October 2026

South Dakota Public Health Laboratory

Medical Microbiology Service Manual

615 East 4th Street
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http://doh.sd.gov/lab/

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1. Mission Statement

The mission of the South Dakota Public Health Laboratory (SDPHL) is to provide assistance to public and private health care providers in their investigation and control of disease. This mission can be best accomplished by the accurate analysis of clinical and reference specimens submitted by the community health departments, hospitals, clinical laboratories, physicians, veterinarians, animal control officers, and law enforcement.

2. Services Provided

The Medical Laboratory offers a listing of services we provide to our clients in the areas of Bacteriology, Serology, Mycobacteriology, Molecular Diagnostics, Blood Lead, Virology and Special Pathogens.

In addition to providing this manual, the SDPHL supports several statewide investigations. When deemed necessary, both environmental and non-human specimens are tested to help investigate outbreaks of diseases. The SDPHL also assists the Centers for Disease Control and Prevention (CDC) by participating in surveillance studies and by providing them with the results of our laboratory findings for several communicable diseases.

The SDPHL provides specimen collection kits and approved mailers by using the on-line order form. For unusual test requests, please contact the SDPHL to ensure proper sample submission.

3. Contact Information

A. Lab Director

Dr. Leo Chugunov
Telephone: 605-280-9501
Fax: 605-773-8201
Email: Leo.Chugunov@state.sd.us

B. Medical Section Phone Numbers

1. Main Laboratory…… 605-773-3368
2. Microbiology…… 605-773-5573
3. Mycobacteriology/TB…… 605-773-4971
4. Serology…… 605-773-4969
   605-773-3593
5. Virology/Antimicrobial Resistance/CRE/CRPA... 605-773-6769
6. WGS…… 605-773-4238
7. Mailroom…… 605-773-3183
8. Special Pathogens…… 605-773-4971

C. Rabies: Questions regarding rabies exposure

1. Disease Prevention…… 605-773-3737
   800-592-1861

4. Hours of Operation

Official Business Hours:
Monday through Friday 8:00 A.M. to 5:00 P.M. Central Time (CT)

After Hour Emergencies:
Disease Prevention: 800-592-1861

5. Specimen Delivery

a. United States Postal Service: Monday – Friday
b. UPS: Monday – Friday
c. Courier Service: Monday – Saturday (specimens arriving on weekends are refrigerated).
d. Delivery in person: Monday – Friday, 7:00 A.M. – 5:00 P.M. Specimens should be delivered to the "Shipping/Receiving Room" adjacent to the loading dock.

6. Guidelines for Specimen Submission

Care must be taken to ensure a proper transport environment. Collect recommended quantities of test specimen and label the specimen with two unique identifiers. Complete a SDPHL requisition for each specimen type and submit it along with the specimen. All specimens require a completed SDPHL requisition accompany them before testing can be completed.

7. Specimen Rejection Policy

In order to produce quality test results; only those specimens which are obtained from an appropriate source, are properly handled, and are completely and clearly labeled will be tested. Unacceptable specimens will be rejected with documentation to the provider. Examples of specimen rejection reasons include:

- Specimen not labeled
- Name on slip and collection device do not match
- Specimen collected from inappropriate source for testing requested
- Specimen leaked/broken in transit
- Insufficient quantity or quality
- Specimen is too old for testing
- Specimen collected with an expired/outdated collection kit
- Specimen collected with incorrect/inappropriate collection kit or device
- Specimen too hemolyzed for testing
- Specimen did not arrive under proper temperature storage conditions.

8. Ordering Supplies

The laboratory provides specimen collection and approved shipping supplies.
Please call 605-773-3183 for supplies. Order Medical Testing Supplies

https://doh.sd.gov/lab/resources/

9. Packaging and Shipping

- See Packaging and Shipping Diagnostic Specimens and Infectious Substances (Etiologic Agents) Supplemental Information
- http://www.iata.org/publications/dgr/Pages/index.aspx

10. Reportable Disease List

- http://doh.sd.gov/diseases/infectious/reporting.aspx

B. A to Z test Listing

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A

Acid Fast Bacilli (AFB) – See Mycobacterium
Adenovirus PCR
Adenovirus F 40/41 PCR
Aerobic bacterial identification
AIDS – See Human Immunodeficiency Virus
Anaerobic bacterial identification
Anthrax – See Bacillus anthracis
Astrovirus PCR

B

Bacillus anthracis
Blood lead
Bordetella FilmArray PCR
Bordetella RT PCR
Borrelia Burgdorferi - See Lyme Disease
Botulism – See Clostridium botulinum
Brucella culture
Bubonic plague – See Yersinia pestis
Burkholderia mallei
Burkholderia pseudomallei

C

Calicivirus – See Norovirus
Campylobacter culture
Campylobacter PCR
Carba-R (Carbapenemase PCR)
Carbapenem-Resistant Enterobacterales (CRE) testing
Chicken Pox- See Varicella Zoster
Chlamydia by Amplified RNA Assay
Chlamydia pneumoniae PCR
Cholera - See Vibrio
Clostridium difficile
Clostridium botulinum
Clostridium perfringens
Corynebacterium diphtheria

Coronavirus PCR
COVID-19 – See SARS COV2
Coxiella burnetii (Q fever)
Cryptosporidium PCR
Cyclospora PCR

D
Diphtheria culture – See Corynebacterium diphtheria

E
Ebola virus
E.coli O157:H7 – See Escherichia coli O157:H7
Entamoeba histolytica PCR
Enteric Stool culture
Enteroaggregative E.coli (EAEC)
Enteropathoginice E.coli (EPEC)
Enterotoxigenic E.coli (ETEC)
Enterovirus/Human Rhinovirus PCR
Escherichia coli O157 PCR
Escherichia coli O157:H7 confirmation
Escherichia coli O157:H7 culture – See Enteric Stool Culture
Escherichia coli non-O157 – See Shigatoxin

F
FilmArray Gastrointestinal Panel
FilmArray Respiratory Panel
Foodborne Illness Outbreak
Francisella tularensis Culture
Francisella tularensis serology

G
Gastroenteritis; Viral - See Norovirus
Giardia lamblia PCR
German Measles – See Rubella
Glanders – See Burkholderia mallei
Gonorrhoeae by Amplified RNA Assay – See Neisseria gonorrhoeae by Amplified RNA Assay
Gonorrhoeae culture – See Neisseria gonorrhoeae culture

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H

Haemophilus influenzae type B
Hantavirus Serology
Hepatitis A Total Antibody IgG/IgM
Hepatitis A Antibody IgM
Hepatitis Acute/Diagnostic Panel
Hepatitis B Acute Panel
Hepatitis B Chronic Panel
Hepatitis B Core Antibody IgM
Hepatitis B Core Antibody Total
Hepatitis B Surface Antibody
Hepatitis B Surface Antigen
Hepatitis C Antibody
Hepatitis C RNA Quantitative
Herpes HSV 1 / 2 PCR
HIV – See Human Immunodeficiency Virus
Human Immunodeficiency Virus
Human Metapneumovirus PCR
Human Rhinovirus/Enterovirus

IJK

Influenza RT-PCR
Influenza A PCR
Influenza B PCR
Interferon Gamma Release Assay (IGRA)
Intestinal Parasites- See FilmArray Gastrointestinal Panel

L

Legionella Culture
Listeria monocytogenes
Lyme Total Antibody
Lyme IgG Antibody
Lyme IgM Antibody

M

Measles, German - see Rubella
Measles PCR
Measles, Rubeola- See Rubeola IgG Serology
Melioidosis – See Burkholderia pseudomallei
Meningitis, Bacterial- See Haemophilus influenza or Neisseria meningitidis
MERS – Middle East Respiratory Syndrome

Miscellaneous Bacterial Culture
Modified Hodge Test – See Carbapenemase-Resistant Enterobacterales (CRE)
Mumps IgG Serology
Mumps PCR
Mycobacterium Culture (Tuberculosis)
Mycobacterium Reference culture
Mycoplasma pneumoniae PCR

N
Neisseria gonorrhoeae by Amplified RNA Assay
Neisseria gonorrhoeae culture
Neisseria meningitidis
Neisseria species
Norovirus PCR

O
Ova and Parasitology Exam no longer performed
Orthopoxviruses

P
Parainfluenza PCR
Pertussis PCR – See Bordetella PCR
Plague – See Yersinia pestis
Plesiomonas shigelloides PCR

Q
Q Fever
QuantiFERON-TB Gold – See Interferon Gamma Release Assay

R
Rabbit Fever- See Francisella tularemia culture
Rabies DFA- no longer done at this lab. See SDSU.
Rabies Serum Titer- Human
Rapid Plasma Reagin (RPR)
Reportable Disease Reporting
Respiratory Syncytial Virus PCR
Ricin Toxin
Rickettsia Serology Panel (Q fever, RMSF and Typhus)
Rocky Mountain Spotted Fever Serology
Rotavirus A
RSV PCR

Rubella IgG Serology (German measles)
Rubeola IgG Serology

S

Salmonella Culture
Salmonella PCR
Salmonella
Sapovirus PCR
SARS COV2 PCR
Shiga toxin-producing E.coli EIA
Shiga-like toxin-producing E.coli (STEC) stx1/stx2 PCR
Shigella Culture
Shigella Serotyping
Shigella/Enteroinvasive E. coli (EIEC) PCR
Shingles – See Varicella Zoster
Smallpox – See Variola Virus
Staphylococcus aureus, Methicillin Resistant (MRSA)- See Aerobic Bacterial Identification
STEC- See Shigatoxin EIA or Shiga-like toxin PCR
Syphilis – See RPR or TPA

T

TB – See Mycobacterium
Tick Borne Diseases - See Rickettsia Serology Panel, RMSF, or Lyme
TPA - Syphilis
Tuberculosis – See Mycobacterium
Tuberculosis screen – See Interferon Gamma Release Assay
Tularemia Culture- See Francisella tularensis culture
Tularemia Serology- See Francisella tularensis serology
Typhoid Fever – See Salmonella

U

Undulant fever – See Brucella

V

Varicella Zoster PCR
Variola Virus (Smallpox)- See Orthopoxviruses
Vibrio Culture
Vibrio Confirmation
Vibrio PCR
Viral Gastroenteritis - See Norovirus

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Viral Serology – See Infectious Disease Serology Supplemental Information

W

West Nile Virus Serology IgM

Whooping cough- See Bordetella

XYZ

Yersinia Culture

Yersinia Confirmation

Yersinia enterocolitica

Yersinia pestis

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Reference Section for Disease Organisms/Test

Test:	**Aerobic Bacterial Identification**
Code:	BMD
Method:	Culture
Specimen:	Pure isolate
Turnaround:	2-14 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	**Anaerobic Bacterial Identification**
Code:	BMD
Method:	Culture
Specimen:	Pure isolate
Turnaround:	2-14 days
Transport:	Ship at 2-25° C in anaerobic environment
Shipping:	Ship as Category B
Additional:	See Anaerobic Bacteriology Supplemental Information

Test:	**Bacillus anthracis**
Code:	BMD
Method:	Culture, biochemical and Laboratory Response Network protocols.
Specimen:	Pure culture, lesion, blood, and respiratory
Turnaround:	2-3 days
Transport:	Ship at 2-28° C
Shipping:	Ship as Suspect Category A, **Notify SDPHL before sending 605-773-3368**
Additional:	See Aerobic Bacteriology Supplemental Information

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Test:	Blood Lead
Code:	BLT
Method:	Atomic Absorption Spectrometry
Specimen:	EDTA whole blood, capillary or venous
Turnaround:	1-5 Business Days
Transport:	Ship at 2-8° C. If drawn on Friday, specimen should be refrigerated until Monday to send.
Shipping:	Ship as Category B
Additional:	See Blood Lead Supplemental Information

Test:	Bordetella pertussis, parapertussis, and holmseii by PCR
Code:	PPR
Method:	PCR
Specimen:	Dry transport sterile NP Flocked Swab, Nasopharyngeal swab in Viral Transport Media (VTM) or Nasopharyngeal aspirate.
Turnaround:	1-3 Business Days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	See Bordetella pertussis Supplemental Information

Test:	Brucella Culture
Code:	BMD
Method:	Culture and Laboratory Response Network protocols
Specimen:	Pure culture on chocolate agar slant
Turnaround:	Within 7 business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Suspect Category A. **Notify Bioterrorism section before shipping. 605-773-3368**
Additional:	See Aerobic Bacteriology Supplemental Information

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Test:	Burkholderia mallei
Code:	BMD
Method:	Culture and Laboratory Response Network protocols
Specimen:	Pure Culture
Pre-Approval:	Contact Office of Disease Prevention before sending. 605-773-3737
Turnaround:	Within 7 business days
Transport:	Ship at 2-28° C
Shipping:	Ship as Suspect Category A. **Notify Bioterrorism Section before shipping. 605-773-3368**
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Burkholderia pseudomallei
Code:	BMD
Method:	Culture and Laboratory Response Network protocols
Specimen:	Pure Culture
Turnaround:	Within 7 business days
Transport:	Ship at 2-28° C
Shipping:	Ship as Suspect Category A. **Notify Bioterrorism section before shipping. 605-773-3368**
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Campylobacter Culture
Code:	CAM
Method:	Culture
Specimen:	Pure Culture or stool in Cary-Blair
Turnaround:	1-5 business days
Transport:	Ship at 2-25° C, ship in microaerophilic environment
Shipping:	Ship as Category B
Additional:	See Campylobacter Supplemental Information

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Test:	Carbapenemase Detection in Enterobacterales
Code:	mCIM
Method:	mCIM
Specimen:	Pure culture of CRE
Turnaround:	3-5 business days
Transport:	Ship at 2-28°C
Shipping:	Ship as Category B
Additional:	https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/testing-services.html

Test:	Carbapenemase Detection in Pseudomonas aeruginosa
Code:	mCIM
Method:	mCIM
Specimen:	Pure culture of CRPA
Turnaround:	3-5 business days
Transport:	2-25° C
Shipping:	Ship as Category B
Additional:	https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/testing-services.html

Test:	Carbapenemase Detection in Acinetobacter baumannii
Code:	CRAB
Method:	PCR
Specimen:	Pure culture of CRS/CRPA
Turnaround:	3-5 business days
Transport:	2-25° C
Shipping:	Ship as Category B
Additional:	https://www.cdc.gov/antimicrobial-resistance-laboratory-networks/php/about/testing-services.html

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Test:	Carba-R (Carbapenemase PCR)
Code:	Carba-R
Method:	PCR
Specimen:	Rectal swab or pure culture of CRE/CRPA
Turnaround:	1-3 business days
Transport:	Ship at 2-28° C
Shipping:	Ship as Category B
Additional:	https://www.cdc.gov/hai/organisms/cre/ See Carba-R Supplemental Information

Test:	Chlamydia
Code:	GPB
Method:	Amplified RNA
Specimen:	Endocervical, male urethral, urine, throat, rectal, vaginal, liquid pap solution
Turnaround:	1-2 business days
Transport:	Ship at 2-8° C. Vaginal, cervical, liquid Pap solution, throat, rectal, or male urethral swabs must be submitted in Hologic Aptima2 collection kit. Urines must be transferred into Hologic specimen transport tubes within 24 hours of collection.
Shipping:	Ship as Category B
Additional:	See Gonorrhea and Chlamydia Gen-Probe Supplemental Information

Test:	Clostridium botulinum
Code:	BMD
Method:	Culture and Laboratory Response Network protocols
Specimen:	Serum, stool, food, wound or culture.
Turnaround:	2-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Botulism Supplemental Information

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Test:	Clostridium perfringens
Code:	BMD
Method:	Culture
Specimen:	Pure culture or stool preserved in Cary-Blair
Turnaround:	2-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Foodborne Illness Supplemental Information

Test:	Corynebacterium diphtheria
Code:	BSD
Method:	Culture
Specimen:	Throat, lesion or membrane swab. Pure isolate.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C. Send dry swab in a sterile container or red top blood tube at room temperature
Shipping:	Ship as Category B
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Coxiella burnetii (Q Fever)
Code:	VQS
Method:	IFA Quantitative Serology
Specimen:	Acute and Convalescent Serum
Turnaround:	As needed
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Infectious Disease Serology Supplemental Information

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Test:	Ebola Virus
Code:	
Method:	rRT-PCR
Specimen:	Two EDTA blood collection tubes. (purple or lavender top)
Turnaround:	As needed
Transport:	Notify Bioterrorism Section before sending. 605-773-3368
Shipping:	Ship as Suspect Category A
Additional:	

Test:	Enteric Stool Culture
Code:	BEP
Method:	Culture for Salmonella, Shigella, E.coli O157:H7 and Campylobacter
Specimen:	Preserved Stool in Cary-Blair
Turnaround:	3-5 Business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Enteric Bacteriology Supplemental Information

Test:	Escherichia coli O157:H7
Code:	BEE
Method:	Culture
Specimen:	Pure culture of sorbitol negative colonies of E.coli
Turnaround:	2-5 Business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Enteric Bacteriology Supplemental Information

Test:	FilmArray Gastrointestinal Panel
Code:	GIP
Method:	Multiplexed Nucleic Acid
Specimen:	Stool in Cary Blair
Turnaround:	1-2 Business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See FilmArray Gastrointestinal Supplemental Information

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Test:	FilmArray Respiratory Panel
Code:	RPP
Method:	Multiplexed Nucleic Acid
Specimen:	Nasopharyngeal Swab or aspirate in Viral Transport Media
Turnaround:	1-2 Business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	See FilmArray Respiratory Supplemental Information

Test:	Foodborne Illness Outbreak
Shipping:	Contact Disease Prevention before sending. 605-773-3368
Additional:	See Foodborne Illness Supplemental Information

Test:	Francisella tularensis Culture
Code:	BMD
Method:	Culture, biochemical and Laboratory Response Network protocols
Specimen:	Blood, Sputum, Lymph Node, Nasopharyngeal Wash, Gastric Aspirate, and Pure Culture
Turnaround:	3-7 Business Days
Transport:	Ship at 2-25° C
Shipping:	Ship as Suspect Category A. **Notify Bioterrorism Section before sending 605-773-3368**
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Francisella tularensis Serology
Code:	STU
Method:	Direct Agglutination, positive will reflex to Tube Titer
Specimen:	Acute and Convalescent Sera
Turnaround:	1-4 business days
Transport:	Ship at <-15° C.
Shipping:	Ship as Category B
Additional:	See Infectious Disease Serology Supplemental Information

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Test:	Haemophilus influenzae Type B
Code:	HFLU
Method:	Serotyping
Specimen:	Pure culture from a sterile site
Turnaround:	Results available same day
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

Test:	Hantavirus serology (Sin Nombre)
Code:	HPS
Method:	Enzyme Immunoassay IgG and IgM
Specimen:	Acute Serum (Convalescent serum collected upon request)
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C
Shipping:	**Contact laboratory before sending 605-773-3368**
Additional:	See Infectious Disease Serology Supplemental Information

Test:	Hepatitis A Total Antibody (HAV IgG/IgM)
Code:	HAV
Method:	Chemiluminescence immunoassay
Specimen:	300 µL Serum or Sodium Heparin plasma separated from red cells/clot within 2 hours of collection.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C. Samples received on the clot will be rejected.
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

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Test:	**Hepatitis A Antibody IgM (HAV IgM)**
Code:	HAM
Method:	Chemiluminescence immunoassay
Specimen:	200 µL of Serum or Plasma separated from the clot/red cells within 2 hours of collection.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C. Samples received on the clot will be rejected.
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	**Hepatitis Acute Panel (HAV IgM, HBc IgM, HBsAg, HCV)**
Code:	HAP
Method:	Chemiluminescence immunoassay
Specimen:	1 mL Serum or Plasma
Turnaround:	3-5 business days
Transport:	Ship as 2-8° C for up to 6 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	**Hepatitis B Acute Panel (HBsAb, HBsAg, HBcIgM)**
Code:	HBD
Method:	Chemiluminescence immunoassay
Specimen:	1 mL Serum or Plasma
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 6 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	**Hepatitis B Chronic Panel (HBcAb, HBsAb, HBsAg)**
Code:	HBC
Method:	Chemiluminescence immunoassay
Specimen:	1 mL Serum or Plasma
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 6 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

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Test:	Hepatitis B Core Antibody IgM (HBc IgM)
Code:	VCM
Method:	Chemiluminescence immunoassay
Specimen:	300 µL Serum or Plasma
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	Hepatitis B Core Total Antibody (HBcAb)
Code:	VHC
Method:	Chemiluminescence immunoassay
Specimen:	300 µL of serum, EDTA, sodium heparin, or lithium heparin plasma.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 4 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	Hepatitis B Surface Antibody (HBsAb)
Code:	VHG or VSG (Post Vaccination Screen)
Method:	Chemiluminescence immunoassay
Specimen:	300 µL Serum or Plasma
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Interpretation of Hepatitis Results

Test:	Hepatitis B Surface Antigen (HBsAg)
Code:	VSB
Method:	Chemiluminescence immunoassay
Specimen:	500 µL of serum or plasma. Additional specimen will be required for confirmation if result is reactive.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 6 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See interpretation of Hepatitis Results

Test:	Hepatitis C Virus (HCV)
Code:	HCV
Method:	Chemiluminescence immunoassay
Specimen:	200 µL of serum or plasma. An additional 700 µL is required for confirmatory testing. Separate from red cells within 6 hours of collection.
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C. Specimens received on the clot or red cells will be unacceptable for confirmatory testing.
Shipping:	Ship as Category B
Additional:	Positive results will be confirmed with the HCV RNA Quantitative Assay

Test:	Hepatitis C RNA Quantitative
Code:	HCVQ
Method:	Transcription Mediated Amplification
Specimen:	700 µL of Serum or EDTA plasma, **separated from cells within 6 hours of collection**
Turnaround:	5-7 business days
Transport:	Plasma or serum shipped at 2-8° C for up to 5 days or frozen at <-20°C
Shipping:	Ship as Category B
Additional:	See interpretation of Hepatitis Results

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Test:	Herpes Simplex Virus Serology
Code:	HSV
Method:	PCR
Specimen:	Acute and convalescent serum or CSF
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C in less than 72 hours of collection; or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Direct Swab RT PCR Supplemental Information

Test:	Human Immunodeficiency Virus (HIV)
Code:	HIV
Method:	Chemiluminescence immunoassay - 4th Generation Ag/Ab Combo Assay
Specimen:	350 µL of serum or plasma. Serum/plasma should be removed from the clot, red cells, or gel separator and aliquoted as soon as possible.
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	Positive results will be confirmed with the Geenius HIV-1/HIV-2 Supplemental Assay
	See HIV Supplemental Information or HIV Recommended Algorithm

Test:	Influenza A/B PCR
Code:	IAB
Method:	RTPCR
Specimen:	Throat swab, NP aspirate or swab, nasal wash, nasal swab
Turnaround:	3-5 business days
Transport:	Ship at 2-8° C for up to 72 hours or frozen at <-70° C. Viral transport media preferred.
Shipping:	Ship as Category B
Additional:	

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Test:	Interferon Gamma Release Assay
Code:	QFT
Method:	Chemiluminescence immunoassay
Specimen:	Whole blood collected in manufacturer QFT tubes (Note: special collection instructions)
Turnaround:	1-5 business days
Transport:	If not incubated: 17-27° C Incubated but **not** centrifuged: 4-27° C Incubated **and** centrifuged: 2-8° C
Shipping:	Ship as Category B
Additional:	Document "Not incubated" on the submission form if applicable. See Quantiferon Gold supplemental information

Test:	Legionella Culture
Code:	BMD
Method:	Bacterial Culture/ Immunofluorescence
Specimen:	Sputum, bronchial washings, or lung biopsy.
Turnaround:	As needed.
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B. **Contact before sending at 605-773-3368.**
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Listeria monocytogenes
Code:	BMD
Method:	Bacterial Culture
Specimen:	Pure culture
Turnaround:	1-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

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Test:	Lyme IgG Antibody
Code:	VLG
Method:	Chemiluminescent immunoassay
Specimen:	200 µL of serum, EDTA or lithium heparin plasma. Separate serum/plasma from red cells or clot as soon as possible.
Turnaround:	5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	Only available as a confirmatory test after a positive Lyme Total antibody.

Test:	Lyme IgM Antibody
Code:	VLM
Method:	Chemiluminescent immunoassay
Specimen:	200 µL of serum, EDTA or lithium heparin plasma. Separate serum/plasma from red cells or clot as soon as possible.
Turnaround:	5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	Only available as a confirmatory test after a positive Lyme Total antibody.

Test:	Lyme Total Antibody
Code:	VLG
Method:	Chemiluminescent immunoassay
Specimen:	200 µL of serum, EDTA or lithium heparin plasma. Separate serum/plasma from red cells or clot as soon as possible.
Turnaround:	5 business days
Transport:	Ship at 2-8° C for up to 7 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	Positive results are confirmed with Lyme IgG and Lyme IgM Ab assays.

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Test:	Measles (Rubeola) IgG
Code:	MSG
Method:	Chemiluminescent immunoassay
Specimen:	200 µL serum only, serum should be removed from the clot as soon as possible.
Turnaround:	5 business days
Transport:	Ship at 2-8° C for up to 9 days or frozen at <-20° C.
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

Test:	Measles (Rubeola) PCR
Code:	PCR
Method:	PCR
Specimen:	Throat, NP or nasal swab in VTM
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B. **Notify SDPHL before shipping (605-773-3368).**
Additional:	See Infectious Disease Supplemental Information

Test:	MERS (Middle East Respiratory Syndrome)
Code:	
Method:	RT-PCR
Specimen:	Broncho alveolar lavage, tracheal aspirate, pleural fluid, sputum, nasopharyngeal swab
Turnaround:	As needed
Transport:	Ship on cool pack
Shipping:	Ship as Category B
Additional:	Contact the Bioterrorism Section before sending. 605-773-3368

Test:	Miscellaneous Bacterial Culture
Code:	BMD
Method:	Culture
Specimen:	Pure Culture
Turnaround:	2-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Aerobic Bacteriology Supplemental Information

Test:	Mumps IgG Serology
Code:	VMA
Method:	Chemiluminescent immunoassay
Specimen:	200 µL serum only, serum should be removed from the clot as soon as possible.
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C for up to 9 days or frozen at <-20° C
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

Test:	Mumps PCR
Code:	MPCR
Method:	RT-PCR
Specimen:	Buccal swab in VTM
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	Contact Virology Laboratory before sending 605-773-3368

Test:	Mycobacterium Culture
Code:	TTB
Method:	Microscopy/Culture/DNA Probe/PCR/Maldi-TOF
Specimen:	Sputum, Urine, Gastric Washings, Pleural fluid, tissue, body fluids, blood and bone marrow.
Turnaround:	Smear 1-2 days, Culture 1-6 weeks
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	See Mycobacteriology Supplemental Information

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Test:	Mycobacterium Reference Culture
Code:	TOT
Method:	Microscopy/Culture/DNA Probe/PCR/Maldi-TOF
Specimen:	Pure culture, NP broth, MGIT broth
Turnaround:	1-6 weeks
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Mycobacteriology Supplemental Information

Test:	Neisseria gonorrhea by Amplified RNA Assay
Code:	GPB
Method:	Amplified RNA
Specimen:	Endocervical, male urethral, urine, rectal, throat, vaginal, liquid pap solution
Turnaround:	1-2 business days
Transport:	Ship at 2-8° C. Vaginal, cervical, liquid Pap solution, throat, rectal, or male urethral swabs must be submitted in Hologic Aptima2 collection kit. Urines must be transferred into Hologic specimen transport tubes within 24 hours of collection.
Shipping:	Ship as Category B
Additional:	See Gonorrheae and Chlamydia Gen-Probe Supplemental Information

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Test:	**Neisseria gonorrhea Culture**
Code:	BGR
Method:	Culture
Specimen:	Pure Isolate, urogenital, throat, rectal, or conjunctival swab
Turnaround:	2-3 business days
Transport:	Ship on Thayer Martin or Chocolate Agar with increased CO_2 at 2-25° C.
Shipping:	Ship as Category B
Additional:	See Neisseria Gonorrhoeae Supplemental Information

Test:	**Neisseria meningitidis serotyping**
Code:	NMEN
Method:	Culture
Specimen:	Pure isolate from sterile site for serotyping A,B,C, Y, and W135.
Turnaround:	1-2 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

Test:	**Neisseria species**
Code:	BMD
Method:	Culture
Specimen:	Reference isolate for identification and serotyping as necessary
Turnaround:	1-3 business days
Transport:	Ship on Thayer Martin or Chocolate Agar with increased CO_2 at 2-25° C.
Shipping:	Ship as Category B

Test:	**Orthopoxviruses**
Method:	RT PCR
Specimen:	Dry swab of lesion
Pre-Approval:	**Contact Office of Disease Prevention before sending. 605-773-3737**
Transport:	Ship at 2-8° C
Shipping:	Ship as Suspect Category A
Additional:	**Pre-approval required. Contact Bioterrorism Section before shipping. 605-773-3368**

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Test:	Q Fever (Coxiella burnetii) Phase 1 and 2
Code:	VQS
Method:	IFA
Specimen:	Acute (Convalescent sera upon request)
Turnaround:	1-5 business days
Transport:	Ship on cool pack
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

Test:	QuantiFERON-TB Gold (QFT)
Code:	QFT
Method:	Chemiluminescent immunoassay
Specimen:	Whole blood collected in manufacturer QFT tubes (Note: special collection instructions)
Turnaround:	1-5 business days
Transport:	If not incubated: 17-27° C Incubated but **not** centrifuged: 4-27° C Incubated **and** centrifuged: 2-8° C
Shipping:	Ship as Category B
Additional:	Document "Not incubated" on the submission form if applicable. See Quantiferon Gold supplemental information

Test:	Rabies Serum Titer - Human
Code:	VRT
Method:	Referred out for Rapid Fluorescent Foci Inhibition Test (RFFIT)
Specimen:	Serum
Turnaround:	3-4 weeks
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	Used for checking antibody levels in persons who have been immunized

Test:	Reportable Disease Reporting
Code:	See the Reportable Disease List for South Dakota
Shipping:	Contact the Office of Disease Prevention. 605-773-3737

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Test:	**Ricin Toxin**
Method:	TRF (Time Resolved Fluorescence)
Specimen:	Environmental swab or powder
Transport:	**Contact Bioterrorism Section before sending. 605-773-3368**

Test:	**Rickettsia Serology Panel (Q-fever, RMSF, and Typhus)**
Code:	VRK
Method:	IFA
Specimen:	Acute and Convalescent sera
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C. **Notify SDPHL before shipping (605-773-3368).**
Shipping:	Ship as Category B
Additional:	Detects IgG antibodies. Diagnostic only with paired sera.
	See Infectious Disease Supplemental Information

Test:	**Rocky Mountain Spotted Fever**
Code:	VSF
Method:	IFA
Specimen:	Acute and Convalescent Sera
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C. **Notify SDPHL before shipping (605-773-3368)**.
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

Test:	**RPR (Rapid Plasma Reagin) Treponema pallidum**
Code:	RPR
Method:	Charcoal Agglutination
Specimen:	Serum, positive specimens will be confirmed with the TPA
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C for up to 5 days or <-20° C.
Shipping:	Ship as Category B
Additional:	See Syphilis Serology Supplemental Information

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Test:	**Rubella IgG Serology**
Code:	VRE
Method:	Chemiluminescent immunoassay
Specimen:	200 µL of serum only. Serum should be removed from the clot as soon as possible.
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C for up to 7 days or <-20° C
Shipping:	Ship as Category B
Additional:	Test to establish immunity
See Infectious Disease Supplemental Information	

Test:	**Salmonella Culture**
Code:	SAL
Method:	Culture
Specimen:	Preserved stool in Cary-Blair Transport Medium
Turnaround:	5-7 business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	Para-Pak Enteric Plus Transport media available.
	See Enteric Bacteriology Supplemental Information

Test:	**Salmonella Confirmation**
Code:	SAL
Method:	Culture
Specimen:	Pure isolate
Turnaround:	3-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

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Test:	SARS COV2 PCR
Code:	COV
Method:	RT PCR
Specimen:	Throat swab, NP swab or aspirate, nasal swab or wash, specimens in VTM preferred.
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C for up to 72 hours; or ship at <-70° C.
Shipping:	Ship as Category B
Additional:	See SARS COV2 Supplemental Information

Test:	Shiga Toxin (STEC)
Code:	STX
Method:	EIA
Specimen:	Preserved stool in Cary-Blair Transport Medium or MacConkey Broth
Turnaround:	5-10 business days
Transport:	Ship at 2-25° C
Shipping:	Ship Category B
Additional:	See Shiga Toxin Supplemental Information

Test:	Shigella Culture
Code:	SHIG
Method:	Culture
Specimen:	Preserved stool in Cary-Blair Transport Medium
Turnaround:	4-7 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	Para-Pak Enteric Plus Transport media available.
	See Enteric Bacteriology Supplemental Information

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Test:	Shigella Confirmation and Serotyping
Code:	SHIG
Method:	Culture and Serotyping
Specimen:	Pure isolate
Turnaround:	3-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	See Enteric Bacteriology Supplemental Information

Test:	TPA (Syphilis Confirmation)
Code:	TPA
Method:	Particle Agglutination
Specimen:	Serum
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C for up to 5 days or <-20° C.
Shipping:	Ship as Category B
Additional:	See Syphilis Serology Supplemental Information

Test:	Varicella Zoster IgG Serology
Code:	VNZ
Method:	Chemiluminescent immunoassay
Specimen:	200 µL of serum, EDTA, sodium heparin, or lithium heparin plasma. Serum/plasma should be removed from the clot, red cells, or gel separator and aliquoted as soon as possible.
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C for up to 7 days or <-20° C
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

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Test:	Varicella Zoster PCR
Code:	VZV
Method:	RT PCR
Specimen:	Cutaneous or Mucocutaneous Swabs
Turnaround:	1-3 business days
Transport:	Ship at 2-8° C
Shipping:	Ship as Category B
Additional:	See Direct Swab RT PCR Supplemental Information

Test:	Vibrio Culture
Code:	BVC
Method:	Culture
Specimen:	Preserved stool in Cary-Blair Transport Medium
Turnaround:	5-7 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	Para-Pak Enteric Plus Transport media available
	See Enteric Bacteriology Supplemental Information

Test:	Vibrio Confirmation
Code:	BVC
Method:	Culture
Specimen:	Pure culture
Turnaround:	3-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

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Test:	West Nile Virus IgM
Code:	WNM
Method:	EIA
Specimen:	Acute serum or CSF
Turnaround:	1-5 business days
Transport:	Ship at 2-8° C for up to 7 days or <-20° C.
Shipping:	Ship as Category B
Additional:	See Infectious Disease Supplemental Information

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Test:	Yersinia Culture
Code:	BYC
Method:	Culture
Specimen:	Preserved stool in Cary-Blair Transport Medium
Turnaround:	5-7 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B
Additional:	Para-Pak Enteric Plus Transport media available.
	See Enteric Bacteriology Supplemental Information

Test:	Yersinia Confirmation
Code:	BYC
Method:	Culture
Specimen:	Pure culture
Turnaround:	3-5 business days
Transport:	Ship at 2-25° C
Shipping:	Ship as Category B

Test:	Yersinia pestis
Code:	BMD
Method:	RT-PCR, biochemical, culture and Laboratory Response Network Protocols
Specimen:	Pure isolate, blood, aspirated fluids from lymph node or bubo.
Turnaround:	1-3 business days
Transport:	Ship on cool pack
Shipping:	Ship as Suspect Category A**. Contact Bioterrorism Section before sending (605-773-3368).**
Additional:	See Aerobic Bacteriology Supplemental Information

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Aerobic Bacteriology Supplemental Information

The Aerobic Bacteriology Section serves primarily as a referral laboratory for bacteria that are unusual or difficult to identify. In this context, aerobic bacteriology refers to the examination of a wide variety of microorganisms. Reference cultures will be accepted from public and private health care providers. Pure culture isolates are required for serotyping and identification of reference specimens. Clinical specimens are accepted for the isolation and identification of specific pathogen if this testing is unavailable at the sending facility. The Aerobic Bacteriology Section does not perform antimicrobial susceptibility testing for patient treatment.

Refer to **Chart I** – **Aerobic Specimens Requiring Special Handling**

Chart I
Aerobic Specimens Requiring Special Handling

Organism or Disease	Collection Instructions	Shipping Requirements	Special Requirements
Bacillus anthracis anthrax	Aseptically collect specimens from lesion, contaminated hair products, or sputum. Subculture isolates to blood or nutrient agar slants. **Use extreme caution.**	Blood culture bottles for blood and spinal fluid, TB plastic tube for sputum. Sterile containers for other specimens. Ship in double-walled shipping container or equivalent.	**Notify Bioterrorism Section before shipping.**
Bordetella pertussis – whooping cough.	Refer to BORDETELLA Section.		
Brucella species Brucellosis or undulant fever	Aseptically collect multiple blood samples, infected tissues, abscess material, bone marrow, or liver biopsies. Subculture isolates to sheep blood, nutrient or Brucella agar slants. **Use extreme caution.**	Blood culture bottles, vented and incubated under 5 to 10% CO_2. Use sterile container. Ship in double walled shipping container or equivalent.	**Notify Bioterrorism Section before shipping.**
Burkholderia mallei and B. pseudomallei melioidosis	Aseptically collect blood. Subculture isolates to nutrient or infusion agar.	Blood culture bottles for blood. Ship in double-walled mailing container or equivalent.	**Notify Bioterrorism Section before shipping.**
Corynebacterium diphtheriae Diphtheria	Collect throat or skin lesion swabs. Insert swab into silica gel pack or dry transport tube such as a red top blood collection tube.	Ship in double walled shipping container or equivalent.	**Notify Bacteriology Section before shipping.**

Chart I Aerobic Specimens Requiring Special Handling			
Organism or Disease	**Collection Instructions**	**Shipping Requirements**	**Special Requirements**
Francisella tularensis Tularemia or rabbit fever	Collect specimens aseptically. Specimens include material from lesions and blood cultures. Use extreme caution. Send isolates on chocolate agar. Slants.	Sterile container, no transport medium. Ship in double walled shipping container or equivalent.	**Notify Bioterrorism Section before shipping.**
Haemophilus ducrei Chancroid	Collect specimens from Lesions or inguinal bubo And inoculate onto Enriched chocolate agar And incubate at 35 to 37°C In 5-10% CO_2.	Heavy growth of 24-48 hour culture scraped with sterile swab, transport as subsurface stabs in chocolate agar. Ship in double-walled shipping container or equivalent.	Primary culture must be done at the local level.
Haemophilus influenzae	Isolates from sterile sites required for surveillance purposes.		
Listeria monocytogenes	Isolates from all sites are requested.		
Neisseria gonorrhoeae	Refer to Neisseria gonorrhoeae		
Neisseria meningitidis	Isolates from sterile sites are required for surveillance purposes.		
Staphylococcus aureus	Isolates from documented outbreak. Only coagulase positive staphylococci accepted.	Isolated organisms on nutrient or infusion agar slants. Ship in double-walled shipping container or equivalent.	Documentation must accompany specimens. **Notify Bacteriology Section before shipping.** Pulsed Field Gel Electrophoresis (PFGE) is performed.
Streptococcus pneumoniae	Isolates from sterile sites are required for surveillance purposes.		
Yersinia pestis	Aseptically collect specimens from bronchial washings, transtracheal aspirate, sputum, nasopharyngeal swab or culture isolates on blood.	Ship in a double-walled shipping container or equivalent.	Notify Bioterrorism Section
Miscellaneous Bacteria	Use blood, chocolate or TSA slant or Cary-Blair transport.	Ship in double-walled shipping containers or equivalent.	

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Specimen Collection

Aseptically collect specimens from sites such as autopsy material, surgically obtained tissue, urine, and the respiratory and urogenital tract using appropriate techniques for the individual type of specimen. Aseptically collect blood samples and inoculate directly into appropriate commercial blood culture bottles. Preferably, all specimens should be cultured at the local laboratory using recommended isolation procedures. To ensure purity, isolates should be subcultured onto appropriate media before transportation to the SDPHL.

Isolated organisms should be submitted on non-carbohydrate-containing agar such as infusion, nutrient, trypticase soy, blood, or chocolate.

Alert the Bacteriology Section at (605) 773-3368 to make special arrangements in urgent situations or unusual circumstances. **Always** telephone in advance when submitting large numbers of isolates, as in an outbreak situation, or when the organism being submitted is classified as a biologically hazardous organism. For specimens requiring special handling refer to Chart I Aerobic Specimens Requiring Special Handling.

Specimen Identification

1. Complete all the provider and patient information areas. Include pertinent clinical information with each specimen.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form **will not be tested.**

Shipment of Specimens

1. Pack the specimen in a double-walled shipping container or the equivalent. Pack it with absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place the form in the outer container. Place the cap on securely.

2. Affix the mailing label, return address, and infectious substance Category B specimen label to the outer container.

3. Ship by courier to the South Dakota Public Health Laboratory in Pierre.

4. Use first-class postage if using US Postal Service.

5. If *Burkholderia mallei, Burkholderia pseudomallei, Bacillus anthracis, Brucella* species, *Francisella tularensis, or Yersinia pestis* is suspected, telephone the **Bioterrorism Section**. 605-773-3368

Reporting Procedures and Interpretation of Results

Most cultures are reported within 5 to 10 working days. Mixed cultures or fastidious bacteria may require more time for identification. Final results on isolates submitted to the CDC for confirmation or further testing require a longer interval for completion.

Organisms are identified to a genus and species level only when culture, morphology, and biochemical test results support the species identification. Genus and species designations are those consistent with designations in the American Society for Microbiology, Manual *of Clinical Microbiology* or according to the *International Code of Nomenclature of Bacteria.* Some organisms encountered in aerobic bacteriology can be identified accurately only to the genus level and are reported as such. Organisms normally encountered as contaminants or those believed to lack clinical significance may be reported only to the genus level especially if the culture was not accompanied by clinical information to the contrary.

Organisms reported as "unidentified" are those which do not fit the description of recognized genera and/or species. These organisms are not routinely forwarded to the CDC for further study unless the nature of the isolate, source of isolation, and/or the clinical history of the patient warrant further identification efforts, or a special request is made to forward the isolate (such a request requires justifying information from the submitter).

Criteria for Unacceptable Specimens

All specimens

1. The specimen was not labeled.
2. The patient identifier on the specimen did not match the identifier on the form.
3. The specimen was broken in transit.
4. The type of specimen was improper for the test requested.
5. The specimen was non-viable.
6. A mixed specimen was submitted.
7. The specimen did not arrive in appropriate transport temperature range.

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Anaerobic Bacteria Supplemental Information

Anaerobic bacteria are a frequent cause of serious infections. The Bacteriology Section generally accepts only pure isolates for identification. In certain cases, clinical material for primary isolation is accepted for cultivation of pathogenic microorganisms. Contact the Bacteriology Section regarding submission of these specimens.

Isolation and identification techniques used include cultural procedures, morphological and biochemical characterization. Anaerobic isolates are not tested for antimicrobial susceptibilities.

Specimen Collection

Since anaerobic organisms make up a major part of the body's indigenous flora, clinical specimens for anaerobic culture must be collected by methods that avoid contamination with normal flora. Aspirates collected with a syringe or tissue specimens are recommended for anaerobic culture.

The Bacteriology Laboratory accepts anaerobic organisms isolated from the following sources:

- Aspirated pus.
- Tissue (biopsy, surgery, autopsy).
- Transtracheal aspirates.
- Direct lung aspirates.
- Body fluids.
- Sulfur granules from suspected cases of actinomycosis.

Anaerobic organisms isolated from the sources listed below are unacceptable for testing. If you submit an isolate from one of these sources, include information that establishes its clinical significance.

- Throat, gingival or nasopharyngeal swabs.
- Skin.
- Voided urine.
- Sputum or gastric contents.
- Superficial wounds.
- Rectal swabs, feces or small bowel contents (except for special testing).
- Vaginal or cervical swabs

The culture must be maintained in an anaerobic environment. Submit a PURE, actively growing culture.

Specimen Identification

1. Complete all the provider and patient information areas. Include pertinent clinical, biochemical, and epidemiological information with each specimen.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form will not be tested.

Shipment of Specimens

1. Pack the specimen in a double-walled shipping container or the equivalent. Pack it with absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place the form in the outer container.
2. Affix the mailing label, return address, and infectious substance Category B specimen label to the outer container.
3. Ship by courier to the South Dakota Public Health Laboratory in Pierre.
4. Use first-class postage if using US Postal Service.

Note: Specimens submitted on plates are acceptable only if they are properly closed in an anaerobic transport bag and delivered by courier to the laboratory.

Reporting Procedures and Interpretation of Results

Most anaerobic cultures are reported within 7 working days. However, fastidious, slow growing, nutritionally deficient organisms or mixed cultures may require several additional days longer to complete. Reports on cultures forwarded to CDC for further identification and/or confirmation may be delayed several months due to high volume workload.
Organisms are identified to genus, species, and subspecies level when appropriate and only if culture, morphology, and biochemical test results support the identification. Genus, species and subspecies designations are consistent with designations in the American Society for *Microbiology's Manual of Clinical Microbiology,* and the *International* Code of *Nomenclature of Bacteria.* Some anaerobes, particularly members of the genus Clostridium and many of the non-sporeforming gram-positive rods can be identified only to the genus level. Generally, *Lactobacillus* organisms are identified only to the genus level.

Criteria for Unacceptable Specimens

1. The specimen was not labeled.
2. The patient identifier on the specimen did not match the identifier on the form.
3. The specimen was broken or leaked in transit.
4. The type of specimen was an improper specimen type for anaerobic culture.
5. The specimen was not submitted under proper anaerobic conditions.
6. The transport media was unsatisfactory for anaerobic transport.
7. The specimen was non-viable.
8. A mixed specimen was submitted.
9. The specimen did not arrive under proper transport conditions.

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Blood Lead Supplemental Information

Atomic Absorption Spectrometry is the method of testing at the SDPHL. Blood lead levels above 3 micrograms/deciliter are targeted for follow-up and treatment if necessary.

Specimen Collection/Labeling/Requisition Form

I. Micro or Fingerstick

A. Procedure for Finger Preparation

1. Select examination gloves and rinse to remove powder from the gloves if present. This will help avoid contamination of the specimen.

2. Thoroughly wash the patient's hands with soap and water, then dry using appropriate toweling (low lint). If water is not available, foam type soap is acceptable. Again, this step is necessary to avoid contamination.

3. Once washed, the finger to be used must not be allowed to come into contact with any surface, including the patient's other fingers.

4. The finger to be punctured (often the middle finger) must be free of any visible infection or wound.

5. Grasp the finger that has been selected for puncture between your thumb and index finger with the palm of the patient's hand facing up.

6. If not done during washing, massage the fleshy portion of the finger gently.

7. Clean the ball or pad of the finger to be punctured with an alcohol swab. Dry the fingertip using sterile gauze.

8. Puncturing the fingers of infants less than one year of age is not recommended. Puncturing the heel is more suitable for these children (NCCLS, 2008).

B. Puncturing of the Finger and Forming Drops of Blood

1. Grasp the finger and quickly puncture it with a sterile lancet in a position slightly lateral of the center of the fingertip.

2. Wipe off the first droplet of blood with the sterile gauze. (This drop contains tissue fluids that will produce inaccurate results).

3. If blood flow is inadequate, gently massage the proximal portion of the finger and then press firmly on the digital joint of the finger. A well beaded drop of blood should form at the puncture site.

4. Do not let the blood run down the finger or onto the fingernail. (This blood is unsuitable).

C. Filling the Collection Container

1. Make sure that the microcontainer you are using contains only EDTA anticoagulant. These tubes have purple or lavender tops and are provided for use by the SDPHL.

2. Continue to grasp the finger, touch the tip of the collection container to the beaded drop of blood.

3. Draw the blood into the container maintaining a continuous flow of blood.

4. Fill the microcontainer to the collection line. Place the cap on the microcontainer.

5. Holding the tube with your thumb and forefinger, immediately invert the tube several times to mix the blood and anticoagulant thoroughly and to avoid the formation of clots. The specimen will be reported unsatisfactory if any clots are noted, or if the quantity of blood is insufficient for testing.

6. When you have finished filling and mixing the container, put a gauze pad on the finger and have the patient or mother hold until the bleeding has stopped. If bleeding continues after 3-5 minutes of applying pressure, consult a physician.

7. Properly label the microcontainer with patient's first and last name. Use a label and marker that will be legible when the specimen reaches the name listed on the testing site.

II. Venous Specimens

A. Select examination gloves and rinse to remove any powder from the gloves. This will avoid contamination of the specimen.

B. Clean the puncture site with an alcohol swab or sponge, apply tourniquet, and perform venipuncture using butterfly needles appropriate for size. Make sure the vacutainer tube you are using contains only EDTA anticoagulant (purple or lavender top).

C. Fill the tube at least one-half and preferable three-fourths full. Immediately invert several times to insure proper mixing of the blood and anticoagulant to prevent clotting.

D. Properly label the tube with a patient's first and last name exactly as it appears on the requisition form. Use a marker that will be legible when the specimen reaches the laboratory.

Requisition Form

1. Fill out the form completely. Important elements to be filled in on the form for the collection of data are:
    a. Submitter name, address and phone number
    b. Patient name
    c. County of residence
    d. Birthdate
    e. Race, ethnicity, gender
    f. Date collected
    g. Method of collection
    h. Test reason

2. Make sure the name on the form exactly matches the name on the specimen.

Blood Lead Screening Schedule

MEDICAID HEALTH KIDS KLUB PERIODICITY SCHEDULE
(American Academy of Pediatrics recommendation)

BIRTH	1 MO.	2 MO.	4 MO.	6 MO.	9 MO.	12 MO.	15 MO.	18 MO.	24 MO.	3 YR.	4 YR.	5 YR.	Annually Through Age 20

Assessment of Risk

The child's risk for high-dose exposure should be assessed using the developed questionnaire.

1. When a child is considered low-risk:

Blood Lead Test is required at 12 months and 24 months of age.

2. When a child is considered high-risk:

Blood Lead Test Beginning at 6 months of age.

    a. If the initial blood test is ≤ 3 micrograms/deciliter a screening blood lead test is required at every visit prescribed by the periodicity schedule through 72 months of age, while the child remains at high risk unless the child has already received a blood lead test within the last 6 months of the periodic visit.

Shipment of Specimens

1. Specimens should be refrigerated and sent to the SDPHL as soon as possible. Specimens drawn on Monday through Thursday should be sent on the same day. Those drawn on Friday or Saturday should be held until Monday to be sent.

2. To prepare for sending, the labeled specimen should be placed in the biobag with the Blood Lead Analysis requisition form in the outside pouch. The biobag is then placed in the

secondary container and this is placed in the outer mailing container. The outside should have a clearly labeled address and biohazard sticker attached.

Reporting and Interpretation of Results

Lead levels above 3 micrograms/deciliter are considered abnormal, and case managers should refer to the guidelines for recommendations on follow-up screening and treatment.

Unacceptable Specimens

Specimens will be reported “no test – unsatisfactory” for the following reasons:

1. Specimen not labeled
2. Discrepancy between patient identification on specimen and requisition form
3. Insufficient quantity for testing
4. Specimen broken or leaked in transit
5. Specimen age exceeds 14 days
6. Specimen clotted
7. Wrong anticoagulant

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Bordetella pertussis (Whooping Cough) Supplemental Information

The Bacteriology Section performs PCR for Bordetella. Nasopharyngeal aspirates along with swabs are acceptable specimens. Specimens may be sent from public and private health care providers.

Dacron or Sterile Flock Swabs are superior to other types of swabs and should be used to collect specimens as follows: pass swab very gently through the nostril until it reaches the posterior nares and leave in place for 15 to 30 seconds (this may induce a cough and in practice only a few seconds may be possible).

Specimen Processing

1. Nasopharyngeal aspirates should be placed into a sterile leak proof container with a minimum volume of 500 ul for required for testing.
2. Nasopharyngeal Puritan Dry Collection System (Sterile Flock) Swabs provided by the SDPHL may be collected and sent as soon as possible in their own collection kit.

Specimen Identification

1. Complete **all** the provider and patient information sections on the SDPHL requisition slips.
2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form **will not be tested**.

Shipment of Specimens

1. Wrap the transport medium in absorbent material.
2. Affix the mailing label, return address, and infectious substance Category B specimen label to the outer mailing container.
3. Courier the specimens to the South Dakota Public Health Laboratory in Pierre.
4. Use first-class postage if using the US Postal Service.

Reporting and Interpretation of Results

PCR, culture or direct FA procedures are recommended for diagnosis of B. pertussis whenever possible. False negative culture results may occur from any procedures that render the organisms nonviable, such as improper handling of plates and transport medium after collection or prolonged antibiotic treatment prior to collection of the specimen.

Criteria for Unacceptable Specimens

All specimens

1. Specimen not labeled.
2. The patient identifier on the specimen did not match the identifier on the form.
3. The specimen was broken in transit.
4. Out-dated collection kit.
5. Quantity of nasopharyngeal aspirate not sufficient.
6. The specimen did not arrive in appropriate temperature transport range.

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Botulism Supplemental Information

Botulism is a neuroparalytic disease caused by the toxin of *Clostridium botulinum.* The classical disease is foodborne and results from the ingestion of food in which *C. botulinum* has grown and produced toxin. In rare cases, botulism may also result from the production of toxin by *C. botulinum* growing in a wound. A third type of botulism, referred to as infant botulism, seems to result from ingestion of the organism or its spores. There is evidence that indicates the ingested organisms grow and produce toxin in the infant gastrointestinal tract.

Procedures for toxin assays and isolation and identification of *Clostridium botulinum* on samples are available through a cooperative agreement with adjacent State Public Health Laboratories, Office of Disease Prevention and the CDC. Please call 605-773-3368 before submitting samples so that all permissions may be granted and the necessary arrangements may be made.

Serum, feces, vomitus, gastric contents, and pus or wound biopsies are tested when botulism is a possible diagnosis. Suspected foods are tested only when patient testing has resulted in a confirmed case of botulism. Foods are rarely tested in cases of infant botulism. Possible sources of spores for infants are multiple, including dust and foods.

Specimen Collection

For clinical specimens and foods– Refer to Chart II Collection of Specimens for Botulism Testing.

Culture isolates – Submit a pure, actively growing culture in a screw-capped tube of liquid or semi-solid medium such as motility medium, thioglycolate, or chopped meat broth.

Specimen Identification

1. Complete **all** the provider and patient information sections on the SDPHL requisition slips. Include pertinent clinical information with each specimen.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form **will not be tested.**

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Chart II Collection of Specimens for Botulism Testing			
Clinical Diagnosis	**Specimen**	**Amount of Specimen**	**Test(s) Performed**
Foodborne	Serum	10 to 15 ml optimal. 2 ml minimum.	Toxin assay.
	Food	100 gm if available. Do not remove from container.	Toxin assay. Isolation and identification of *C. botulinum.*
	Feces	100 gm if available.	
	Gastric contents	100 gm if available.	
	Vomitus	100 gm if available.	
Wound	Serum	10 to 15 ml optimal. 2 ml minimum.	Toxin assay.
	Feces	100 gm if available	Toxin assay. Isolation and identification of *C. botulinum.*
	Pus from wound or biopsied material	Collect in anaerobic collector. **Do not refrigerate.**	Isolation and identification of *C. botulinum.*
Infant	Feces Bowel	25 gm if available. Use water enema, 20 ml.	Toxin assay. Isolation and identification of *C. botulinum.*

- Collect specimens before antitoxin is given.
- Collect feces, vomitus, and gastric contents in sterile containers. Do <u>not</u> use Cary-Blair transport medium. Ship refrigerated at 2 - 8^{0}C.
- Leave suspect foods in original containers. Leave unopened containers sealed. Ship refrigerated at 2 - 8^{0}C.
- Separate serum from blood cells. Ship refrigerated at 2 - 8^{0}C.
- Collect specimens for wound botulism in an anaerobic collector. Do not refrigerate.

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Shipment of Specimens

1. **Serum, food, feces, gastric contents, vomitus, and bowel specimens**
   Wrap the specimen to cushion it. Place the specimen in a leak-proof, insulated container, and pack with cool packs. Do not pack with dry ice. The specimens should stay cold, but not frozen, until they reach the laboratory. Place the requisition form in a plastic bag to prevent wetting and contamination.

   Wound botulism specimens
   Place the pus or biopsied tissue from suspected wound botulism in an anaerobic collector and ship in a double-walled mailing container. Do not refrigerate.

   Reference isolates
   Submit a PURE, actively growing culture. Ship in a double-walled mailing container. Do not refrigerate.

2. Affix the mailing label, return address, and infectious substance Category B specimen label to the outer container.

3. Ship the specimen by the quickest means available to the South Dakota Public Health Laboratory in Pierre. Suggestions for rapid delivery include courier service, taxi, bus, or plane. Follow the courier's shipping regulations.

4. Notify the Bioterrorism Section at (605) 773-3368 to the method of transportation and when the specimens are scheduled to arrive.

Reporting Procedures and Interpretation of Results

The South Dakota Public Health Laboratory issues preliminary results to the State epidemiologist and the Office of Disease Prevention by telephone within 24 hours. Communication continues until the testing is complete. Additional specimens may be requested and additional tests performed depending on the patient's condition and laboratory results. A written report is made when all tests are complete.

Toxin is identified by the Centers for Disease Control and Prevention. Seven toxigenic types of C. *botulinum* are recognized based on the antigenically distinct toxins produced by the different strains classified in this species (A, B, C, D, E, F, and G). Cases of human botulism are usually associated with toxin Types A, B, and E. Type E is usually associated with foodborne outbreaks involving seafood. Infant botulism is predominately Type A or B.

The results of all specimen requests are reported to the health care provider submitting the specimen, and the Office of Disease Prevention in the Department of Health.

Criteria for Unacceptable Specimens

1. The specimen was not labeled.
2. The identifier on the specimen does not exactly match the identifier on the form.
3. The specimen was broken or leaked in transit.
4. The specimen submitted was not suitable for testing.

5. The patient's symptoms do not warrant performance of the test requested.
6. The specimen was submitted improperly.
7. A stool was not submitted refrigerated.
8. A wound culture or isolate was not submitted under anaerobic conditions.
9. A wound culture specimen or isolate was submitted refrigerated.
10. The specimen did not arrive in appropriate temperature transport range.

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Campylobacter Supplemental Information

Campylobacter are microaerophilic organisms that are identified by morphological and biochemical characteristics. They are small, curved or spiral gram-negative rods with a corkscrew-like motility. *Campylobacter* organisms may be isolated from fecal specimens or blood cultures. Antimicrobial susceptibilities are not performed on these isolates.

Both stool specimens for suspected Campylobacter infections and reference isolates for confirmation are tested at the South Dakota State Public Health Laboratory.

***Campylobacter* illness is a notifiable disease.**

Specimen Collection

For a suspected infection, use the enteric bacteria collection kit. One method for collecting a reference isolate for confirmation is to harvest the pure growth from a plate with a swab. Inoculate a Cary-Blair and leave the swab in the medium. Send the Cary-Blair refrigerated. Another method is to inoculate appropriate agar and send in campy pack with increased CO_2.

Specimen Identification

1. Complete **all** the provider and patient information areas on the SDPHL requisition slip. Include pertinent clinical and biochemical information with each specimen.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form **will not be tested.**

Shipment of Specimens

1. Wrap the specimen in absorbent material. Place it in a leak proof insulated container and pack with wet ice or freezer packs. Place the requisition form in a plastic bag to prevent wetting or contamination.

2. Affix the mailing label, return address, and infectious substance Category B specimen label to the outer container.

3. Courier the cultures to the South Dakota Public Health Laboratory in Pierre.

4. Use first-class postage if using the US Postal Service.

Specimens submitted on plates are acceptable only if they are properly closed in a *Campylobacter* transport bag and delivered by courier to the laboratory.

Reporting Procedures and Interpretation of Results

Most *Campylobacter* cultures are reported within 1 to 3 working days after receipt in the laboratory.

Organisms are identified to the genus and species level only when culture, morphology, and biochemical test results support the species identification. *Campylobacter* species designations are consistent with the American Society for Microbiology's *Manual of Clinical Microbiology* or according to the *International* Code of *Nomenclature* of Bacteria.

The results of all specimens are reported to the health care provider submitting the specimen and the Office of Disease Prevention in the SD State Health Department.

Criteria for Unacceptable Specimens

1. The specimen was not labeled.
2. The patient identifier on the specimen does not match that on the form.
3. The specimen was broken or leaked in transit.
4. The specimen was non-viable.
5. The specimen was submitted under improper atmospheric conditions.
6. A mixed specimen was submitted.
7. The specimen did not arrive in appropriate temperature transport range (2-25°C).

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Carba-R Supplemental Information

The Cepheid GeneXpert Carba-R Assay is a comprehensive test that detects and differentiates the most prevalent carbapenemase gene families (KPC, NDM, VIM, IMP-1 and OXA-48). It is important for a successful infection control program. MCIM positive CRE/CRPA isolates are reflexed to the Carba-R Assay.

Specimen Collection

Rectal swabs are collected in the standard manner and sent in a Copan eSwab Amies transport container to the SDPHL as soon as possible. Specimens are stable for up to 5 days at 2–8°C, or up to 24 hours at 20–30°C (room temperature).

Specimen Identification

Complete **all** the provider and patient information areas on the SDPHL requisition slip. Include pertinent clinical and biochemical information with each specimen.

1. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form **will not be tested.**

Shipment of Specimens

1. Transport specimens to the SDPHL by courier.
2. Ship with first class postage if sending by US Postal Service.

Criteria for Unacceptable Specimens

1. No patient identifier on specimen or culture.
2. Specimens received more than 5 days after collection (they will be tested, but a disclaimer will be added to the report indicating that negative results are questionable).
3. Specimen submitted in unsuitable collection kit.
4. The specimen did not arrive in appropriate temperature transport range.

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Direct Swab RT PCR Supplemental Information

Real-Time Polymerase Chain Reaction (RT PCR) Assays offer a molecular option for the detection of Herpes Simplex 1 and 2 as well as Varicella Zoster DNA in the specimen. In these Direct Swab Assays, fluorescent probes are used together with corresponding forward and reverse primers to amplify HSV or VZV and internal control targets. A well-conserved region of the HSV or VZV DNA polymerase gene is targeted to identify viral DNA in the specimen and internal controls are used to detect PCR failure and/or inhibition.

Specimen Collection

1. Acceptable specimen types are cutaneous and/or mucocutaneous lesion swabs stored in UTM (BD UVT), Remel M4, Remel, M4RT, Remel M5, Remel M6 and transport media.
2. Do not use calcium alginate swabs. They may contain substances that inhibit PCR testing.

Specimen Identification

1. Complete all the provider and patient information sections of the SDPHL requisition slips.
2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens with a patient identifier that does not match the identifier on the requisition form **will not be tested**.

Shipment of Specimens

1. Specimens should be shipped cold (2-8 °C)
2. Pack the specimen in a double-walled shipping container (or the equivalent) with absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place the requisition form in the outer container (or at least a sealed plastic bag) so that it doesn't absorb fluid in case of breakage or leakage.
3. Affix the mailing label, return address and infectious substance Category B specimen label to the outer container
4. Ship by courier to the South Dakota Public Health Laboratory in Pierre.
5. Use first-class postage if using US Postal Service.

Interpretation of Results

1. Detected – Result indicates the presence of virus DNA in the patient sample.
2. Not Detected – Result indicates the absence of virus DNA in the patient sample.
3. Invalid – Result indicates inability to conclusively determine the presence or absence of virus DNA in the patient sample. This may be due to: 1) Internal Control (IC) failure or 2) failure to detect sufficient specimen volume. The sample needs to be retested.

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Enteric Bacteriology Supplemental Information

The Bacteriology Section examines feces and other specimens for the presence of enteric pathogens, namely *Salmonella* serotypes, *Shigella*, *Campylobacter*, and *E.coli* O157:H7, on a routine basis. Testing for Shiga-like toxin (SLT), *Yersinia* and *Vibrio* are performed upon request.

All isolates of *Salmonella*, *Shigella*, *Campylobacter*, *E.coli* O157:H7, *Yersinia enterocolitica*, and *Vibrio* recovered from specimens by other clinical laboratories in South Dakota should be referred to the SDPHL. Referred isolates will be further characterized by various methods, such as biochemical reactions, serogrouping/serotyping or Pulsed-field gel electrophoresis (PFGE), depending upon the organism. Tests for occult blood and fecal WBC counts are not performed at the SDPHL.

Specimen Collection/Labeling/Requisition Form

A. Feces specimens for *Salmonella, Shigella, Campylobacter, Yersinia, E.coli* O157, *Shiga-like toxin, Listeria,* and *Vibrio*:

   1. Feces specimens for the above agents should be collected in the appropriate culture collection kit such as a C&S kit which may have green, orange, or yellow-colored top (do not use the Parasitology O&P kit, because it contains formalin that kills bacteria). Collect freshly passed feces as soon as possible after onset of illness and before antimicrobial therapy has been initiated. Select portions of feces which contain blood or mucous, if present. Use the spoon in the lid of the collection vial to facilitate placing a portion of the feces into the vial, adding specimen only to the fill line on the vial; tighten the cap securely, and invert several times. Two to three specimens collected on different days may be necessary for diagnosis.

   2. Rectal swabs containing detectable feces may be collected and placed in a culturette with Stuarts, Cary-Blair, or other commercially available transport medium (not provided by the SDPHL), if a feces specimen cannot be obtained.

   3. Store and ship refrigerated.

B. Feces specimens for *Clostridium perfringens*, *Clostridium botulinum*, and *Bacillus cereus*:

   1. For these agents, collect fresh stool specimens and place in a leak-proof, non-crushable, clean container (not provided by SDPHL).

   2. For *C.perfringens* and *B.cereus*, stool specimens must be collected within 48 hours from the time symptoms begin.

   3. Store and ship refrigerated.

C. Each stool specimen must be clearly labeled with the patient's identifier and accompanied by a properly completed accession form. The form must include the following information:

1. Patient identifier (name or number)
2. Patient birthdate
3. Date of collection
4. Agent suspected, if applicable
5. Submitter's name and address
6. Symptoms

D. Referred Cultures (for identification)
Submit an overnight, pure culture of the isolated bacteria on carbohydrate-free media (TSA and TSI are acceptable). Label tube with the patient's identifier and complete the accession form. The form must include the following information:

1. Patient identifier (name or number)
2. Patient birthdate
3. Date of collection
4. Source of specimen
5. Agents suspected
6. Submitter's name and address

The patient identifier (name, number, or both) indicated on the requisition form should match that written on the specimen or culture. Unlabeled or mismatched specimens or cultures will not be tested.

Shipment of Specimens

Ship clinical specimens for routine screening of enteric pathogens and all reference cultures under refrigeration to the South Dakota Public Health Laboratory in Pierre.

1. Routine screening specimen – Wrap the specimen in absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place it in a leak-proof insulated container and pack with cold packs. Place the form in a plastic bag to prevent wetting or contamination.

   The specimen must be received in the laboratory within 48 hours. (Storage at a temperature of –20^{0}C is acceptable for 3 days.)

2. Reference isolates – Pack the specimen with absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place it in a double-walled shipping container or the equivalent. Place the form in the outer container. Place the cap on securely. Refrigeration is not required.

3. Affix the mailing label, return address, and specimen label to the container.

4. Use the courier to send the specimen to the SDPHL or send with first class postage through the US Postal Service.

5. When an unusually large number of specimens are anticipated (as in an outbreak), telephone the laboratory before mailing the specimen so that necessary preparations may be made.

Note: Specimens submitted on plates are acceptable only if a courier delivers them to the laboratory. (Plates should be sealed)

Reporting and Interpretation of Results

Negative stool specimen results are reported within 3 to 6 working days. Final results are reported within 4 to 6 working days.

Serotyping and confirmation or identification results are usually reported within 3 to 5 working days for Salmonella, Shigella, Aeromonas, Vibrio, and Yersinia spp., and within 4 to 6 working days for E.coli O157:H7. Other organisms will be reported, as appropriate, per request.

The following enteric pathogens, whether isolated from stool specimens or submitted as referred cultures are identified/confirmed to the species or serotype level:

Salmonella sp.	*Aeromonas* sp.
Shigella sp. and serotype	*Vibrio* sp.
Campylobacter sp.	*Yersinia enterocolitica* and serotype
E.coli O157:H7	STEC positive/negative and serotype

Unacceptable Specimens

1. Specimens submitted in wrong preservative, e.g., PVA or 10% formalin.
2. Raw stool in no preservative.
3. No patient identifier on specimen or culture.
4. Specimens received more than 7 days after collection (they will be tested, but a disclaimer will be added to the report indicating that negative results are questionable).
5. Specimen submitted in unsuitable collection kit.
6. The specimen did not arrive in appropriate temperature transport range (2-25°C)

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FilmArray Gastrointestinal Panel

The FilmArray Gastrointestinal (GI) Panel tests for most common gastrointestinal pathogens including viruses, bacteria and parasites that causes infectious diarrhea and other gastrointestinal symptoms.

Despite advances in food safety, sanitation and medical treatment, infectious gastroenteritis remains a significant problem in industrialized countries among all age groups. It is particularly challenging in healthcare environments, due to risk of spreading healthcare-associated infections.

The FilmArray provides clinicians with fast and accurate diagnosis of important pathogens, thus resulting in improved patient outcomes and decreased healthcare costs.

Collection and Shipment of Specimens

Stools in Cary Blair media should be tested as soon as possible, though they may be stored at room temperature or under refrigeration for up to four days. It has not been validated for use with other stool transport media, raw stool, rectal swabs endoscopy stool aspirates, or vomitus. It should not be used to test stools in fixative such as formalin or PVA.

Reporting Procedures and Interpretation of Results

The FilmArray simultaneously tests for 22 pathogens from stool specimens collected in Cary Blair transport medium. Results from the FilmArray GI Panel are available the same day of testing. The following are detected:

Bacteria

- Campylobacter (Campylobacter jejuni/C.coli/ C upsaliensis)
- Clostridium difficile (toxin A/B)
- Plesiomonas shigelloides
- Salmonella
- Vibrio (V. parahaemolyticus/V. vunificus/V. cholerae) and V. cholerae
- Yersinia enterocolitica

Viruses

- Adenovirus F 40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus (Genogroups I,II, IV, and V)

Diarrheagenic E. coli/Shigella

- Enteroaggregative E.coli (EAEC)
- Enteropathogenic E.coli (EPEC)
- Enterotoxigenic E.coli (ETEC) lt/st
- Shiga-like toxin-producing E.coli (STEC) stx1/stx2 and E.coli O157

- Shigella/Enteroinvasive E.coli (EIEC)

Parasites

- Cryptosporidium
- Cyclospora cayetanensis
- Entamoeba histolytica
- Giardia lamblia

Shipment of Specimens

1. Transport specimens to the SDPHL by courier.
2. Ship with first class postage if sending by US Postal Service.

Criteria for Unacceptable Specimens

1. Specimens submitted in wrong preservative, e.g., PVA or 10% formalin.
2. No patient identifier on specimen or culture.
3. Specimens received more than 7 days after collection (they will be tested, but a disclaimer will be added to the report indicating that negative results are questionable).
4. Specimen submitted in unsuitable collection kit.
5. The specimen did not arrive in appropriate temperature transport range (2-25°C).

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FilmArray Respiratory Panel

The FilmArray Respiratory Panel tests for 17 viruses and 3 bacteria which cause upper respiratory tract infections. Rapid and accurate identification of the causative agent of upper respiratory tract infections may improve patient management by informing timely and effective antibiotic or antiviral therapy, preventing secondary spread of infection, shortening hospital stays and reducing costs of unnecessary ancillary tests.

Collection and Shipment of Specimens

Nasopharyngeal swab specimens should be collected and immediately placed in viral transport media. Specimens should be processed and tested as soon as possible. They can be held refrigerated for up to 3 days or frozen for up to 30 days.

Reporting Procedures

The FilmArray Respiratory panel detects multiple respiratory pathogen nucleic acids in nasopharyngeal swabs obtained from individuals suspected on respiratory tract infections. The following organism types and subtypes are identified:

- Adenovirus
- Bocavirus
- Coronavirus 229E, HKU1, OC43, NL63
- Influenza A (subtypes H, 2009 H1, and H3)
- Influenza B
- Human Metapneumovirus
- Parainfluenza Virus 1
- Parainfluenza Virus 2
- Parainfluenza Virus 3
- Parainfluenza Virus 4
- Respiratory Syncytial Virus (RSV)
- Enterovirus
- Human Rhinovirus
- Bordetella pertussis
- Chlamydia pneumoniae
- Mycoplasma pneumoniae

Shipment of Specimens

1. Transport specimens to the SDPHL by courier.
2. Ship with first class postage if sending by US Postal Service.

Criteria for Unacceptable Specimens

1. Any specimen other than nasopharyngeal swabs will be rejected.
2. No patient identifier on specimen or culture.
3. Specimen submitted in unsuitable collection kit.
4. The specimen did not arrive in appropriate temperature transport range (2-8°C for up to 3 days or ≤-20°C for up to 30 days).

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Foodborne Illness Supplemental Information

Testing for foodborne illness is available at the South Dakota Public Health Laboratory.

A foodborne disease outbreak is defined as three or more persons with vomiting or diarrhea who attended the same event or consumed the same meal. Single isolate cases or complaints are not considered outbreaks. EXCEPTION: One case of Botulism is subject to notification and investigation. Refer to BOTULISM.

When you suspect a possible foodborne disease, notify the Health Department immediately so investigation procedures and sample collection can be started if necessary. Contact the Health Department whenever any enteric disease outbreak is suspected in a daycare center, a restaurant, or other facility. Additional assistance in the investigation is available by contacting the Office of Disease Prevention at 605-773-3737 or 1-800-592-1804.

Outbreak investigation involves the cooperation of several disciplines within the health department, including the epidemiologist, the health department, and the laboratory. The investigation requires interviewing patients, collecting clinical specimens, and laboratory testing. Communication between the various members is essential for the prompt and precise handling of an outbreak.

A wide variety of organisms can cause gastrointestinal illness. Listed below are some of the organisms that are implicated in foodborne outbreaks:

- *Bacillus cereus*
- *Campylobacter jejuni*
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Escherichia coli* 0157
- *Listeria monocytogenes*
- *Salmonella* species
- *Staphylococcus aureus*
- *Vibrio* species
- *Yersinia enterocolitica*

Organisms that can cause an enteric illness outbreak not associated with food include:

- *Cryptosporidium*
- *Giardia*
- *Shigella* species

Collection and Shipment of Specimens

The health department should be notified when an outbreak is suspected. If there is a danger to the community, the Office of Disease Prevention will take action to prevent further spread of the disease.

Clinical specimens should be collected from a representative number of ill persons and an equal number of exposed but well persons.

Reporting Procedures and Interpretation of Results

Communications among the SD public health officials, the SDPHL, and the health care providers are continuous from the time an outbreak is reported until the results are reported. Work-up of specimens requires a constant exchange of information between the laboratory and the epidemiology team. Additional testing is performed as needed.

The results of all specimens are reported to the health care provider who submitted the specimen. The Office of Disease Prevention is also sent a report if a foodborne illness is detected.

Criteria for Unacceptable Specimens

Unsatisfactory specimens will be assessed on an individual basis.
The specimen should be properly identified, and the specimen identifier should match the information on the form. The specimen needs to arrive in appropriate temperature range.

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Neisseria gonorrhoeae and *Chlamydia trachomatis* Gen-Probe Aptima Combo 2 Assay

Chlamydia (C.) trachomatis is the most common treatable sexually transmitted infection affecting females of reproductive age in the United States today, with an estimated four million new cases each year. Up to 80% of infected females have few or no symptoms. Asymptomatic infection in females can persist for up to 15 months. Complications of untreated chlamydial infection in females include acute pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, and infertility.

Gonorrhea affects both males and females with symptoms ranging from purulent discharge to very mild symptoms. Symptoms may pass unnoticed with the health consequence that asymptomatic carriers contribute significantly to the public health problem of gonorrhea.

The Serology Section uses the Gen-Probe Aptima Combo 2 Assay to detect both chlamydia and gonorrhea infections utilizing urine from either males or females, or female endocervical swabs, male urethral swabs, vaginal swabs, pharyngeal swabs and rectal swabs or liquid pap solution.

This method is not recommended for medicolegal cases. The SDPHL will also continue to perform culture tests for *N. gonorrhoeae* under these circumstances if requested. Antimicrobial tests are not performed. The South Dakota Public Health Laboratory does not perform culture tests for *Chlamydia.*

Only swabs supplied with the specimen collection systems should be used for specimen collection.

Specimen Collection and Storage

The APTIMA Combo 2 Assay is designed to detect the presence of *C. trachomatis* and *N. gonorrhoeae* in endocervical and male urethral specimens, and in female and male urine specimens. The SDPHL can also test vaginal, rectal, urine, pharyngeal and liquid pap specimens in Aptima transport medium. Only the swabs and the specimen transport tubes contained in the APTIMA Combo 2 Assay Unisex Swab Specimen Collection Kit for Endocervical and Urethral Swab Specimens should be used to collect patient swab specimens. A unisex swab is used for both male and female specimens. These collection kits are intended to be used only with the Hologic APTIMA Combo 2 Assay. Performance has not been established with other products.

Swab specimens must be transported to the laboratory in the swab specimen transport medium and tube. Swab specimens must be transported to the laboratory at 2°- 30°C and tested within 60 days of collection.

Urine specimens must be transferred into the Hologic specimen transport tube within 24 hours of collection. Once transferred, urine specimens can be stored at 2°- 30°C for up to 30 days after collection.

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A. Instructions for collection:

1. **Endocervical swab specimens:**
   a. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). **Discard this swab.**

   b. Insert the specimen collection swab (blue shaft swab in the package with green printing) into the endocervical canal.

   c. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.

   d. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.

   e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

   f. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

   g. Re-cap the swab specimen transport tube tightly.

2. **Male urethral swab specimens:**
   a. The patient should not have urinated for at least one hour prior to specimen collection.

   b. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 - 4 cm into the urethra.

   c. Gently rotate the swab clockwise for 2 - 3 seconds in the urethra to ensure adequate sampling.

   d. Withdraw the swab carefully.

   e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.

   f. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

   g. Re-cap the swab specimen transport tube tightly.

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3. **Urine Specimens:**
   a. The patient should not have urinated for at least one hour prior to specimen collection.

   b. Direct the patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a 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 the labial area prior to providing the specimen.

   c. 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 fill lines on the urine transport tube label.

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

4. **Rectal or Vaginal Swabs:**
   a. Insert the specimen collection swab (blue shaft swab in the package with green printing) into the vagina or rectum.

   b. Gently rotate the swab clockwise for 10 - 30 seconds in the rectum or vaginal canal to ensure adequate sampling.

   c. Withdraw the swab carefully.

   d. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

   e. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

   f. Re-cap the swab specimen transport tube tightly.

5. **Pharyngeal Swabs:**
   a. Insert the specimen collection swab (blue shaft swab in the package with green printing) into back of the throat.

   b. Gently rotate the swab clockwise for 10 to 30 seconds at the back of the throat to ensure adequate sampling.

   c. Withdraw the swab carefully.

   d. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

   e. Carefully break the swab shaft at the score line; use care to avoid splashing of the contents.

f. Re-cap the swab specimen transport tube tightly.

B. Specimen transport and storage before testing:

1. Swab specimens:

Once collected, transport and store the swab in the swab specimen transport tube at 2°-30°C until tested. Specimens must be assayed with the APTIMA Combo 2 Assay within 60 days of collection. If longer storage is needed, freeze at -20° to -70°C for up to 90 days after collection.

2. Urine Specimens:

After collection, transport the processed urine specimens in the Hologic APTIMA Combo 2 urine specimen transport tube at 2° to 30°C until tested. Processed urine specimens should be assayed with the APTIMA Combo 2 Assay within 30 days of collection. If longer storage is needed, freeze at -20° to -70°C for up to 90 days after collection.

Specimen Identification

1. Complete **all** the provider and patient information areas.

2. Label each specimen with the date of collection and the patient's first and last name. Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form will not be tested.

Shipment of Specimens

1. Pack the specimen in a double-walled shipping container or the equivalent. Pack with absorbent material to prevent breakage and to absorb the fluid if breakage or leakage should occur. Place the form in the outer container. (Specimens can be shipped at 2- 30°C.)

2. Affix the mailing label, return address, and infectious substance label to the outer container.

3. Ship the specimen to the South Dakota Public Health Laboratory in Pierre.

4. Use first-class postage on US mail.

5. Transport the specimen so that it arrives within 48 hours.

Reporting and Interpretation of Results

The goal of the Serology Section is to test and report all Chlamydia/Gonorrhea Probe specimens within a 24 hour turnaround period, except for borderline or equivocal specimens which will take 48 hours. Copies of all positive Chlamydia and Gonorrhea reports are sent to the Sexually Transmitted Disease (STD) Program.

Results are reported as follows:

POSITIVE – Positive for Chlamydia trachomatis and/or Neisseria gonorrheae.

NEGATIVE – Negative for Chlamydia trachomatis and/or Neisseria gonorrheae.

EQUIVOCAL – Borderline for Chlamydia trachomatis and/or Neisseria gonorrheae. Submit another specimen.

UNSATISFACTORY – Specimen comprised in some manner making it unsatisfactory for testing. The reason for each "Unsatisfactory" specimen will be detailed on the report.

Criteria for Unacceptable Specimens

1. The specimen was not labeled.
2. The patient identifier on the specimen did not match the identifier on the form.
3. The specimen was collected by use of swabs and/or tubes (collection kit) other than by the Hologic kit.
4. The specimen was collected from a site other than endocervical, urethral or urine, rectal, vaginal or pharyngeal.
5. The specimen was too old for testing.
6. The specimen had no collection swab in the transport tube upon receipt in the laboratory.
7. The specimen had two collection swabs in the transport tube.
8. The specimen was received in an out-of-date collection kit.
9. The media had leaked in transport or something has been added to the tube for example the tube was too full or was a strange color.
10. The specimen did not arrive in appropriate temperature transport range (2-8°C).

Neisseria Gonorrhea Reference Cultures

To submit reference cultures of *Neisseria gonorrhoeae*, transfer a well-isolated colony from the primary isolation plate to a fresh plate. Incubate under CO_2 overnight or until growth is visible. Place the culture in a CO_2 environmental transport system. Ship by Courier to the South Dakota Public Health Laboratory or use First Class postage if using the US Postal Service.

Reporting and Interpretation of Results

Positive specimens are reported within 1 - 4 working days after arrival in the laboratory. Negative and unsatisfactory specimens are incubated for a total of 72 hours before reporting.

Reporting of unsatisfactory specimens: Unsatisfactory specimens are examined for a total of 72 hours. Any unsatisfactory specimen that can be reported as positive, regardless of the unsatisfactory condition, will be reported as positive. (Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form will not be tested.) Negative unsatisfactory specimens will be reported as unsatisfactory with the reason given.

The results of all specimens are reported to the provider who submitted the specimen. In addition, the Office of Disease Prevention is sent reports on specimens testing positive for gonorrhea.

Criteria for Unacceptable Specimens

Specimens may be reported as unsatisfactory for the isolation of *Neisseria gonorrhoeae* for the following reasons:

1. Loss of Carbon Dioxide
    a. No $C0_2$ generating tablet
    b. Bag not sealed
    c. Improper $C0_2$ bag used
2. Media Conditions
    a. Out of date
    b. Frozen
    c. Dehydrated
3. Incubation
    a. Too long in transit
    b. Collected and mailed on same day
4. Other
    a. No specimen received
    b. Improper inoculation
    c. No apparent inoculation
    d. No date of collection
    e. Overgrowth by contaminants
    f. Failure to properly identify specimen
    g. Broken in transit
    h. Laboratory accident
    i. The specimen did not arrive in appropriate transport temperature range (2-25°C)

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Interpretation of Hepatitis Results

Hepatitis A		
HAV Total	**HAV IgM**	**Interpretation**
Negative		No immunity
Positive	Negative	Immunity due to natural infection or Hepatitis A vaccination
Positive	Positive	Acute infection or recent immunization

Hepatitis B				
HBsAg	**HBcAb**	**HBsAb**	**HBc IgM**	**Interpretation**
Non-Reactive	Non-Reactive	Non-Reactive		No immunity
Non-Reactive	Non-Reactive	Reactive		Immunity due to vaccination
Non-Reactive	Reactive	Reactive		Immunity due to natural infection
Reactive	Reactive	Non-Reactive	Reactive	Acute Infection
Reactive	Reactive	Non-Reactive	Non-Reactive	Chronic Infection
Non-Reactive	Reactive	Non-Reactive		Interpretation unclear; possibilities: 1. Resolved infection 2. False-reactive HBcAb 3. “Low level” chronic infection 4. Resolving acute infection

Hepatitis C	
HCV Antibody Result	**Interpretation**
Non-Reactive	HCV infection not indicated; does not exclude the possibility of exposure to HCV.
Reactive	HCV infection indicated.

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HCV RNA Quantitative Interpretation			
Value		**Comment**	
Not detected		No current HCV infection. Follow up testing is recommended as per national HCV guidelines for viral load assessment, and no further testing is recommended for diagnosis of HCV. As per CDC treatment guidelines, repeat HCV RNA testing is recommended after three months for patients exposed to HCV infection within 6 months or patients with clinical evidence of HCV infection.	
Detected		See below	
Invalid			

HCV IU/mL	HCV Log IU/mL	
If <10 IU/mL	**<1 Log IU/mL**	Follow up testing is recommended as per national HCV guidelines for viral load assessment, and no further testing is recommended for diagnosis of HCV.
If **10 to 25 IU/mL**	**1.0 to 1.40 Log IU/mL**	Provide guidance for treatment and care based on national HCV treatment guidelines for diagnosis of HCV and viral load assessment.
If **25 to 100,000,000 IU/mL**	**1.40 to 8.00 Log IU/mL**	Current HCV infection. Provide guidance for treatment and care based on national HCV treatment guidelines for diagnosis of HCV and viral load assessment.
If **>100,000,000 IU/mL**	**>8.0 Log IU/mL**	Current HCV infection. HCV RNA is detected above the Upper Limit of Quantification. For HCV Diagnosis and Viral Load Assessment. Provide guidance for treatment and care based on current national HCV treatment guidelines.

Human Immunodeficiency Virus Serology (HIV) Supplemental Information

Serologic assays are available for the detection of antibodies to the human immunodeficiency virus. The SDPHL follows the CDC algorithm and utilizes a Fourth Generation HIV Ag/Ab Combo assay. The Assay tests for a qualitative detection of HIV p24 antigen and antibodies to HIV-1 and HIV-2. All reactive tests are repeated in duplicate to verify the initially reactive test result. All repeatedly reactive tests (two or more reactive) are confirmed by the Geenius HIV 1/2 Supplemental Assay.

Specimen Collection/Labeling/Requisition Form

1. Serum/Plasma Specimen
   Collect approximately three to five milliliters of whole blood (or serum) in a red top tube (no additive), labeled with patient's identifier, date, and name of the submitter. Plasma specimens are acceptable in tubes with the following anticoagulants: EDTA, sodium heparin and lithium heparin.

Requisition Form

Complete the SDPHL requisition form providing:

1. Name or unique patient identifier
2. Test(s) requested
3. Date specimen collected
4. Submitter's name and address
5. Any information submitter needs for patient identification, e.g., chart number, address, physician name, contact person and phone number
6. Race, sex and age/DOB

Shipment of Specimens

Specimens may be mailed, shipped by common carrier, or delivered to the laboratory by courier. Place the biohazard bag with its contents inside the cardboard outer can. Please place only one or two specimens in the cardboard can so they can be removed without mishap. If a screw-cap mailed is shipped by the Postal Service, the cap must be secured by tape, or the Postal Service will return them for taping. Be sure to use the proper mailing label for the final specimen destination.

Reporting and Interpretation of Results

When HIV Ag/Ab Combo results are negative, the test results will be reported as "Negative" and no further testing will be performed on this sample. Repeat sampling at a later date may be necessary in order to detect developing antibodies.

When the Combo test has repeatedly reactive results, the Geenius Supplemental Assay will automatically be run. Both results will be reported to the provider.

When the HIV Ag/Ab Combo test is reactive and the Geenius Supplemental Assay is Negative or Indeterminate, the specimen should be tested for HIV-1 by RNA Nucleic Acid Amplification Testing (NAAT). The RNA Qualitative Assay has very specific specimen guidelines. If the guidelines are met, the specimen will be sent off immediately. If not, a new specimen will be requested before submitting to the CDC.

- Whole Blood, Plasma, or Serum may be run up to 72 hours ≤25°C.
- After centrifugation, may be held an additional 5 days at 2-8°C.
- Plasma may be stored≤ 20°C for longer periods.

HIV-2 confirmation will be sent to the CDC at physician's request if criteria are met.

The following recommendations are made regarding follow-up specimens:

1. If the result of the HIV Geenius is indeterminate, submit another specimen for testing within a month. If the second specimen is also indeterminate, the patient should be tested again at three and six months.

2. When a patient receives his/her first positive test result and has not identified a high-risk behavior, collect a verification specimen at the time the patient is given the results of the first test.

Unacceptable Specimens

1. Identification on form and specimen do not match
2. No identification on specimen
3. Specimen over 7 days old
4. Specimen transport tube broken in transit
5. Insufficient quantity for testing
6. No sample received with form
7. The specimen did not arrive in appropriate temperature range.

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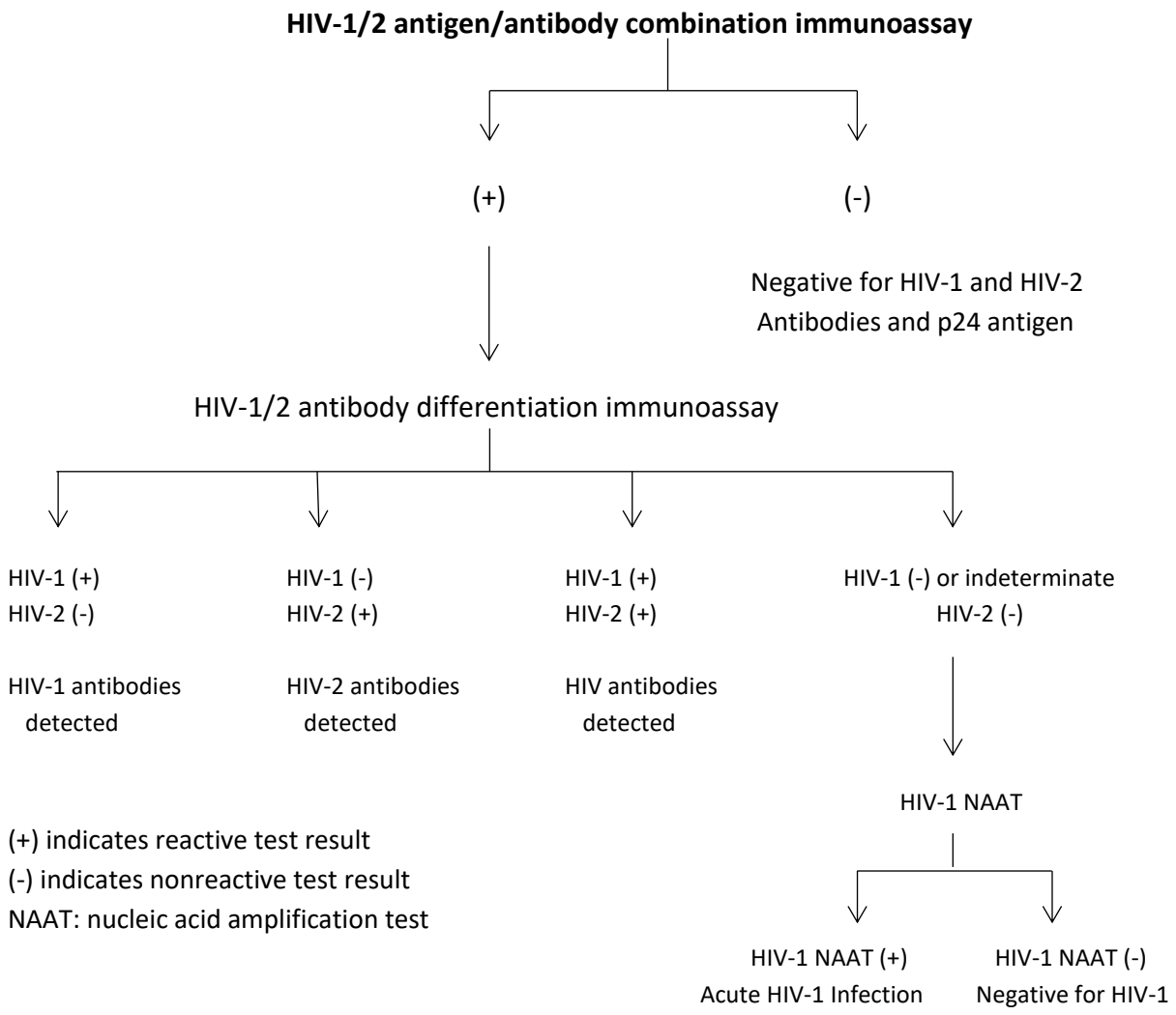
Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



(+) indicates reactive test result
(-) indicates nonreactive test result
NAAT: nucleic acid amplification test

Reference: Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations Published June 27, 2014.
https://stacks.cdc.gov/view/cdc/23447

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Infectious Disease Serology Supplemental Information

Diagnostic and immune status serologic assays are performed for various viral, rickettsial, fungal, chlamydial, and mycoplasmal agents. The assay methods vary depending upon the specific agent for which testing is requested. For specific agents and assay methods refer to Chart III Serological Tests Available.

Serological testing for infectious agents that are not performed by the South Dakota Public Health Laboratory may be available at the Centers for Disease Control and Prevention (CDC) in Atlanta.

Specimen Acceptance Policy

Serologic testing is available to all public and private health care providers.

Type of Specimen Required

Immunity Screening – A single, whole clotted blood or serum is required for immunity screening.

Diagnostic Testing – As a rule, acute and convalescent sera must be submitted for diagnostic serological testing. The acute serum should be collected as soon after the onset of illness as possible. For most of the serological testing offered by the SDPH Laboratory, the convalescent serum should be collected 14 days from the time the acute specimen was collected.

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Chart III
Serological Tests Available from the Laboratory

Testing for infectious agents not listed in this chart may be available at the CDC.
Consult with the Laboratory concerning testing not listed.

Chart III **Serological Tests Available from the Laboratory**			
Agent or Disease Suspected	**Specimen Needed**	**Test Method**	**Normal Reference Range**
Francisella tularensis (tularemia)	Acute and convalescent sera	Agglutination	Negative
Hantavirus	Acute	EIA lgG EIA lgM	Negative Negative
Herpes simplex virus HSV I IgG, HSV II IgG	Serum	EIA	Negative
Human immunodeficiency virus Screen: HIV 1/2 and P24 Ag Confirmatory: HIV 1/2 Ab Differentiation	Whole blood, clotted blood, or serum.	Screening – EIA Confirmation – EIA	Non-Reactive Non-Reactive
Measles virus (Rubeola)	Immunity Screening – Whole clotted blood or serum	EIA (IgG)	Positive (Immune)
Measles virus (Rubeola)	Diagnostic – Acute and Convalescent (14 days) sera	EIA (IgM capture)	No Change in Titer Negative
Mumps virus	Immunity Screening – Whole clotted blood or serum	EIA (IgG)	Positive (Immune)

Chart III Serological Tests Available from the Laboratory			
Agent or Disease Suspected	**Specimen Needed**	**Test Method**	**Normal Reference Range**
Mumps virus	Diagnostic – Acute and convalescent (14 days) sera	IFA	No Change in Titer
Q Fever (Coxiella burnetii) Phases 1 and 2	Acute and convalescent (28 days) sera	IFA	<1:64
Rocky Mountain Spotted Fever (Rickettsia rickettsii)	Acute and convalescent (28 days) sera	IFA	<1:64
Rubella virus	Immunity Screening – Whole clotted blood or serum	EIA (IgG)	Positive (Immune)
St. Louis encephalitis virus	Acute and convalescent (14 days) sera	EIA (IgG) EIA (IgM)	No Change in Titer Negative
Western Equine encephalitis virus	Acute and convalescent (14 days) sera	EIA (IgG) EIA (IgM)	No Change in Titer Negative
West Nile Virus	Acute	EIA (IgG) EIA (IgM)	Negative Negative

Abbreviations

EIA	Enzyme Immunoassay	IgG	Class Immunoglobulin
IFA	Indirect Fluorescent Antibody	IgM	Class Immunoglobulin

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Specimen Collection

Blood

1. Collect an acute serum as soon after the onset of the illness as possible. A convalescent serum should be collected 14 days after the collection of the acute serum. Exceptions to this general rule of collection of specimens are noted in Chart III.

2. Draw at least 5 - 7 ml of blood into a red-stoppered vacuum tube allowing the tube to fill completely. Allow the tube to stand at room temperature to ensure complete clotting of blood. Blood should not be taken for 1 hour after a meal to avoid chylous serum.

3. Store the specimen in a refrigerator until it is sent to the laboratory. If the serum is to be sent to the laboratory, separate the serum from the blood clot by centrifuging the whole clotted blood at 1500 - 2000 rpm at room temperature for 10 minutes. Pipette the serum into a new red-stoppered vacuum tube or a sterile plastic screw-capped vial. **A minimum of 1 ml of serum should be sent to the laboratory for testing.**

   Serum-separating tubes may be used to collect the specimens for serological testing. These specimens should be sent to arrive in the laboratory within 48 - 72 hours of collection to avoid having the red blood cells hemolyze and "spill" into the upper portion of the tube.

4. Acute serum that is held until the collection of a convalescent serum should be separated from the blood clot and stored frozen until collection of the convalescent serum. Convalescent specimens may be run as stand-alone specimens in limited situations. Consultation before the convalescent serum will be tested singly.

Specimen Identification

1. **Complete all the information on the form.** Include pertinent clinical information with each specimen. Be specific about why the specimen is being submitted to the laboratory.

   For rubella, measles (rubeola), and mumps, indicate whether the specimen is for diagnosis of a current infection or for immunity screening.

2. Label each specimen with the patient's first and last name and the date of collection. Unlabeled specimens or specimens containing information that does not match the information on the accompanying test request form **will not be tested.**

Shipment of Specimens

1. Place the specimen in a plastic bag. Pack it in a double-walled shipping container or the equivalent. Pack it with absorbent material to prevent breakage and to absorb fluid if breakage or leakage should occur. Place the test request form in the outer container and secure the cap with tape. Ship at ambient temperatures.

2. Place the mailing label, return address, and infectious substance (etiologic agent) specimen label on the container.

3. Ship specimens via courier to the South Dakota Public Health Laboratory in Pierre

4. Use first-class postage on US mail.

Reporting Procedure and Interpretation

An interpretation of the results is given with each report. **For specimens sent to the CDC, the CDC will provide interpretation of test results.**

Paired acute and convalescent sera – When paired (acute and convalescent) sera are tested, the demonstration of a 4-fold increase in antibody titer from the acute to the convalescent serum strongly suggests recent infection with the agent for which the test was performed.

Final Reporting

The results of all specimen requests are reported to the provider who submitted the specimen.

If the result of the specimen is positive for a notifiable disease, this result is also reported to the Office of Disease Prevention.

Criteria for Unacceptable Specimens

1. The specimen is not properly identified with the patient's name or identifier and the date of collection.

2. The patient identifier on the specimen does not match the identifier on the form.

3. The specimen is broken or leaked in transit.

4. The specimen is extensively hemolyzed, lipemic (chylous), extremely turbid, or grossly contaminated with bacteria.

5. Whole, clotted blood was collected more than 7 days prior to receipt by the laboratory.

6. The quantity of the specimen received is not sufficient to allow accurate completion of test(s) requested. (QNS-Quantity Not Sufficient).

7. The convalescent serum was collected sooner than 10 days from the date of collection of the acute serum. (The provider will be notified and asked to provide a more appropriately timed convalescent serum.)

8. No test request form was received with the specimen, or no specimen was received with the form.

9. The specimen did not arrive in appropriate transport range.

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QuantiFERON-TB Gold (QFT) Supplemental Information

Tuberculosis is a communicable disease caused by infection with M. Tuberculosis complex organisms, which typically spreads to new hosts via airborne droplet nuclei from patients with respiratory tuberculosis disease. A newly infected individual can become ill from tuberculosis within weeks to months, but most infected individuals remain well. Latent tuberculosis infection (LTBI), a non-communicable asymptomatic condition, persists in some, who might develop tuberculosis disease months or years later. The main purpose of diagnosing LTBI is to consider medical treatment for preventing tuberculosis disease. Until recently the tuberculin skin test (TST) was the only available method for diagnosing LTBI. The QFT test is both a test for LTBI and a helpful aid for diagnosing M. tuberculosis complex infection in sick patients. A positive result supports the diagnosis of tuberculosis disease, but infection by other mycobacteria could also lead to positive results. Other medical and diagnostic evaluations are necessary to confirm or exclude tuberculosis disease.

Specimen Collection

1. **Collect Blood**
   - Use only the provided QuantiFERON-TB Gold Plus tubes
   - Tubes should be stored at 17°-25°C
   - Fill each tube to the black mark
   - 1 ml of blood is needed in each tube
   - Do not overfill or underfill tubes
2. **Shake Tubes**
   - Shake tubes ten times after filling
   - Ensure the entire inner surface of the tube is coated with blood
3. **Label Tubes**
   - Label all tubes with patient name or unique identifier
   - Do not cover or in any way obscure the fill line on the tube
4. **Determine if specimens will be incubated at your facility or at the SDPHL**

Option 1: Incubate at Your Facility

- Reshake if tubes were not immediately incubated following blood draw
- Incubate tubes upright at 37°C for 16-24 hours
- Label tubes as “Incubated”
- Place the series of four tubes and requisition form in biohazard specimen bag
- Ship to the SDPHL within 3 days of incubation.
- Draw Mon-Wed only to allow transport to the lab within 3 days of incubation.

Option 2: Incubate at the SDPHL

- Label tubes as “Not Incubated”
- Place the series of four tubes and requisition form in biohazard specimen bag
- Ship to the SDPHL
- Tubes **MUST be received within 16 hours** of collection

Shipment

1. Ship specimens and completed requisition forms to the SDPHL using the Courier System
2. Contact Shipping and Receiving to request QFT tubes. 773-3368

Criteria for Unacceptable Specimens

1. The specimen was not properly labeled with the patient's name or a unique identifier.
2. The patient identifier on the specimen does not match the identifier on the form.
3. Blood not incubated within 16 hours of collection.
4. Blood not centrifuged within 3 days of collection.
5. The specimen did not contain the correct volume of blood.
6. The specimen did not arrive in appropriate temperature transport range.

Warnings and Precautions

- A negative QFT results does not preclude the possibility of M. Tuberculosis infection or tuberculosis disease: false negative results can be due to stage of infection (e.g., specimen obtained prior to the development of cellular immune response), co-morbid conditions which affect immune functions, incorrect handling of the blood collection tubes following venipuncture, incorrect performance of the assay, or other immunological variables.
- A positive QFT result should be followed by further medical evaluation and diagnostic evaluation for active tuberculosis disease (e.g., AFB smear and culture, chest X-ray).
- A positive QFT result should not be the sole or definitive basis for determining infection with M. Tuberculosis. Incorrect performance of the assay may cause false-positive responses.

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SARS COV2 PCR Supplemental Information

Summary

The SDPHL utilizes a Real-Time PCR Diagnostic Panel intended for the qualitative detection of nucleic acid and is based on widely used nucleic acid amplification technology. The SDPHL has brought on several molecular platforms to detect SARS COV2.

Specimen collection

The SDPHL will test nasopharyngeal, nasal, oropharyngeal and sputum specimens. Samples must be collected in viral transport medium, sterile saline, or sterile PBS.

Specimen storage

Once collected, samples need to be couriered to the SDPHL on an ice pack within 72 hours. If longer transport is needed, sample can be frozen and shipped on dry ice. Please note on the requisition form that sample was frozen.

Reporting Procedure and Interpretation

Shipment
Criteria for unacceptable specimens
Warnings and Precautions

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Shiga Toxin (STEC) Supplemental Information

Disease caused by Shiga toxin-producing *Escherichia coli* ranges from self-limiting diarrhea to hemorrhagic colitis and hemolytic uremic syndrome. Serotype 0157:H7, the most frequently implicated serotype, has been isolated from large food-borne outbreaks as well as sporadic cases. However, 60 serotypes have been implicated in diarrheal disease and several non-0157:H7 serotypes have been identified in food-borne outbreaks and cases of HUS. *E. coli* 0157:H7 is easily distinguished from other *E. coli* because of its inability to rapidly ferment sorbitol. Use of MacConkey agar with sorbitol provides a quick and easy screening method for *E. coli* 0157:H7. Non-0157:H7 STEC are phenotypically similar to commensal non-pathogenic *E. coli* and are not detected with sorbitol MacConkey agar. To detect these non-0157:H7 STEC, non-culture methods are used (Enzyme immunoassay or PCR). The South Dakota Public Health Laboratory uses a microwell format enzyme immunoassay for the detection of Shiga-like toxins I and II (Verotoxins) in stool specimens.

Specimen Collection

Stool samples (collected in clean containers) or rectal swabs should be placed into enteric transport media and transported to the laboratory on cool packs.

Specimen Identification

1. Complete **all** the provider and patient information areas on the SDPHL requisition form. Include pertinent clinical information with each specimen.

2. Label each specimen with the date of collection and the patient's first and last name (or a unique identifier). Unlabeled specimens or specimens where the patient identifier on the specimen does not match the identifier on the form will not be tested.

Specimen Shipment

1. Place the specimen container inside a plastic bag with the form in the outer envelope. Place the bag in a double-walled shipping container or the equivalent. Package with absorbent material to prevent breakage and to absorb fluid if breakage or leakage should occur. Include cool packs.

2. Affix the mailing label, return address, and infectious substance label on the container.

3. Ship to the South Dakota Public Health Laboratory in Pierre by quickest way.

4. Use first-class postage if US Mail service is used.

Criteria for Unacceptable Specimens

1. The specimen was not properly labeled with the patient's name or a unique identifier.
2. The patient identifier on the specimen does not match the identifier on the form.
3. The specimen did not arrive in appropriate temperature transport range.

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Streptococcus Group A Supplemental Information

The principal streptococcal species producing communicable disease in humans, Lancefield Group A *streptococci* or *Streptococcus pyogenes,* is primarily a resident of the pharynx. This microorganism causes a variety of respiratory tract diseases, including pharyngitis, rhinitis, tonsillitis, pneumonia, and scarlet fever. In addition, group A streptococci are found in pyoderma and impetigo lesions, in wound infections, and in the blood of patients with erysipelas, cellulitis, and septicemia. Nonsuppurative disease such as acute rheumatic fever and acute glomerulonephritis may follow streptococcal pharyngitis.

CDC rarely gives approval for Streptococcus A serotyping. The Director of the department requires that all requests be emailed to him directly for approval. The physician will need to email his/her request with all the specific information to the CDC. Contact the Bacteriology laboratory for further information.

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Syphilis Serology Supplemental Information

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. Serological tests greatly aid in the diagnosis of syphilis. Serologic assays used to screen patients for syphilis are non-treponemal tests. The non-treponemal test performed by the South Dakota Public Health Laboratory is the Rapid Plasma Reagin test (RPR). Quantitative RPR results may be used to monitor therapy for *T. Pallidum* infections.

Confirmation of reactive screening test results (RPR) is obtained with specific treponemal tests for syphilis. The *Treponema pallidum*-Particle Agglutination test (TP-PA) is the South Dakota Public Health Laboratory's primary confirmatory test for *T. Pallidum*-specific antibody. Suspected biologically false-positive results sometimes produced in the RPR test may be investigated with a TP-PA test. The Fluorescent Treponema Antibody Stain (FTA) also detects *T. Pallidum*-specific antibody. The TP-PA is **not a screening procedure** and is only performed when required for proper patient management.

Specimen Acceptance Policy

Testing for syphilis, non-treponemal and treponemal-specific, is available to all health care providers.

South Dakota does not require premarital testing for syphilis.

Type of Specimen Required

Refer to Chart V-2.

Chart V – 2
Serological Tests for Syphilis

	Test	Specimen Required	Application of Test
Nontreponemal Tests	RPR	Whole, clotted blood, serum, or plasma *	Screening (for example, prenatal or STD clinics), monitoring treatment.
Treponemal Antibody Tests**	TP-PA	Whole, clotted blood or serum	Detection of false-positive RPR results, monitoring of infants for possible congenital syphilis.

* Plasma can be tested with the RPR test, but plasma is not the preferred specimen. Serum is preferred because it is required for subsequent treponemal antibody tests that may need to be performed after the RPR test is completed. Also, plasma must be tested within 48 hours of collection or the risk of false RPR results is greatly increased.

** Treponemal antibody tests will not routinely be performed on specimens that produce negative results on the screening test (RPR). An exception is that the TP-PA will be performed at the provider's

request on specimens that may produce negative RPR results but are from patients (birth to 15-months-old) who may have congenital syphilis.

Specimen Collection

Draw one blood tube on each patient, even for those requiring a confirmatory test. Additional tubes are unnecessary.

WHOLE, CLOTTED BLOOD OR SERUM

Draw at least 5 to 7 ml of blood into a red-stoppered vacuum tube allowing the tube to fill completely. Allow the tube to stand at room temperature to ensure complete clotting of blood. Blood should not be taken for 1 hour after a meal to avoid chylous serum.

Store the specimen in a refrigerator (2 to 8^0C) until it is sent to the laboratory. If serum is to be sent, separate the serum from the blood clot by centrifuging the whole, clotted blood at 1,500 to 2,000 rpms at room temperature for 10 minutes. Pipette the serum into a new red-stoppered vacuum tube or plastic screw-capped vial. Submit at least 2 ml of serum.

PLASMA

Plasma is not a recommended specimen for syphilis testing. It may be submitted (1 to 2 ml) for the screening procedure for syphilis (RPR) but is not a suitable specimen for subsequent TP-PA procedure. Plasma must be tested within 48 hours from the time of collection to produce reliable RPR results.

Shipment of Specimens

1. Place the specimen in a plastic bag. Pack it in a double-walled shipping container or the equivalent. Pack it with absorbent material to prevent breakage and to absorb fluid if breakage or leakage should occur. Place the form in the outer container and secure the cap with tape. Ship it at ambient temperatures.

2. Place the mailing label, return address, and specimen label on the container.

3. Ship blood or serum specimens to South Dakota Public Health Laboratory in Pierre

Interpretation of Laboratory Results

Screening (RPR)

Normal:	Non-reactive
Abnormal:	Reactive

Confirmatory(TP-PA)

Normal:	Non-reactive, if no prior infection
	Reactive, if documented previous infection
Abnormal:	Reactive

Positive reactions will occur within 10 to 90 days following exposure or 7 to 10 days after onset of primary lesion.

Biological false-positive readings may occur normally or may also indicate the presence of serious disease other than syphilis. Possible causes for biological false-positive RPR results:

Narcotic addiction
Aging
Terminal malignancy
Viral diseases, e.g., chickenpox, measles, Infectious mononucleosis, pneumonia, etc.
Malaria
Hepatitis
Leprosy
Pregnancy
Rheumatoid arthritis
Systemic lupus erythematosus

Reporting Procedure and Interpretation

Results of the non-treponemal tests for syphilis and the TP-PA performed on serum is available within 3 working days of receipt of the specimen.

Patients with primary syphilis may have a non-reactive RPR and/or TP-PA. However, these tests will usually soon become reactive. Most patients treated for primary syphilis will have a reversion of the nontreponemal tests to non-reactive within two to three years. The TP-PA test will usually remain reactive after treatment. Non-reactive serologic tests and normal clinical evaluations do not exclude incubating syphilis.

The results of all specimen requests are reported to the provider who submitted the specimen. In addition, the Office of Disease Prevention and the STD control coordinator are sent reports on positive specimens.

Criteria for Unacceptable Specimens

1. The specimen is not properly identified with the patient's name.
2. The patient identifier on the specimen does not match that on test request form.
3. The specimen is broken or leaked in transit.
4. The specimen is extensively hemolyzed, lipemic (chylous), extremely turbid, or grossly contaminated with bacteria.
5. Whole, clotted blood collected more than 7 days prior to receipt by the laboratory.
6. Plasma collected more than 48 hours prior to receipt by the laboratory.
7. The quantity of the specimen received is not sufficient to allow accurate completion of test requested. (QNS-Quantity Not Sufficient.)
8. No test request form was received with the specimen, or no specimen was received with the request form.
9. The specimen did not arrive in appropriate temperature transport range.

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Packaging and Shipping Diagnostic Specimens and Infectious Substances (Etiologic Agents)

General Considerations:

1. Actively growing cultures of organisms should be submitted in tubes with screw-cap closures and on media appropriate for the organism. The cap should additionally be sealed with waterproof tape.
2. Cultures on Petri dishes are not an acceptable form of transport media.
3. All specimen containers should be closed tightly and sealed in order to prevent leakage and contamination.
4. The following definitions and classification criteria are taken from a 29 CFR, Section 1910.1030; IATA (International Air Transport Association) Dangerous Goods Regulations; ICAO (International Civil Aviation Organization) Technical Instructions for the Safe Transport of Dangerous Goods and US Postal Regulations (Domestic) and are current as of the time of this printing. It is the responsibility of the shipper to make sure that specimens and packages are sent under the proper guidelines and that proper training has been undertaken in order to understand the rules for proper shipping.

Definitions and Classification Criteria – 49 CFR 173.134, Class 6, Division 6.2:

1. Division 6.2 (Infectious Substance): A material known to contain or suspected of containing a pathogen. A pathogen is a virus, or microorganism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous particle (prion) that has the potential to cause disease in humans or animals. An infectious substance must be assigned the identification number UN 2814, UN 2900, UN 3373 or Un 3291 as appropriate, and must be assigned one of the following categories:
    a. **Category A:** 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. A Category A infectious substance must be assigned to identification number UN 2814 or UN 2900 as appropriate. Assignment to either of these numbers 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 for the source human or animal.
    b. Category B: An infectious substance that is not in a form generally 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. A Category B infectious substance must be described as “Biological substance, Category B” and assigned identification number UN 3733.

General Packing Requirements

Diagnostic Specimens:

1. Watertight primary receptacle(s). (Maximum quantity must not exceed 500 ml).
2. Watertight secondary packaging (maximum per outer package must not exceed 4 Liter).
3. Absorbent material placed between the primary receptacle and the secondary package sufficient to absorb all the specimen.
4. Outer packaging of adequate strength for its capacity, weight and intended use. Packaging must be manufactured and assembled to be capable of successfully passing the prescribed tests and conforming to the requirements of 42 CFR, part 173.24.
5. Packages must be at least 4 inches in the smallest overall external dimension.
6. If sent by air, the primary receptacle OR the secondary packaging must be capable of withstanding without leakage, an internal pressure which produces a pressure differential of not less than 95kPa in the range of – 40 C to +55 C.
7. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
8. The package should be marked “Diagnostic Specimen”.
9. A biohazard label and/or an etiologic agent label must be permanently affixed to outer package.
10. For detailed instructions refer to 49 CFR, IATA/IACO and/or 42 CFR.

Infectious Substances:

1. Watertight primary receptacle(s). (Total volume not to exceed 50 ml or 50g).
2. Multiple primary receptacles placed in a single secondary package must be wrapped individually, separated and/or supported to ensure that contact between them is prevented.
3. Watertight secondary packaging.
4. Absorbent material of sufficient quantity to absorb the contents of all the primary receptacle(s) located between the primary and secondary package.
5. The outer package must be of adequate strength for its capacity, weight and intended use. Packaging must be manufactured and assembled to be capable of successfully passing the prescribed tests and conforming to the requirements of 42 CFR, part 173.24. The outer package must bear the Specification Markings for shipment of infectious substances. Packages must be at least 4 inches in the smallest overall external dimension.
6. If sent by air, the primary receptacle OR the secondary packing must be capable of withstanding without leakage an internal pressure which produces a pressure differential of not less than 95 kPa in the range of – 40 C to +55 C.
7. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
8. All packages containing infectious substances must be marked durably and legibly on the outside of the package with the Name and Telephone Number of a person responsible for the shipment.

9. Shipments of infectious substances require the shipper to make advance arrangements with the receiver.
10. Appropriate labels including 6.2 Infectious Substances label must be applied to the outer packaging.
11. For detailed instructions refer to 49 CFR, ICAO/IATA and/or 42 CFR.

Use of Dry Ice When Shipping Specimens:

Dry Ice (carbon dioxide, solid) is prohibited in international mail. Dry ice is permitted in domestic mail or surface transportation when used as a refrigerant to cool the contents of a mail piece. The dry ice must be packed in a container that is designed to permit the release of carbon dioxide gas, prevent build-up of pressure and possible rupture of the package. Do NOT place inside the primary, or secondary packaging.

For air transportation, each package may not contain more than 5 pounds of dry ice. The address side of the package must be clearly marked "Carbon Dioxide Solid, UN 1845" or "Dry Ice, UN 1845" along with the net weight of the dry ice and the identity of the contents being cooled. A shipper's declaration prepared in triplicate and a DOT Class 9 warning label for miscellaneous hazardous materials must be affixed to the outer packaging.

For surface transportation the address side of the package must be clearly marked "Carbon Dioxide Solid, UN 1845" or "Dry Ice, UN 1845" along with the net weight of the dry ice (which may exceed 5 pounds for surface transportation) and the identity of the contents being cooled.

Shipper's Declaration:

IATA requires a particular form to be used as the dangerous goods declaration shipping paper. This dangerous goods declaration is in addition to the air waybill (regular air cargo shipping form) and must accompany the air waybill. IATA requires that the Shipper's Declaration be signed by the **shipper**, not the shipper's agent.

Shipment of Etiologic Agents from:

Interstate Shipment of Etiologic Agents, 42 CFR Part 72, Federal Register, Vol. 45, No. 141-Monday, July 21, 1980, Centers for Disease Control and Prevention, Office of Health and Safety, Biosafety Branch, (Last Modified: 5/20/97)
https://www.cdc.gov/laboratory/specimen-submission/shipping-packing.html

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Etiologic Agents from 42 CFR Part §72.3

"Etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease. The following agents are considered etiologic agents:

Bacterial Agents

Acinetobacter calcoaceticus, A. baumannii
Actinobacillus – all species.
Actinomycetacease – all members.
Aeromonas hydrophilia.
Arachnia propionica.
Arizona hinshawii – all serotypes.
Bacillus anthracis.

Bacteroides spp.
Bartonella – all species.
Bordetella – all species.
Borrelia recurrentis, B. vincenti.
Brucella – all species.
Campylobacter (Vibrio) foetus, C. (Vibrio*) jejuni*.
Chlamydia psittaci, C. Trachomatis.
Clostridium botulinum, Cl. Chauvoei, Cl. Haemolyticum, Cl. Histolyticum, Cl novyi, Cl. Septicum, Cl. tetani.
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.
Edwarsiella tarda.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella [Pasteurella] Tularensis.
Haemophilus ducreyi, H. Influenzae.

Klebsiella – all species and all serotypes.
Legionella – all species and all Legionella-like organisms.
Leptospira interrogans-all serovars.
Listeria – all species.
Mimae polymorhpa.
Moraxella – all species.
Mycobacterium – all species.
Mycoplasma – all species.
Neisseria gonorrhoeae, N. meningitidis
Nocardia asteroides.
Pasteurella – all species.
Plesiomonas shigelloides.
Proteus – all species.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Salmonella – all species and all serotypes.
Shigella – all species and all serotypes.

Sphaerophorus necrophorus.

Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pneumoniae.
Streptococcus pyogenes.
Treponema careteum, T. Pallidum, and T. pertenue.
Vibrio cholerae, V. Parahaemolyticus
Yersinia (Pasteurella) pestis, Y. enterocolitica.

Fungal Agents

Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.
Candida auris

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Viral and Rickettsial Agents

Adenoviruses – human – all types.
Arboviruses – all types.
Coxiella burnetii.
Coxsackie A and B viruses – all types.
Creutzfeldt – Jacob agent.
Cytomegaloviruses.
Dengue viruses – all types.
Ebola viruses.
Echoviruses – all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents including, *but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.*
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
Herpesvirus – all members.
Infectious bronchitis – like virus.
Influenza viruses – all types.
Kuru agent.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses – all types.
Polioviruses – all types.
Rabies virus – all strains.
Reoviruses – all types.
Respiratory syncytial virus.
Rhinoviruses – all types.
Rickettsia – all species.
Rocha limaea quintana.
Rotaviruses – all types.
Rubella virus.
Simian virus 40.
Tick – borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
Vaccinia virus.
Varicella virus.
Variola major and Variola minor viruses
Vesicular stomatis viruses – all types
White pox viruses.
Yellow fever virus.[2]

[2] This list may be revised from time to time by Notice published in the Federal Register to identify additional agents which must be packaged in accordance with the requirements contained in this part.

42 CFR Part §72.3 (c) Dry ice.
If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

42 CFR Part §72.3 (e) Damaged packages.
The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, by telephone (404) 633-5313. The carrier shall also notify the sender.

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42 CFR Part §72.3 (f) Registered mail or equivalent system
Transportation of the following etiologic agents should all be by registered mail or an equivalent system, which requires or provides for the sending of notification of receipt to the sender immediately upon delivery:

- Coccidioides *immitis.*
- Ebola virus.
- *Francisella* (Pasteurella) tularensis.
- Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
- Herpesvirus simiae [B virus].
- *Histoplasma capsulatum*.
- Lassa virus.
- Marburg virus.
- *Pseudomonas mallei.*
- *Pseudomonas pseudomallei.*
- Trick-borne encephalitis virus complex including but not limited to Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
- Variola major and Variola minor and White pox viruses.
- *Yersinia (Pasteurella) pestis*

42 CFR Part §72.4 Notice of delivery; failure to receive
When notice of delivery of materials known to contain etiologic agents listed in 72.3[f] is not received by the sender within 5 days following the anticipated delivery of the package, the sender shall notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, by telephone (404) 633-5313. This section does not apply to select agents and toxins that are subject to requirements under the provisions of 42 CFR 73.16 concerning transfer of select agents and toxins.

A complete listing of select agents along with other information can be found at:
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73/section-73.3

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