - Conc & ID 87209 - Trichrome 87206 - Acid Fast 87168 - Macrosc.	Acceptable Specimen: Stool specimen in Total-Fix preservative includes wet mount, trichrome stain and acid-fast stain (for <i>Cryptosporidium, Cyclospora</i> and <i>Cystoisospora belli</i>). Microsporidia examination is not included. If fresh stool sample is collected, sample must be placed in Total-Fix collection container within 30 minutes. Two specimens are recommended, while three specimens offer the best chance of organism recovery. Antibiotics such as metronidazole or tetracycline may interfere with the recovery of intestinal parasites, particularly the protozoa. If specimen is collected in formalin, trichrome stain will not be performed. *If Schistosomiasis is suspected, please send urine and stool specimens. Contact Laboratory Services for collection kits. Stability: Ambient: 7 days; Frozen: Unacceptable Normal Value: No parasites seen Turn Around Time: 2 days	\$30

Clinical Laboratory Testing and Fee Schedule

TEST	EXPLANATION	COST
0.		
	Acceptable Specimen: 2 ml serum	
Surface Antigen	Stability: Ambient: 3 days; Refrigerated: 7 days; Frozen: >7 days	\$27
CPT CODE: 87340	Normal Value: Nonreactive	ΨΖΙ
	Turn Around Time: 1 day	
	Serum for IFA testing will be referred to a reference laboratory.	
Q Fever, Total Ig IFA	Acceptable Specimen: 2 ml acute and convalescent (3 weeks post onset) phase sera	
(<i>Coxiella burnetii</i>) CPT CODE: 86638	Stability: Ambient: 1 day; Refrigerated: 6 days; Frozen: >6 days	\$27
	Normal Value: < 1:256 or a less than fourfold increase in titer between acute and convalescent sera.	
	Turn Around Time: 7 days	
	Acceptable Specimen: Whole Blood and Environmental samples	
Q Fever PCR	(Liquid, soil, powder, wipes, swabs, and paper)	
(<i>Coxiella burnetii</i>) CPT CODE:	Stability: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: 2 months	No Charge
87798	Normal Value: Not Detected	
	Turn Around Time: 1 day	
	Call Laboratory Services for a collection kit. Samples must be received Monday through Thursday.	
Quantiferon TB Gold Plus (Mycobactorium)	Acceptable Specimen: Four tube blood collection kit or 5-6 ml lithium heparin without gel	\$42
tuberculosis) CPT CODE: 86480	Stability: Refer to Specimen Collection and Handling Section for instructions. Incubated and Centrifuged plasma in QFT-Plus tubes-Refrigerated: 28 days; Frozen: >28 days	
	Normal Value: Negative	
	Turn Around Time: 3 days	
	Acceptable Specimen: Animal testing only. Full cross section of brain stem and cerebellum.	
Rabies Direct Antigen Detection	Contact Laboratory Services if animal brain cannot be removed prior to submission.	No Charge
DFA	**\$50 charge will be assessed for brain extraction of animals larger than a rodent	
	Stability: Ambient: Unacceptable; Refrigerated: Specimen must be shipped cold; Frozen: Unacceptable	
	Normal Value: Negative	
	Turn Around Time: 1 day	

Clinical Laboratory Testing and Fee Schedule

теот		COST
IESI	EXPLANATION	0051
Respiratory Panel (RP2) PCR CPT CODE: 87633-Viruses 87798x2-Bordetella 87486-Chlamydia 87581-Mycoplasma	 Acceptable Specimen: Nasopharyngeal swabs in viral transport medium or saline. This assay simultaneously tests for the following pathogens: Adenovirus, Coronavirus HKU1, NL63, 229E, OC43, SARS CoV-2, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H3, Influenza A/H1-2009, Influenza B, Parainfluenza 1, 2, 3 & 4, Respiratory Syncytial Virus (RSV), Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae Stability: Ambient: 4 hours; Refrigerated: 3 days; Frozen: 30 days 	\$168
	Normal Value: Not Detected	
	Turn Around Time: 2 days	
Rickettsia PCR CPT CODE: 87798	Acceptable Specimen: Venous whole blood preserved with EDTA or acid citrate dextrose Solution A (ACD-A) This assay is intended for the qualitative detection and differentiation of <i>R. rickettsii</i> and <i>R. prowazekii</i> DNA. Specimens can be collected from individuals with signs or symptoms indicative of Rocky Mountain Spotted Fever or epidemic typhus and epidemiological risk factors consistent with potential exposure. Stability: Ambient: Unacceptable; Refrigerated: 7 days; Frozen: Unacceptable Normal Value: Negative Turn Around Time: 2 days	\$63
Rocky Mountain Spotted Fever (Rickettsia) Antibody IFA CPT CODE: 86757	 Acceptable Specimen: 2 ml acute and convalescent (3 weeks post onset) phase sera Stability: Ambient: 1 day; Refrigerated: 3 days; Frozen: >3 days Normal Value: < 1:64 or less than fourfold increase in titer between acute and convalescent sera. Turn Around Time: 1 day 	\$32
	Acceptable Specimen: 2 ml serum	
RPR - Rapid Plasma Reagin CPT CODE: 86592	 Stability: Ambient: 3 days; Refrigerated: 7 days; Frozen: >7 days Normal Value: Nonreactive *Reactive RPR can be confirmed by TP-PA at facilities request. Contact the Laboratory Services to order. 	\$10
	Turn Around Time: 1 day	

Analytical Baye: menady through throug		
TEST	EXPLANATION	COST

	Acceptable Specimen: 2 ml acute phase serum	
Rubella (German Measles) Virus IgM	Stability: Refrigerated: 7 days; Frozen: >7 days	
Antibody CLIA CPT CODE:	Normal Value: Negative	\$79
86762	Turn Around Time: 1 day	
Rubella Virus	Acceptable Specimen: 2 ml serum	
Antibody, IgG Immune Screen CLIA	Stability: Refrigerated: 7 days; Frozen: >7 days	\$32
CPT CODE: 86762	Normal Value: Positive	ΨOZ
	Turn Around Time: 1 day	
Rubeola (Measles)	Refer to Measles Virus	
	Acceptable Specimen: 2 ml serum or plasma	
SARS-CoV-2 TrimericS IgG CLIA	Stability: Ambient: 2 days: Refrigerated: 21 days: Frozen: >21 days	No
CPT CODE: 86769		NO Charge
	Normal Value: Negative	_
	Turn Around Time: 3 days	
	Acceptable Specimen: Nasopharyngeal swab in viral transport medium or Hologic collection device in sterile screw cap container	
CPT CODE:	Stability: Refrigerated: 3 days; Frozen: -70 degrees C, Ship on dry ice	No
87033	Normal Value: Negative	Charge
	Turn Around Time: 2 days	
St. Louis Encephalitis Ab IFA	Refer to Arboviral Encephalitis Panel	
	Acceptable Specimen: 2 ml serum	
Syphilis Testing Panel CPT CODE:	This panel starts with chemiluminescent microparticle immunoassay screen (CLIA). If positive cases are identified, follow up testing will include RPR, and TPPA as needed.	
86780 - CLIA 86592 - RPR 86780 - TPPA	Stability: Refrigerated: 7 days; Frozen: >7 days	\$10*
00700 - 11 T A	Normal Value: Nonreactive	
	Turn Around Time: 1 day *\$16 charge when reflex testing is needed for reactive cases	

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

TEST	EXPLANATION	COST
<i>Treponema</i> <i>pallidum</i> Particle Agglutination CPT CODE: 86780	Acceptable Specimen: 2 ml serum Stability: Ambient: 3 days; Refrigerated: 5 days; Frozen: >5 days Normal Value: Nonreactive Turn Around Time: 1 day	\$10
Trioplex (Dengue, Chikungunya and Zika) PCR CPT CODE: 87801	Acceptable Specimen: 1.5 mL serum, 1.0 mL urine, CSF and amniotic fluid *Must meet CDC requirements for testing. https://www.cdc.gov/zika/hc-providers/testing-guidance.html Stability: Ambient: 8 hours; Refrigerated: 2 days; Frozen: >2 days Normal Value: Zika Negative Chikungunya Negative Dengue Negative Turn Around Time: 7 days	No Charge
Varicella zoster Virus Antibody, IgM IFA CPT CODE: 86787	Acceptable Specimen: 2 ml acute phase serum Stability: Ambient: 1 day; Refrigerated: 7 days; Frozen: >7 days Normal Value: < 1:8 Turn Around Time: 1 day	\$32

Clinical Laboratory Testing and Fee Schedule Analytical Days: Monday through Friday unless otherwise indicated.

TEST	EXPLANATION	COST
	Acceptable Specimen: 2 ml serum	
Varicella zoster Virus Antibody, IgG CLIA CPT CODE: 86787	Stability: Refrigerated: 7 days; Frozen: >7 days Normal Value: Positive Turn Around Time: 1 day	\$32
Varicella zoster/ Herpes Simplex	Acceptable Specimen: Swab, in viral transport medium, from any lesion.	
Virus 1 & 2 HDA CPT CODE:	Stability: Ambient: 2 days; Refrigerated: 7 days; Frozen: 7 days	\$63
Herpes – 87529 Varicella - 87798	Normal Value: Negative	
	Turn Around Time: 1 Day	
Western Equine Encephalitis Ab IFA	Refer to Arboviral Encephalitis Panel	
West Nile Virus Antibody, IgM EIA CPT CODE: 86788	Acceptable Specimen: 2 ml late acute phase serum Stability: Ambient: 8 hours; Refrigerated: 2 days; Frozen: >2 days	\$63
	Normal Value: Negative	
	Turn Around Time: 3 days	
FOR THE MOST ACCUF	SPECIFIC TESTS NOT IN THIS LISTING MAY BE AVAILABLE. CONSULT LABORATORY SERVICES AT 701.328.6272. RATE CPT CODE ASSIGNMENT, PLEASE REFER TO THE 2024 CURRENT PRO TERMINOLOGY MANUAL.	DCEDURAL

Mandatory Reportable Conditions

NORTH Mandatory Reportable Infectious Conditions			
	Report a	Il other conditions within one business day	
Be Legendary.™			
Acute Flaccid Myelitis	Hepatitis C*	Rabies	
Anaplasmosis	Hepatitis D	• Animal	
Anthrax 🗞 🐨	Hepatitis E	• Human 🗇	
Arboviral infection (other)	HIV/AIDS infection**	Rocky Mountain spotted fever	
Babesiosis	Influenza	Rubella 🗇	
Botulism 🕸 🕏	Pediatric deaths	Salmonellosis 🗞	
Brucellosis 🕸 🤡	Seasonal	Scabies outbreaks in institutions	
Campylobacteriosis	Suspect novel, PCR influenza A	Shigellosis 🗞	
Candida auris 🗇	unsubtypable 🗇	Smallpox 🕸	
Carbapenem-resistant organisms	Jamestown Canyon virus disease	Staphylococcus aureus	
• Enterobacteriaceae 🗇	Laboratory incidents with possible	Vancomycin-resistant and	
• Pseudomonas aeruginosa 🗞	release of category A agents or	intermediate resistant (VRSA and	
Chickenpox (varicella)	novel influenza virus 🐨	VISA) – any site 🗇	
Chikungunya virus disease	La Crosse encephalitis	Staphylococcus enterotoxin B	
Chlamydial infection	Legionellosis	intoxication 🕸 🐨	
Cholera 🗇	Leptospirosis	St. Louis encephalitis	
Cluster of severe or unexplained	Listeriosis 🗇	Streptococcus pneumoniae infection	
illnesses and deaths	Lyme disease	(invasive) 🗇	
Coccidioidomycosis	Malaria 🗇	Syphilis	
Creutzfeldt-Jakob disease	Measles (rubeola) 🗇	Tetanus	
Cryptosporidiosis	Melioidosis 🕸 🕏	Tickborne disease (other)	
Cyclosporiasis	Meningococcal disease (invasive) 🗞	Trichinosis	
Dengue	Mumps 🗇	Tuberculosis***	
Diphtheria 🗞	Nipah virus infections 🕸 🕏	• Disease 🗇	
Eastern equine encephalitis 🕏	Nosocomial outbreaks	Infection	
E. coli (Shiga toxin-producing) 🗇	Novel severe acute respiratory	Tularemia 🕸 🐨	
Ehrlichiosis	illness 🗞 🕏	Typhoid fever 🗞	
Foodborne/waterborne outbreaks	Pertussis	Unexplained or emerging critical	
Giardiasis	Plague 🛷	illness/death	
Glanders 🗞 🕏	Poliomyelitis 🗞	Vibriosis 🕸	
Gonorrhea	Powassan virus disease	Viral hemorrhagic fevers 🕸 🐨	
Haemonhilus influenzae (invasive)	Pregnancy in person infected with:	Weapons of Mass Destruction	
Hantavirus 🗞	• Hepatitis B	suspected event 🐨	
Hemolytic uremic syndrome	• HIV	Western equine encephalitis	
Henatitis A 🗞	Q fever �♥	West Nile virus	
Henatitis B		Yellow fever 🗇	
rieputtis b		Zika virus	

Send isolate or sample to North Dakota Department of Health Division of Microbiology.

This is a Select Agent when confirmed. Notify the Division of Microbiology at 701-328-6272. Report any possible lab exposures.

*Hepatitis C: All positive/reactive test results, hepatitis C genotypes, all hepatitis C nucleic acid test results (including nondetectable)

**HIV/AIDS: Any positive/reactive test results, gene sequencing and drug resistance patterns, all HIV nucleic acid test results (including nondetectable), all CD4 test results

***TB: All positive PPD & IGRA results. All results for AFB Smears, cultures and rapid methodologies performed when M. tuberculosis complex is suspected.

How to Report: • Secure website: <u>www.ndhealth.gov/disease/reportcard/</u> • Telephone: 701-328-2378 or 800-472-2180 • Secure Fax: 701-328-0355 • Electronic laboratory reporting: <u>www.ndhealth.gov/disease/ELR/</u>

North Dakota Administrative Code 33-06-01, North Dakota Century Code 23-07-01



Other Mandatory Reportable Conditions

If highlighted red, report immediately: 701-328-2372 Report all other conditions within seven days

- Autism*
- Cancer+
- Cluster of severe or unexplained illnesses or deaths
- Critical congenital heart disease (CCHD)
- Fetal alcohol syndrome (FAS)
- Lead level results (all)
- Neonatal abstinence syndrome (NAS)
- Overdoses
- Suicide and suicide attempts
- Tumors of the central nervous system+
- Violent deaths^
- Visible congenital deformity

^ Homicides, legal intervention, unintentional fire-arm related injury death, deaths of unknown intent and terrorism.

How to Report:

- + Submit report to the North Dakota Cancer Registry. Call 800-280-5512 for assistance.
- * Autism report form: <u>www.nd.gov/eforms/Doc/sfn60804.pdf</u>
- Telephone: 701-328-2372
- Secure Fax: 701-328-2785
- Secure website: www.ndhealth.gov/disease/reportcard/
- Electronic reporting may be available. Email <u>dohstateepi@nd.gov</u> for more information.

North Dakota Administrative Code 33-06-01, North Dakota Century Code 23-07-01 North Dakota Century Code 23-01-41 (Autism)

North Dakota Century Code 23-41-04 and 23-41-05 (Visible congenital deformity)

North Dakota Department of Health and Human Services Mandatory Reportable Condition Testing

Refer to North Dakota Administrative Code 33-06-01 (Statutory Authority NDCC 23-07-01) for a complete list of mandatory reportable conditions.

There is No Charge for Mandatory Reportable Condition testing.

Stability: Ambient: 7 days; Refrigerated: 7 days; Frozen: Unacceptable

Test	Source/Collection	Comments
Candida auris or Candida haemulonii	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	A report with the organism identification will be issued to the submitting facility.
Carbapenem Resistant Organism Confirmation	 Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted. *Please submit antimicrobial susceptibility results from instrument printout. 	A report containing test results to support infection prevention measures will be issued to the submitting facility.
<i>Corynebacterium diphtheriae</i> Confirmation	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	A report with the organism identification will be issued to the submitting facility.
<i>Escherichia coli</i> O157 Serotyping	 Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted. *Facilities using molecular methods without conventional culture may send original stool sample. *Cultures of verotoxigenic <i>E. coli</i> need to be shipped as a Category A specimen. 	A report with serotyping results will be issued to the submitting facility.
<i>Haemophilus influenzae</i> Serotyping	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	The isolate will be forwarded to Minnesota Public Health Laboratory for testing. A report with serotyping results will be issued to the submitting facility.
Malaria Confirmation	Acceptable Specimen: Whole blood sample in EDTA prior to treatment plus thick and thin blood films made from fresh blood or EDTA (if prepared within one hour) if available.	The sample will be forwarded to CDC for species confirmation and evaluation of emerging drug resistance.
	Stability: Ambient:7 days; Refrigerated:Unacceptable; Frozen:Unacceptable	A report will be issued to the submitting facility.
<i>Neisseria meningitidis</i> Serogrouping	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	The isolate will be forwarded to Minnesota Public Health Laboratory for testing. A report with serotyping results will be issued to the submitting facility.

<i>Salmonella</i> Serotyping	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted. *Facilities using molecular methods without conventional culture may send original stool sample.	A report indicating if the isolate is a Salmonella species will be issued to the submitting facility. * Serotypes will no longer be reported back to the submitting facility.
Shigella Serotyping	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted. *Facilities using molecular methods without conventional culture may send original stool sample.	A report with serotyping results will be issued to the submitting facility.
Shiga toxin-producing <i>Escherichia coli</i> confirmation	Acceptable Specimen: Shiga toxin positive specimen in appropriate transport media (MacConkey broth, GN broth, etc.) *Facilities using molecular methods without conventional culture may send original stool sample. *Cultures of verotoxigenic <i>E. coli</i> need to be shipped as a Category A specimen.	A report indicating if Shiga toxin- producing <i>Escherichia coli</i> was isolated will be issued to the submitting facility.
<i>Streptococcus pneumoniae</i> Isolate Submission	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	Our laboratory participates in a project for the Antimicrobial Resistance Laboratory Network (ARLN). Isolate will be forwarded to the Minnesota Public Health Laboratory for serotyping and susceptibility testing. *A report with serotyping results is available upon request.
Vancomycin- Resistant/Intermediate <i>Staphylococcus aureus</i> Confirmation	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	A report with susceptibility to vancomycin will be issued to the submitting facility.
Vibrio Confirmation	Acceptable Specimen: Pure isolate in appropriate tubed medium or Amies (with charcoal) transport medium. Plates not accepted.	A report with the organism identification will be issued to the submitting facility.

Bioterrorism Agent Testing

North Dakota Department of Health and Human Services Bioterrorism Agent Testing

Notify Laboratory Services and Disease Control if Bioterrorism is suspected.

Notify Laboratory Services for referral instructions if your laboratory is unable to rule out BT agents.

Please refer to <u>www.asm.org</u> for the most current sentinel site laboratory rule out procedures.

After normal work hours, contact the on-call microbiologist directly at 701.319.8569, or if Bioterrorism is suspected call State Radio at 1.800.472.2121 to speak to the case manager.

There is No Charge for Bioterrorism Agent Testing.

<i>Bacillus anthracis</i> (Anthrax) Confirmation PCR/Culture	 Acceptable Specimen: Isolate in appropriate tubed transport medium or a piece of agar with growth in a sterile container. Plates are not accepted. Cutaneous collect in vesicular fluid with sterile swab or collect from beneath the eschar. Gastrointestinal collect blood, stool, or rectal swabs. Inhalational collect blood. Transport: Cutaneous, gastrointestinal and inhalational at room temperature.
	Turn Around Time: 1 to 2 days
Brucellosis Confirmation PCR/Culture	Acceptable Specimen: Isolate in appropriate tubed transport medium or a piece of agar with growth in a sterile container. Plates are not accepted. For primary isolation and PCR, collect blood or bone marrow Transport: Room temperature Turn Around Time: 7 days
Burkholderia mallei (Glanders) or Burkholderia pseudomallei (Melioidosis) PCR/Culture	 Acceptable Specimen: Isolate in appropriate tubed transport medium or a piece of agar with growth in a sterile container. Plates are not accepted. Transport: Blood, bone marrow, sputum, abscess and wound swabs, urine transport blood room temp; all others transport at 2 to 8 °C.
	Turn Around Time: 1 to 2 days
<i>Clostridium botulinum</i> toxin DIG ELISA/ PCR/Mouse Bioassay	Acceptable Specimen: Contact Laboratory Services for specific recommendation regarding collection and transportation. All testing will be performed by the Minnesota Department of Health and/or the Centers for Disease Control and Prevention.

Test	Source/Collection	
<i>Francisella tularensis</i> (Tularemia) Confirmation PCR/Culture	 Acceptable Specimen: Isolate in appropriate tubed transport medium or a piece of agar with growth in a sterile container. Plates are not accepted. For primary isolation and PCR collect blood, biopsied tissue or ulcer scraping. Transport: Blood at room temperature Tissue and ulcer samples at 2 to 8°C Turn Around Time: 2 to 4 days 	
Ricin Toxin TRF	Acceptable Specimen: Liquid, soil, powder, wipes, swabs, paper, plant material and food samples Turn Around Time: 1 day	
Smallpox/ Vaccinia PCR (Orthopox Panel)	 Acceptable Specimen: Contact Laboratory Services for specific recommendation regarding collection and transportation. Call the North Dakota Department of Health and Human Services if you suspect smallpox, an adverse reaction to smallpox vaccination or require consultation on an unusual or pustular rash illness. Confirmation for Smallpox will be performed by the Minnesota Department of Health and/or the Centers for Disease Control and Prevention. The smallpox risk level should be clearly noted on the laboratory requisition form accompanying any specimen labeled as "vesicle," "blister," "rash," or otherwise suggestive of acute/generalized vesicular or pustular rash illness. Turn Around Time: Preliminary PCR results within 1 day for vaccinia, VZV and non variola panel 	
<i>Yersinia pestis</i> (Plague) Confirmation PCR/Culture	 Acceptable Specimen: Isolate in appropriate tubed transport medium or a piece of agar with growth in a sterile container. Plates are not accepted. For primary isolation and PCR, collect blood, tissue aspirate or biopsied tissue. Transport: Blood at room temperature; Tissue samples at 2 to 8°C Turn Around Time: 3 to 5 days 	

Specimen Collection and Handling

North Dakota Department of Health and Human Services Mycobacteria Collection and Handling

Source	Collection <i>Do not use fixatives or preservatives.</i>	Volume	*Container/Transport Use sterile, leak-proof containers. Never mail cultures in petri dishes or
			specimens in urine cups.
Body Fluids	Disinfect site with alcohol if collecting with syringe.	Abdominal 10 - 15ml Pericardial,	Refrigerate at 2 to 8°C
		Synovial 3 - 5ml CSF 2ml	
Blood and	Disinfect site as for routine blood culture.	5 - 10ml	SPS (yellow top) is preferred.
Bone			Sodium heparin may be used. No
Marrow			Keen at room temperature
Bronchial	Avoid contaminating bronchoscope with	5 - 7ml	Refrigerate at 2 to 8°C
Wash	tap water.		
Gastric	Collect a fasting early-morning specimen. Use sterile saline. If specimen transport is delayed >4hours from collection, add 100mg sodium	5 - 10ml	Refrigerate at 2 to 8°C
	carbonate or 4% NaOH immediately to neutralize the pH.		
Sputum	Aseptically collect a series of three sputum specimens, 8-24 hours apart, at least one of which is an early morning specimen. Collect the material that is brought up after a deep, productive cough.	5 - 10ml Do not pool specimens	Ship specimens within 24 hours. Do not wait and send consecutively collected specimens together. Refrigerate at 2 to 8°C
	Specimens collected <8 hours apart will be considered the same and only one		
Stool	Collect without contaminating with urine.		Refrigerate at 2 to 8°C
Swab	Not an acceptable specimen. The hydrophobic nature of the mycobacteria cell wall inhibits transfer of the organism from the swab to the aqueous media.		If only specimen available, add sufficient sterile saline to keep moist and send in sterile, leak proof container. Refrigerate at 2-8°C
Tissue	Aseptically collect in sterile container without fixatives or preservatives. Add only enough sterile saline to prevent drying. Do not wrap in gauze or send on swab.	1gram	Refrigerate at 2 to 8°C
Urine	First morning void collected on three consecutive days. Either clean-catch or catheterization. Do not pool specimens or obtain from catheter bag.	40 ml	Refrigerate at 2 to 8°C

QuantiFERON[®]-TB Gold Plus — blood collection

Option 1: Draw blood directly into QFT[®]-Plus Blood Collection Tubes

Blood collection

1. Label QFT-Plus Blood Collection Tubes appropriately.

Important: QFT-Plus Blood Collection Tubes should be at room temperature $(17-25^{\circ}C)$ at the time of blood collection.

- 2. Collect 1 ml of blood by venipuncture directly into each of the QFT-Plus Blood Collection Tubes.
 - 2a. As 1 ml tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling.
 - 2b. The black mark on the side of the tubes indicates the validated range of 0.8 to 1.2 ml. If the level of blood in any tube is outside of the indicator mark, a new blood sample should be obtained.
 - 2c. If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus Blood Collection Tubes being used.

Tube shaking

1. Immediately after filling the tubes, shake them ten (10) times just firmly enough to make sure the entire inner surface of the tube is coated with blood. This will dissolve antigens on tube walls.

Important: Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

Shipping and incubation

- 1. QFT-Plus tubes must be transferred to a $37^{\circ}C \pm 1^{\circ}C$ incubator within 16 hours of collection.
- 2. Option 1 Incubate QFT-Plus Blood Collection Tubes at the blood collection site
 - 2a. If tubes are not incubated immediately after blood collection, remix tubes by inverting 10 times immediately prior to incubation.
 - 2b. Incubate tubes UPRIGHT at $37^{\circ}C \pm 1^{\circ}C$ for 16-24 hours.

Technical tip: Label tubes as "Incubated".

- 2c. After incubation, tubes may be held between 4°C and 27°C for up to 3 days prior to centrifugation at the testing laboratory.
- 3. Option 2 Incubate QFT-Plus Blood Collection Tubes at the testing laboratory
 - 3a. Ship tubes to the testing laboratory at 22°C \pm 5°C.

Technical tip: label tubes as "Not Incubated".











Option 2: Draw blood into a lithium-heparin tube

Blood collection

1. Label lithium-heparin tubes appropriately

Important: Tubes should be at room temperature (17–25°C) at the time of blood collection.

2. Fill a lithium-heparin blood collection tube (minimum volume 5 ml) and gently mix by inverting the tube several times to dissolve the heparin.

Shipping

1. Option **1** – Lithium-Heparin Tube Room Temperature Storage and Handling

1a. Blood collected in a lithium-heparin tube must be maintained at room temperature (22°C ± 5°C) for no more than 12 hours from the time of collection prior to transfer to QFT-Plus Blood Collection Tubes and subsequent incubation.

2. Option 2 - Lithium-Heparin Tube Refrigerated Storage and Handling

- 2a. Prior to refrigeration, blood drawn into a lithium-heparin tube must be held at room temperature (17–25°C) between 15 minutes and 3 hours after collection.
- 2b. Ship the lithium-heparin tube to the testing laboratory at 2–8°C.
- 2c. Blood drawn into lithium-heparin tube may be refrigerated (2–8°C) for 16 to 48 hours prior to transfer to QFT-Plus Blood Collection Tubes at the testing laboratory.

Transfer of blood specimen to QFT-Plus Blood Collection Tubes

 Procedures for transferring blood specimen from lithium-heparin tubes to the QFT-Plus Blood Collection Tubes at the testing site are described in the QuantiFERON-TB Gold Plus – assay quick guide.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

For comprehensive instructions for use, refer to the QFT-Plus ELISA package insert, available in multiple languages, at **www.QuantiFERON.com**.

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Ordering www.qiagen.com/shop | Technical Support support.qiagen.com | Website www.QuantiFERON.com





Be Legendary.

Collection instructions for Mumps virus testing

Preferred specimen: Parotid gland duct swab for mumps test collected within 5 days of onset of symptoms.

Collection of a mumps specimen for viral and PCR testing:

- Massage the parotid (salivary) glands for 30 seconds.
- Swab the buccal cavity, which is the space near the upper rear molars between the cheek and • the teeth. Swab the area between the cheek and gum by sweeping the swab near the upper molar to the lower molar area.

Specimen Preparation: Swabs should be placed in 2 ml of standard viral transport medium. Allow the swab to remain in VTM for at least 1 hour (4°C). Ream the swab around the rim of the tube to retain cells and fluid in the tube. The swab can be broken off and left in the tube or discarded.

Storage and Shipment: Following collection, samples should be maintained at 4°C and shipped on cold packs (4°C) within 24 hours. If there is a delay in shipment, the sample is best preserved by freezing at -70°C. Frozen samples should be shipped on dry ice.



HOLOGIC[®]

Clinician collection procedure guide

Collection for vaginal swab specimens



Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)
- Trichomonas vaginalis (TV)
- Bacterial vaginosis (BV)
- Candida vaginitis (CV)



Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the vial. Discard the top portion of the shaft.

Tightly screw the cap onto the tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for the specimen location.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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Aptima® Multitest Swab Specimen Collection Kit



Patient collection procedure guide

Collection for vaginal swab specimens



Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially peel open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down or dropped, request a new Aptima Multitest Swab Specimen Collection Kit. Hold the swab, placing thumb and forefinger in the middle of the shaft over the black score line.



Carefully insert the swab into the opening of the vagina, about 2 inches (5 cm), and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.





While holding the swab in your hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the swab shaft. The swab will drop to bottom of the vial. Discard the top portion of the shaft.



Tightly screw the cap onto the tube. Return the tube as instructed by your healthcare provider.

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Aptima® Multitest Swab Specimen Collection Kit



Specimen processing guide

Collection for multitest swab specimens



Swab specimen collection guide for:

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)
- Trichomonas vaginalis (TV)
- Bacterial vaginosis (BV)
- Candida vaginitis (CV)
- Herpes simplex virus 1 & 2 (HSV)

After collection, immediately hold the swab in the transport tube so the black score line is at the top of the tube.



Align the score line with the top edge of the tube and carefully break the swab shaft.



The swab will drop to the bottom of the vial. Screw the cap on tightly and send to the lab.



REJECT 🛞



Visually inspect to confirm the swab is broken at the score line.

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Aptima[®] Unisex Swab Specimen Collection Kit

Female collection procedure guide

Collection for endocervical swab specimens



Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa. Discard this swab.

Swab specimen collection guide for:

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)
- Trichomonas vaginalis (TV)



Insert collection swab (blue shaft swab with green printing) into endocervical canal. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa.



While holding swab in hand, unscrew the tube cap. Do not spill tube contents. **If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

- After collection, transport and store swab in the unisex specimen transport tube between 2°C to 30°C until tested for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- Specimens must be assayed within 60 days of collection for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- If longer storage is needed, after collection in the Aptima unisex specimen transport tube freeze between -20°C to -70°C for up to 12 months for Aptima Combo 2® assay, up to 90 days for Aptima® Mycoplasma genitalium assay and up to 24 months for the Aptima® Trichomonas vaginalis assay.



Male collection procedure guide

Collection for male urethral swab specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.

> Discard cleaning swab (white shaft with red print on label). The cleaning swab is

Swab specimen collection guide for:

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)



NOT needed for male specimen collection.

Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling. Withdraw swab carefully.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube. Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

- After collection, transport and store swab in the unisex specimen transport tube between 2°C to 30°C until tested for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- Specimens must be assayed within 60 days of collection for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- · If longer storage is needed, after collection in the Aptima unisex specimen transport tube freeze between -20°C to -70°C for up to 12 months for Aptima Combo 2® assay, up to 90 days for Aptima® Mycoplasma genitalium assay and up to 24 months for the Aptima® Trichomonas vaginalis assay.

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Aptima® Urine Specimen Collection Procedure

Aptima Combo 2° Assay for CT/NG

Aptima[®] Mycoplasma genitalium Assay Aptima[®] Trichomonas vaginalis Assav Aptima[®] Zika Virus Assay



Overfilling or underfilling will require a new sample collection tube to obtain a valid result.

Transfer urine into collection tube.

Fill between black lines only.

ACCEPT

OVERFILLED REJECT



Refer to the geography-specific package insert for specific sample type availability.

* The Aptima Zika Virus assay:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection undersection 564(b)(1) of the Act, 21 U.S.C.§ 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Aptima® Urine Collection Kit Collection procedure guide



Collection for male and female urine specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.



Direct patient to provide **first-catch** urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.



Remove cap from urine specimen transport tube and transfer 2 mL of urine into 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 fill lines on urine specimen transport tube label.

collection guide for:

Urine specimen

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Mycoplasma genitalium (MG)
- Trichomonas vaginalis (TV) for female only
- Zika virus (Zika) (collect alongside a blood sample)

Confirm with your laboratory if these samples types are acceptable.



Re-cap urine specimen transport tube tightly. This is now known as the "processed urine specimen."

Specimen transport and storage

- Urine samples still in primary collection container must be transported to the lab between 2°C to 30°C. Transfer urine sample into Aptima urine specimen transport tube within 24 hours of collection for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay or Aptima[®] Trichomonas vaginalis assay and within 72 hours for Aptima® Zika virus assay.
- Transport and store processed urine specimens in the Aptima urine specimen transport tube between 2°C to 30°C until tested.
- Processed urine specimens should be assayed for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay, Aptima® Trichomonas vaginalis assay and Aptima® Zika virus assay within 30 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C. Consult package inserts for allowable duration.

The Aptima Zika Virus assay:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories; This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/ or diagnosis of Zika virus infection undersection 564(b)(1) of the Act, 21 U.S.C.§ 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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