

Public Health Laboratory

Guide to Laboratory Services

SC DHEC Public Health Laboratory

James A Hayne Building 8231 Parklane Road Columbia, SC 29223

May 2023

Guide to Laboratory Services Table of Contents

I. ADMINISTRATION

ORGANIZATION								
General Information	(Purpose	Mission	Statement.	Address.	Hours,	etc.))I-	1

))
Laboratory Certification	I-1
Specimen Receiving	I-2
After Hours Delivery of Specimens & Contact Persons	I-2
TESTING POLICIES	
Ordering of Tests	I-3
Specimen Referral to CDC for Testing	I-3
Confirmatory Testing	I-4
Correction of Patient Information	
SPECIMEN REJECTION & DISCLAIMER POLICIES	
No Specimen Received / No Request Form Received	I 5

No Specimen Received / No Request Form Received	l-5
No Name on Specimen / No Name on Request Form	I-5
No Test Requested / Other Missing Information	I-5
Mismatched Information	
Specimen Broken or Leaked in Transit	I-6
Incorrect or Unsatisfactory Specimens Received	I-6
~ I	

II. ALPHABETICAL LISTING OF TEST INFORMATION......II-1

III. ORDERING SUPPLIES AND SPECIMEN COLLECTION

ORDERING SUPPLIES

Collection Kits	III-1
Transport Medium	III-1
Shipping Containers	III-1
Test Request Forms	
County Codes / Sender Numbers	
Billing Numbers / Program Numbers	

SPECIMEN COLLECTION PROCEDURES

Venipuncture Using the Vacuum System	III-12
Venipuncture Using the Butterfly System	III-16
Fingerstick Procedure for Patients > 1 Year Old	III-21
Fingerstick for Patients > 1 Year Old: Dried Blood Spots Collection	III-24
Heel-stick Procedure for Patients Less Than 1 Year Old	III-27
QuantiFERON-TB Gold Plus (QFT-Plus) Collection Procedure	III-31
Specimen Collection for Culture and ID	
Enteric Pathogens	III-33
Neisseria gonorrhoeae	III-34

	Diphtheria Mycobacterium (TB)	
	Specimen Collection for Other Tests and Procedures	
	Chlamydia/GC & Trichomonas vaginalis by Gen-Probe Apt	imaIII-40
	Herpes Simplex 1 & 2 Assay	
IV.	TRANSPORTING AND SHIPPING INFECTIOUS SUBSTANCES	
	Introduction	IV-1
	Regulatory Requirements	IV-1
	Training Requirements	IV-2
	Exemptions	IV-3
	Definitions	IV-4
	Instructions for Packing Infections Substances	IV-6
	1. Step 1: Classifying Infectious Substances	IV-6
	2. Step 2: Proper Shipping Names and UN Numbers	IV-8
	3. Step 3: Packaging Selection and Requirements	IV-9
	a) Packaging Selection	IV-9
	b) Triple Packaging Requirements	
	c) Shipping at Controlled Temperatures	IV-14
	4. Step 4: Shipping Paperwork	IV-21
	5. Step 5: Marks and Labels	
	Special Situations	
	Contact Information and Support	
	11	

V. FEES AND BILLING PROCEDURES

Test Fee Policy and Billing Procedure	<i>V</i> -	-1
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Purpose

The purpose of this manual is to provide our clients with information about laboratory testing availability and to provide a guide for collecting and submitting specimens.

Mission Statement

The mission of the Public Health Laboratory (PHL) is to provide specialized laboratory testing for accurate screening, diagnosis, prevention and surveillance of disease, foodborne illness, and congenital disorders to improve public health and the quality of life for the South Carolina community.

General Information

Laboratory Certification for Clinical Testing- CLIA ID# 42D0658606

The Public Health Laboratory of the South Carolina Department of Health and Environmental Control (SC DHEC), formerly named the Bureau of Laboratories, is a multi-disciplinary, integrated source of diagnostic services including analytical support and consultation for physicians, private laboratories, hospitals, and county health departments. The PHL is prepared to assist in any national public health emergency.

Physical Address

The Public Health Laboratory is located in the James A. Hayne Building at 8231 Parklane Road, Columbia, SC 29223, on the campus of the State Park Health Center. State Park is located between Highway 555 (Farrow Road), Parklane Road and the I-77 connector (or SC I-277) two miles north of I-20; 2 miles west of Columbia Mall. Using the Parklane Road Entrance, the Hayne Building is at the end of the first left turn.

Hours of Business

The official working hours are from 8:00 A.M. to 4:00 P.M. Monday through Friday.

After Hours, Weekends and Holidays

The laboratory maintains an On-Call Roster for all weekends and holidays. Individuals requesting information or services of an emergency nature can call the main number, 803-896-0800. This number transfers to an answering service who will contact the Director on call.

A list of state holidays for the current year can be found on the SCDHEC website at: <u>https://www.scdhec.gov/about-dhec/state-holidays</u>.

Emergency Response / Disaster Preparedness

As part of DHEC's Emergency Preparedness Plan of Action, the Public Health Laboratory is equipped and staff are trained to respond rapidly and effectively to a medical emergency, natural disaster, and / or act of bioterrorism or chemical terrorism. If the emergency occurs outside of regular working hours, personnel will be called back or work overtime as needed to provide laboratory support.

Specimen Receiving

Apart from Newborn Screening, specimens transported by DHEC's courier service are placed in specially marked boxes and are picked up by lab staff from the Sims-Aycock building between 5:00 AM and 6:00 AM Tuesday through Saturday. Specimens sent by first class mail are picked up by lab staff from the U.S. Post Office at 8:30 AM Monday through Saturday. The U.S. Post Office delivers any overflow packages at approximately 12:30 PM, Monday through Friday.

On DHEC-observed non-federal holidays, specimens are picked up by laboratory staff between 7:00 AM and 8:00 AM from the Sims-Aycock building and the U.S. Post Office. These are sorted and stored according to established protocols to be accessioned on the next working day.

Specimens are accepted at the Hayne Building during the business hours of 8:00 AM to 4:00 PM Monday through Friday, except for state holidays. Private couriers delivering specimens at the back entrance of the Hayne Building should call Specimen Management Section at 803-896-0898 for pick up at the loading dock. Private couriers and/or individuals delivering specimens through the front entrance are assisted by the Security Officer at the front desk.

After-Hours Delivery of Specimens

Specimens other than Newborn Screening specimens will not be accepted after hours unless special arrangements have been made with the laboratory section conducting the test. This person will notify the Security Officer on duty that a delivery is expected.

The after-hours depository located in the rear of the Hayne Building is for animal heads being delivered for rabies testing only. Please do not put specimens and cultures in the depository.

Newborn screening specimens can be accepted at the Security Desk of the Hayne Building after business hours. Couriers delivering from hospitals will sign the specimens in on a log kept at the Security Desk. Holiday and Saturday delivery of Newborn Screening specimens shipped using FedEx/UPS are also accepted by the Security Desk.

Contact Persons and Phone Numbers

Laboratory Test Results	(803) 896-0800
Laboratory Request Forms/Mailing Containers	(803) 896-0913
Facilities Maintenance (Laboratory Instrument Services)	(803) 896-0919
Laboratory Director	(803) 896-0965
Assistant Laboratory Director	(803) 896-9725
Director, Chemistry Division	(803) 896-0991
Director, Virology Serology and Advanced Molecular Detection Division (VSA)	(803) 896-7709
Director, Microbiology Division	(803) 896-0870
Support Division Manager	(803) 896-2331
Director, Logistic Division	(803) 896-0923
Office of Quality Assurance	(803) 896-3897
Office of Laboratory Safety	(803) 896-0956
Laboratory Information Management Systems (LIMS) Administrator	
Complaints(803) 896-389	97 or (803) 896-0899

Testing Policies

Persons Authorized to Order Tests

The Laboratory will accept clinical laboratory specimens for testing from physicians, health departments, and hospital laboratories, or as provided by South Carolina statutes. These senders will be responsible for receiving, relating, interpreting, and/or distributing the data. A clinical laboratory specimen is described as any material derived from the human body for the purpose of diagnosis, prevention, treatment or assessment for medical or legal purposes. Inanimate substances and other samples submitted for examination (e.g., environmental lead samples, etc.) may be accepted from private citizens at the discretion of the Division Director, Laboratory Supervisor, Assistant Laboratory Director, or Laboratory Director.

Verification of Orally Ordered Tests

When additional tests are requested by telephone, the caller is asked to follow up with a written request on letterhead or to send an additional laboratory requisition form for that test to the Public Health Laboratory. Please send written requests to the attention of the Section Supervisor or to the Specimen Management Section. The additional test(s) will not be performed until the written request is received. With time sensitive tests, the specimen(s) may be tested immediately, and the results held until the written request is received. Exception: No HIV tests will be performed without written request at the time of testing. All blood specimens will be discarded if a written request is not received within seven working days.

Requesting Additional Testing on a Serology Specimen

To request an additional serology test, call the Specimen Management Section at (803) 896-0898. Specimens are discarded after seven working days. A request must be made within that time period. Additional testing on the same specimen may not always be feasible. The testing laboratory may request additional information to determine specimen acceptability. In some cases, a second (new) specimen for testing may be recommended. In other cases, the patient's clinical history may provide an explanation for the initial result, and additional testing or retesting may not be necessary.

Specimens Referred for Testing to the CDC

Laboratories wishing to send specimens directly to the CDC should contact the Microbiology Division at (803) 896-0870 or, when appropriate, the Virology, Serology, and Advanced Molecular Detection (VSA) Division at (803)-896-0897. The sender will be assigned a State Health Department Number and will be asked to forward the Public Health Laboratory (PHL) a copy of the information being sent. CDC forms are also available from the PHL.

Other Reference Laboratories

If a specimen is sent to a reference laboratory for initial, follow-up, or verification testing by the Public Health Laboratory, the sender will be notified that the specimen has been referred. Either the original result report from the reference laboratory is forwarded to the sender, or the results will be reported using the PHL's laboratory information system, noting where the test was performed. A copy of the report is maintained by the laboratory.

STAT Testing

Requests received in the morning will be put in the day's run. The results will be telephoned to the

requestor, followed by a hard copy report or electronic accessible report. If the request is for a test that will not be performed immediately, the requestor will be informed by telephone when the test will be performed and the result available.

Confirmatory Testing

When confirmatory tests are necessary, preliminary results are reported until all testing is completed. Once all testing is complete, a final report will follow.

Laboratory Specimens Sent to the Public Health Laboratory in Error

Specimens sent to the laboratory in error will be returned to the sender as soon as possible.

Correction of Patient Information

All requested changes to the request form by the sender must be documented on letterhead, dated, and signed by the requestor. A returned copy of the original laboratory report requesting the missing information is also acceptable to communicate changes needed as long as the sender states clearly what is needed, dates, and signs the report. The patient's record will be updated to reflect the change.

Specimen Rejection & Disclaimer Criteria

The following rejection criteria and disclaimers are considered universal, as they apply to all specimens submitted for testing. Specific test related rejections are listed in the Alphabetical Listing of Test (Section II) and the Collection Procedures (Section III).

No Specimen Received

When a request form is received without a specimen, notification to the client will be made about the specimen and the laboratory's inability to perform testing. The laboratory test report will state that no specimen was received, and that testing was not performed.

No Requisition Received

If a specimen is received without a request form and the sender cannot be identified from the specimen label, the specimen will be held awaiting telephone inquiry or delayed receipt of the requisition form. After seven days, blood specimens are discarded. Gen-Probe Aptima swab specimens are discarded after 60 days and the Gen-Probe Aptima urine specimens are discarded after 30 days.

No Name on Specimen

When a specimen is received without an identifying number or patient name, it WILL NOT be tested. An exception may be made at the discretion of the Supervisor, Division Director, or Laboratory Director for a specimen that cannot be recollected because of its unique anatomic source, collection method, or time of collection. Examples include: CSF, peritoneal pleural and synovial fluids, autopsy, biopsy, or organ specimens, and specimens collected prior to the initiation of antimicrobial therapy.

No Name on Requisition

When a requisition form is received without a name, and there is no other identification on the form that matches the information on the specimen, notification will be made to the submitter requesting a corrected requisition. The specimen will be tested ONLY after the corrected lab requisition form is received.

No Test Requested

When a specimen is received and there is no test marked on the lab requisition, notification will be made to the sender, informing them that no test was requested. When a corrected requisition form is received, only then, will the specimen be tested.

Other Missing Information

If other necessary information is missing, the specimen will be tested, and the missing information will be requested by phone, fax, mail, or email. The result will be held until the missing information is received.

Mismatched Information

When the name on the request form and the specimen do not match, the specimen will NOT be tested. It will be reported as, "Name on specimen differs from name on request form".

Partial Information Matches

When there is a partial name match with other identifiers and information on the requisition matching the specimen, it is most probably the same patient. The name on the tube is documented on the requisition, the test is performed, and a disclaimer is added to the report.

Verification made by contacting the submitter will be documented, along with the data/time and name of the person spoken with.

Specimen Broken or Leaked in Transit

When a broken or leaking specimen is received, every attempt will be made to salvage it without compromising the integrity of the specimen.

If the sample CANNOT be salvaged, a notation that the sample broke/leaked in transit is made in the lab information system (LIS) to be included on the report. The laboratory report will notify the submitter that testing was not performed.

Verbal notifications made to submitters will be documented in the computer system with the date/time and name of the person notified.

Incorrect Specimen Received

If the specimen received is incorrect for the test requested, notification will be made to the client about the specimen and the laboratory's inability to perform testing. The laboratory test report will state that the incorrect specimen type was received, and that testing was not performed.

Unsatisfactory Specimens

The Public Health Laboratory will discard specimens which are received in unsatisfactory condition. The reasons for the rejection will be reported to the submitter on the laboratory test report. Unsatisfactory conditions include, but are not limited to:

- Hemolyzed, chylous, or contaminated specimen,
- Specimen received beyond the acceptable time for testing,
- Specimen collected too soon or too late during the disease-state for the test requested,
- Specimen was stored and shipped at improper temperature,
- Specimen is nonviable, or decomposed,
- Specimen quantity insufficient

Specimens that have some degree of hemolysis, icteric, or chylous, will be tested if the degree of hemolysis or lipemia does not interfere with the analysis. The unsatisfactory condition will be indicated on the laboratory test report.

Results Reporting Policies

All laboratory reports generated are considered confidential information. The reports will be released only to authorized persons. Reports can be accessed via the internet through a laboratory web portal, allowing immediate access to results. Reports are mailed daily to clients without access to the laboratory web portal, as requested. Clients can only view information on orders that have been logged in with their customer ID. Contact the laboratory at 803-896-4777 for any issues regarding web portal access.

Telephone Results

Panic/critical values and/or public health emergencies are telephoned to the appropriate person(s). A result will NOT be left on voice mail or an answering machine. A message to call the Public Health Laboratory for results will be left.

Copies of Test Reports

Newborn Screening: Laboratory reports are available via the internet through eReports, a laboratory web portal for the hospital submitting the specimen and for the physician whose name has been entered on the request form as the healthcare provider. An account must be set up by the LIMS office to access reports on eReports. **All other tests**: Reports can be accessed electronically through the OpenELIS web portal. Copies of test reports will be provided to the name entered in the sender section of the requisition, or to the provider, upon request.

Remailing of Test Reports

If a physician or clinic to which the patient has been referred requests a copy of a test results, the report will be reprinted with the original sender number and sent as requested. If the report is not received, please call 803-896-0800 or 803-896-4777.

Correcting Reporting Errors

If an error or the possibility of an error is discovered by the laboratory after results have been reported, the sender will be notified immediately by telephone. The error will be explained, and the correct result given. A new report will be issued that will be labeled as, "Corrected Report".

If an error in reporting is discovered by the sender, the laboratory should be notified immediately. The error will be corrected, and an updated report will be generated. The corrected report will be labeled as, "Corrected Report" if a result has been changed, or "Amended Report" for other error types (e.g., patient demographics).

Disease Reporting

The Code of Laws of South Carolina (1976) Section 44-29-10: Regulation 61-20 mandates that the Commissioner of DHEC is to publish annually a list of diseases to be reported by physicians and laboratories. This list can be found on the Internet at <u>https://scdhec.gov/sites/default/files/Library/CR-009025.pdf</u>.

All communicable disease outbreaks and unusual disease occurrences should be reported, so that appropriate control measures can be implemented.

SECTION II

ALPHABETICAL LISTING OF TEST INFORMATION

Test	BACILLUS ANTHRACIS
Synonym:	Anthrax
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118
Days Performed:	As needed
Turnaround Time:	72 hours
Specimen Required:	Clinical specimens / isolates
Specimen Identification:	Specimens should be labeled with the patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.
Specimen Volume (optimum):	Determined during pre-approval consultation.
Specimen Volume (minimum):	Determined during pre-approval consultation.
Collect:	Clinical specimen / Pure isolate on slant
Form:	DHEC 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for specimen type and write " <i>Bacillus anthracis</i> " for "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior to submission.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at (803) 896-0777 / (803) 767-8118
Transport Conditions:	Determined during pre-approval consultation.
Specimen Rejection Criteria:	Determined during pre-approval consultation.
Availability:	24 hours / 7 days a week
Results and Interpretations:	Preliminary results (when applicable) and final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.
Additional Information:	<i>Bacillus anthracis</i> is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Bacillus anthracis</i> detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.
Purpose of Test:	To detect <i>B. anthracis</i> in clinical specimens or referred isolates.
Method:	A variety of sentinel and Laboratory Response Network (LRN) Methods are used to detect Bacillus anthracis.
Interfering Substances:	N/A
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

Test	BRUCELLA
Synonym:	Brucellosis
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767- 8118
Days Performed:	As Needed
, Turnaround Time:	7- 21 days from time of specimen receipt in the laboratory
Specimen Required:	Clinical Specimens / isolates
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.
Specimen Volume (optimum):	Determined during pre-approval consultation.
Specimen Volume (minimum):	Determined during pre-approval consultation.
Collect:	Call the Special Pathogens Laboratory.
Form:	Form 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for specimen type and write " <i>Brucella sp.</i> " for "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the
Special Instructions:	specimen. Specimen must be pre-approved by Special Pathogens Supervisor prior
·	to testing.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at (803) 896-0777 / (803) 767-8118.
Transport Conditions:	Determined during pre-approval consultation.
Specimen Rejection Criteria:	Determined during pre-approval consultation.
Availability:	24 hours / 7 days a week
Results and Interpretations:	Preliminary (when applicable) and final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.
Additional Information:	<i>Brucella</i> abortus, <i>melitensis</i> , and <i>suis</i> are designated as Select Agents (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Brucella</i> detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.
Purpose of Test:	To detect Brucella organisms in clinical specimens / To confirm suspect isolates
Method:	A variety of sentinel and Laboratory Response Network (LRN) Methods are used to detect and speciate <i>Brucella</i> organisms.
Interfering Substances:	N/A
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

Test	BRUCELLA ANTIBODY (TOTAL) by AGGLUTINATION
Synonym:	Brucella Microagglutination Test (BMAT)
Lab Section/Phone:	Special Pathogens / (803) 896-0777 or (803) 767-8118
Days Performed:	Monday-Thursday
Turnaround Time	5 days
Specimen Required:	Serum
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.
Specimen Volume (optimum):	2 mL
Specimen Volume (minimum):	500 mL
Collect:	Serum Separator Tube (SST)
Form:	Form 1335-OE; In the "Serological Testing" box, check "BMAT". DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior to testing.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777 / 803-767-8118.
Transport Conditions:	Serum specimens should be stored at 2-8°C and shipped on frozen cold packs to maintain specimens at 2-8°C until receipt at the PHL.
Specimen Rejection Criteria:	Hemolysis; lipemia; gross bacterial contamination; improper temperature; For universal rejections, See Section I.
Availability:	As needed
Results and Interpretations:	 A single serum titer of 1:160 or higher is suggestive of exposure to Brucella at some time. Titer results ≥ 1:160 will automatically reflex to a repeat test with the "reduced" serum for acute/convalescence determination. Cross-reactions may occur between <i>Brucella</i> and <i>F. tularensis</i> antigens and antisera. Preliminary (when applicable) and final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.
Additional Information:	N/A
Purpose of Test:	To presumptively detect smooth strain brucella antibodies in human sera. This test will not detect exposure to <i>Brucella canis</i> or <i>Brucella abortus RB51</i> rough strains.
Method:	Semi-Quantitative Agglutination
Interfering Substances:	Hemolysis; lipemia; gross bacterial contamination
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

Test	BURKHOLDERIA MALLEI	
Synonym:	Glanders	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767- 8118	
Days Performed:	As needed	
Turnaround Time	7 to 10 days from the time of specimen receipt in the laboratory.	
Specimen Required:	Clinical Specimens / isolates	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.	
Specimen Volume (optimum):	Determined during pre-approval consultation.	
Specimen Volume (minimum):	Determined during pre-approval consultation.	
Collect:	Determined during pre-approval consultation.	
Form:	DHEC 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for specimen type and write " <i>B. mallei</i> " for "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.	
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior to testing.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at (803) 896-0777 / (803) 767-8118.	
Transport Conditions:	Determined during pre-approval consultation.	
Specimen Rejection Criteria:	Determined during pre-approval consultation.	
Availability:	As needed	
Results and Interpretations:	Preliminary results (when applicable) and final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.	
Additional Information:	Burkholderia mallei is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of Burkholderia mallei detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.	
Purpose of Test:	To detect <i>B. mallei</i> in clinical specimens / To confirm referred isolates.	
Method:	A variety of sentinel and LRN methods are used to grow, confirm, or rule- out bacterial isolates.	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogen Laboratory with any questions or concerns.	

Test	BURKHOLDERIA PSEUDOMALLEI	
Synonym:	Melioidosis	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767- 8118	
Days Performed:	As needed	
Turnaround Time	7 to 10 days from the time of specimen receipt in the laboratory.	
Specimen Required:	Clinical Specimens and clinical isolates	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.	
Specimen Volume (optimum):	Determined during pre-approval consultation.	
Specimen Volume (minimum):	Determined during pre-approval consultation.	
Collect:	Determined during pre-approval consultation.	
Form:	DHEC 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for specimen type and write " <i>Burkholderia pseudomallei</i> " for "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.	
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior to testing.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at (803) 896-0777 / (803) 767-8118.	
Transport Conditions:	Determined during pre-approval consultation.	
Specimen Rejection Criteria:	Determined during pre-approval consultation.	
Availability:	As needed	
Results and Interpretations:	Preliminary (when applicable) and final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.	
Additional Information:	Burkholderia pseudomallei is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of Burkholderia pseudomallei detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.	
Purpose of Test:	To detect <i>Burkholderia psuedomallei</i> in clinical specimens / To confirm referred isolates	
Method:	A variety of sentinel and LRN methods are used to grow, confirm or rule- out bacterial isolates.	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogen Laboratory with any questions or concerns.	

Test	CADMIUM, LEAD, MERCURY SCREEN IN WHOLE BLOOD	
Synonym:	Blood Metals (Cadmium (Cd), Lead (Pb), and Mercury (Hg) in Whole	
	Blood)	
Lab Section/Phone:	Analytical Chemistry, 803-896-0886 or 803-896-0991	
Days Performed:	As requested	
Turnaround Time:	5 Days	
Specimen Required:	1 mL of whole blood from venipuncture	
Specimen Identification:	Specimen container must be labelled with patient's full name, and a	
	second patient identifier such as DOB, Specimen #, etc. DHEC	
	requisition must be completed in full.	
Specimen Volume	> 1 mL	
(optimum):		
Specimen Volume	500 μL	
(minimum):		
Collect:	In general, if more than one evacuated tube of blood is to be drawn	
	from an individual, the blood metals tube should be drawn second or	
	later. Draw the blood through a stainless-steel needle into a	
	Vacutainer [™] .	
Form:	DHEC 1332, Test #882	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Specimens can be stored at 2-8°C and shipped on frozen cold packs to	
	maintain specimens at 2-8°C until receipt at the PHL. Specimens must	
	be received for testing within 10 days of collection.	
Specimen Rejection	Clotted blood, insufficient quantity (QNS), improper temperature. For	
Criteria:	universal rejections, See Section I.	
Availability:	Monday – Friday	
Results and	Blood lead levels in children under the age of 16 are considered	
Interpretations:	elevated at or above 3.5 μ g/dL and chelation treatment should be	
	considered at confirmed blood lead levels of 45 μ g/dL. The	
	Occupational Safety and Health Administration regulations use a blood	
	lead level of 40 μ g/dL as cause for written notification and a medical	
	exam, and a blood lead level of 60 μ g/dL as cause for medical removal	
	from exposure.	
	Levels of concern for cadmium in blood is > 5 μ g/L.	
	The American Conference of Governmental Industrial Hygienists has a	
	biological exposure index (BEI) of 15 μ g/L for inorganic mercury in	
	blood.	
Additional Information:	N/A	
Purpose of Test:	Identify exposure to Cadmium, Lead, and Mercury.	
Method:	Inductively Coupled Plasma Mass Spectrometry (ICP-MS)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	CAMPYLOBACTER	
Synonym:	Organism for ID, Enteric Culture	
Lab Section/Phone:	Clinical Microbiology – 803 896-0805	
Days Performed:	Monday – Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Isolate or PCR+ stool transport if unable to isolate Campylobacter isolate	
Specimen Identification:	Isolates and Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Organism or Specimen should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	Isolate – send culturette or slant.	
Specimen Volume (minimum):	Specimen – send a walnut sized portion of feces or 5-10ml of liquid stool in stool transport. Infant specimens may be collected in a disposable diaper with outside facing in.	
Collect:	Isolate ship on slant or culturette. Stool must be in transport medium.	
Form:	DHEC 1335-OE; isolate="Organism for ID", Stool Transport="Enteric Culture"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store stool preserved in transport media in refrigerator at 2-8°C. Ship ALL specimens and isolates on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection.	
Specimen Rejection Criteria:	Quantity insufficient, specimen too old, improper transport media or conditions, improper temperature. For universal rejections, See Section I.	
Availability:	Monday – Friday	
Results and Interpretations:	Campylobacter genus and species	
Additional Information:	Specimen submission to the Public Health Laboratory (PHL) is required. If unable to isolate, ship stool in transport media, such as Cary Blair and Para-Pak ASAP, as the recovery of Campylobacter goes drastically down after 3 days from collection. Isolates once incubated overnight in microaerophilic conditions can be shipped within 3 business days on frozen cold packs in approved and specialized insulated shippers to maintain a temperature range of 2-8°C until received at the PHL.	
Purpose of Test:	SC Disease Reportable Conditions required submission, Confirm or identify Campylobacter.	
Method:	bioMerieux VITEK MS	
Interfering Substances:	None	
Comment:	Important – Maintain specimen at 2-8°C and ship to be received within 3	
	days of collection at the PHL in the temperature range of 2-8°C.	

Test	CAMPYLOBACTER STOOL CULTURE	
Synonym:	Enteric Culture	
Lab Section/Phone:	Clinical Microbiology – 803 896-0805	
Days Performed:	Monday – Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Stool in transport media.	
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Organism or Specimen should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	Specimen – send a walnut sized portion of feces or 5-10 mL of liquid stool in	
(optimum):	stool transport. Infant specimens may be collected in a disposable diaper with outside facing in.	
Specimen Volume (minimum):	N/A	
Collect:	N/A	
Form:	DHEC 1335-OE, "Enteric Culture"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV	
Transport Conditions:	Store the stool preserved in transport media in refrigerator at 2-8°C. Ship ALL specimens and isolates in approved and specialized shippers on frozen cold packs to maintain a temperature range of 2-8°C for receipt at the PHL within 3 days of collection.	
Specimen Rejection Criteria:	Quantity insufficient, specimen too old, improper transport media or	
Availability	conditions, improper temperature. For universal rejections, See <u>Section I</u> .	
Availability:	Monday – Friday	
Results and Interpretations: Additional Information:	Campylobacter genus and species Specimen submission to the Public Health Laboratory (PHL) is required. If unable to isolate, ship stool in transport media, such as Cary Blair and Para-Pak ASAP, as the recovery of Campylobacter goes drastically down after 3 days from collection. Isolates once incubated overnight in microaerophilic conditions can be shipped within 3 business days on frozen cold packs in approved and specialized insulated shippers to maintain a temperature range of 2-8°C.	
Purpose of Test:	SC Disease Reportable Conditions required submission, isolate Campylobacter from culture	
Method:	bioMerieux VITEK MS	
Interfering Substances:	None	
Comment:	Important – Maintain specimen at 2-8°C and ship to be received within 3	
	days of collection at the PHL in the temperature range of 2-8°C.	

CANDIDA AURIS		
Candida not Candida albicans, Candid	da unable to speciate	
Clinical Microbiology 803-896-0805		
· · ·		
Isolate submission on slant		
Submitter Identification Method	Isolates to Submit	
	A random subset of isolates	
	Germ tube-negative isolates	
	Isolates that are NOT green or	
	blue (so no <i>C. albicans</i> or <i>C.</i>	
	tropicalis or C. dubliniensis)	
API 20C or API 32C	Isolates that are NOT <i>C. albicans</i>	
	or C. tropicalis or C. dubliniensis	
VITEK 2. MicroScan. Phoenix	Isolates that are NOT <i>C. albicans</i>	
,,	or C. tropicalis or C. dubliniensis	
MALDI-TOF or molecular	Isolates that are NOT <i>C. albicans</i> ,	
identification	C. tropicalis, C. parapsilosis, C.	
	lusitaniae, C. dubliniensis or C.	
	krusei	
Isolates must be labelled with patient's first and last name, and a second		
patient identifier such as DOB, MCI #	, Specimen #. Organism isolate should	
have the date of isolate or collection,	, and initials of the person collecting the	
specimen. DHEC requisition must be	completed in full.	
N/A		
N/A		
Isolate of Candida possible auris on s	lant. See chart below.	
DHEC 1335-OE - mark "Organism for ID"		
Write on form any testing performed	l	
See Transporting and Shipping Infectious Substances in Section IV.		
Ship in approved shippers to maintain	n temperature within the range of	
15-25°C until received at the PHL.		
Isolate mixed, isolate not a Candida s	pecies, improper temperature; For	
universal rejections, See Section I.		
To identify possible Candida auris, or	other rare newly emerging Candida	
	, , ,	
species.		
species. bioMerieux VITEK MS		
•		
	Candida not Candida albicans, Candid Clinical Microbiology 803-896-0805 Monday – Friday 10 Business days Isolate submission on slant Submitter Identification Method No identification Germ tube only Chromagar only API 20C or API 32C VITEK 2, MicroScan, Phoenix MALDI-TOF or molecular identification Isolates must be labelled with patien patient identifier such as DOB, MCI # have the date of isolate or collection specimen. DHEC requisition must be N/A N/A Isolate of Candida possible auris on s DHEC 1335-OE - mark "Organism for Write on form any testing performed See <u>Transporting and Shipping Inf</u> Ship in approved shippers to maintai 15-25°C until received at the PHL. Isolate mixed, isolate not a Candida s universal rejections, See <u>Section I</u> . Monday – Friday Candida species identified N/A	

Test	CHIKUNGUNYA IgM Capture ELISA	
Synonym:	Chik IgM Serology	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	N/A	
Turnaround Time:	CDC Submission	
Specimen Required:	Serum	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is	
	required on the specimen and requisition.	
Specimen Volume (optimum):	2 mL	
Specimen Volume	0.5 mL	
(minimum):		
Collect:	Serum Separator vacuum tube (SST), centrifuged appropriately. (Red	
	top vacuum tubes may be used if the specimen is centrifuged, and	
	serum is removed from the clot and put into a labeled secondary	
	container/tube. Please follow manufacturer's guidelines. See <u>Specimen</u>	
	Collection: Venipuncture Procedure in Section III if needed.	
Form:	DHEC 1332	
Special Instructions:	N/A	
Packing and Shipping*:	See <u>Transporting and Shipping Infectious Substances in Section IV</u> .	
Transport Conditions:	Serum specimens can be stored at 2-8°C and shipped on frozen cold	
	packs to maintain specimens at 2-8°C until received at the PHL or can be	
	stored frozen at -20°C or lower and shipped on dry ice to maintain the	
Crasina an Deiestian	specimen at -20°C or lower until received at the PHL.	
Specimen Rejection Criteria:	See Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	N/A	
Results and	N/A N/A	
Interpretations:		
Additional Information:	Positive specimens will be referred to CDC for additional testing.	
Purpose of Test:	To detect IgM antibodies for the Chikungunya virus to determine a	
	current infection.	
Method:	IgM Capture ELISA (Enzyme-Linked Immunosorbent Assay)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	CHLAMYDIA (CT) DETECTION BY NUCLEIC ACID AMPLIFICATION	
Synonym:	Gen-Probe, C. trachomatis Amplified Nucleic Acid Probe, Chlamydia rRNA, CT Aptima	
Lab Section/Phone:	Diagnostic Serology, 803-896-0811	
Days Performed:	Monday-Friday	
Turnaround Time:	3 - 5 Business Days	
Specimen Required:	Swab specimen: Endocervical, rectal and pharyngeal swab, and/or male urethral	
speemen neganea.	specimens in Gen-Probe Aptima Unisex Swab Specimen Collection Kit for Endocervical	
	and Male Urethral Swab Specimens (Blue label/Blue collection swab).	
	Vaginal specimens: Vaginal specimens are collected using the Gen-Probe Aptima	
	Multitest Swab Specimen Collection kit. (Orange label/ Pink collection swab).	
	Urine specimen: Patient should not have voided within one hour of collection. Collect	
	first 20 - 30 mL of the first-catch urine stream into collection cup. Transfer 2 mL of	
	urine into Aptima Urine Specimen Transport tube so that the urine level falls within	
	the two lines on the transport tube labeled: "fill area". (Yellow Label). Urine must be	
	transferred to the Urine Collection Tubes within 24 hours. See <u>GC/Chlamydia Gen-</u>	
	Probe Collection Procedure, Section III.	
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient	
specification.	identifier such as DOB, MCI #, or Specimen #. DHEC requisition must be completed.	
Specimen Volume (optimum):	Urine should be collected up to fall within the "fill area" lines. Swab collection kits	
specifien volume (optimum).	should contain an adequate amount of transport media for testing.	
Specimen Volume (minimum):	Urine should be collected up to the "fill area" lines. Swab collection kits should contain	
specifien volume (minimum).	the adequate amount of transport media for testing.	
Collect:		
Collect.	See specimen requirements and <u>GC/Chlamydia Gen-Probe Collection Procedure</u> ,	
F ormer:	Section III.	
Form:	DHEC 1332, Test – CT only, Test – GC only and CT/GC, GC/Chlamydia/Trich. vaginalis	
Special Instructions:	Only use Gen-Probe Aptima specimen collection kit (unisex swab, multitest swab, or	
	urine).	
Packing and Shipping*:	See <u>Transporting and Shipping Infectious Substances in Section IV</u> .	
Transport Conditions:	Store and ship urogenital swabs at 2-30°C, rectal and pharyngeal swabs at 4-30°C, and	
	urine at 2-30°C. Swab specimens must be tested within 60 days of collection. Urine	
	specimens should be tested within 30 days of collection. For longer storage, freeze	
	transport tube within 7 days of collection at \leq -20 °C.	
Specimen Rejection Criteria:	Specimen with no swab or incorrect swab in transport media; white swab in transport	
	media; two swabs in transport media; urine above or below designated black lines on	
	transport tube labeled fill area; swab specimen more than 60 days old, or urine	
	specimen more than 30 days old. Specimens received at improper temperature. For	
	universal rejections, See <u>Section I</u> .	
Availability:	Monday - Friday	
Results and Interpretations:	Positive, Negative, or Indeterminate	
Additional Information:	This test is not appropriate in cases of sexual assault or abuse. A negative result does	
	not preclude the presence of a CT or GC infection because results are dependent on	
	adequate specimen collection, absence of inhibitors, and sufficient rRNA to be	
	detected. Test results may be affected by improper specimen collection, improper	
	specimen storage, technical error, or specimen mix-up. Therapeutic failure or success	
	cannot be determined with the Aptima Combo 2 Assay since nucleic acid may persist	
	following appropriate antimicrobial therapy.	
Purpose of Test:	For the detection of Chlamydia in pharyngeal, rectal, vaginal, cervical, urethral and	
	urine specimens.	
Method:	Nucleic Acid Amplification Test	
Interfering Substances:	N/A	
Comment:	N/A	

Test	CORYNEBACTERIUM DIPHTHERIAE, CULTURE & ID	
Synonym:	C. diphtheriae	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Isolate on slant; culture upon approval by CDC (throat swab, NP swab,	
	skin, clinical material on Loeffler's slant)	
Specimen Identification:	Isolates and specimens must be labelled with patient's first and last	
	name, and a second patient identifier such as DOB, MCI #, Specimen #.	
	Organism or specimen should have the date of isolate or collection, and	
	initials of the person collecting the specimen. DHEC requisition must be	
	completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	N/A	
(minimum):		
Collect:	N/A	
Form:	DHEC 1335-OE; "Organism for ID" (referred isolate), "Non-Enteric	
	Culture and ID" (CDC approval)	
Special Instructions:	Notify Clinical Microbiology Laboratory Section prior to submission;	
	Specimens must be received within 24 hours of collection.	
Packing and Shipping*:	See <u>Transporting and Shipping Infectious Substances in Section IV</u> .	
Transport Conditions:	Ship specimens in approved shippers to maintain temperature of	
	specimen within the range of 15-25°C until received at the PHL.	
Specimen Rejection	Transport swab not used or ampule in transport swab not crushed.	
Criteria:	Culture: must be received within 24 hours of collection unless	
	submitted on Loeffler's medium. Specimens received at improper	
	temperature. For universal rejections, see <u>Section I</u> .	
Availability:	Monday - Friday	
Results and	N/A	
Interpretations:		
Additional Information:	Per SC List of Reportable Conditions, specimen submission to the Public	
	Health Laboratory (PHL) is required within 1 business day of reporting.	
Purpose of Test:	N/A	
Method:	Conventional culture methods, Traditional Biochemicals	
Interfering Substances:	N/A	
Comment:	N/A	

Test	COVID-19		
Synonym:	SARS-CoV-2		
Lab Section/Phone:	Virology/Rabies, 803-896-0819		
Days Performed:	Monday - Friday		
Turn a Round time	2 Business days		
Specimen Required:		specimens (nasopharyngeal (NP), oropharyngeal, anterior na	asal, and
opeointen negan ear		al swabs, nasopharyngeal aspirate) and bronchoalveolar lava	
	(BALS) specimens		9~
Specimen Identification:	. , ,	e and patient ID # (or other unique identifier) is required on t	he
	specimen and requisition.		
Specimen Volume (optimum):		f viral transport media.	
Specimen Volume (minimum):		ral transport media.	
Collect:		fiber swabs with plastic shafts. Do not use calcium alginate s	wahs or
		en shafts, as they may contain substances that inactivate som	
		PCR testing. Place swabs immediately into sterile tubes cont	
	- 3 mL of viral tran		unnig z
Form:	DHEC 1335-OE		
Special Instructions:	N/A		
Packing and Shipping*:		and Shipping Infectious Substances in Section IV if needed.	
Transport Conditions:		t 2 - 8°C for up to 72 hours after collection.	
	•	hip without delay, ship overnight on frozen cold packs to mai	intain
	specimens at 2-8°C until received at the PHL. If a delay in shipping will result in receipt of the specimen at the PHL more than 72 hours after collection, store at ≤-20°C and		
		dry ice to maintain temperature until received at the PHL.	anu
Specimen Rejection Criteria:		ection & Disclaimer Criteria in Section I.	
Availability:	6 days/week	ection & Disclaimer Criteria in Section 1.	
Results and Interpretations:	Result	Interpretation	
Results and interpretations.		Hologic Panther Fusion SARS-CoV-2 Assay	
	Detected	SARS-CoV-2 detected	
	Not Detected	SARS-CoV-2 not detected	
	Invalid	Recollect specimen ner COVID-19 Real Time PCR Assay Multiplex, ThermoFisher TaqPath	
	Detected	Positive SARS-CoV-2	
	-		
	Not Detected	SARS-CoV-2 not detected	
	Inconclusive	Recollect specimen	
Additional Information:		s emergency use authorized (EUA) assay for patients and pro	oviders
		t the following link: <u>https://www.fda.gov/medical-</u>	dical
	devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical- devices/vitro-diagnostics-euas#individual-molecular		
Durness of Tast			
Purpose of Test:		Qualitative detection of nucleic acid from the 2019-nCoV in upper respiratory	
	specimens (such as nasopharyngeal swabs) collected from individuals who meet 2019-		
	nCoV clinical and/or epidemiological criteria (e.g., clinical signs and symptoms		
	associated with 2019-nCoV infection, contact with a probable or confirmed 2019-nCoV case, history of travel to geographic locations where 2019-nCoV cases were detected,		
	or other epidemiologic links for which 2019-nCoV testing may be indicated as part of a		
	public health investigation).		
Mathad:			
Method:		sher COVID-19 Real Time PCR Assay Multiplex, ThermoFisher	r
	TaqPath		
		anther Fusion SARS-CoV-2 Assay	
Interfering Substances:	N/A		
Comment:	N/A		

Test	CRE, CRPA, CRAB	
Synonym:	CRE = Carbapenem-resistant Enterobacterial (former Enterobacteriacea),	
	Ship All, Do Not send duplicates. Only one isolate per patient regardless of	
	source. Includes the following: E.coli, Enterobacter, Klebsiella, Proteus,	
	Providencia, Serratia, and Morganella. (With the exceptions of Serratia which	
	are both resistant to carbapenems and sensitive to a 3 rd generation	
	cephalosporin and Enterobacter spp. which are sensitive to Cefepime. These	
	both represent a different mechanism of resistance than a carbapenemase.)	
	Ertapenem non-susceptibility is the most sensitive indicator of carbapenemase	
	production.	
	CRPA = Carbapenem resistant Pseudomonas aeruginosa Send all non-mucoid P.	
	aeruginosa resistant to imipenem, meropenem, or doripenem AND Not	
	Susceptible to cefepime or ceftazidime. Do not send duplicates.	
	CRAB = Carbapenem resistant Acinetobacter baumanii complex	
	Send in all pan-resistant Acinetobacter spp.	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Isolate submitted on slant.	
Specimen Identification:	Isolates must be labelled with patient's first and last name, and a second patient	
	identifier such as DOB, MCI #, Specimen #. Organism Isolate should have the	
	date of isolate or collection, and initials of the person collecting the specimen.	
	DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Carbapenem-resistant Enterobacteriaceae and Acinetobacter baumanni from all	
	specimen types are required to be submitted.	
Form:	DHEC requisition 1335-OE, check "CRE/CRPA/CRAB"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV if needed.	
Transport Conditions:	Ship isolates in approved shippers to maintain temperature of specimen within	
	the range of 15-25°C until received at the PHL.	
Specimen Rejection Criteria:	Quantity insufficient, specimen too old, improper transport media or conditions,	
	improper temperature; For universal rejections, See Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	Organism identification will be confirmed and reported, mCIM test will be set up	
	and reported, all Positive and indeterminant mCIM isolates will have a PCR test	
	performed to identify carbapenemase enzyme, and an AST (antimicrobial	
	sensitivity test) will be performed.	
Additional Information:	INCLUDE DRUG SUSCEPTIBILITY PROFILE, Specimen submission to the Public	
	Health Laboratory (PHL) is required. Ship within 3 business days.	
Purpose of Test:	N/A	
Method:	bioMerieux VITEK MS, mCIM, Cepheid, STRECK kit, KBS, Sensititre	
Interfering Substances:	N/A	
Comment:	N/A	

Test	CRYPTOSPORIDIUM ANTIGEN	
Synonym:	Cryptosporidium antigen testing is available for outbreaks as	
	determined by the SC DHEC Division of Acute Disease Epidemiology.	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	5 Business days	
Specimen Required:	Walnut sized portion fresh stool or 3 mL of liquid stool, 10% formalin preserved stool, Cary-Blair, C & S, or concentrated stool sediment. Specimen must be placed in a leakproof container. Do Not use PVA.	
Specimen Identification:	Specimen container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	N/A	
(minimum):		
Collect:	N/A	
Form:	DHEC requisition form 1335-OE	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV, if needed.	
Transport Conditions:	Store stool preserved in transport media in refrigerator at 2-8°C. Ship ALL specimens and isolates on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection.	
Specimen Rejection	Specimen preserved in PVA, improper labeling, improper temperature;	
Criteria:	For universal rejections, see Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	Negative = Cryptosporidium antigen is absent or below detectable levels. Positive = Cryptosporidium antigen detected.	
Additional Information:	N/A	
Purpose of Test:	To detect the presence of <i>Cryptosporidium</i> oocysts.	
Method:	Rapid immunoassay for the qualitative detection of <i>Cryptosporidium</i>	
Methou.	parvum antigen.	
Interfering Substances:	The test is designed for use with stool specimens collected in an acceptable transport media. The use of colonic washes, aspirates or other diluted specimen types has not been established and could affect the performance of the assay. Stool specimens contaminated by products with an oily or particulate base (e.g., Barium, mineral oil, etc.) could interfere with the test and are not recommended.	
Comment:	N/A	

Test	DENGUE IgM		
Synonym:	Dengue IgM Serology		
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	N/A		
Turnaround Time:	CDC Submission		
Specimen Required:	Serum		
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on		
	the specimen an	d requisition.	
Specimen Volume	2 mL serum		
(optimum):			
Specimen Volume	0.5 mL serum		
(minimum):			
Collect:		vacuum tube (SST) centrifuged appropriately according to	
	-	uidelines. (Red top vacuum tubes may be used if the	
		rifuged, and serum is removed from the clot and put into a	
		ry container/tube.) Please follow manufacturer's guidelines.	
-	See <u>Specimen Collection: Venipuncture Procedure in Section III,</u> if needed.		
Form:	DHEC 1332		
Special Instructions:		s are NOT required.	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.		
Transport Conditions:	Serum specimen	s may be stored at 2-8°C and shipped on frozen cold packs to	
	maintain specimens at 2-8°C until received at the PHL or may be stored frozen		
		and shipped on dry ice to maintain the specimen at -20°C or	
	lower until received by the PHL.		
Specimen Rejection Criteria:		ejection & Disclaimer Criteria in Section I.	
Availability:	Weekly		
Results and Interpretations:	Result	Interpretation	
	Negative	No detectable IgM antibody, individual does not	
		appear to be infected with Dengue virus. The result	
		does not rule out Dengue virus infection.	
	Equivocal	Dengue virus IgM antibody cannot be determined.	
		Submit another specimen for testing.	
	Positive	Presence of detectable IgM antibody, presumptive	
		infection with Dengue virus. Confirmatory testing to	
		follow. A positive IgM result may not indicate a	
		recent infection because IgM may persist for several	
		months after infection.	
Additional Information:	Positive results will be referred to CDC for additional testing.		
Purpose of Test:	To detect IgM antibodies for the Dengue virus to determine a current infection.		
Method:	IgM Capture ELISA (Enzyme-Linked Immunosorbent Assay)		
Interfering Substances:	N/A		
interreting Substances.	N/A		

Test	EBOLA VIRUS REAL-TIME RT-PCR ASSAY (EBOLA)	
Synonym:	N/A	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
Days Performed:	As needed	
Turnaround Time:	24 hours	
Specimen Required:	Whole blood - Please contact the Special Pathogens Laboratory for special	
	instructions at 803-896-0777 / 803-767-8118.	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or	
	other unique ID #, date and time of collection, initials of the person collecting the	
	specimen, and the specimen source.	
Specimen Volume (optimum):	Communicated during consultation.	
Specimen Volume	Communicated during consultation.	
(minimum):		
Collect:	The Special Pathogens Laboratory must be contacted (803-896-0777 / 803-767- 8118) prior to and after collection for special instructions.	
Form:	DHEC 1335-OE; In the Special Pathogen box, check "Other" under Molecular	
	testing for viral pathogens and write "Ebola" as the "Suspect Agent"	
	DHEC requisition must be completed in full and should include the date of birth	
	and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate /	
	collection, initials of the person collecting the specimen and a contact name and	
	phone number for verbal reporting.	
Special Instructions:	Pre-approval Needed - Hospitals must contact SC DHEC DADE (Division of Acute	
	Disease Epidemiology) and the Special Pathogens Laboratory prior to	
	submitting specimens. Contact information can be located on the back of the	
	List of Reportable Conditions. DHEC will seek CDC approval for patient testing.	
	Contact the Special Pathogens Laboratory (803-896-0777 / 803-767-8118) for	
	test notification, specimen collection, storage conditions, shipping	
	conditions/methods, and contacts.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special	
	instructions at 803-896-0777 / 803-767-8118.	
Transport Conditions:	Communicated during consultation	
Specimen Rejection Criteria:	Communicated during consultation.	
Availability:	As needed	
Results and Interpretations:	- Final results are verbally communicated to the sender to ensure correct	
	interpretation. Final reports are provided via fax or e-mail.	
	- The definitive identification of Ebola virus requires additional testing to be	
	performed by CDC.	
	- Negative results do not preclude Ebola virus infection and should not be used as	
	the sole basis for patient management decisions.	
Additional Information:	Ebola Virus is designated as a Tier 1 Select Agent (Select Agent Regulation, 42	
	CFR, 73, Final Rule). In the event of <i>Ebola</i> detection, the Special Pathogens	
	Laboratory will assist the sender in the timely submission of the required federal	
	documentation.	
Purpose of Test:	To presumptively identify Ebola virus in clinical specimens	
Method:	PCR Assay	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.	

Test	ENTERIC GI PANEL by FilmArray (PCR)	
Synonym:	GI Panel, GI Outbreak	
	Bacteria : Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio species, Vibrio cholerae, Yersinia enterocolitica;	
	Diarrheagenic E. coli/Shigella: Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st. Shiga-like producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC); Parasites: Cyclospora cayetanensis, Crytosporidium, Entamoeba histolytica, Giardia lamblia; Viruses: Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A,	
	Sapovirus	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	Monday - Friday	
Turnaround Time:	Note: For same day test results, specimen must be received by noon.	
Specimen Required:	Stool (walnut sized portion of formed or 5 - 10 mL of liquid) preserved in Cary Blair media in transport tube.	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and requisition.	
Specimen Volume (optimum):	Walnut sized portion of formed stool or 5 - 10 mL of liquid stool	
Specimen Volume (minimum):	N/A	
Collect:	Stool preserved in Cary-Blair media transport tube	
Form:	DHEC 1335-OE	
Special Instructions:	Call Virology Laboratory	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store the stool preserved in transport media at 2-8°C. Ship on frozen cold packs to maintain a temperature range of 2-8°C for receipt at the PHL within 3 days of collection.	
Specimen Rejection Criteria:	Unpreserved stool and specimen preserved in PVA, improper temperature; For universal rejections, see Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	N/A	
Results and	N/A	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	To detect the presence of enteric pathogens in a GI outbreak situation.	
Method:	Film Array GI panel (PCR)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	ENTERIC PATHOGENS CULTURE	
Synonym:	Fecal culture, stool culture, enteric culture, Salmonella culture, Shigella	
	culture, <i>E coli 0157</i> culture, <i>Campylobacter</i> culture, <i>Vibrio</i> culture, toxin	
	culture for Staphylococcus aureus, Bacillus cereus, and Clostridium perfringens.	
Lab Section/Phone:	Clinical Microbiology 803-896-3360	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Walnut sized portion of feces or 5-10 mL of liquid stool in stool transport.	
	Infant specimens may be collected in a disposable diaper with plastic side	
	facing inside.	
Specimen Identification:	Specimen container must be labelled with patient's first and last name, and a	
	second patient identifier such as DOB, MCI #, Specimen #. Specimen container	
	should have the date of isolate or collection, and initials of the person	
	collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	N/A	
(minimum):		
Collect:	Use stool transport such as Cary Blair or ParaPak	
Form:	DHEC requisition 1335-OE, check "Enteric Culture"	
Special Instructions:	Specimen must be maintained at 2-8°C.	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store the stool preserved in transport media at 2-8°C. Ship ALL specimens and	
	isolates in approved and specialized shippers on frozen cold packs to be	
	maintained in temperature range of 2-8°C until receipt at the PHL within 3	
	days of collection.	
Specimen Rejection Criteria:	Quantity insufficient; specimen too old; improper transport media or	
	conditions, improper temperature; For universal rejections, refer to Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	N/A	
Additional Information:	N/A	
Purpose of Test:	Culture and identification of the following pathogens: Salmonella, Shigella,	
	Campylobacter, Vibrio, Shiga-toxin producing Escherichia coli, Aeromonas,	
	Yersinia enterocolitica, Plesiomonas shigelloides, Staphylococcus aureus,	
	Bacillus cereus, Clostridium perfringens.	
Method:	Traditional culture, conventional biochemicals, serotyping, bioMerieux VITEK	
	MS	
Interfering Substances:	Do not use PVA	
Comment:	Enteric Pathogen culture testing is available for outbreaks as determined by	
	the SC DHEC DADE (Division of Acute Disease Epidemiology). Epidemiology	
	to note on requisition slip which pathogens are suspected.	

Test	ENTERIC PATHOGENS submitted by NON-CULTURE INDEPENDENT METHODS (PCR)	
Synonym:	Fecal culture, stool culture, enteric culture, <i>Salmonella</i> culture, <i>Shigella</i> culture, <i>Campylobacter</i> culture, <i>Vibrio</i> culture, shiga-toxin producing Escherichia coli.	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Walnut sized portion of feces or 5 - 10 mL of liquid stool in stool transport. Infant specimens may be collected in a disposable diaper with plastic side facing inside.	
Specimen Identification:	Specimen container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	Note: For same day test results, specimens must be received by noon.	
Collect:	Use stool transport such as Cary Blair or ParaPak.	
Form:	DHEC requisition 1335-OE, check "Enteric Culture"	
Special Instructions:	Specimen must be maintained at 2-8 C.	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store the stool preserved in transport media at 2-8°C. Ship ALL specimens and isolates in approved and specialized shippers on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection.	
Specimen Rejection Criteria:	Quantity insufficient; specimen too old; improper transport media or conditions, improper temperature; For universal rejections. See Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	N/A	
Additional Information:	Specimen submission to the Public Health Laboratory (PHL) is required. Ship ASAP on cold packs in insulated shippers to improve recovery of PCR+ organism.	
Purpose of Test:	Culture and identification of the following pathogens: Salmonella, Shigella, Campylobacter, Vibrio, Shiga-toxin producing Escherichia coli, Aeromonas, Yersinia enterocolitica, Plesiomonas shigelloides.	
Method:	Traditional culture, conventional biochemicals, serotyping, bioMerieux VITEK MS	
Interfering Substances:	Do not use PVA	
Comment:	Important – Maintain specimen at 2-8°C and ship to be received within 3	
	days of collection at the PHL in the temperature range of 2-8°C.	

Test	ESCHERICIA COLI – SHIGA-TOXIN PRODUCING	
Synonym:	E. coli O157:H7, E. coli non-O157, STEC, EHEC, Shiga toxin positive	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Isolate, or PCR+ stool transport/ broth if unable to isolate.	
Specimen Identification:	Isolate, Broth, or Specimen container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	N/A	
Form:	DHEC 1335-OE, check "Culture/Isolate for Shiga toxin producing <i>E. coli</i> " or "Broth/specimen for Shiga toxin producing <i>E. coli</i> ", as appropriate.	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Ship isolates in approved shippers to maintain temperature of specimen within the range of 15-25°C until received at the PHL. Store the stool preserved in stool transport and broth at 2-8°C and ship ALL specimens and broths in approved and specialized shippers on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection.	
Specimen Rejection Criteria:	Quantity insufficient; specimen too old; improper transport media or conditions, improper temperature; For universal rejections, refer to Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	N/A	
Additional Information:	Specimen submission to the Public Health Laboratory (PHL) is required. Ship PCR + stool transport specimens and broths ASAP to increase ability to recover isolate. Ship Shiga toxin positive isolates within 1 business day.	
Purpose of Test:	Culture as needed and identification of Shiga-toxin producing E. coli	
Method:	Immunochromatographic rapid test for Shiga-toxin	
Interfering Substances:	N/A	
Comment:	N/A	

Test	FOODBORNE ILLNESSES (FOOD POISONING)
Days Performed:	Monday- Friday
Special Instructions:	The Food Microbiology section assists in the epidemiological investigation of suspected foodborne illness. A physician with a patient suspected of having a foodborne illness should contact Food Protection in the county health department. The laboratory does not accept specimens from patients.

Test	FRANCISELLA TULARENSIS	
Synonym:	Tularemia, rabbit fever, deerfly fever	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803)767-	
,	8118	
Days Performed:	As needed	
Turnaround Time:	7 to 10 days from the time of specimen receipt in the laboratory	
Specimen Required:	Clinical Specimens / isolates	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB,	
	MCI # or other unique ID #, date and time of collection, initials of the	
	person collecting the specimen, and the specimen source.	
Specimen Volume	Determined during pre-approval consultation	
(optimum):		
Specimen Volume	Determined during pre-approval consultation	
(minimum):		
Collect:	Determined during pre-approval consultation	
Form:	DHEC 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for	
	specimen type and write "F. tularemia" for "Suspect Agent"	
	DHEC requisition must be completed in full and should include the date	
	of birth and a second patient identifier (e.g., Local ID or Clinical ID), the	
	date of isolate / collection, and initials of the person collecting the	
	specimen.	
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior	
	to testing.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special	
	instructions at 803-896-0777 / 803-767-8118.	
Transport Conditions:	Determined during pre-approval consultation	
Specimen Rejection	Determined during pre-approval consultation	
Criteria:		
Availability:	As needed	
Results and	Preliminary (when applicable) and final results are verbally	
Interpretations:	communicated to the sender to ensure correct interpretation. Final	
	reports are provided via fax or e-mail.	
Additional Information:	Francisella tularensis is designated as a Tier 1 Select Agent (Select Agent	
	Regulation, 42 CFR, 73, Final Rule). In the event of Francisella tularensis	
	detection, the Special Pathogens Laboratory will assist the sender in the	
	timely submission of the required federal documentation	
Purpose of Test:	To detect F. tularensis in clinical specimens / To confirm referred	
	isolates	
Method:	A variety of sentinel and LRN methods are used to grow, confirm, or	
	rule- out bacterial isolates.	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogen Laboratory with any questions or	
	concerns	

Test	GIARDIA ANTIGEN	
Synonym:	N/A	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday – Friday	
Turnaround Time:	5 Business days	
Specimen Required:	Walnut sized portion fresh stool or 3 mL of liquid stool, 10% formalin preserved stool, Cary-Blair, C & S, or concentrated stool sediment. Specimen must be placed in a leakproof container. Do Not use PVA.	
Specimen Identification:	Specimen container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	N/A	
Form:	DHEC requisition form 1335-OE, check "Cryptosporidium Antigen"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store the stool preserved in stool transport at 2-8°C. Ship ALL specimens and isolates in approved and specialized shippers on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection.	
Specimen Rejection	Specimen preserved in PVA, improper labeling, improper temperature;	
Criteria:	For universal rejections, refer to Section I.	
Availability:	Monday – Friday	
Results and Interpretations:	Negative = Giardia antigen is absent or below detectable levels. Positive = Giardia antigen detected.	
Additional Information:	N/A	
Purpose of Test:	To detect the presence of Giardia antigen.	
Method:	Rapid immunoassay for the qualitative detection of <i>Cryptosporidium</i> parvum and <i>Giardia lamblia</i> .	
Interfering Substances:	The test is designed for use with stool specimens collected in an acceptable transport media. The use of colonic washes, aspirates or other diluted specimen types have not been established and may affect the performance of the assay. Stool specimens contaminated by products with an oily or particulate base (e.g., Barium, mineral oil, etc.) may interfere with the test and are not recommended.	
Comment:	Giardia antigen testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology (DADE).	

Test	GIOUTBREAK		
Synonym:	Norwalk Virus, Norovirus PCR, Enteric C	Dutbreak	
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	Monday - Friday		
Turnaround Time:	N/A		
Specimen Required:	Two separate collections are required:		
opeointen nequi eu		e PCR a peanut-sized or tablespoon volume of	
	1. For Norovirus Detection by Real-Time PCR, a peanut-sized or tablespoon volume of fresh diarrheal stool. Specimens collected within 48 - 72 hours of symptom onset are		
	preferred. Specimens collected within 10 days of symptom onset will be accepted.		
	Rectal swabs are not acceptable.		
	-	nut sized portion of feces or 5 - 10 mL of liquid	
		ns may be collected in a disposable diaper with	
	plastic side facing inside.	.,	
Specimen Identification:		other unique identifier) is required on both	
	specimens and requisition.	etter anque identitiely is required on som	
Specimen Volume (optimum):	N/A		
Specimen Volume (minimum):		e PCR, a peanut-sized or tablespoon volume of	
opeointen volume (minimum).	fresh diarrheal stool.		
		nut sized portion of feces or 5 - 10 mL of liquid	
	stool in stool transport.		
Collect:		Real-Time PCR, use a sterile, screw capped,	
	leak-proof, 50 mL conical tube or urine		
	For <u>Enteric Pathogens Culture</u>, use transport tube with Cary-Blair medium included in Enteric Kit provided by the Public Health Laboratory		
Form:		t panel, please write GI Outbreak on the	
	submission form.		
Special Instructions:		ological investigations. This test should be used	
	when a GI outbreak is suspected, and multiple etiologies are suspected. Please consult		
	your Regional Epidemiological contact.		
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.		
Transport Conditions:	Store and ship to be maintained at 2-8°C until received at the PHL.		
Specimen Rejection Criteria:	See Specimen Rejection & Disclaimer (
Availability:	N/A	citteria in Section 1.	
Results and Interpretations:		Internetation	
Results and interpretations:	Result	Interpretation	
	Detected	Organism detected	
	Not detected	No organism detected	
Additional Information:	Please write GI Outbreak on the submission form. This panel designates a testing		
	algorithm for GI outbreak of unknown etiology. This panel includes tests for Norovirus		
	rRT-PCR, BioFire FilmArray GI Panel, and enteric culture (in this order). Testing will		
	cease when a positive identification is made. If enteric pathogens other than		
	Salmonella, E. coli O157:H7 or Shigella		
Purpose of Test:	GI Outbreak testing is available for outbreaks as determined by the SC DHEC Division of		
	Acute Disease Epidemiology.		
Method:	1. Norovirus: Real-time reverse transcriptase polymerase chain reaction (real-time RT- PCR		
	2. BioFire GI Panel: Multiplex PCR Panel		
	3. Enteric Pathogens Culture: Traditional culture, conventional biochemicals,		
	serotyping, bioMerieux VITEK MS		
Interfering Substances:	N/A		
Comment:	N/A		
comment.			

Test	GONOCOCCAL (GONORRHEA) CULTURE	
Synonym:	GC culture, Neisseria gonorrhoeae culture	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	5 Business days	
Specimen Required:	Transgrow bottle	
Specimen Identification:	Transgrow bottle must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full. Do Not place label over clear glass viewing area, layer patient label over existing label.	
Specimen Volume (optimum):	See <u>N. gonorrhoeae</u> Collection Procedure, Section III.	
Specimen Volume (minimum):	N/A	
Collect:	Bring transgrow bottle to room temperature before inoculating. <u>Hold bottle</u> <u>upright</u> and roll swab over entire surface of medium; discard swab. NOTE: Ship for overnight delivery. Do not ship specimens for arrival over a weekend.	
Form:	DHEC 1335-OE, check "GC Culture & ID"	
Special Instructions:	Collect specimens Monday thru Wednesday ONLY.	
Packing and Shipping*:	See <u>Transporting and Shipping Infectious Substances in Section IV</u> . If an incubator is available, incubate inoculated transgrow bottle upright at 35°C until shipped, and indicate incubation time on request form. If an incubator is not available, make sure culture is shipped on the same day as collected. DO NOT REFRIGERATE AFTER INOCULATION.	
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15- 25°C until received at the PHL.	
Specimen Rejection Criteria:	Transgrow media not used; specimen in transit more than 5 days, improper temperature; For universal rejections, See <u>Section I</u> .	
Availability:	Monday - Wednesday	
Results and Interpretations:	Neisseria gonorrhoeae isolated or not isolated.	
Additional Information:	If Drug Treatment failure is expected, notate this on DHEC requisition. If <i>Neisseria gonorrhoeae</i> is isolated, isolate will be sent out for Antimicrobial Susceptibility Testing (AST).	
Purpose of Test:	Culture for growth of <i>Neisseria gonorrhoeae,</i> this is needed if drug treatment failure is expected.	
Method:	BioMerieux VITEK MS	
Interfering Substances:	N/A	
Comment:	N/A	

Test	GONOCOCCAL (GC) DETECTION by NUCLEIC ACID AMPLIFICATION
Synonym:	Gen-Probe N. gonorrhoeae Amplified Nucleic Acid Probe, Gonorrhea rRNA, GC Aptima
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday-Friday
Turnaround Time:	3-5 Business days
Specimen Required:	 Swab specimen: Endocervical, rectal and pharyngeal swab, and/or male urethral specimens in Gen-Probe Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Blue Label/blue collection swab). Vaginal specimens: Vaginal specimens are collected using the Gen-Probe Aptima Multitest Swab Specimen Collection kit. (Orange label/ Pink collection swab). Urine specimens: Patient should not have voided within one hour of collection. Collect 20 - 30 mL of the first-catch urine stream into collection cup. Transfer 2 mL of urine into Aptima Urine Specimen Transport tube so that the urine level falls within the two lines on the transport tube labeled: "fill area". (Yellow Label). Urine must be transferred to the Urine Collection Tubes within 24 hours. See GC/Chlamydia Gen-Probe Collection Procedure, Section III.
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, or Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	Urine should be collected up to fall within the "fill area" lines. Swab collection kits should contain the adequate amount of transport media for testing.
Collect:	See specimen requirements and <u>GC/Chlamydia Gen-Probe Collection Procedure,</u> <u>Section III</u> .
Form:	DHEC 1332
Special Instructions:	Only use Gen-Probe Aptima specimen collection kit (unisex swab, vaginal swab, or urine).
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship urogenital swabs at 2-30°C, rectal and pharyngeal swabs at 4-30°C, and urine at 2-30°C. Swab specimens must be tested within 60 days of collection. Urine specimens must be tested within 30 days of collection. For longer storage, freeze transport tube within 7 days of collection at \leq -20 °C and ship on dry ice to maintain at temperature of \leq -20°C until received at the PHL.
Specimen Rejection Criteria:	Specimen with no swab or incorrect swab in transport media; white swab in transport media; two swabs in transport media; urine above or below designated black lines on transport tube labeled fill area; swab specimen more than 60 days old, or urine specimen more than 30 days old; specimens received at the improper temperature; For universal rejections, See <u>Section I</u> .
Availability:	Monday - Friday
Results and Interpretations:	Positive, Negative, or Indeterminate
Additional Information:	This test is not appropriate in cases of sexual assault or abuse. A negative result does not preclude the presence of a CT or GC infection because results are dependent on adequate specimen collection, absence of inhibitors, and sufficient rRNA to be detected. Test results may be affected by improper specimen collection, improper specimen storage, technical error, or specimen mix-up. Therapeutic failure or success cannot be determined with the Aptima Combo 2 Assay since nucleic acid may persist following appropriate antimicrobial therapy.
Purpose of Test:	For the detection of <i>Neisseria gonorrhoeae</i> in pharyngeal, rectal, vaginal, cervical, urethral and urine specimens.
Method:	Nucleic Acid Amplification Test

Test	HAEMOPHILUS INFLUENZAE
Synonym:	H. influenzae
Lab Section/Phone:	Clinical Microbiology 803-896-0805
Days Performed:	Monday - Friday
Turnaround Time:	5 Business days
Specimen Required:	Agar slant that will support growth of isolate
Specimen Identification:	Isolate container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
Collect:	Pure bacterial isolate on agar slant (chocolate agar is preferred)
Form:	DHEC requisition form 1335-OE, check "Organism for ID"
Special Instructions:	Inoculate chocolate agar slant with isolated organism, incubate overnight in 35°C CO2 incubator, observe for growth, and ship isolate to maintain temperature of specimen within the range of 15-25°C until received at the PHL.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Ship isolates to maintain temperature of specimen within the range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	Culture non-viable; culture mixed, improper temperature; For universal rejections, See <u>Section I</u> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	Only <i>H. influenzae</i> isolates from normally sterile sites should be tested. Always specify site of isolate. Urgently reportable; ship within 1 business day.
Purpose of Test:	Confirm identification of Haemophilus influenzae and serotype.
Method:	bioMereiux VITEK MS, serotyping
Interfering Substances:	N/A
Comment:	N/A

Test	HEMOGLOBIN (Hgb) ELECTROPHORESIS
Synonym:	Adult Sickle Cell Screen
Lab Section/Phone:	Newborn Screening, 803-896-0874 or 803-896-0891
Days Performed:	Available upon request
Turnaround Time:	5 days
Specimen Required:	Dried blood spot; collected on DHEC 1339 collection form
Specimen Identification:	Patient's full name and date of birth written on DHEC 1339 collection form
Specimen Volume (optimum):	2 filled circles on DHEC 1339 collection form.
Specimen Volume (minimum):	1 filled circle on DHEC 1339 collection form
Collect:	Fingerstick
Form:	DHEC 1339
Special Instructions:	Fill each circle with one large blood drop that soaks through to the other side. Do not layer blood drops. Allow the specimen(s) to dry horizontally for 3 - 4 hours before packing for shipment. To protect the specimen, fold over the biohazard labeled flap once the specimen is dry.
Packing and Shipping*:	Place dried and covered specimen in paper/cardboard mailer. Do not ship in plastic.
Transport Conditions:	Do NOT use plastic bags or any other airtight, leakproof, or sealed containers.
Specimen Rejection Criteria:	Specimen(s) received in plastic bags; specimens collected on expired collection forms; specimens older than 14 days; specimen quality and/or quantity inadequate.
Availability:	N/A
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	Screen for abnormal hemoglobin's
Method:	Iso-electric focusing and/or High-Performance Liquid Chromatography
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS A SEROLOGY
Synonym:	HAVAB-G; Anti-HAV; HAVAB-IgG; Antibody to Hepatitis HAV-IgG; Anti-HAV, IgG; Antibody to Hepatitis A Virus, IgG; HAVAB-M; HAVAB-IgM; Antibody to HAV-IgM; Anti-HAV, IgM; Antibody to Hepatitis A Virus, IgM
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Available upon request
Days renomica.	
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.0 mL of serum
Specimen Volume (minimum):	0.5 mL of serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332, Test - Hepatitis A, IgG; Test - Hepatitis A, IgM
Special Instructions:	All Hepatitis A outbreak investigations should be reported to the laboratory supervisor (803-896-0811) or Division Director (803-896-0870) prior to shipment of specimens. After collecting the specimen, invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours from the time of collection. Specimens must be centrifuged within 2 hours of collection to separate the serum from the clot.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 7 days of collection at the PHL; for storage longer than 7 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 7 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection & Disclaimer Policies in Section I</u> .
Availability:	Testing performed as needed.
Results and Interpretations:	Reactive or Nonreactive
Additional Information:	N/A
Purpose of Test:	For the detection of Hepatitis A in serological specimens
Method:	Chemiluminescence (CMIA)
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS B CORE IgM ANTIBODY
Synonym:	Anti-HBc, IgM; HBcAb,IgM; Antibody to Hepatitis B Core Antigen, IgM
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Available upon request
Turnaround Time:	1 - 5 Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	0.5 mL of serum
Specimen Volume (minimum):	0.25 mL of serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 7 days of collection at the PHL; for storage longer than 7 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 7 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see Specimen Rejection & Disclaimer Policies in Section I.
Availability:	As needed
Results and Interpretations:	Reactive or Nonreactive
Additional Information:	*Test automatically performed on patients with reactive anti-HBc total antibody in absence of reactive HBsAg or anti-HBs on Diagnostic Profile (test #223), and test automatically performed on patients with reactive Hepatitis B surface antigen on Diagnostic Test Panel #223*.
Purpose of Test:	N/A
Method:	Chemiluminescence
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS B CORE TOTAL ANTIBODY SCREEN
Synonym:	Anti-HBc; Core Antibody; HBcAb, Total; Antibody to Hepatitis B Core Antigen
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.0 mL of Serum
Specimen Volume (minimum):	0.5 mL of Serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332, Test #226
Special Instructions:	After collecting the specimen, invert the serum-separator tube gently 5 times, allow to clot for at least 30 minutes and centrifuge within 2 hours from the time of collection. Specimens must be centrifuged within 2 hours of collection to separate the serum from the clot. See <u>Specimen Collection: Venipuncture</u> Procedure in Section III , if needed.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 7 days of collection at the PHL; for storage longer than 7 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 7 days old when received, not shipped on dry ice and received at -20°C or colder. A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection & Disclaimer Policies in Section I</u> .
Availability:	As needed
Results and Interpretations:	Reactive or Nonreactive
Additional Information:	N/A
Purpose of Test:	N/A
Method:	Chemiluminescence
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS B DIAGNOSTIC PROFILE
Synonym:	Includes tests for HBsAg, anti-HBs, and anti-HBc, and anti-core IgM are
	performed if indicated.
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second
	patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be
	completed in full.
Specimen Volume	2 mL of serum
(optimum):	
Specimen Volume	2 mL of serum
(minimum):	
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged,
	and serum from red top tubes must be removed from the clot and put into a
	labeled secondary container/tube. See Specimen Collection: Venipuncture
	Procedure in Section III, if needed.
Form:	DHEC 1332
Special Instructions:	After collecting the specimen, invert the serum-separator tube gently 5 times,
	allow to clot for at least 30 minutes and centrifuge within 2 hours of
	collection. Specimens must be centrifuged within 2 hours of collection to
	separate the serum from the clot. See Specimen Collection: Venipuncture
	Procedure in Section III, if needed.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 6 days of
	collection at the PHL; for storage longer than 6 days, remove the serum from
	the clot or gel, place in a secondary container and freeze at -20°C or colder,
	and ship on dry ice to maintain specimen at temperature of -20°C or colder
	until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or
	microbial contaminated specimens; specimens greater than 6 days old when
	received, not shipped on dry ice and received at -20°C or colder; A second
	specimen will need to be collected if any specimens are rejected. For universal
	rejections, see Specimen Rejection & Disclaimer Policies in Section I.
Availability:	As needed
Results and Interpretations:	N/A
Additional Information:	Includes tests for HBsAg, anti-HBs and anti-HBc, and anti-core IgM, if
	indicated.
Purpose of Test:	N/A
Method:	N/A
Interfering Substances:	N/A
Comment:	Specimen requirements allow for HBsAg, anti-HBs and anti-HBc, and anti-core
	IgM, to be performed, if indicated.

Test	HEPATITIS B IMMUNE STATUS/POST-IMMUNIZATION
Synonym:	Anti-HBs and Anti-HBc
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.5 mL of Serum
Specimen Volume (minimum):	1.0 mL of Serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	Tests include Anti-HBs and Anti-HBc
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 7 days of collection at the PHL; for storage longer than 7 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 7 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection & Disclaimer Policies in Section I</u> .
Availability:	As needed
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	N/A
Method:	Chemiluminescence
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS B SURFACE ANTIBODY
Synonym:	HBsAb; Anti-HBs; Antibody to Hepatitis B Surface Antigen
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.5 mL of serum
Specimen Volume (minimum):	1.0 mL of serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 7 days of collection at the PHL; for storage longer than 7 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 7 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection & Disclaimer Policies in Section I</u> .
Availability:	Monday-Friday
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	N/A
Method:	Chemiluminescence (CMIA)
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS B SURFACE ANTIGEN
Synonym:	HBsAg; Hepatitis-Associated Antigen
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.5 mL of serum
Specimen Volume (minimum):	1.0 mL of serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen</u> <u>Collection: Venipuncture Procedure in Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 6 days of collection at the PHL; for storage longer than 6 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of - 20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or microbial contaminated specimens; specimens greater than 6 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection &</u> <u>Disclaimer Policies in Section I.</u>
Availability:	Monday - Friday
Results and	N/A
Interpretations:	
Additional Information:	N/A
Purpose of Test:	N/A
Method:	Chemiluminescence
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS C TOTAL ANTIBODY
Synonym:	Antibody to Hepatitis C Virus; Anti-HCV
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday-Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with the patient's first and last name, and a
	second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition
	must be completed in full.
Specimen Volume	3 mL of serum
(optimum):	
Specimen Volume	0.25 mL of serum (if reactive, a total of 2.25 mL serum needs to be collected
(minimum):	and sent for confirmatory testing).
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged,
	and serum from red top tubes must be removed from the clot and put into a
	labeled secondary container/tube. See Specimen Collection: Venipuncture
	Procedure in Section III, if needed.
Form:	DHEC 1332
Special Instructions:	For sites requesting HCV RNA if total antibody reactive by EIA, collect blood in
•	a serum separator tube, spin down within 6 hours of collection. Label outside
	of box "HCV Viral Load" with indelible marker or sticker that cannot easily be
	removed. Viral loads can be shipped with any STD specimen but MUST be
	packed on frozen cold packs to maintain specimen at a temperature of 2-8 °C
	until received at the PHL.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 5 days of
	collection at the PHL; for storage longer than 5 days, remove the serum from
	the clot or gel, place in a secondary container and freeze at -20°C or colder,
	and ship on dry ice to maintain specimen at temperature of -20°C or colder
	until received at the PHL.
Specimen Rejection Criteria:	Improperly stored/shipped, heat-inactivated, pooled, grossly hemolyzed or
	microbial contaminated specimens (Test #224 only); specimens greater than 5
	days old when received, not shipped on dry ice and received at -20°C or
	colder; A second specimen will need to be collected if any specimens are
	rejected. For universal rejections, see Specimen Rejection & Disclaimer
	Policies in Section I.
Availability:	Monday - Friday
Results and Interpretations:	Reactive; Confirmatory testing to follow, , Reactive; Unable to perform
	confimatory testing, Nonreactive, Grayzone; Confirmatory testing to follow,
	Grayzone; Unable to perform confirmatory testing
Additional Information:	Reactive specimens that were shipped/collected appropriately (in an SST,
	centrifuged, and shipped on cold packs) will be reflexed to viral load testing
	automatically.
Purpose of Test:	N/A
Method:	Chemiluminescence (CMIA)
Interfering Substances:	N/A
Comment:	Positive HCV Total Antibody results will be confirmed using the HCV Viral Load
	test, provided the Special Instructions listed above are followed.
	Specimen requirements allow for reflexed testing to be performed, if needed.

Test	HEPATITIS C QUANTITATION BY PCR (RNA)
Synonym:	HCV Viral Load test
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	
	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	3 mL of serum
Specimen Volume (minimum):	1 mL of serum
Collect:	Serum-separator tube (SST) or serum. Tubes must be adequately centrifuged, and serum from red top tubes must be removed from the clot and put in a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture Procedure in</u> <u>Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	Collect blood in a serum separator tube (SST) or red top tube, allow to clot for at least 30 minutes, spin down within 6 hours of collection, and ship SST or serum at 2-8°C on frozen cold packs to arrive within 5 days of collection (please send in as soon as possible). Label outside of box "HCV Viral Load" with indelible marker or sticker that cannot easily be removed. Viral loads can be shipped with any STD specimen, but MUST be packed on frozen cold packs to maintain specimen at a temperature of 2-8 °C until received at the PHL.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 5 days of collection at the PHL; for storage longer than 5 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Whole clotted blood not centrifuged and separated within 6 hours of collection; specimens greater than 5 days old when received, not shipped on dry ice and received at -20°C or colder; A second specimen will need to be collected if any specimens are rejected. For universal rejections, see <u>Specimen Rejection & Disclaimer Policies in</u> <u>Section I.</u>
Availability:	
	Monday - Friday
Results and Interpretations:	
•	Monday - Friday The measurable reportable range for this procedure is 10-10,000,000 IU/mL and 1.00- 7.0 log 10; Specimen testing within this range will be reported as the measured IU/mL value and the log 10 value of the measured IU/mL value e.g., 30,000 IU/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 IU/ mL and > 7.0 log 10. Specimens testing less than 10 IU/mL and less than 1.00 log 10 will be reported as less than < 10 IU/mL as and less than < 1.00 log 10. Specimens with
Results and Interpretations:	Monday - Friday The measurable reportable range for this procedure is 10-10,000,000 IU/mL and 1.00- 7.0 log 10; Specimen testing within this range will be reported as the measured IU/mL value and the log 10 value of the measured IU/mL value e.g., 30,000 IU/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 IU/ mL and > 7.0 log 10. Specimens testing less than 10 IU/mL and less than 1.00 log 10 will be reported as less than < 10 IU/mL as and less than < 1.00 log 10. Specimens with nothing detected will be reported as Not Detected.
Results and Interpretations: Additional Information:	Monday - FridayThe measurable reportable range for this procedure is 10-10,000,000 IU/mL and 1.00-7.0 log 10; Specimen testing within this range will be reported as the measured IU/mLvalue and the log 10 value of the measured IU/mL value e.g., 30,000 IU/mL and 4.48log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 IU/ mLand > 7.0 log 10. Specimens testing less than 10 IU/mL and less than 1.00 log 10 will bereported as less than < 10 IU/mL as and less than < 1.00 log 10. Specimens with
Results and Interpretations: Additional Information: Purpose of Test:	Monday - Friday The measurable reportable range for this procedure is 10-10,000,000 IU/mL and 1.00- 7.0 log 10; Specimen testing within this range will be reported as the measured IU/mL value and the log 10 value of the measured IU/mL value e.g., 30,000 IU/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 IU/ mL and > 7.0 log 10. Specimens testing less than 10 IU/mL and less than 1.00 log 10 will be reported as less than < 10 IU/mL as and less than < 1.00 log 10. Specimens with nothing detected will be reported as Not Detected. N/A

Test	HERPES SIMPLEX 1 & 2 Assay			
Synonym:	N/A			
Lab Section/Phone:	Virology & Rabies, 803-896-0819			
Days Performed:	Monday - Friday			
Turnaround Time:	5 Days			
Specimen Required:	· · · ·	from anogenita	al lesions ONLY, placed in the Aptima Mult	titest
	Swab Specimen (-		
Specimen Identification:	•	· · · · · · · · · · · · · · · · · · ·	D # (or other unique identifier) is required	d on
	the specimen and	•		
Specimen Volume	N/A	•		
(optimum):				
Specimen Volume	N/A			
(minimum):				
Collect:	Polyester-tipped	swab specimer	ns from anogenital lesions ONLY placed in	
		•	n Collection Kit (Orange Tube) (available u	
	request; Orderin	g Supplies in Se	ection III, p.1)	•
Form:	DHEC 1335-OE			
Special Instructions:	N/A			
Packing and Shipping*:	See Transporting	and Shipping	Infectious Substances in Section IV.	
Transport Conditions:			of collection; maintain specimen at 2-30°	С
	until received at the PHL.			
Specimen Rejection Criteria:	See Specimen Rejection & Disclaimer Criteria in Section I.			
Availability:	Monday - Friday			
Results and Interpretations:	HSV-1 Result	HSV-2	Interpretation	
		Result		
	HSV-1 neg	HSV-2 neg	Negative: No HSV-1 or HSV-2 mRNA	
			detected	
	HSV-1 neg	HSV-2 pos	HSV-2 positive: HSV-2 mRNA	
			detected	
	HSV-1 pos	HSV-2 neg	HSV-1 positive: HSV-1 mRNA	
			detected	
	HSV-1 pos	HSV-2 pos	HSV-1 and HSV-2 positive: HSV-1 and	
			HSV-2 mRNA detected	
Additional Information:	Please do NOT mark "wound, pus, drainage" or write "lesion", but rather			
	specify "Genital" as the specimen or include where the lesion is located in t		n the	
	anogenital regior	۱.		
Purpose of Test:	Qualitative detection and differentiation of messenger RNA (mRNA) from			
	Herpes simplex virus type1 (HSV-1) and type 2 (HSV-2) DNA.			
Method:	Nucleic Acid Amplification Test (NAAT) using real-time transcription-mediated			
	amplification (TMA)			
	ampineation (m			
Interfering Substances:	N/A	··· /		

Test	HIV-1 PCR QUANTITATIVE (RNA)
Synonym:	HIV-1 Viral Load Test
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Twice weekly
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Minimum 2.0 mL EDTA anticoagulated plasma, See <u>Specimen Collection: Venipuncture Procedure</u> <u>in Section III</u> , if needed. If using EDTA vacutainer, separate the plasma from the packed cells within 24 hours of collection by centrifugation for 20 minutes at room temperature (18-30°C). Remove the plasma from the cells using a sterile transfer pipette to a sterile polypropylene transport tube. Note: Remove as much of the plasma from the cells as possible without aspirating the cells The assay requires 1.0 mL of plasma. The PPT separator tube can be shipped after centrifugation
	without transferring plasma to another tube. Invert tube after centrifugation to ensure complete separation of cells from plasma. If cells are present in plasma, re-centrifuge before shipping.
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	2.0 mL of plasma
Specimen Volume (minimum):	1.0 mL of plasma
Collect:	PPT vacutainer (supplied by the Public Health Laboratory call 803-896-0913 to order) or polypropylene tube to which plasma cells have been transferred from the Lavender top (EDTA) vacuum tube or K2 EDTA with gel separator.
Form:	DHEC 1332
Special Instructions:	The specimen MUST BE kept at 2-8 °C. Label outside of shipping container as "HIV-1". Make sure label will not come off. Please check with the laboratory during a holiday to ensure that it will arrive within 3 days of collection or freeze the specimen at \leq - 20°C and ship on dry ice to maintain specimen at \leq - 20°C until received at the PHL.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship at 2° - 8 °C. Transport on frozen cold packs in a shipping container labeled on the outside of the container as "HIV-1". Specimens must arrive at the PHL within 3 days of collection. Viral loads can be shipped with any STD specimen but MUST be packed on frozen cold packs to maintain specimen at a temperature of 2° - 8 °C until received at the PHL. If specimen will not be received at the PHL within 3 days of collection, transfer plasma into a secondary container and freeze the plasma at \leq - 20°C and then ship on dry ice to maintain specimen at \leq - 20°C until received at the PHL.
Specimen Rejection Criteria:	Clotted whole blood specimens and specimens >3 days old not maintained at ≤ - 20°C or colder; improper temperature.; For universal rejections, See Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	As needed
Results and Interpretations:	The measurable reportable range for this procedure is 30 - 10,000,000 copies/mL and 1.47 - 7.0 log 10. Specimens testing within this range will be reported as the measured copy value and the log 10 value of the measured copy value e.g., 30,000 copies/mL and 4.48 log 10. Specimens testing above 10,000,000 will be reported as > 10,000,000 copies/mL and > 7.0 log 10. Specimens testing less than < 30 copies/mL and less than < 1.47 log 10 will be reported as less than < 30 copies/mL and less than < 1.47 log 10. Specimens with nothing detected will be reported as Not Detected.
Additional Information:	N/A
Purpose of Test:	Therapeutic monitoring of HIV infection
Method:	Nucleic acid amplification test
Interfering Substances:	N/A
Comment:	N/A

Test	HIV-1/HIV-2 SEROLOGY
Synonym:	HIV-1/HIV-2 antibody, HIV-1, HIV-2 antibodies, HIV-1 antigen
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday – Friday
, Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen	Specimens must be labelled with patient's first and last name, and a second patient
Identification:	identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume	1.5 mL of serum
(optimum):	
Specimen Volume	1 mL of serum
(minimum):	
Collect:	Serum-separator tube (SST) or serum. Tubes must be properly centrifuged, and serum
	from red top tubes must be removed from the clot and put into a different labeled
	container/tube. See Specimen Collection: Venipuncture Procedure in Section III, if needed.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2 - 8°C and received within 7 days of collection at the
	PHL.
	For specimens that will not be received at the PHL within 7 days of collection, remove the
	serum from the clot or gel, place in secondary container, and freeze the serum at -20° C
	or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder
	until received at the PHL.
Specimen Rejection Criteria:	Specimens received at the improper temperature; specimens greater than 7 days old not maintained at -20 ° C or colder when received; A second specimen will need to be
	collected if any specimens are rejected. For universal rejections, see Specimen Rejection
	& Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and	Reactive, Nonreactive
Interpretations:	
Additional Information:	Repeatedly reactive specimens are confirmed by Geenius HIV 1 /2. Repeat reactive
	specimens not confirmed by Geenius HIV1/2 will be submitted for HIV-1 NAT.
	Recommend repeat testing on all first-time positive patient results including CD4 and Viral
	load (HIV-1 RNA).
Purpose of Test:	To aid in the detection and diagnosis of HIV-1/HIV-2
Method:	Multiplex flow immunoassay
Interfering Substances:	N/A
Comment:	N/A

Test	INFLUENZA A: H5N1 (ASIAN CLADE)
Synonym:	Avian Flu/ Bird Flu
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evening - (803) 767-8118
Days Performed:	As needed
Turnaround Time:	48 Hours
Specimen Required:	Throat swabs, Nasal washings/aspirates, nasopharyngeal swabs, sputum,
	bronchoalveolar lavage, tracheal aspirates, and bronchial washings.
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or
	other unique ID #, date and time of collection, initials of the person collecting
	the specimen, and the specimen source.
Specimen Volume	Determined during Special Pathogen notification.
(optimum):	
Specimen Volume	Determined during Special Pathogen notification.
(minimum):	
Collect:	Determined during Special Pathogen notification.
Form:	DHEC 1335-OE-OE; in the Special Pathogens test section, check "Avian
	Influenza" box and indicate "H5" as "Suspect Agent".
Special Instructions:	Pre-approval Needed - Hospitals must obtain approval from the DHEC health
	department and Public Health Laboratory prior to submitting specimens to the
	Special Pathogens Laboratory. Contact information can be located on the back
	of the List of Reportable Conditions. Contact the Special Pathogens Laboratory
	(803)896-0777 / (803)767-8118 for test notification, specimen collection,
	storage conditions, and shipping conditions/methods.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special
	instructions at (803)896-0777 / (803)767-8118.
Transport Conditions:	Determined during Special Pathogen notification.
Specimen Rejection Criteria:	Determined during Special Pathogen notification.
Availability:	As needed
Results and Interpretations:	Final results are verbally communicated to the sender to ensure correct
	interpretation. Final reports are provided via fax or e-mail.
	The definitive identification of Influenza A:H5N1 virus requires additional
	testing to be performed by CDC.
Additional Information:	Testing for Influenza A: H5N1 will be concurrent with Influenza A:H7N9 testing
Purpose of Test:	To presumptively detect Influenza A:H5N1 RNA in clinical specimens
Method:	CDC Real Time RT-PCR Assay, EUA
Interfering Substances:	N/A
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

Test	INFLUENZA A: H7N9 (EURASIAN LINEAGE)	
Synonym:	Avian Flu / Bird Flu	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
Days Performed:	As needed	
Turnaround Time:	48 hours	
Specimen Required:	Throat swabs, Nasal washings / aspirates, nasopharyngeal swabs, sputum,	
	bronchoalveolar lavage, tracheal aspirates, and bronchial washings.	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or	
	other unique ID #, date and time of collection, initials of the person collecting	
	the specimen, and the specimen source.	
Specimen Volume	Determined during Special Pathogen notification.	
(optimum):		
Specimen Volume	Determined during Special Pathogen notification.	
(minimum):		
Collect:	Determined during Special Pathogen notification.	
Form:	DHEC 1335-OE -OE; in the Special Pathogens test section, check "Other" box	
	and indicate "H7" as "Suspect Agent".	
Special Instructions: Pre-approval Needed - Hospitals must obtain approval from the		
	department and Public Health Laboratory prior to submitting specimens to the	
	Special Pathogens Laboratory. Contact information can be located on the back	
	of the List of Reportable Conditions. Contact the Special Pathogens Laboratory	
	(803)896-0777 / (803)767-8118 for test notification, specimen collection,	
	storage conditions, and shipping conditions / methods.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special	
	instructions at 803-896-0777 / 803-767-8118.	
Transport Conditions:	Determined during Special Pathogen notification.	
Specimen Rejection Criteria:	Determined during Special Pathogen notification.	
Availability:	As needed	
Results and Interpretations:	Final results are verbally communicated to the sender to ensure correct	
	interpretation. Final reports are provided via fax or e-mail.	
	The definitive identification of Influenza A:H7N9 virus requires additional	
	testing to be performed by CDC.	
Additional Information:	Testing for Influenza A: H5N1 will be concurrent with Influenza A:H7N9 testing	
Purpose of Test:	To presumptively detect Influenza A:H7 RNA in clinical specimens	
Method:	CDC Real Time RT-PCR Assay, EUA	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns	

Test	INFLUENZA DETECTION BY REAL-TIME (RT) PCR	
Synonym:	Influenza Surveillance, Influenza Detection	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	Monday - Friday	
Turnaround Time:	15 days	
Specimen Required:	Nasopharyngeal swab (NP), nasal aspirate (NA), nasal wash (NW), dual nasopharyngeal/throat swab (NP/TS), bronchoalveolar lavage (BAL), bronchial wash (BW), tracheal aspirate (TA), and sputum (SPT) placed in 2 - 3 mL viral transport media.	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and requisition.	
Specimen Volume (optimum):	Swab specimen (see above) placed in 2 - 3 mL viral transport media.	
Specimen Volume (minimum):	N/A	
Collect:	Screw-capped tube of viral transport media.	
Form:	DHEC 1335-OE	
Special Instructions:	Year round, the Public Health Laboratory (PHL) participates in the World Health Organization's (WHO) Influenza Surveillance Program. Collection kits are provided. Please contact the Virology laboratory for more information at (803)896-0819. ****If Influenza A/H5N1, A H7, or a newly emerging, highly pathogenic human	
	Influenza strain is suspected, please contact your regional public health office for consultation. Contact information for the regional public health offices is located on the back of the South Carolina List of Reportable Diseases. Upon testing approval, please contact the DHEC PHL at 803-896-0777 or 803-767-8118 for specimen collection, storage and transportation. Testing for A/H5N1, A/H7, and for newly emerging highly pathogenic influenza strains is provided in the Special Pathogens Laboratory.	
Packing and Shipping*:	Send to the attention of Virology & Rabies Laboratory. See <u>Transporting and</u> <u>Shipping Infectious Substances in Section IV</u> .	
Transport Conditions:	Store specimens at 2-8°C and ship to maintain temperature at 2-8°C for receipt at the PHL within 72 hours of collection. If specimen transport is delayed and will not be received at the PHL within 72 hours, freeze specimens at \leq -20°C and ship on dry ice to maintain the temperature of \leq -20°C until received by the PHL.	
Specimen Rejection Criteria:	Specimens received on calcium alginate swabs, cotton swabs, or swabs with wooden shafts, improper temperature; See Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	N/A	
Results and Interpretations:	N/A	
Additional Information:	Influenza testing also includes a full respiratory viral panel to identify other respiratory viral pathogens.	
Purpose of Test:	N/A	
Method:	Real-time reverse transcription polymerase chain reaction (real-time RT-PCR)	
Interfering Substances:	N/A	

Test	LEAD ANALYSIS, BLOOD
Synonym:	Blood Lead (Blood Pb)
Lab Section/Phone:	Analytical Chemistry, 803-896-0886
Days Performed:	As Requested
Turnaround Time:	10 Business Days
Specimen Required:	1 mL whole blood collected from venipuncture; 500 μ L whole blood from finger stick or heel stick collected for infant screening. Venipuncture is preferred for confirmation of an elevated lead level. Collection containers must contain an anti-coagulant and should be certified lead-free or metals-free. Venous Specimens: A royal blue-top (EDTA) tube or tan-top lead-free collection tube should be used. A green-top (Heparin) collection tube is acceptable if the collection tube is certified metals/lead-free. Capillary Specimens: Collect using a certified lead- free capillary microcollection container (EDTA). These containers usually have a lavender top and must be certified lead-free by the manufacturer. Due to contamination risk, elevated blood lead results on capillary specimens should be confirmed using a venous specimen.
Specimen Identification:	Specimen container must be labelled with patient's full name, and a second patient identifier such as DOB, Specimen #, etc. DHEC requisition must be completed in full.
Specimen Volume (optimum):	>1 mL
Specimen Volume (minimum):	500 μL
Collect:	In general, if more than one evacuated tube of blood is to be drawn from an individual, the blood lead tube should be drawn second or later to avoid cross contamination. Draw the blood through a stainless-steel needle into a Vacutainer [™] .
Form:	DHEC 1332, Test #882
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Specimens should be stored at 2-8°C and shipped on frozen cold packs to maintain specimens at 2-8°C until receipt at the PHL. Specimens must be received for testing within 10 days of collection.
Specimen Rejection Criteria:	Clotted blood, insufficient quantity (QNS), improper temperature; For universal rejections, See Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and Interpretations:	Blood lead levels in children under the age of 16 are considered elevated at or above 3.5 mg/dL and chelation treatment should be considered at confirmed blood lead levels of 45 mg/dL. The Occupational Safety and Health Administration regulations use a blood lead level of 40 mg/dL as cause for written notification and a medical exam, and a blood lead level of 60 mg/dL as cause for medical removal from exposure.
	Action levels for blood Pb in children and adults print on result reports. Screening (finger stick/heel stick) levels $\ge 3.5 \ \mu g/dL$ requires venipuncture confirmation.
Additional Information:	N/A
Purpose of Test:	Identify exposure to Lead.
Method:	Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
Interfering Substances:	N/A
Comment:	N/A

Test	LEGIONELLA URINARY ANTIGEN TEST	
Synonym:	Lateral-flow immunoassay for Legionella pneumophila serogroup 1 antigen in	
	human urine specimens.	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	3 Business days	
Specimen Required:	1 mL or > of Urine collected in either airtight transport container or airtight	
	Boric Acid Urine Tube.	
Specimen Identification:	Specimen container must be labelled with patient's first and last name, and a	
	second patient identifier such as DOB, MCI #, Specimen #. Specimen container	
	should have the date of isolate or collection, and initials of the person	
	collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	1 mL	
(minimum):		
Collect:	Human Urine specimens, Unpreserved: Specimens should be stored at	
	2 - 8°C in an airtight transport container to prevent leaking. Specimens must	
	be received within 7 days of collection. Test is available only for outbreaks of	
	Public Health importance as determined by a DHEC Epidemiologist.	
Form:	DHEC requisition 1335-OE form, check "Legionella Urine Antigen"	
Special Instructions:	N/A	
Packing and Shipping*:	Urine is considered an Infectious substance. See Transporting and Shipping	
	Infectious Substances in Section IV.	
Transport Conditions:	Store in refrigerator at 2-8°C and ship with frozen cold packs to maintain	
	temperature at 2-8°C until received at the PHL.	
Specimen Rejection Criteria:	Improper transport media or conditions; improper temperature; For universal	
	rejections, See Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	Monday - Friday	
Results and Interpretations:	Negative Test: Report test results as "No Legionella pneumophila serogroup 1	
	antigens detected". A negative result does not exclude infection with	
	Legionella pneumophila serogroup 1, nor does it rule out other microbial-	
	caused respiratory infections or diseases caused by other serogroups of	
	Legionella pneumophila.	
	Positive Test: Report test result as Legionella pneumophila serogroup 1	
	antigens detected. This result does not rule out co-infection with other	
	pathogens.	
Additional Information:	N/A	
Purpose of Test:	N/A	
Method:	Rapid, lateral-flow immunoassay for the qualitative detection of Legionella	
	pneumophila serogroup 1 antigen in human urine specimens. It is designed to	
	test specimens from patients with symptoms of pneumonia. Test results are to	
	be used as an aid in diagnosis of Legionella pneumophila serogroup 1	
	infection. A negative result does not preclude infection with Legionella	
	pneumophila serogroup 1. Test results are to be used in conjunction with	
	information obtained from the patient's clinical evaluation and other	
	diagnostic procedures.	
Comment:	Test available only for Division of Acute Disease Epidemiology (DADE).	

Test	LISTERIA SPECIES	
Synonym:	Listeria monocytogenes	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business Days	
Specimen Required:	Pure bacterial isolate on an agar slant that will support the growth of the isolate.	
Specimen Identification:	Isolate must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Pure isolate subcultured from isolated colonies to a slant that is able to support growth.	
Form:	DHEC 1335-OE requisition, check "Organism for ID"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Ship isolates in approved shippers to maintain temperature of specimen within the range of 15-25°C until received at the PHL.	
Specimen Rejection	Culture non-viable; culture mixed; improper temperature; For universal	
Criteria:	rejections, See Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	Monday - Friday	
Results and	Listeria monocytogenes isolated or not isolated.	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	Submission to PHL is required. Ship within 3 business days.	
Method:	bioMerieux VITEK MS	
Interfering Substances:	N/A	
Comment:	N/A	

Test	MALARIA ANTIGEN TEST (BINAXNOW)	
Synonym:	Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium	
	malariae	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
Days Performed:	As needed	
Turnaround Time:	24 hours	
Specimen Required:	3 - 5 mL EDTA and thin and thick pre-stained slides - See "Malaria Smear" (below).	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.	
Specimen Volume	3 - 5 mL	
(optimum):		
Specimen Volume (minimum):	3 mL	
Collect:	N/A	
Form:	Form 1335-OE; In "Serological Testing" box, check "Malaria"	
	DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (ex. Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.	
Special Instructions:	Notification of the test request must be made to the Special Pathogens Laboratory prior to testing.	
Packing and Shipping*:	Special handling criteria apply. Please contact the Special Pathogens Laboratory instructions at (803)896-0777 / (803)767-8118.	
Transport Conditions:	Determined during consultation.	
Specimen Rejection Criteria:	Determined during consultation.	
Availability:	As needed	
Results and Interpretations:	Test results will be verbally communicated, and a hard copy report will be e- mailed or faxed.	
Additional Information:	Negative results must be confirmed by thin / thick smear microscopy. Microscopy review is required to identify non-falciparum species and to detect potential mixed infections.	
Purpose of Test:	To aid in the rapid diagnosis of human malaria infections and in the differential diagnosis of <i>Plasmodium falciparum</i> (P.f.) infections from other less virulent malarial infections.	
Method:	Immunochromatographic assay	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.	

Test	MALARIA SMEAR	
Synonym:	Giemsa stain, Plasmodium	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
	THIS TEST IS REFERRED TO AND PERFORMED BY the CDC.	
Days Performed:	As needed	
Turnaround Time:	24 hours	
Specimen Required:	Digital images of stained thick and thin blood smears	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or	
	other unique ID #, date and time of collection, initials of the person collecting	
	the specimen, and the specimen source.	
Specimen Volume (optimum):	Blood smears: Digital images of 2 sets of smears	
Specimen Volume (minimum):	N/A	
Collect:	Thick and thin stained blood smears	
Form:	DHEC 1335-OE; Write in "Malarial Smear" next to "Malaria" in the Special	
	Pathogen's test section.	
	DHEC requisition must be completed in full and should include the date of	
	birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of	
	isolate / collection, and initials of the person collecting the specimen.	
Special Instructions:	Notification of the test request must be made to the Special Pathogens	
	Laboratory, (803)896-0777 / (803)767-8118, prior to shipment.	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Please contact the Special Pathogens Laboratory for instructions at	
	(803)896-0777 / (803)767-8118.	
Specimen Rejection Criteria:	Smears made from EDTA blood > 1 hour old; blood smears > 3 days old.	
	For universal rejections, see Specimen Rejection & Disclaimer Criteria in	
	Section I.	
Availability:	Monday – Friday	
Results and Interpretations:	This test is performed by the CDC through the Special Pathogens Laboratory.	
	The Division of Parasitic Disease (DPDx) at the CDC performs microscopic	
	malarial species confirmation and malaria drug resistance surveillance.	
Additional Information:	Images are submitted to the CDC for rapid identification.	
Purpose of Test:	To detect and speciate plasmodium species in blood smears	
Method:	Microscopic examination of Giemsa-stained smear	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.	

Test	MEASLES (RUBEOLA) RNA DETECTION BY REAL-TIME (RT) PCR		
Synonym:	Measles (Rubeola) PCR, RT-PCR, or rRT-PCR		
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	Monday - Friday, weekend and holiday testing approved on a case-by-case basis		
Turnaround Time:	3 Days		
Specimen Required:	ONLY throat swabs or nasopharyngeal (NP) swabs will be accepted. Ideally, specimens should be collected within 3 days of symptom onset: however, specimens collected up to 14 days from symptom onset will be accepted. Use swabs with synthetic (polyester, nylon, etc.) tips and aluminum or plastic shafts. DO NOT USE swabs with cotton or calcium alginate tips or wooden shafts. Place the swab in viral transport media for storage and shipment.		
Specimen Identification:		r other unique identifier) is required on the	
Specimen Volume (optimum):	N/A		
Specimen Volume (minimum):	N/A		
Collect:	Sterile, leak-proof, screw-cap tube con	itaining viral transport media.	
Form:	DHEC 1335-OE		
Special Instructions:	All submissions require prior approval from the Virology section supervisor (803)896- 0819, the Microbiology Division Director (803-896-0870), or designee.		
Packing and Shipping*:	See Transporting and Shipping Infection	ous Substances in Section IV.	
Transport Conditions:	Store at 2-8°C and ship to be maintained at 2-8°C and received within 72 hours of collection at the PHL. If shipment is delayed and specimen will not be received within 72 hours of collection, store specimen at ≤ -20 °C and ship on dry ice to maintain specimen at the temperature of ≤ -20 °C until received at the PHL.		
Specimen Rejection Criteria:	Specimen type other than throat or nasopharyngeal (NP)swabs; Swabs with cotton or calcium alginate tips or wooden shafts; Specimens collected more than 14 days after symptom onset; Specimens shipped without transport media; non-frozen specimens received more than 72 hours after collection. Specimens received at improper temperature.; See Specimen Rejection & Disclaimer Criteria in Section I.		
Availability:	Monday - Friday, weekend and holiday testing approved on a case-by-case basis		
Results and Interpretations:	Result	Interpretation	
•	Detected	Measles RNA detected by RT-PCR	
	Not Detected	Unable to detect Measles RNA by RT- PCR	
	Inconclusive	Indeterminant: Unable to rule out the presence of Measles RNA	
	Unable to detect Human DNA. Results suggest sub-optimal specimen collection, transport, and/or storage conditions.	Recollect specimen	
Additional Information:	N/A		
Purpose of Test:	To detect the presence of Measles (Rubeola) virus nucleic acid (RNA). This test will NOT detect the German Measles (Rubella).		
Method:	Real-time RT-PCR		
Interfering Substances:	N/A		
	N/A		

Test	MERCURY IN URINE	
Synonym:	Hg in Urine	
Lab Section/Phone:	Analytical Chemistry, 803-896-0886	
Days Performed:	As requested	
Turnaround Time:	10 Days	
Specimen Required:	Urine	
Specimen Identification:	Specimen container must be labelled with patient's full name, and a	
	second patient identifier such as DOB, Specimen #, etc. DHEC	
	requisition must be completed in full.	
Specimen Volume	2 - 5 mL	
(optimum):		
Specimen Volume	500 μL	
(minimum):		
Collect:	Sterile urine cups	
Form:	DHEC 1332	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Urine specimens stored at ≤ -20°C and transported frozen by packing on	
	dry ice to maintain \leq -20°C temperature until received at the PHL is	
	preferred, when possible. Urine may also be stored at 2-8°C and	
	shipped on frozen cold packs to maintain specimens at 2-8°C until	
	receipt at the PHL. Urines stored and shipped at 2-8°C must be received	
	at the PHL within 10 days of collection.	
Specimen Rejection	Insufficient quantity (QNS); improper collection container; improper	
Criteria:	temperature; For universal rejections, See Specimen Rejection & Disclaimer	
	Criteria in Section I.	
Availability:	Monday – Friday	
Results and	N/A	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	Identify exposure to inorganic (metallic) mercury	
Method:	Inductively Coupled Plasma Mass Spectrometry (ICP-MS)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	MERS (MIDDLE EASTERN RESPIRATORY SYNDROME) NOVEL CORONAVIRUS	
Synonym:	MERS	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
Days Performed:	As needed	
Turnaround Time:	24 hours	
Specimen Required:	Nasopharyngeal and /or oropharyngeal swabs, sputum, lower respiratory aspirate/washes, serum; volume depends on specimen type. Call the Special Pathogens Laboratory for more information.	
Specimen Identification:	Specimens should be labeled with the patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.	
Specimen Volume (optimum):	Determined during Special Pathogens Laboratory notification.	
Specimen Volume (minimum):	Determined during Special Pathogens Laboratory notification.	
Collect:	Determined during Special Pathogens Laboratory notification.	
Form:	DHEC 1335-OE; Check "MERS" in the "Molecular Testing for Viral Pathogens" box. DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.	
Special Instructions:	Pre-approval needed - hospitals must obtain approval from the DHEC health department prior to submitting specimens to the Special pathogens Laboratory. Contact information can be located on the back of the <i>List of</i> <i>Reportable Conditions</i> . Contact the Special Pathogens Laboratory (803)896- 0777 / (803)767-8118) for test notification, specimen collection, storage conditions, and shipping conditions/methods.	
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777 / 803-767-8118.	
Transport Conditions:	Determined during Special Pathogens Laboratory notification.	
Specimen Rejection Criteria:	Determined during Special Pathogens Laboratory notification.	
Availability:	As needed	
Results and Interpretations:	Final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail. The definitive identification of MERS virus requires additional testing to be performed by the CDC.	
Additional Information:	N/A	
Purpose of Test:	To presumptively detect MERS RNA in clinical specimens	
Method:	CDC/LRN Real Time RT-PCR Assay, EUA	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.	

Test	Monkeypox	
Synonym:	Mpox, MPX	
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118	
Days Performed:	As needed	
Turnaround Time:	48 hours	
Specimen Required:	Plain, sterile container with a dacron, nylon, or polyester swab that does not have a wooden shaft.	
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source. Please designate the source and "A" on the label of the first double swab and the source and "B" on the second swab from each vesicle.	
Specimen Volume (optimum):	4 total swab minimum.	
Specimen Volume (minimum):	N/A	
Collect:	2 swabs from at least 2 vesicleS	
Form:	DHEC 1335-OE; In the Special Pathogen box, check "Other" under Molecular testing for viral pathogens and write "Monkeypox" as the "Suspect Agent". DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, initials of the person collecting the specimen and a contact name and phone number for verbal reporting.	
Special Instructions:	Please notify the Special Pathogens Laboratory (803-896-0777 / 803-767- 8118) prior to submitting specimens and for questions concerning specimen collection, storage conditions, and shipping conditions/methods.	
Packing and Shipping*:	Specimens may be shipped in accordance with DOT/IATA category B shipping guidelines. Please contact the Special Pathogens Laboratory at 803-896-0777 / 803-767-8118 if additional information is needed.	
Transport Conditions:	Specimens must be maintained and shipped at 2-8°C.	
Specimen Rejection Criteria:	Organic/semi-organic swabs, specimens stored incorrectly, refrigerated specimens older than 7 days	
Availability:	As needed	
Results and Interpretations:	Due to the current Monkeypox outbreak and lack of other circulating Orthopox viruses, a positive Orthopox result is highly suggestive of Monkeypox virus.	
Additional Information:	This assay detects the DNA of common Non-variola Orthopoxvirus human pathogens, including Vaccinia, Cowpox, and Monkeypox viruses.	
Purpose of Test:	To detect Monkeypox in clinical specimens.	
Method:	CDC/LRN Real Time PCR Assay	
Interfering Substances:	N/A	
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.	

Test	MUMPS RNA DETECT	TION BY REAL-TIME RT PCR
Synonym:	Mumps PCR, Mumps RT-PCR	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	Monday - Friday, weekend and holiday testing approved on a case-by-case basis.	
Turnaround Time:	3 days	
Specimen Required:	One buccal swab collected within 14 days of symptom onset. Ideal collections of	
		otom onset. Use swabs with polyester or nylon tips and aluminum
		NOT USE cotton, wood, or calcium alginate swabs. Place swab in
	-	for storage and shipment. See Viral Media Collection for
	Virology Specimens i	
Specimen Identification:	Patient's full name an	nd patient ID # (or other unique identifier) is required on the
	specimen and requisi	tion.
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Buccal swab placed ir	a sterile, leak-proof, screw-cap tube containing viral transport
	media.	
Form:	DHEC 1335-OE	
Special Instructions:	All submissions requi	re prior approval from the Virology section supervisor (803-896-
		ogy Division Director (803-896-0870), or designee. Only
	specimens submitted	as part of an epidemiological investigation will be accepted.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store at 2-8°C and ship to be maintained at 2-8°C and received within 72 hours of	
		If shipment is delayed and specimen will not be received within
		a, store specimen at \leq -20°C and ship on dry ice to maintain
		perature of \leq -20°C until received at the PHL.
Specimen Rejection Criteria:		calcium alginate tips or wooden shafts; Specimens collected
	-	ter symptom onset; Specimens shipped without transport media;
		s received more than 72 hours after collection. Specimens
	-	per temperature.; See Specimen Rejection & Disclaimer Criteria
	in Section I.	
Availability:		ekend and holiday testing approved on a case-by-case basis
Results and Interpretations:	Result	Interpretation
	Detected	Mumps RNA detected by RT-PCR
	Not Detected	Unable to detect Mumps RNA by RT-PCR
	Inconclusive	Indeterminant: Unable to rule out the presence of
	Unable to detect	Mumps RNA
	Human DNA.	Recollect specimen
	Results suggest	
	sub-optimal	
	specimen	
	collection,	
	transport, or	
	storage conditions.	
Additional Information:	Only specimens submitted as part of an epidemiological investigation will be accepted.	
Purpose of Test:	To detect the presence of Mumps virus nucleic acid (RNA).	
Method:	Real-time reverse transcriptase polymerase chain reaction.	
Interfering Substances:	N/A	
Comment:	N/A	
	1 ·	

Test	MUMPS VIRUS	SEROLOGY IgG and IgM	
Synonym:	Parotitis Epider		
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	Per request		
Turnaround Time:	IgG: 10 days		
	IgM: 5 days		
Specimen Required:	Serum		
Specimen Identification:	Patient's full na	me and patient ID # (or other unique identifier) is required on the	
	specimen and r	equisition.	
Specimen Volume (optimum):	2 mL serum		
Specimen Volume (minimum):	1 mL serum		
Collect:	Serum Separate	or vacuum tube (SST) centrifuged appropriately. (Red top vacuum tubes	
		the specimen is centrifuged and serum is removed from the clot and	
	-	led secondary container/tube.) Please follow manufacturer's	
		Specimen Collection: Venipuncture Procedure in Section III, if needed.	
Form:	DHEC 1332	<u> </u>	
Special Instructions:	None		
Packing and Shipping*:		ng and Shipping Infectious Substances in Section IV.	
Transport Conditions:		and ship within 36 hours of collection to maintain specimen at 2-8°C	
		y the PHL. If shipment is delayed longer than 36 hours, store specimen	
		ship on dry ice to maintain the temperature of \leq -20°C until received by	
	the PHL.		
Specimen Rejection Criteria:	See Specimen Rejection & Disclaimer Criteria in Section I.		
Availability:		ce/week; Mumps IgM as needed.	
Results and Interpretations:		nune status reported as positive, negative, or equivocal.	
······		ported as positive or negative.	
Additional Information:	Results	Interpretations	
		Mumps IgG	
	Positive	IgG antibodies to the Mumps virus were detected. A positive	
		test indicates a current or past infection, or prior vaccination	
		against the Mumps virus.	
	Negative	Indicates no detectable IgG antibodies to the Mumps virus. A	
		non-reactive result indicates no current or previous infection	
		with the Mumps virus. Such patients are presumed to be	
		non-immune and are therefore susceptible to a primary	
		infection. A non-reactive result may be obtained early in	
		seroconversion of infected individuals. If this is suspected,	
		obtain an additional specimen in 3 - 5 weeks for re-testing.	
	Equivocal	Re-evaluate by collecting and testing another specimen after	
		14 days.	
		Mumps IgM	
	Positive	Indicates an acute infection.	
	Negative	Indicates no detectable IgM antibody to the Mumps virus.	
Purpose of Test:		detect Mumps IgG antibodies for determining immune status.	
		detect Mumps IgM antibodies for diagnosing a current infection.	
Method:	EIA for Mumps IgG; IFA for Mumps IgM.		
Interfering Substances:	N/A		
Comment:	N/A		

Test	MYCOBACTERIAL CULTURE, BLOOD	
Synonym:	TB, AFB	
Lab Section/Phone:	Mycobacteriology (TB), 803-896-0828	
Days Performed:	Monday-Friday	
Turnaround Time:	56 days	
Specimen Required:	1 - 5 mL whole blood; with optimum recovery obtained at 3 mL to 5 mL	
Specimen Identification:	Specimen must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	The range of blood volume which can be cultured is 1 mL to 5 mL, with optimum recovery obtained at 3 mL to 5 mL.	
Specimen Volume (minimum):	The range of blood volume which can be cultured is 1 mL to 5 mL, with optimum recovery obtained at 3 mL to 5 mL.	
Collect:	1 - 5 mL whole blood in BD BACTEC Myco/F Lytic Culture Vials	
Form:	DHEC 1335-OE	
Special Instructions:	The specimen must be collected using sterile techniques to reduce the chance of contamination.	
Packing and Shipping*:	See Section IV, Transporting and Shipping Infectious Substances.	
Transport Conditions:	Incubate at 37°C if shipping is delayed over 24 hours. Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.	
Specimen Rejection	For universal rejections, See Specimen Rejection and Disclaimer	
Criteria:	Criteria in Section I, p. I-5	
Availability:	Monday - Friday	
Results and	N/A	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	Detection of mycobacteria in blood.	
Method:	BACTEC FX40 system, bioMerieux VITEK MS	
Interfering Substances:	Other aerobic organisms including bacteria may, if present, interfere with the recovery of slower growing mycobacteria.	
Comment:	Organisms identified as <i>M. tuberculosis complex</i> referred by PHL for drug susceptibility testing, as indicated.	

Test	MYCOBACTERIAL CULTURE, Other than Blood	
Synonym:	AFB, TB	
Lab Section/Phone:	Mycobacteriology (TB), 803-896-0828	
Days Performed:	Monday – Friday	
Turnaround Time:	56 days	
Specimen Required:	Sputum, body fluids, tissue	
Specimen Identification:	Specimen must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.	
Specimen Volume	5 - 10 mL sputum, and other body fluids; 10 mL urine or gastric	
(optimum):	washings, walnut sized portion of feces or 10 mL liquid stool. See Mycobacterium Culture Collection Procedure.	
Specimen Volume (minimum):	N/A	
Collect:	Screw cap 50 mL polypropylene conical tube	
Form:	DHEC 1335-OE	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store specimens at 2-30°C and ship specimens to be maintained at 2-30°C until received at the PHL within 3 days of collection. If there is a delay of more than 3 days between collection and shipping, store specimens refrigerated at 2-8°C and ship on frozen cold packs to maintain at 2-8°C until received by the PHL.	
Specimen Rejection	Specimen > 5 days old when received (Sputum and Urine). Specimens	
Criteria:	received at the improper temperature.; For universal rejections, see	
	Specimen Rejection and Disclaimer Criteria in Section I, p. I - 5.	
Availability:	Monday - Friday	
Results and	N/A	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	Detection of Mycobacteria in clinical specimens.	
Method:	Conventional culture methods, GeneXpert MTB/RIF for rapid	
	identification of Mycobacterium tuberculosis DNA and resistance to	
	rifampicin (sputum specimens only), bioMerieux VITEK MS	
Interfering Substances:	N/A	
Comment:	Organisms identified as <i>M. tuberculosis complex</i> referred by PHL for drug susceptibility testing, as indicated.	

Test	MYCOBACTERIAL CULTURE, REFERRED FOR IDENTIFICATION	
Synonym:	AFB, TB	
Lab Section/Phone:	Mycobacteriology (TB), 803-896-0828	
Days Performed:	Monday - Friday	
Turnaround Time:	1 week	
Specimen Required:	Send only pure culture with sufficient growth to perform test	
Specimen Identification:	Isolate must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	Sufficient growth to perform test	
Specimen Volume (minimum):	Sufficient growth to perform test	
Collect:	Pure culture; LJ slant preferred	
Form:	DHEC 1335-OE	
Special Instructions:	Send only pure culture with sufficient growth to perform test	
Packing and Shipping*:	See Section IV, Transporting and Shipping Infectious Substances.	
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.	
Specimen Rejection	For universal rejections, see Section I Specimen Rejection and	
Criteria:	Disclaimer Criteria, p. I - 5	
Availability:	Monday - Friday	
Results and	N/A	
Interpretations:		
Additional Information:	N/A	
Purpose of Test:	Identification of Mycobacterium from culture.	
Method:	bioMerieux VITEK MS	
Interfering Substances:	N/A	
Comment:	Organisms identified as <i>M. tuberculosis complex</i> referred by PHL for drug susceptibility testing, as indicated.	

Test	NEISSERIA MENINGITIDIS	
Synonym:	Bacterial meningitis	
Lab Section/Phone:	Clinical Microbiology, 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	5 Business days	
Specimen Required:	Pure bacterial isolate on an agar slant that will support the growth of the isolate (Chocolate agar slant is preferred).	
Specimen Identification:	Isolate container must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Submit well isolated colonies subbed to a slant that will support the growth, incubate overnight in CO ₂ .	
Form:	DHEC 1335-OE requisition, check "Organism for ID"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store in a 35°C CO2 incubator and ship in an approved shipper to maintain specimen at 15-25°C until received at the PHL.	
Specimen Rejection Criteria:	Culture non-viable; culture mixed; improper temperature; For universal rejections, see <u>Specimen Rejection & Disclaimer Criteria in Section I</u> .	
Availability:	Monday - Friday	
Results and Interpretations:	Isolate will be confirmed and serogrouped.	
Additional Information:	Submit all <i>N. meningitidis</i> isolated from normally sterile sites within 1 business day.	
Purpose of Test:	Confirmation of identification and serogroup	
Method:	bioMerieux VITEK MS, Serogroup	
Interfering Substances:	N/A	
Comment:	N/A	

Test	NEWBORN SCREENING PANEL		
Synonym:	N/A;		
-,,	Panel includes screening for:		
	Amino Acid Disorders		
	Organic Acid Conditions		
	Fatty Acid Disorders		
	Biotinidase Deficiency		
	Classic Galactosemia		
	Cystic Fibrosis		
	Certain Hemoglobinopathies		
	Primary Congenital Hypothyroidism		
	Congenital Adrenal Hyperplasia		
	Severe Combined Immunodeficiencies		
	Pompe Disease		
	Mucopolysaccharidosis Type I (MPS-I)		
	 Spinal Muscular Atrophy Type I (SMA-I) 		
	 Krabbe Disease 		
Lab Section/Phone:	Newborn Screening/ 803-896-0874 or 803-896-0891		
Days Performed:	Monday - Saturday		
Turnaround Time:	4 days		
Specimen Required:	Dried blood spot collected on DHEC 1327 collection form		
Specimen Identification:	Patient's full name and date of birth written on DHEC 1327 collection form.		
Specimen Volume (optimum):	All circles filled		
Specimen Volume (minimum):	Varies depending on how full each circle is, how well the blood saturates the paper, and if		
speemen volume (minimum).	any repeat testing is needed		
Collect:	Heelstick; See Specimen Collection: Heel-Stick Procedure for Patients Less than 1 Year		
	Old, Section III, p. III-29.		
Form:	DHEC 1327		
Special Instructions:	Allow the specimen to dry horizontally for at least 3 to 4 hours prior to packing; fold over		
	Biohazard labeled flap once specimen is dry; don't use capillary tubes for collection; don't		
	layer blood spots.		
Packing and Shipping*:	Place dried specimens in paper envelope/cardboard mailer (no plastic).		
Transport Conditions:	Do NOT use plastic bags or any other airtight, leakproof, or sealed containers.		
Specimen Rejection Criteria:	Specimens received in plastic bags; specimens collected on expired collection forms;		
	specimens older than 14 days; patient older than 1 year; specimen quality or quantity		
	inadequate/insufficient		
Availability:	N/A		
Results and Interpretations:	N/A		
Additional Information:	N/A		
Purpose of Test:	Identifies newborns that may be at an increased risk of having a certain serious condition		
Method:	Tandem Mass Spectrometry: Amino Acid Disorders, Organic Acid Conditions,		
	Fatty Acid Disorders		
	Enzymatic & Fluorescence: Biotinidase Deficiency, Classic Galactosemia		
	Fluorimmuno assay and/or PCR: Cystic Fibrosis		
	High Performance Liquid Chromatography and/or Iso-electric focusing: Certain		
	Hemoglobinopathies		
	Fluorimmuno assay: Primary Congenital Hypothyroidism, Congenital Adrenal		
	Hyperplasia		
	PCR: Severe Combined Immunodeficiency, SMA-I		
	Flow Injection Analysis Tandem Mass Spectrometry: Pompe, MPS-I, Krabbe		
Interfering Substances:	N/A		

Test	NOROVIRUS DETECTION BY REAL TIME RT PCR	
Synonym:	Norwalk Virus, Norovirus PCR, GI Outbreak	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	Monday - Friday	
Turnaround Time:	N/A	
Specimen Required:	A peanut-sized or tablespoon volume of fresh diarrheal stool.	
	Specimens collected within 48 - 72 hours of symptom onset are	
	preferred. Specimens collected within 10 days of symptom onset will be	
	accepted. Rectal swabs are not acceptable.	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is	
	required on the specimen and requisition.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	A peanut-sized or tablespoon volume of fresh diarrheal stool.	
Collect:	Stool in a sterile, screw capped, leak-proof, 50 mL conical tube or urine	
	container.	
Form:	DHEC 1335-OE	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Store at 2 - 8°C and ship to maintain specimen at 2 - 8°C until received by the PHL.	
Specimen Rejection	Specimens placed in any type of media; Specimen more than 10 days	
Criteria:	old when received. Specimens received at the improper temperature.; See Specimen Rejection & Disclaimer Criteria in Section I.	
Availability:	Monday - Friday; Availability of this test is restricted to epidemiological	
	investigations.	
Results and	Results are reported as negative or positive for the presence of	
Interpretations:	genogroup I or genogroup II Norovirus.	
Additional Information:		
Purpose of Test:	To detect the presence of Norovirus nucleic acid (RNA).	
Method:	Real-time reverse transcriptase polymerase chain reaction (real-time RT-PCR)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	ORGANISM for IDENTIFICATION	
Synonym:	Any bacterial isolates required to be submitted per the South Carolina	
	List of Reportable Conditions.	
Lab Section/Phone:	Clinical Microbiology, 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Pure bacterial isolates subbed from an isolated colony to an agar slant	
	that will permit growth of the organism.	
Specimen Identification:	Isolate must be labelled with patient's first and last name, and a second	
	patient identifier such as DOB, MCI #, Specimen #. Specimen container	
	should have the date of isolate or collection, and initials of the person	
	collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	N/A	
(minimum):		
Collect:	Pure culture of isolate, subbed from an isolated colony to an agar slant	
	that will permit growth of the organism.	
Form:	DHEC 1335-OE requisition, check "Organism for ID"	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.	
Transport Conditions:	Ship according to directions listed under specific organism.	
Specimen Rejection	Mixed isolate. Specimens received at the improper temperature.; For	
Criteria:	universal rejections, See Specimen Rejection & Disclaimer Criteria in	
	Section I.	
Availability:	Monday – Friday unless otherwise noted for specific organism.	
Results and	Organism identification confirmed or not. Serotyping and serogrouping	
Interpretations:	as needed.	
Additional Information:	N/A	
Purpose of Test:	N/A	
Method:	bioMeriuex VITEK MS, Conventional methods, biochemicals,	
	serotyping/grouping	
Interfering Substances:	N/A	
Comment:	N/A	

Test	QuantiFERON-TB G	old Plus (QFT Plus)	
Synonym:	QFT, Interferon-Gamma Release Assay (IGRA)		
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	Monday-Friday; weekend testing available with prior approval by Supervisor or		
	Division Director.		
Turnaround Time:	7 days		
Specimen Required:	Whole blood in 4 Q	FT-Plus blood collection tubes	
Specimen Identification:	Patient's full name	and patient ID # (or other unique identifier) is required on the	
	specimen and requi	sition.	
Specimen Volume (optimum):	1 mL whole blood		
Specimen Volume (minimum):	0.8 mL – 1.2 mL, as	indicated on tube labels with 2 black fill lines	
Collect:	4 QuantiFERON-TB	Gold Plus tubes:	
	Nil antigen	(Grey cap)	
	TB 1 antige	en (Green cap)	
	TB 2 antige	en (Yellow cap)	
	Mitogen (P	Purple cap)	
	Specific collection r	equirements are needed. For detailed collection procedure, see	
	QuantiFERON-TB G	old Plus (QFT-Plus) Collection Procedure in Section III p. III-33.	
Form:	DHEC 1335-OE; be s	DHEC 1335-OE; be sure to write the incubation start and end times on this form.	
Special Instructions:	QFT-Plus Blood Coll	QFT-Plus Blood Collection Tubes should be at 17-25°C at time of blood collection.	
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.		
Transport Conditions:	Store tubes at 17 - 27°C prior to and after incubation. Specimens should be shipped		
	and received within 3 days post-incubation, or within 16 hours of collection if NOT		
	incubated in the regions. Place the specimen inside designated QFT-Plus shipper (large		
	white shipper with pink label) labeled to the attention of Virology and ship to maintain		
		rature range of 17-27°C until receipt at the PHL.	
Specimen Rejection Criteria:	Specimens with volumes below 0.8 mL or above 1.2 mL, as indicated by the black fill		
		; Specimens not incubated within the proper incubation period;	
	Specimens requiring incubation at 37°C that are not received by the PHL within 16		
	hours of collection. Specimens received at the improper temperature.; See <u>Specimen</u>		
A 11 - 1	Rejection & Disclaimer Criteria in Section I.		
Availability:	Monday - Friday		
Results and Interpretations:	Result	Interpretation	
	Positive	M. tuberculosis infection likely	
	Negative	M. tuberculosis infection not likely	
	Indeterminate	Likelihood of <i>M. tuberculosis</i> infection cannot be	
		determined	
Additional Information:	N/A		
Purpose of Test:	Aids in the diagnosis of Mycobacterium tuberculosis (TB) infection		
Method:	Detection of interferon-y by ELISA		
Interfering Substances:	N/A		
Comment:	N/A		

Test	RABIES EXAMINATION
Synonym:	N/A
Lab Section/Phone:	Virology & Rabies, 803-896-0819
Days Performed:	Monday - Friday only. Weekends and holidays only with notification and emergency testing criteria being met, specifically: (a) An unprovoked wild animal bite to a human, such as bites from a raccoon, fox, skunk, bobcat, coyote, etc.; or (b) A bat when there is an obvious bat bite, or if individuals awaken and find a bat in their room, or if there is a bat in a room with an unattended child or near a mentally impaired or intoxicated person.
Turnaround Time:	24 hours
Specimen Required:	Brain tissue
Specimen Identification:	N/A
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	Whole animal head
Collect:	Ship whole animal head. Heads are only submitted by DHEC Rabies Control Staff.
Form:	DHEC 1308
Special Instructions:	Contact the <u>local county health department</u> for the information on specimen collection and shipping instructions. Confirmation is a postmortem procedure; because the standard procedure currently requires the examination of brain tissue, the suspect animal must either be sacrificed or have died before the examination can be performed. All county health departments maintain containers appropriate for shipping specimens for examination, information on the management of animals suspected of being rabid, and information to obtain vaccine for persons exposed to a rabid animal after consultation with the state epidemiologist.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store at 2-8°C and ship on frozen cold packs to maintain the temperature at 2-8°C until receipt at the PHL. See Special Instructions above.
Specimen Rejection Criteria:	No brain tissue or tissue decomposed or grossly contaminated. See <u>Specimen</u> <u>Rejection & Disclaimer Criteria in Section I</u> .
Availability:	See Days Performed above.
Results and Interpretations:	Reported as Positive or Negative. All Positive reports are called directly to the county health department, or after regular working hours, to the county environmentalist who submitted the specimen.
Additional Information:	N/A
Purpose of Test:	To detect the rabies viral antigen in brain tissue of suspected animals, for the protection of persons exposed.
Method:	Fluorescent Antibody (FA)
Interfering Substances:	N/A
Comment:	The PHL is the only laboratory in SC that performs testing for rabies in animals. Human testing is only performed at CDC with prior approval. Call Virology & Rabies before sending to obtain proper documentation, 803-896-0819.

Test	RESPIRATORY PANEL 2 by FilmArray (PCR)
Synonym:	Adenovirus (AdV); Coronavirus (CoV) 229E, HKU1, NL63, OC43; Enterovirus (EV); c
	Human Rhinovirus (RHV); Human Metapneumovirus (hMPV); Influenza A (Flu A)
	(subtypes H1, H1-2009, and H3); Influenza B (Flu B); Parainfluenza Virus 1 (PIV1);
	Parainfluenza Virus 2 (PIV2); Parainfluenza Virus 3 (PIV3); Parainfluenza Virus 4 (PIV4);
	Respiratory Syncytial Virus (RSV); Bordetella pertussis; Bordetella parapertussis;
	Chlamydophila pneumoniae; and Mycoplasma pneumoniae
Lab Section/Phone:	Virology & Rabies, 803-896-0819
Days Performed:	Monday – Friday, only with prior approval as part of a respiratory outbreak
	investigation
Turnaround Time:	5 days
Specimen Required:	Nasopharyngeal (NP) swab placed in viral transport media
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the
	specimen and requisition.
Specimen Volume (optimum):	1 - 3 mL of viral transport media containing a nasopharyngeal (NP) swab
Specimen Volume (minimum):	N/A
Collect:	Nasopharyngeal (NP) swab placed immediately into sterile tubes containing 2 - 3 mL of
	viral transport media. Use only synthetic fiber swabs with plastic shafts. Do not use
	calcium alginate swabs or swabs with wooden shafts, as they may contain substances
	that inactivate some viruses and inhibit PCR testing. See Viral Media Collection for
	Virology Specimens in Section III, p. III-42.
Form:	DHEC 1335-OE; Request BioFire FilmArray RP2 Panel
Special Instructions:	Call Virology at 803-896-0819
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store at 2-8°C and ship on frozen cold packs to maintain the temperature at 2-8°C
	until receipt at the PHL. If shipping is delayed more than 48 hours, freeze at \leq -15°C
	and ship on dry ice to maintain specimen at temperature of ≤ -15°C until received at
	the PHL. Specimen frozen at \leq -15°C must be received at the PHL within 30 days of
	collection.
Specimen Rejection Criteria:	Specimen type other than nasopharyngeal (NP) swab; Use of calcium alginate swabs
	or swabs with wooden shafts; Specimens received at the improper temperature;
	See Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	For outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	To identify Adenovirus (AdV); Coronavirus (CoV) 229E, HKU1, NL63, OC43; Enterovirus
	(EV); Human Rhinovirus (RHV); Human Metapneumovirus (hMPV); Influenza A (Flu A)
	(subtypes H1, H1-2009, and H3); Influenza B (Flu B); Parainfluenza Virus 1 (PIV1);
	Parainfluenza Virus 2 (PIV2); Parainfluenza Virus 3 (PIV3); Parainfluenza Virus 4 (PIV4);
	Respiratory Syncytial Virus (RSV); Bordetella pertussis; Bordetella parapertussis;
	Chlamydophila pneumoniae; and Mycoplasma pneumoniae.
Method:	Multiplex Real-time PCR
Interfering Substances:	N/A
Comment:	N/A

Test	RPR (RAPID PLASMA REAGIN)
Synonym:	RPR, Non-Treponemal Antibody
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.5 mL of serum
Specimen Volume (minimum):	1.0 mL of serum
Collect:	Serum-separator tube or serum. Tubes must be properly centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection</u> : <u>Venipuncture Procedure in Section III</u> , if needed.
Form:	DHEC 1332 Test #001, 002, 004 or Test #235 (All specimens submitted to the PHL will undergo the reverse-algorithm unless otherwise indicated). Special requests should be in writing on the form under special instructions.
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store at 2-8°C and ship to be maintained at 2-8°C and received within 5 days of collection at the PHL; for storage longer than 5 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection	Plasma specimen; received after 5 days not maintained at -20° C or
Criteria:	colder; received at the improper temperature; For universal rejections, see Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	Reflex test for reactive and equivocal Syphilis TP's; Quantitation performed on RPR reactive specimens.
Purpose of Test:	To aid in the detection, diagnosis, and staging of syphilis
Method:	Charcoal flocculation
Interfering Substances:	N/A
Comment:	N/A

Test	RUBELLA SEROLO	GY- IgG and IgM
Synonym:	German Measles antibody, Rubella immune screen, Rubella IgG and IgM	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	N/A	
Turnaround Time:	lgG: 10 days	
	lgM: N/A	
Specimen Required:	Serum	
Specimen Identification:	Patient's full name specimen and rec	e and patient ID # (or other unique identifier) is required on the quisition.
Specimen Volume (optimum):	2 mL serum	
Specimen Volume (minimum):	1 mL serum	
Collect:	tubes may be used and put into a lab	vacuum tube (SST), centrifuged appropriately. (Red top vacuum d if the specimen is centrifuged and serum is removed from the clot eled secondary container/tube.) Please follow manufacturer's ecimen Collection: Venipuncture Procedure in Section III, if
Form:	DHEC 1332	
Special Instructions:	Call Virology, 803 require notificatio	-896-0819, prior to sending specimens for IgM. Rubella IgG does not
Packing and Shipping*:		and Shipping Infectious Substances in Section IV.
Transport Conditions:	See <u>Transporting and Snipping Infectious Substances in Section IV</u> . Store at 2 - 8°C and ship within 36 hours of collection to maintain specimen at 2 - 8°C	
Specimen Rejection Criteria:	should be stored a ≤ -20°C until recei	· · · · · · · · · · · · · · · · · · ·
Availability:	See Specimen Rejection & Disclaimer Criteria in Section I. IgG: As requested	
Avanabinty.	IgM: Referred to C	
Results and Interpretations:	Result	Interpretation
		Rubella IgG
		ndicates a current or previous infection with Rubella virus, or rior vaccination against Rubella virus.
	Equivocal C	ollect and test another specimen.
	re R a d Ig	lo detectable IgG antibodies to the Rubella virus. A non- eactive result indicates no current or previous infection with ubella virus. Such patients are presumed to be susceptible to primary infection. However, specimens taken too early uring a primary infection may not have detectable levels of gG antibody. If this is suspected, collect and test another pecimen in 8 - 14 days.
Additional Information:	N/A	
Purpose of Test:	IgM: Used in diagnosis of German Measles and during possible outbreaks. IgM antibodies usually appear 3 - 5 days after onset of rash. IgG: Used to determine immune status of patient.	
Method:	EIA (Enzyme Immunoassay)	
Interfering Substances:	N/A N/A	

Test	RUBEOLA (Measles) VIRUS SEROLO	GY-IMMUNE STATUS/DIAGNOSTIC	
Synonym:	Measles Serology IgM and IgG		
Lab Section/Phone:	Virology & Rabies, 803-896-0819		
Days Performed:	N/A		
Turnaround Time:	lgG: 10 days		
	IgM: Referred to CDC		
Specimen Required:	Serum		
Specimen Identification:	specimen and requisition.	(or other unique identifier) is required on the	
Specimen Volume (optimum):	2 mL serum		
Specimen Volume (minimum):	1 mL serum		
Collect:	may be used if the specimen is centre	, centrifuged appropriately. (Red top vacuum tubes ifuged and serum is removed from the clot and ainer/tube. different container/tube). Please	
	follow manufacturer's guidelines. Se <u>in Section III,</u> if needed.	e Specimen Collection: Venipuncture Procedure	
Form:	DHEC 1332		
Special Instructions:	Call Virology, 803-896-0819, prior to require notification.	b sending specimen for IgM. Rubeola IgG does not	
Packing and Shipping*:	See Transporting and Shipping Infec	tious Substances in Section IV.	
Transport Conditions:	until received by the PHL. If shipme	ours of collection to maintain specimen at 2 - 8°C nt is delayed longer than 36 hours, store specimen ntain at temperature of ≤ -20°C until received at	
Specimen Rejection Criteria:	See Specimen Rejection & Disclaime	er Criteria in Section I.	
Availability:	IgG: As requested		
	IgM: Referred to CDC		
Results and Interpretations:	Result	Interpretation	
		Measles IgG	
	Positive	Reactive to IgG antibodies to Rubeola virus. Indicates a current or previous infection with Rubeola virus, or prior vaccination against Rubeola virus.	
	Equivocal	Obtain and test another specimen.	
	Negative	Indicates no detectable IgG antibodies to the Rubeola virus. A non-reactive result indicates no current or previous infection with Rubeola virus. Such patients are presumed to be non-immune and are therefore susceptible to a primary infection. A non-reactive result may be obtained early in seroconversion of infected individuals. If this is suspected, obtain and test an additional specimen in 8 - 14 days.	
Additional Information:	N/A		
Purpose of Test:	IgG: Used to determine immune status of the patient. IgM: Used in diagnosis of measles and during possible outbreaks. IgM antibodies usually appear 3 - 5 days after onset of rash.		
	usually appear 3 - 5 days after onset	of rash.	
Method:	usually appear 3 - 5 days after onset EIA (Enzyme Immunoassay)	of rash.	
Method: Interfering Substances:		of rash.	

Test	STAPHYLOCOCCUS
Synonym:	Enteric Pathogen Culture, Staphylococcus aureus, for VISA/VRSA
	confirmation, see Staphylococcus (VISA/VRSA) isolates.
Lab Section/Phone:	Clinical specimens and isolates – Clinical Microbiology, 803-896-0805
	Food Samples – Food Microbiology, 803-896-0872
	MRSA/VRSA isolates from suspected outbreaks – Molecular
	Microbiology, 803-896-0826
Days Performed:	Monday - Friday
Turnaround Time:	10 Business days
Specimen Required:	Swabs – transport in media that will support the growth of the
	organism.
	Referred Isolate – transport on an agar slant that will support growth
	Food – call the food microbiology laboratory before shipping food
	samples (803-896-0872)
Specimen Identification:	Specimen container and Isolates must be labelled with patient's first
	and last name, and a second patient identifier such as DOB, MCI #,
	Specimen #. Specimen container or isolates should have the date of
	isolate or collection, and initials of the person collecting the specimen.
	DHEC requisition must be completed in full.
Specimen Volume	N/A
(optimum):	
Specimen Volume	N/A
(minimum):	
Collect:	N/A
Form:	DHEC requisition 1335-OE
Special Instructions:	N/A
Packing and Shipping*:	See Packing and Shipping Instructions in Section IV.
Transport Conditions:	Ship isolates in approved shippers to maintain temperature within the
	range of 15-25°C until received at the PHL. Ship swabs in transport
	media on frozen cold packs to be maintained in temperature range of
	2-8°C until receipt at the PHL.
Specimen Rejection	Culture non-viable; culture mixed; improper temperature; For universal
Criteria:	rejections, see Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and	N/A
Interpretations:	
Additional Information:	N/A
Purpose of Test:	N/A
Method:	Conventional culture methods and biochemical analysis. bioMerieux
	VITEK MS, WGS for outbreak investigations.
Interfering Substances:	N/A
Comment:	N/A

Test	STAPHYLOCOCCUS (VISA/VRSA) ISOLATES	
Synonym:	Vancomycin Intermediate Staphylococcus aureus, Vancomycin Resista	
	Staphylococcus aureus Staphylococcus aureus, vancomycin-resistant	
	or intermediate with a VA > 6 MIC.	
Lab Section/Phone:	Clinical Microbiology, 803-896-0805	
Days Performed:	Monday - Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Pure, low passage isolate on a non-inhibitory, non-selective agar plate or slant that will support the growth of the isolate. Include both isolated colony and at least one original culture plate as resistance can be lost over time and subbing out organism.	
Specimen Identification:	Isolate must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Isolate should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.	
Specimen Volume	N/A	
(optimum):		
Specimen Volume	N/A	
(minimum):		
Collect:	Be sure to submit a pure bacterial isolate, subbed from an isolated colony.	
Form:	DHEC 1335-OE requisition, check "Organism for ID"	
Special Instructions:	According to CDC and CLSI, only isolates with a commercial instrument	
	MIC or E-test > 6 need sent to a reference laboratory for confirmation.	
	CDC states results from Vitek 2, MicroScan, Phoenix, or E-test are	
	accurate and correlate with studies performed at the CDC. MIC values	
	of 2, 3, and 4 are not uncommon.	
Packing and Shipping*:	See Packing and Shipping Instructions in Section IV.	
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.	
Specimen Rejection	Culture non-viable, culture mixed, specimens received at the improper	
Criteria:	temperature; For universal rejections, see Specimen Rejection &	
	Disclaimer Criteria in Section I.	
Availability:	Monday - Friday	
Results and	N/A	
Interpretations:		
Additional Information:	Specimen submission to the Public Health Laboratory (PHL) is required. Ship within 1 business day.	
Purpose of Test:	N/A	
Method:	bioMerieux VITEK MS, E-test	
Interfering Substances:	N/A	

Test	STREPTOCOCCUS (BETA HEMOLYTIC GROUP A)
Synonym:	Group A Strep, Streptococcus pyrogenes
Lab Section/Phone:	Clinical Microbiology, 803-896-0803
Days Performed:	Monday - Friday
Turnaround Time:	10 Business days
Specimen Required:	Isolate on agar slant able to promote growth; Use ESwab for Outbreak Colonization Screenings authorized by DADE.
Specimen Identification:	Isolate or ESwab must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Isolate should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.
Specimen Volume	N/A
(optimum):	
Specimen Volume (minimum):	N/A
Collect:	For Outbreak Colonization, collect ESwab and ship at 15-25°C overnight. ESwab is only good for 2 days at room temperature (15-25°C) or 6 days refrigerated (2-8°C).
Form:	DHEC 1335-OE requisition form, check "Organism for ID" and under "Special Instructions", write "Freeze organism". For Outbreak Colonization, mark for "Non-enteric Culture" and note the Outbreak Number.
Special Instructions:	Submit Group A Beta hemolytic <i>Streptococcus</i> (<i>S. Pyrogens</i>) organisms that are of epidemiologic concern, to be frozen for possible surveillance studies at a later date.
Packing and Shipping*:	See Packing and Shipping Instructions in Section IV.
Transport Conditions:	Ship isolates in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	See Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	All Group A Strep submitted will be logged and frozen on freezer beads for possible epidemiological surveillance at a later date. Outbreak Colonization Screening specimens in which S. pyogenes is isolated, with permission from the CDC, will be sent to the CDC for further testing.
Purpose of Test:	N/A
Method:	bioMereieux VITEK MS, freezer beads, Cepheid Xpert Xpress Grp A
Interfering Substances:	N/A
Comment:	N/A

Test	STREPTOCOCCUS PNEUMONIAE
Synonym:	Strep pneumo, invasive (pneumococcal)
Lab Section/Phone:	Clinical Microbiology, 803-896-0805
Days Performed:	Monday - Friday
Turnaround Time:	10 Business days
Specimen Required:	Pure isolate on a Chocolate or Blood agar slant
Specimen Identification:	Isolate must be labelled with patient's first and last name, and a second
	patient identifier such as DOB, MCI #, Specimen #. Isolate should have
	the date of isolate or collection, and initials of the person collecting the
	specimen. DHEC requisition must be completed in full.
Specimen Volume	N/A
(optimum):	
Specimen Volume	N/A
(minimum):	
Collect:	Submit <i>S. pneumoniae</i> isolate from patients of any age, ALL CSF isolates,
	and invasive sterile body sites that are non-susceptible to any relevant
F	antibiotics according to CLSI for further testing and serotyping.
Form:	DHEC 1335-OE requisition, check "Organism for ID"
Special Instructions:	Invasive disease = isolated from normally sterile site. Always specify site of isolate.
Decking and Chinging*	
Packing and Shipping*:	See Packing and Shipping Instructions in Section IV.
Transport Conditions:	Store in 35°C CO ₂ incubator and ship in approved shippers which will maintain temperature within the range of 15, 25° C uptil received at the
	maintain temperature within the range of 15-25°C until received at the PHL.
Specimen Rejection	For universal rejections, See Specimen Rejection & Disclaimer Criteria
Criteria:	in Section I.
Availability:	Monday - Friday
Results and	N/A
Interpretations:	
Additional Information:	Specimen submission to the PHL is required for <i>Streptococcus</i>
	pneumoniae, isolate from patients of any age, ALL CSF isolates, and
	invasive sterile body sites that are non-susceptible to any relevant
	antibiotics according to CLIS for further testing and serotyping. Shipped
	to Wisconsin State Laboratory of Hygiene (WSLH) for serotyping by PCR.
Purpose of Test:	Submission required for epidemiologic surveillance.
Method:	PCR
Interfering Substances:	N/A
Comment:	N/A

Test	SYPHILIS SEROLOGY SCREEN
Synonym:	Syphilis Total Antibodies, Reverse-Algorithm, Treponemal Antibodies
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday – Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1.5 mL of serum
Specimen Volume (minimum):	1.0 mL of serum
Collect:	Serum-separator tube or serum. Tubes must be properly centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection: Venipuncture</u> <u>Procedure in Section III</u> , if needed.
Form:	DHEC 1332 (All specimens submitted to the PHL for syphilis testing will undergo the reverse-algorithm unless otherwise indicated.)
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 5 days of collection at the PHL; for storage longer than 5 days, remove the serum from the clot or gel, place in a labelled secondary container and freeze at - 20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection Criteria:	Plasma specimen; Specimens received at the improper temperature; specimens received after 5 days not maintained at -20° C or colder; For universal rejections, see <u>Specimen Rejection & Disclaimer Criteria in</u> <u>Section I</u> .
Availability:	Monday – Friday
Results and Interpretations:	Reactive, Nonreactive, or Equivocal
Additional Information:	Reactive and Equivocal Syphilis TP specimens will automatically be reflexed for RPR testing. If the RPR is nonreactive, the specimen(s) will be automatically reflexed for manual TP-PA testing.
Purpose of Test:	The qualitative detection of antibodies (IgG and IgM) directed against Treponema pallidum (TP) in human serum.
Method:	Multiplex flow immunoassay
Interfering Substances:	Assay interference due to circulating antibodies against yaws, pinta, and bejel has not been evaluated. Cross-reactivity with these treponemal disease conditions is to be expected.
Comment:	RPR automatically performed on positives and equivocals.

Test	TP-PA SEROLOGY
Synonym:	MHA-TP, Treponemal Antibody Serology
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday – Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	1 mL of serum
Specimen Volume (minimum):	0.5 mL of serum
Collect:	Serum-separator tube or serum. Tubes must be properly centrifuged, and serum from red top tubes must be removed from the clot and put into a labeled secondary container/tube. See <u>Specimen Collection:</u> <u>Venipuncture Procedure in Section III</u> , if needed.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store and ship to be maintained at 2-8°C and received within 5 days of collection at the PHL; for storage longer than 5 days, remove the serum from the clot or gel, place in a secondary container and freeze at -20°C or colder, and ship on dry ice to maintain specimen at temperature of -20°C or colder until received at the PHL.
Specimen Rejection	Plasma specimen; received after 5 days not maintained at -20° C or
Criteria:	colder; Grossly contaminated, grossly lipemic, excessively hemolyzed, or chylous; Specimens received at the improper temperature. For universal rejections, See <u>Specimen Rejection & Disclaimer Criteria in</u> <u>Section I</u> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive, Nonreactive, or Indeterminate Not a screening test; Reactive test is usually reactive for life (85% of cases). Specimens are reflexed for TP-PA testing only if the initial Syphilis TP is reactive or equivocal and the RPR is non-reactive.
Additional Information:	N/A
Purpose of Test:	An aid to resolve discrepant results between screening treponemal (Syphilis TP) and nontreponemal (RPR) test results.
Method:	Particle Agglutination
Interfering Substances:	N/A
Comment:	N/A

Test	TRACE HEAVY METALS IN URINE
Synonym:	Urine Metals
Lab Section/Phone:	Analytical Chemistry, 803-896-0886
Days Performed:	As requested
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Urine
Specimen Identification:	Specimen container must be labelled with patient's full name, and a
	second patient identifier such as DOB, Specimen #, etc. DHEC
	requisition must be completed in full.
Specimen Volume	2 - 5 mL
(optimum):	
Specimen Volume	500 μL
(minimum):	
Collect:	Sterile urine cups
Form:	DHEC 1332, Test #885
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Urine specimens stored at ≤ -20°C and transported frozen by packing on
	dry ice to maintain \leq -20°C temperature until received at the PHL is
	preferred, when possible. Urine may also be stored at 2-8°C and
	shipped on frozen cold packs to maintain specimens at 2-8°C until
	receipt at the PHL. Urines stored and shipped at 2-8°C must be received
	at the PHL within 10 days of collection.
Specimen Rejection	Insufficient quantity (QNS); improper collection container; specimens
Criteria:	received at the improper temperature; For universal rejections, see
	Specimen Rejection & Disclaimer Criteria in Section I
Availability:	Monday – Friday
Results and	N/A
Interpretations:	
Additional Information:	Metals included: Arsenic (As), Barium (Ba), Beryllium (Be), Cadmium
	(Cd), Lead (Pb), Thallium (Tl), Uranium (U)
Purpose of Test:	Identify exposure to As, Ba, Be, Cd, Pb, Tl, and U
Method:	Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
Interfering Substances:	N/A
Comment:	N/A

Test	TRICHOMONAS VAGINALIS DETECTION BY NUCLEIC ACID AMPLIFICATION
Synonym:	Hologic Trichomonas vaginalis Amplified Nucleic Acid Test (NAAT), Trichomonas
	vaginalis rRNA, Aptima TV
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday - Friday
Turnaround Time:	1 - 5 Business Days
Specimen Required:	 The assay may be used to test the following specimens from symptomatic or asymptomatic <u>female patients</u>: Unisex swab (blue shafted swab) for endocervical specimens Multi-test swab (orange/coral swab) for vaginal specimens Urine transport tube for female urines
	<u>Male specimens</u> : Urine transport tube ONLY
Specimen Identification:	Specimens must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC requisition must be completed in full.
Specimen Volume (optimum):	Urine should be collected up to the "fill area" lines. Swab collection kits should contain an adequate amount of transport media for testing.
Specimen Volume (minimum):	Urine should be collected up to the "fill area" lines. Swab collection kits should contain an adequate amount of transport media for testing.
Collect:	Only use Gen-Probe Aptima Specimen Collection Kits. See Special Instructions for more information.
Form:	DHEC 1332
Special Instructions:	Only use Gen-Probe Aptima Specimen Collection Kits. Female and male urine specimens: Patients should not have voided within one hour of collection. Collect first 20 - 30 mL of the first-catch urine stream into a collection cup. Transfer 2 mL of urine into Aptima Urine Specimen Transport tube so that the urine level falls within the two lines on the transport tube labeled: "fill area" (Yellow Label). See <u>GC/Chlamydia Gen-Probe Collection Procedure, Section III</u> Male testing will ONLY be performed on urine specimens.
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store specimens at 2-30°C and ship specimens to be maintained at 2-30°C until received at the PHL. For longer storage, freeze transport tube within 7 days of collection at \leq -20 °C and ship on dry ice to maintain at temperature of \leq -20°C until received at the PHL; Swab specimens must be tested within 60 days of collection. Urine specimens should be tested within 30 days of collection (urine must be transferred to the Urine Collection Tubes within 24 hours).
Specimen Rejection Criteria:	Specimens with no swab in transport media; white swab in transport media; two swabs in transport media; urine above or below designated black lines on transport tube labeled fill area; swab specimen more than 60 days old, or urine specimens more than 30 days old; specimens received at the improper temperature; For universal rejections, see <u>Specimen Rejection & Disclaimer Criteria in Section I</u> .
Availability:	Monday - Friday
Results and Interpretations:	Positive or Negative
Additional Information:	N/A
Purpose of Test:	For the detection and aid in the diagnosis of trichomoniasis.
Method:	Nucleic acid amplification test (NAAT)
Interfering Substances:	N/A
Comment:	N/A

Test	VARICELLA VI	RUS SEROLOGY (IgG)
Synonym:	Chickenpox, V	aricella zoster virus
Lab Section/Phone:	Virology & Ra	bies, 803-896-0819
Days Performed:	N/A	
Turnaround Time:	10 days	
Specimen Required:	Serum	
Specimen Identification:	Patient's full r	name and patient ID # (or other unique identifier) is required on
	the specimen	and requisition.
Specimen Volume (optimum):	2 mL serum	
Specimen Volume (minimum):	1 mL serum	
Collect:	vacuum tubes removed from	tor vacuum tube (SST), centrifuged appropriately. (Red top may be used if the specimen is centrifuged and serum is the clot and put into a different container/tube). Please follow s guidelines. See <u>Specimen Collection: Venipuncture Procedure</u> if needed.
Form:	DHEC 1332	
Special Instructions:	N/A	
Packing and Shipping*:	See Transport	ing and Shipping Infectious Substances in Section IV.
Transport Conditions:	2 - 8°C until re specimen sho temperature o	C and ship within 36 hours of collection to maintain specimen at eceived by the PHL. If shipment is delayed longer than 36 hours, and be stored at \leq -20°C and shipped on dry ice to maintain the of \leq -20°C until received by the PHL.
Specimen Rejection Criteria:	See Specimen	Rejection & Disclaimer Criteria in Section I.
Availability:	As requested	
Results and Interpretations:	Immune statu	s: Positive, Negative or Equivocal
Additional Information:	Result	Interpretation
	Positive	Indicates IgG antibodies to Varicella virus were detected. A positive test result indicates a current or previous infection with Varicella virus, or prior vaccination against Varicella virus.
	Equivocal	Re-evaluate by collecting and testing another specimen.
	Negative	Indicates no detectable IgG antibodies to the Varicella virus. A non-reactive result indicates no current or previous infection with Varicella virus. Such patients are presumed to be non- immune and are therefore susceptible to a primary infection. A non-reactive result may be obtained early in seroconversion of infected individuals. If this is suspected, collect and test another specimen in 8 - 14 days.
Purpose of Test:	To detect Vari	cella zoster virus IgG antibodies for determining immune status.
Method:	EIA (Enzyme li	
Interfering Substances:	N/A	
Comment:	N/A	

Test	VARIOLA
Synonym:	Small Pox
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767-8118
Days Performed:	As needed
Turnaround Time:	48 hours
Specimen Required:	Clinical specimens
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.
Specimen Volume (optimum):	Determined during Special Pathogens Laboratory notification.
Specimen Volume (minimum):	Determined during Special Pathogens Laboratory notification.
Collect:	Determined during Special Pathogens Laboratory notification.
Form:	DHEC 1335-OE; In the "Molecular Testing for Viral Pathogens", check "Other" and write "Variola" as the "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.
Special Instructions:	Pre-approval Needed - Hospitals must obtain approval from SC DHEC DADE
	(Division of Acute Disease Epidemiology) and the Special Pathogens Laboratory prior to submitting specimens. Contact information can be located on the back of the <i>List of Reportable Conditions</i> . Contact the Special Pathogens Laboratory (803-896-0777 / 803-767-8118) for test notification, specimen collection, storage conditions, and shipping conditions/methods.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777 / 803-767-8118.
Transport Conditions:	Determined during Special Pathogens Laboratory notification
Specimen Rejection Criteria:	Determined during Special Pathogens Laboratory notification
Availability:	As needed
Results and Interpretations:	Final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail. The definitive identification of <i>Variola</i> virus requires additional testing to be performed by CDC.
Additional Information:	Variola Virus is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Variola</i> detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.
Purpose of Test:	To presumptively detect Variola DNA in clinical specimens
Method:	CDC/LRN Real Time PCR Assay
Interfering Substances:	N/A
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

Test	VIBRIO, all types, including Vibrio cholerae O1 and O139
Synonym:	N/A
Lab Section/Phone:	Clinical Microbiology, 803-896-0803
Days Performed:	Monday - Friday
Turnaround Time:	10 Business Days
Specimen Required:	Isolate or stool collected in stool transport medium.
Specimen Identification:	Specimen container and Isolates must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container or isolates should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.
Specimen Volume	N/A
(optimum):	
Specimen Volume (minimum):	N/A
Collect:	Pure isolate subbed to agar slant that supports growth.; Stool in transport medium, such as Cary Blair and Para Pak.
Form:	DHEC 1335-OE requisition; check "Organism for ID" for isolates and "Enteric Culture" for stool in transport medium.
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	 Ship isolates in approved shippers to maintain temperature of specimen within the range of 15-25°C until received at the PHL. Ship stool in transport medium on frozen cold packs in approved specialized insulated shippers to maintain temperature of specimen within the range of 2-8°C until received at the PHL.
Specimen Rejection Criteria:	For universal rejections, see Specimen Rejection & Disclaimer Criteria in Section I.
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	Specimen submission to the Public Health Laboratory (PHL) is required. Ship +PCR specimens ASAP to promote recovery. Ship isolates within 1 business day.
Purpose of Test:	N/A
Method:	bioMerieux VITEK MS, conventional biochemicals, serotyping
Interfering Substances:	N/A
Comment:	N/A

Test	WEST NILE VIRUS SEROLOGY-	IgM
Synonym:	Arbovirus Serology	
Lab Section/Phone:	Virology & Rabies, 803-896-08	19
Days Performed:	N/A	
Turnaround Time:	15 days	
Specimen Required:	Cerebrospinal fluid (CSF) or Se	rum
Specimen Identification:	Patient's full name and patient	: ID # (or other unique identifier) is required
	on the specimen and requisition	on.
Specimen Volume (optimum):	CSF: 2 mL	
	Serum: 2 mL	
Specimen Volume (minimum):	CSF: 1 mL	
	Serum: 1 mL	
Collect:	vacuum tubes may be used if t removed from the clot and put	
Form:	DHEC 1332	
Special Instructions:	N/A	
Packing and Shipping*:	See Transporting and Shipping	g Infectious Substances in Section IV.
Transport Conditions:	2-8°C until received at the PHL received at the PHL at a tempe Store Serum at 2 - 8°C and ship specimen at 2 - 8°C until receiv than 36 hours, Serum specime	thin 24 hours to maintain the temperature at . After 24 hours, ship CSF on dry ice to be erature of \leq -20°C. by within 36 hours of collection to maintain yed by the PHL. If shipment is delayed longer in should be stored at \leq -20°C and shipped on trature of \leq -20°C until received by the PHL.
Specimen Rejection Criteria:	See Specimen Rejection & Disc	
Availability:	N/A	
Results and Interpretations:	Result	Interpretation
	Positive	Indicates IgM antibodies to West Nile virus were detected.
	Negative	Indicates no detectable IgM antibodies to West Nile virus.
	Equivocal	Collect and submit another specimen for testing.
	Unable to Interpret	Non-specific interference. Unable to interpret.
Additional Information:	Positive specimens will be refe	rred to CDC for additional testing.
Purpose of Test:	To detect IgM antibodies for th infection.	ne West Nile virus to determine a current
Method:	EIA (Enzyme Immunoassay)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	YERSINIA ENTERCOLITICA
Synonym:	Y. enterocolitica
Lab Section/Phone:	Clinical Microbiology, 803-896-0805
Days Performed:	Monday - Friday
Turnaround Time:	10 Business Days
Specimen Required:	Walnut sized portion of feces or 5 - 10mL of liquid stool in stool transport medium. Infant specimens may be collected in a disposable diaper with outside facing in. Submit referred isolate on agar slant in a screw capped tube.
Specimen Identification:	Specimen container or Isolate must be labelled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. Specimen container and Isolate should have the date of isolate or collection, and initials of the person collecting the specimen. DHEC requisition must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume	N/A
(minimum):	
Collect:	N/A
Form:	DHEC 1335-OE requisition, check "Enteric Culture" or "Organism for ID"
Special Instructions:	N/A
Packing and Shipping*:	See Transporting and Shipping Infectious Substances in Section IV.
Transport Conditions:	Store specimen at 2-8°C. Ship stool preserved in Cary-Blair or Para-Pak transport medium on frozen cold packs in approved specialized insulated shipper to maintain specimen at a temperature range of 2-8°C until received at the PHL. Ship slants in approved shippers to maintain the temperature range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	Quantity insufficient; specimen too old; improper transport media or conditions; Specimens received at the improper temperature; For universal rejections, see <u>Specimen Rejection & Disclaimer Criteria in</u> <u>Section I</u> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	<i>Yersinia enterocolitica</i> testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology (DADE).
Purpose of Test:	N/A
Method:	bioMerieux, Vitek MS
Interfering Substances:	N/A
Comment:	N/A

Test	YERSINIA PESTIS
Synonym:	Bubonic Plague
Lab Section/Phone:	Special Pathogens / Daytime - (803) 896-0777 or Evenings - (803) 767- 8118
Days Performed:	As needed
Turnaround Time:	7 to 10 days from the time of specimen receipt at the PHL
Specimen Required:	Clinical Specimens / Isolates
Specimen Identification:	Specimens should be labeled with patient's first and last name, DOB, MCI # or other unique ID #, date and time of collection, initials of the person collecting the specimen, and the specimen source.
Specimen Volume (optimum):	Determined during pre-approval consultation.
Specimen Volume (minimum):	Determined during pre-approval consultation.
Collect:	Determined during pre-approval consultation.
Form:	DHEC 1335-OE; In the "Rule-Out Testing" box, check the appropriate box for specimen type and write "Yersinia pestis" for "Suspect Agent" DHEC requisition must be completed in full and should include the date of birth and a second patient identifier (e.g., Local ID or Clinical ID), the date of isolate / collection, and initials of the person collecting the specimen.
Special Instructions:	Specimen must be pre-approved by Special Pathogens Supervisor prior to testing.
Packing and Shipping*:	Special handling criteria apply. Please contact the laboratory for special instructions at 803-896-0777 / 803-767-8118.
Transport Conditions:	Determined during pre-approval consultation.
Specimen Rejection Criteria:	Determined during pre-approval consultation.
Availability:	As needed
Results and Interpretations:	Preliminary (when applicable) and final results are verbally called to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.
Additional Information:	 Yersinia pestis is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of Yersinia pestis detection, the Special Pathogens Laboratory will assist the sender in the timely submission of the required federal documentation.
Purpose of Test:	To detect Y. pestis in clinical specimens / To confirm referred isolates
Method:	A variety of sentinel and LRN methods are used to grow, isolate, confirm, and rule-out bacterial isolates.
Interfering Substances:	N/A
Comment:	Please call the Special Pathogens Laboratory with any questions or concerns.

SECTION III

ORDERING SUPPLIES AND SPECIMEN COLLECTION

ORDERING SUPPLIES/FORMS/SHIPPING CONTAINERS

The Public Health Laboratory (PHL) will provide request forms, kits, media, and shipping containers for the collection and shipping of laboratory specimens. These supplies are provided free of charge. Please use them judiciously and use them **ONLY** to send laboratory specimens to the Public Health Laboratory, SCDHEC, 8231 Parklane Road, Columbia, SC 29223. Supplies may be obtained by completing and submitting the **DHEC 1323 form**, "Request for Laboratory Supplies". Email <u>PHL-Supply@dhec.sc.gov</u> to request the 1323 form. An electronic fillable form will be sent by email. Return the completed DHEC 1323 form by email to <u>PHL-Supply@dhec.sc.gov</u>. Be sure to provide the sender number, so the requested supplies are sent to the correct location. A confirmation email will be sent after receipt of the completed DHEC 1323 form. The Supply Section can be reached at (803) 896-0913, if needed.

COLLECTION KITS

These kits contain collection materials and a requisition form. Each kit is to be used for only one specimen.

Enteric kit (for Bact. Culture) Influenza kit Mycobacteriology (collection kit for TB) Pink Label Insulated Shipper Yellow Label

TRANSPORT MEDIUM

(Order request forms and shipping container separately.)

GC Culture medium Cary Blair Media Viral Transport Media

OTHER SUPPLIES

Absorbent Packs
Biohazard Bags
Envelopes (for Newborn Screening and Hb electrophoresis blood spots)
GC/Chlamydia/Trichomonas (for Antigen Detection) Unisex swab, MTS (Multitest) swab, also known as the orange/coral vaginal swab), or urine collection kit
PPT Tubes for Viral Load
OuantiFERON-TB Gold Plus (OFT Plus) Tubes

SHIPPING CONTAINERS

(use for shipping infectious specimens)

Commercial carriers must use special approved mailing containers. These are distributed for PHL use ONLY and will be returned to senders for re-use.

Shipping Containers

Thermosafe and Uline Infecon 5000 Infecon 5500 Category A Cold Shipper Rabies Container

REQUEST FORMS

The request forms provided by the Public Health Laboratory are listed below. Forms marked with a + will be preaddressed with your name, address and sender number. Since an over-supply cannot be returned to stock, please use discretion in the number you request. **DO NOT LOAN OR BORROW** pre-printed forms to another client. The pre-printed sender number determines where result reports are mailed or made available to electronically. Forms are periodically revised. Please discontinue use of old forms once a revision has been made.

A separate DHEC 1323 form (Request for Laboratory Supplies) must be submitted for each location requesting supplies, using its unique sender number.

Form #	Test (revision date)	Form color
1308	+Rabies	White
1323	Request for Lab Supplies	N/A (Electronic form)
1327	Newborn Screening	White
	(Check expiration date on form)	
1332	+GC/ Chlamydia Screening	White
1332	+ HIV Hepatitis /Syphilis Serology	White
1332	+Immunology	White
1332	+Lead Analysis	White
1335-OE	+Bacteriology	White
1335-OE	+ Molecular	White
1335-OE	+Mycobacteriology	White (Included in kit)
1335-OE	+Parasitology	White
1335-OE	+Virus Detection/Herpes	White
1339	Hemoglobin Electrophoresis	Lt. Green

+Pre-addressed



DHEC 1332 Submission Form DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL Public Health Laboratory-8231 Parklane Road Columbia, SC 29223

ALIGN BARCODE LABEL TO TOP OF BOX

(803) 896-0800

		(803) 896	-0800		CLIA # 42	D06586	506						
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Contact-Chlamydia		🗖 Fast T	rack Services		erred-Other				Fe	ever:			
Contact-Gonorrhea		G Follow		🗖 Ref	ferred – Self				-	uration:			
Contact-Hepatitis A		🗖 Pregna			oeat Test/Firs	t Test				ash (Type):			15
Contact-Hepatitis B			Festing Services		itine Screen					Conjunctivit		Paraly	
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Contact-Syphilis			Test Negative	🗖 Unk	nown					Muscle Weal	kness	□ Vomit	ting
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DHEC 1332			1										



INSTRUCTIONS FOR COMPLETING REQUEST FORM (May use printed patient lab label)

- Enter patient name. 1.
- Write M = Male; F = Female or TX = Transgender M2F (Male to Female); or TY = Transgender F2M (Female 2. to Male) in Sex box.
- 3. Enter ethnicity as follows: H = Hispanic/Latino, N = Non-Hispanic/Latino and U = Unknown
 - Enter race as follows: A = Asian
 - W= White

B = Black/African American I = American Indian/Alaskan Native

O= Other

- P = Native Hawaiian/Other Pacific Islander
- U = Unknown/Unclassified
- Enter date of birth (month, day and year. Example: Enter 03/06/1960 for the birthday March 6, 5. 1960.)
- 6. Enter the patient address and five-digit zip code.
- 7. Enter county of residence and the 10-digit telephone number.
- Enter Country of Birth. 8.
- 9 Fill in patient MCI ID number (DHEC Clients only).
- 10. Enter local and clinic ID if applicable. (Private clients must provide a clinic ID)
- 11. Enter Sender number and Sender name.
- Enter billing number if billing number is different from sender number 12.
- 13. Enter Program number.
- 14. Enter Clinic Type.
- 15. In the Reason for Visit/Test box, check all that apply. Enter Date of Onset if applicable and check all symptoms that apply.
- 16. Enter the date and time of collection.
- 17. Enter Ordering Physician, Provider and/or Nurse if applicable. Note: Please print.
- Check type/source of specimen. 18.

19.

4.

Use th	 e codes below to identify client and partner Risk Factors during the PAST 12 MONTHS. (Circle all that apply) 1. Sex w/Female (F) 2. Sex w/Male (M) 3. Sex w/Transgender (T) 4. Injection Drug Use (IDU) 5. Used non-injectable drug or alcohol anytime during past 12-months
CLIENT RISK	Received drugs/money in exchange for sex with a: 6. F/partner 7. M/partner 8. T/partner Had sex while high on drugs with a: 9. F/partner 10. M/partner 11. T/partner 12. Child of HIV infected mother 13. Refused 14. Other 31. Without Condom 32. Oral Sex w/Female 33. Oral sex w/Male 33. Oral sex w/Male
PARTNER RISK	Client had sex with: 15. F/IDU 16. F/HIV + 17. F/of unknown status 18. F/who exchanges sex for drugs/money 19. F/who has transfusions/transplant recipient 20. M/IDU 21. M/HIV + 22. M/who exchanges sex for drugs/money 23. Person who is a known MSM (for female clients only) 24. M/of unknown status 25. M/who has transfusions/transplant recipient 26. T/IDU 27. T/HIV + 28. T/of unknown status 29. T/who exchanges sex for drugs/money 30. T/who has transfusions/transplant recipient 26. T/IDU 27. T/HIV +

- 20. Chlamydia test: Check pregnancy status, risk, and symptom.
- 21. Enter Special Instructions and/or Comments.
- 22. Check test(s) requested.
- 23. Send one copy of the form with the specimen(s) to the lab. Please Retain an Additional Copy For Your Records.

Request forms will be retained following DHEC records retention schedule 8581, "Requests for Laboratory Analysis", Records Group Number: 169.

DHEC 1332

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INSTRUCTIONS FOR COMPLETING REQUEST FORM DHEC 1335

(May use printed patient lab label)

- Enter patient name. 1.
- Enter M = Male; F = Female; TX = Transgender M2F (Male to Female); or TY = F2M (Female to 2. Male) in Sex box.
- Enter ethnicity as follows: H = Hispanic/Latino and N = NonHispanic/Latino. 3. 4.
 - Enter race as follows: A = Asian
- B = Black/African American
- W= White
- I = American Indian/Alaskan Native
- P = Native Hawaiian/ O= Other
 - Other Pacific Islander U = Unknown/Unclassified
- 5. Enter date of birth (month, day and year.) Example: enter 03/06/1960 for the birthday March 6, 1960.
- Enter the patient address and five-digit zip code. 6.
- Enter county of residence and the 10-digit telephone number. 7.
- Fill in patient MCI ID number (DHEC Clients only). 8.
- Enter local and clinic ID if applicable. (Private clients must provide a clinic ID) 9.
- 10. Enter Program number.
- 11. Enter Country of Birth.
- Enter billing number if billing number is different from sender number. 12
- Enter the Outbreak number. 13.
- 14. Enter the date and time of collection and initial.
- 15. Check type/source of specimen.
- Enter Ordering Physician, Provider and/or Nurse if applicable. Note: Please print. 16.
- Enter in the Special Instructions and/or comments where you vacated (travel history). 17.
- Enter Date of Onset if applicable. 18.
- List agents, organisms, or virus suspected. 19.
- 20. Enter clinical diagnosis.
- 21. Check symptoms that apply.
- 22. Mark test requested.
- Answer the four questions in Mycobacteriology Section. 23.
- 24. Send one copy of the form with the specimen(s) to the lab. PLEASE RETAIN AN ADDITIONAL COPY FOR YOUR RECORDS.

Request forms will be retained following DHEC records retention schedule 8581, "Requests for Laboratory Analysis", Records Group Number: 169.

Sc depa	Public I 8231 Parklane	TH AND ENVIRONMENTAL CO Jealth Laboratory Road Columbia, SC 29223 03)896 -0800	BOL Specimen Number NTROL Sample Master Number 8606
		CLIA	# 42D065
□Cat □Dog □Bat □Fox □Race	coon □Skunk	□Wild □Pet □S	tray Date of Death
□Rodent (Specify)			MO DAY Y
Other (Specify)		Has the animal been vacc rabies? □Yes □No	inated against Date of Vaccination □Unknown DAY Y
Sender Number Abri	is Number	County Health Department Personnel	Office Phone Number Cell Phone Numbe
Sender Address		Address where	e the animal was found
		Street	City
			Zip Code:
Was the animal shot in the head? Was the animal frozen prior to shipmen?	D.10 D 10	Was the animal buried prior to shipm	nent? 🗆 Yes 🗆 No
Reason for Testing: Human Exposu		mal Exposure Other	
Type of Exposure: Bite Scrate			
Date of Exposure:		Exposure was Provoked	
Name of Owner (Animal being tested)	Street	City/Zip Code	Telephone Number
	HUMAN EXPOSU	RE (Complete the following)	
Name of Person(s) Exposed	Street	City/Zip Code Telephone N	
DOM	IESTIC ANIMAL E	XPOSURE (Complete the follow	ving)
Type of Animal Exposed			Name of Owner
Dog Cat Livestock (Specify)			
Street		City/Zip Code	Telephone Number
DO NOT WI	RITE BELOW THIS	LINE - FOR LABORATORY	USE ONLY
	ive □Negative ntisfactory for testing,	specimen decomposed or deterio	
		orain stem unavailable for testing	
EXCEPTION: Not tested. Brain			
LINOI lested. NO DE	an present in skuit.		

DHEC 1308 (Revised 06/17)

Personal information provided on this document is subject to public scrutiny or release.

Instruction for Completing Rabies Request Form

- 1. Check the appropriate box to identify the type of animal sent in for testing. If rodent or other is checked, specify the type of rodent (example: rat, mouse, etc) or type of other (example: opossum, horse, etc).
- 2. Check the appropriate box to identify the animal as wild, pet, or stray.
- 3. Enter the date of death.
- 4. Check box to indicate the animal's vaccination status. If inoculated against rabies, enter the vaccination date.
- 5. Enter sender number if not pre-printed on form.
- 6. Enter sender address if not pre-printed on form.
- 7. Enter Abris number used by the sender to identify the animal being tested for rabies.
- 8. Enter a contact person who will be responsible for receiving results.
- 9. Enter an office and home or cell phone number for the contact person.
- 10. Enter the address where the animal was found.
- 11. Check box to indicate if the animal was shot in the head, buried, or frozen priorto shipment.
- 12. Check the reason for testing and the type of exposure. Enter the date of exposure.
- 13. Check if the exposure was provoked or unprovoked.
- 14. Enter the name and address of the owner of the animal being tested. If the animal is stray or wild, leave blank.
- 15. If there was human exposure, give the name of the person(s) exposed, address, and phone number.
- 16. If there was pet exposure, check the type of pet or domestic animal exposed. Fill in the name of the owner of the animal exposed, the street address, city, zip code, and phone number.
- 17. Do not write in the "For Laboratory Use Only" box.
- 18. Send the top two copies to the form with the animal head. Retain the third copy for your records.

DHEC 1308 (Revised 10/16)

		01718	Line	SC DEPT. OF HEALTH LABORATORY SC DEPT. OF HEALTH LABORATORY SC DEPT. OF HEALTH AND ENVIRONMENTAL CONTROL 231 PARKLANE ROAD, COLUMBIA, SC 29223 803-986-0874		Use By 2026-01-31	
BIOHAZARD BIOHAZARD DU NU I AFFLY BLUUU IU BUTH SIDES	RUINS	101		BABY'S LAST NAME MOTHER'S LAST NAME MOTHER'S ADDRESS CITY	BABY'S FIRST NAME MOTHER'S FIRST NAME	DATE OF BIRTH DATE OF COLLECTION COLLECTOR ID / INITIALS SEX M Mala F Female RACE	TIME OF BIRTH . Mik TIME OF COLLECTION . Mik TIME 1. White 4. Asian 2. AF-Amer. 5. Anne. Ind
	SN SENDER COPY	STATE COUNTY ZIP CODE PA MEDICAL RECORD NO.	RENT(S) / GUARDIAN'S PHONE NO.	3. Hispanic 6. Other BIRTH WEIGHT IN GRAMS PRESENT WEIGHT IN GRAMS MULTIPLE BIRTHS YES NO IF MULTIPLE A. B. C. etc.			
	TON DO	ιpγ	DO NOT DETACH LAB COPY	STREET ADDRESS CITY, STATE PHONE NUMBER NBS TEST PANEL REQUESTED 1" NBS TEST REPEAT NBS TEST PHE	STREET ADDRESS CITY, STATE, ZIP		ACTOSE

LL ALL 5 CIRCLES COMPLETELY. DIRECTIONS ON REVERSE	SC DEPT OF HEALTH AND ENVIRONMMENTAL CONTROL B231 PARKLANE ROAD, COLUMBIA, SC 29223 CLIA#42DO658606 B03-696-0874 LAST NAME LAST NAME ID / INFORMATION DATE SPECIMEN COLINITY OF RESIDENCE COLINITY OF RESIDENCE COLINITY OF RESIDENCE	INITIAL INITIAL INITIAL INITIAL INITIAL INITIAL INITIAL SEX COLL (:) MIL TIME OF COLLECTION	
MPLETELY	COUNTY OF RESIDENCE COLLECTED MONTH DAY YEAR	PATIENT INFORMATION TRANSFUSION WITHIN 120 DAYS	TEST REQUESTED
RCLES CO	SENDER'S NAME/ADDRESS	IF CHILD, WRITE MOTHER'S NAME	
ALL S CI	NOTES 1) FORM DHEC-1327 SHOULD BE USED FOR PATIENTS LESS THAN ONE YEAR OF AGE 2) RESULTS OF THIS TEST SHOULD NOT BE USED TO DETERMINE PATERNITY AND DOES NOT DETECT ALL HEMOGLOBINS AND THALASSEMIA.	Pe	kinElmer 226 Ahlstrom DHEC-1339 (REV. 10/2019)

COUNTY CODES

Abbeville	01	Greenwood	24
Aiken	02	Hampton	25
Allendale	03	Horry	26
Anderson	04	Jasper	27
Bamberg	05	Kershaw	28
Barnwell	06	Lancaster	29
Beaufort	07	Laurens	30
Berkeley	08	Lee	31
Calhoun	09	Lexington	32
Charleston	10	Marion	33
Cherokee	11	Marlboro	34
Chester	12	McCormick	35
Chesterfield	13	Newberry	36
Clarendon	14	Oconee	37
Colleton	15	Orangeburg	38
Darlington	16	Pickens	39
Dillon	17	Richland	40
Dorchester	18	Saluda	41
Edgefield	19	Spartanburg	42
Fairfield	20	Sumter	43
Florence	21	Union	44
Georgetown	22	Williamsburg	45
Greenville	23	York	46

SENDER NUMBERS

Private Physician	Usually consists of the SC Medical License number preceded by the letter M.
Group Practice	A number preceded by the letter G will be assigned to group practices at their request. Use of the group number will ensure that a single bill will be sent for tests submitted by all physicians in the practice. If you desire to be billed in this manner, please contact (803) 896-0800 for assignment of a group number. If each physician wishes to be billed separately, use the appropriate assigned sender number.
Hospital	Consists of the hospital license number preceded by the letter H. If the test result is to be mailed directly to the patient's physician, use the physician's name, address and sender number in the appropriate spaces on the form and write the hospital sender number in the billing number space.
Private Laboratory	A number assigned by the Public Health Laboratory. If not known, contact the lab at (803) 896-0800 for assignment.
DHEC County Health Depts.	Consists of the assigned county code number preceded by a C.

BILLING NUMBERS

A billing number is only necessary if the test is to be billed to someone other than the sender.

PROGRAM NUMBERS

Used only when billing to a DHEC Program

- 0001 Immunization-VFC Operations
- 0002 Children with Special Health Care Needs (CSHCN)
- 0004 Family Planning
- 0005 Sickle Cell Program
- 0006 Maternal and Child Health (MCH)
- 0007 Cancer Control
- 0009 Tuberculosis Services Outpatient
- 0011 Sexually Transmitted Diseases (STD)
- 0026 Adult Health
- 0027 Birth Defects (Metabolic Screening Program)
- 0031 Expanded & Integrated Human HIV Testing- Non-Clinical
- 0035 Expanded and Integrated HIV Testing for Populations-Clinical
- 0043 Environmental Health
- 0053 Newborn Metabolic Screening & Follow-Up
- 0055 Infant and Child Health Screening & Follow-Up
- 0059 WCS (Women & Children's Services)
- 0063 Employee Health Services
- 0070 Epidemiology Disease Control
- 0072 HIV-AIDS Alcohol & Drug Abuse Project
- 0095 WIC
- 0111 HIV/AIDS
- 0202 Immunization Program
- 0301 BT CDC Public Health Emergency Preparedness

SPECIMEN COLLECTION PROCEDURES

Specimen Collection: Venipuncture Using the Vacuum System

Precaution: Wear non-latex gloves and liquid impervious laboratory coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

- 1. Vacuum tube system
- 2. Vacuum needle, 1 inch or 1 ¹/₂ inch; 18, 20, 21, 22, or 23 gauge
- 3. Disposable vacuum needle holder
- 4. Disposable tourniquet
- 5. 70% isopropyl alcohol or benzylkonium chloride pads
- 6. Sterile gauze pads (NO COTTON BALLS!)
- 7. Band-aids (optional)
- 8. Sharps disposal container (with stand or wall mounted)
- 9. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if you wear contacts)
- 3. Liquid resistant/impervious lab coat or apron (required during collection)
- 4. Additional protection as recommended by OSHA and/or Safety Data Sheet (SDS)

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a venipuncture without direct supervision.

- 1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card.
 - a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 70% alcohol content.
 - b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.
- 2. Position the patient for taking blood from the antecubital vein, or the median cubital vein, or the cephalic vein.
 - a. DIS can ONLY use one of these sites to collect venipuncture.
 - b. MDs, APRNs, RNs, MTs, MLTs can use other sites on the arm or hand, if trained using standard Training Checklist and passed Competency Evaluation annually.
- 3. Apply disposable tourniquet to the arm just above the elbow and instruct the patient to make a fist; it is NOT necessary for the patient to "pump" their fist.
 - a. Always palpate the vein with the disposable tourniquet BEFORE making a decision to puncture the vein.
 - b. DO NOT leave the tourniquet on for > 2 minutes during a venipuncture!
- 4. Select the best vein and clean the skin over the puncture site with 70% alcohol or benzylkonium chloride in

ONE DIRECTION!

- a. **DO NOT** wipe back and forth with the 70 % alcohol/benzylkonium chloride.
- b. Allow to dry without blowing on the site or fanning the site.
- c. Once the site is dry, **DO NOT** palpate the vein with gloved finger; these are not sterile gloves.
- 5. Use sterile vacuum needle and attach (screwed onto) to a disposable adaptor.
 - a. The vacuum collection tube may be inserted into the adaptor without danger of breaking the vacuum.
 - b. **DO NOT** pierce the vacuum on the tube with the adapter needle.
- 6. "Fix" the vein selected for the venipuncture.
 - a. Left thumb about an inch below where the needle is to enter.
 - b. Press down on the arm and pull the skin toward the hand.
 - c. The needle is to be in line with the vein.
 - d. The needle is to be BEVEL SIDE UP!
 - e. The needle is to be at approximately a 15-degree angle with the arm.
 - f. You can adjust the angle depending on the depth of the vein.
- 7. Puncture the skin with a clean, smooth motion. BEVEL SIDE UP!
 - a. **DO NOT** hesitate; this hurts.
 - b. As the needle enters the vein, a little "give" will be felt.
 - c. When inside the vein, grip the tube holder firmly and keep the holder steady.
 - d. Press the vacuum tube onto the needle portion inside the holder.
- 8. While the needle is inside the vein, collect the required tubes of blood.
 - a. Note: Collect blood in plain (red stopper) tubes before collecting blood in tubes with additives (e.g., EDTA)
 - b. Note: DIS are ONLY allowed to collect a single tube per venipuncture.
 - c. Mix tubes with additives by gently inverting 5 10 times to prevent clotting.
 - d. **DO NOT** shake the tube(s)!
 - e. Allow the red top tubes to stand in a test tube rack, upright, for at least 30 minutes to allow clotting before centrifugation.
 - f. Note: some patients may take longer to clot, so allow extra time if the patient is on maintenance doses of Coumadin and/or other platelet aggregate inhibitors.
- Release tourniquet, withdraw needle from vein and apply pressure on venipuncture site with dry gauze.
 a. **DO NOT** cover the injection site with an alcohol sponge while withdrawing the needle.
 - b. DO NOT apply pressure on the venipuncture site with gauze if the needle is still in the arm!
 - 0 Have patient apply pressure on the vening state for 2 3 minutes to prevent leakage of blood under t
- 10. Have patient apply pressure on the venipuncture site for 2 3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site no longer bleeds, a bandage may be applied if desired.
 - a. Ask the patient to hold their arm straight up and lock their elbow.
 - b. If the patient cannot do this, hold the arm straight up for them.
- 11. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Note: if you use a computer label, just add time and initials of person collecting specimen.

- 12. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335-OE.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Test required
 - e. Type of specimen
 - f. Ordering physician, APRN, RN, DIS
 - g. Test(s) requested
 - h. Sender Address or Sender code number
 - i. Any specimen instructions or other important information
 - j. Note: if you use a computer label, just add time and initials of person collecting specimen.
 - k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
 - 1. You will send the original top copy of the DHEC 1332/1335-OE with the specimen(s)
 - m. Retain the third copy for your files in the County Health laboratory.
- 13. Properly dispose of needles (in biohazard puncture proof sharps container) and other contaminated materials used during venipuncture.
 - a. Place all blood-soaked material in the contaminated waste bag (Biohazard).
 - b. Place all sharps in the sharps container and DO NOT fill above 2/3!
 - c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!
- 14. Remove PPEs in this order:
 - a. Remove contaminated gloves.
 - b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
 - c. Remove any eye protection.
 - d. Remove liquid impervious/resistant lab coat or apron.
 - e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
- 15. BEFORE allowing the patient/client to leave, take the gauze off of the venipuncture site to ensure it has stopped bleeding.
 - a. DO NOT wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
 - b. DO NOT allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!
- 16. NOTE: DIS staff can ONLY draw one tube; no multi-draws or multiple tubes collected from the same venipuncture collection site.
- 17. No DIS staff can be trained and/or use a butterfly to collect a venipuncture.

Specimen Preparation:

- 1. Blood collected in a plain red stopper tube or in a serum separator tube (SST): allow the tube of blood to remain undisturbed in an upright position at room temperature for 20-30 minutes.
 - a. When the specimen has clotted, DO NOT allow the serum to sit on the clot, whether collected in a red tube or SST tube, without separating through centrifugation; then store according to instructions in the Reference Laboratory manual for specimen collection and transport.
 - b. Note: check manufacturer's package insert for maximum time blood can sit on clot BEFORE centrifugation, if using an SST (serum separator tube).

- 2. After a clot has formed, gently loosen the clot at the top; "rim" with a sterile applicator stick, if necessary.
- 3. Centrifuge tubes for 10-15 minutes.
 - a. Since all centrifuges are calibrated by Instrumentation Department (Facilities Management Division, Public Health Laboratory), the time for most centrifugation needs will be on the instrument.
 - b. CHECK OUT THE CALIBRATED TIME/SPEED ON YOUR CENTRIFUGE!
- 4. Remove the serum carefully with a sterile transfer pipette, and transfer to a clean sterile rubber- stoppered tube or to a screw-top, plastic vial/tube. Avoid transferring any red cells.
- 5. Label tube or plastic vial running up the length of the tube.
 - a. **Do NOT** wrap the label around or "flag" the label by pressing ends together and extending from the tube.
 - b. This includes ALL vacuum tubes for chemistry, hematology and serology; red top, SST, or purple (EDTA) top tubes would be the common ones.
- 6. Store tubes of labeled serum in a refrigerator until the specimens are ready to ship to the clinic laboratory or the Public Health Laboratory.

Special Procedural Notes:

- 1. If sending whole blood in a vacuum tube, omit steps 2 and 4 (see page III-6).
- 2. If using serum separator tubes (gel in the bottom of the tube, SST) omit steps 2 and 4 above. Be sure the gel forms a distinct barrier between serum and clot.
- 3. During the summer months, pack all SST specimens with a cold pack since the gel can possibly breakdown at temperatures experienced during the summer months. The breakdown of the gel allows the red blood cells to "leak" into the serum contaminating the specimen and possibly rendering the specimen unacceptable for testing.
- 4. Never use a gauge needle size smaller than a 23: this can cause hemolysis!
- 6. Always allow the blood to flow into a vacuum tube without adding additional pressure.
- 7. **DO NOT** take disposable tourniquet off until you have collected ALL of the tubes and the tubes are filled: when you take the tourniquet off once you are inside you run the risk of slow blood flow and/or short draws and/or insufficient blood volume.
- 8. For special considerations using a butterfly for a venipuncture, see the next procedure.

Specimen Collection: Venipuncture Using a Butterfly System

Precaution: Wear non-latex gloves and liquid impervious laboratory coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

- 1. Vacuum tube system
- 2. Butterfly needle: 21g, 22g, or 23g (NO SMALLER THAN 23G!)
- 3. Disposable vacuum needle holder
- 4. Disposable tourniquet
- 5. 70% isopropyl alcohol or benzylkonium chloride pads
- 6. Sterile gauze pads (NO COTTON BALLS!)
- 7. Band-aids (optional)
- 8. Sharps disposal container (with stand or wall mounted)
- 9. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if you wear contacts)
- 3. Liquid resistant/impervious lab coat or apron (required during collection)
- 4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a venipuncture without direct supervision. No DIS staff can be trained using this method.

Note: the use of a butterfly is to be used ONLY in special circumstances: elderly patients with non- patent veins; young children (less than 4 years old) or babies; patients with non-patent veins and the hand is the site of choice.

- 1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card.
 - a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
 - b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.
- 2. Position the patient for taking blood from the antecubital vein, or the median cubital vein, or the cephalic vein: these are all on the arm.
 - a. DIS can ONLY use one of these sites to collect venipuncture.
 - b. MDs, APRNs, RNs, MTs, MLTs can use other sites on the arm or hand, if trained using standard Training Checklist and passed Competency Evaluation annually.
 - 1) Veins from the hand that can be used are: basilic veins (runs along the 5th digit, little finger).
 - 2) Veins from the hand that can be used are: metacarpal veins (runs along the 2nd or 4th digit, index/pointer finger and ring finger).
 - 3) Veins from the hand that can be used are: cephalic vein (runs along the side of wrist area or just above the thumb).

- 4) NO OTHER sites are to be used with the butterfly other than those listed in the venipuncture using the vacuum and the butterfly; no femoral, no temporal, no jugular, etc.
- 3. Apply disposable tourniquet to the arm just above the elbow, or on the forearm if using the hand, and instruct the patient to make a fist; it is NOT necessary for the patient to "pump" their fist.
 - a. Always palpate the vein with the disposable tourniquet BEFORE making a decision to puncture the vein.
 - b. DO NOT leave the tourniquet on for >2 minutes during a venipuncture!
- 4. Select the best vein and cleanse the skin over the puncture site with 70% alcohol or benzylkonium chloride in **ONE DIRECTION!**
 - a. **DO NOT** wipe back and forth with the 70 % alcohol/benzylkonium chloride.
 - b. Allow to dry without blowing on the site or fanning the site.
 - c. Once the site is dry, **DO NOT** palpate the vein with gloved finger; these are not sterile gloves.
- 5. Use sterile butterfly needle and attach (screwed onto) to a disposable adaptor.
 - a. If a butterfly is used with a syringe (5cc, 7cc or 10cc), collect the specimen following the same steps, except you will fill the vacuum tubes with the blood from the syringe.
 - b. **DO NOT** put blood into the vacuum tubes by pressing the needle through the rubber septum; take the rubber septum off and gently add blood to the tube.
 - c. The vacuum collection tube may be inserted into the adaptor without danger of breaking the vacuum.
 - d. **DO NOT** pierce the vacuum on the tube with the adapter needle.
- 6. "Fix" the vein selected for the venipuncture.
 - a. Left thumb about an inch below where the needle is to enter.
 - b. Press down on the arm and pull the skin toward the hand.
 - c. The needle is to be in line with the vein.
 - d. The needle is to be BEVEL SIDE UP!
 - e. The needle is to be at approximately a 15 degree angle with the arm.
 - f. You can adjust the angle depending on the depth of the vein.
- 7. Puncture the skin with a clean, smooth motion. BEVEL SIDE UP!
 - a. **DO NOT** hesitate; this hurts.
 - b. As the needle enters the vein, a little "give" will be felt.
 - c. When inside the vein, grip the tube holder firmly and keep the holder steady.
 - d. Press the vacuum tube onto the needle portion inside the holder.
- 8. While the needle is inside the vein, collect the required tubes of blood.
 - a. Note: Collect blood in plain (red stopper) tubes before collecting blood in tubes with additives (e.g. EDTA).
 - b. Note: DIS is ONLY allowed to collect a single tube per venipuncture.
 - c. Mix tubes with additives by gently inverting 5-10 times to prevent clotting.
 - d. **DO NOT** shake the tube(s)!
 - e. Allow the red top tubes to stand in a test tube rack, upright, for at least 30 minutes to allow clotting before centrifugation.
 - f. Note: some patients may take longer to clot, so allow extra time if patient is on maintenance doses of Coumadin and/or other platelet aggregate inhibitors.

- 9. Release tourniquet, withdraw needle from vein and apply pressure on venipuncture site with dry gauze.
 - a. **DO NOT** cover the injection site with an alcohol sponge while withdrawing needle.
 - b. **DO NOT** apply pressure on the venipuncture site with gauze if the needle is still in the arm!
- 10. Have patient apply pressure on the venipuncture site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site no longer bleeds, a bandage may be applied if desired.
 - a. Ask the patient to hold their arm straight up and lock their elbow.
 - b. If the patient cannot do this, hold the arm straight up for them.
- 11. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Note: if you use a computer label, just add time and initials of person collecting specimen.
- 12. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335-OE.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Test required
 - e. Type of specimen
 - f. Ordering physician, APRN, RN, DIS
 - g. Test(s) requested
 - h. Sender Address or Sender code number
 - i. Any specimen instructions or other important information
 - j. Note: if you use a computer label, just add time and initials of person collecting specimen.
 - k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
 - 1. You will send the original top copy of the DHEC 1332/1335-OE with the specimen(s)
 - m. Retain the third copy for your files in the County Health laboratory.
- 13. Properly dispose of needles (in biohazard puncture proof sharps container) and other contaminated materials used during venipuncture.
 - a. Place all blood-soaked material in the contaminated waste bag (Biohazard).
 - b. Place all sharps in the sharps container and DO NOT fill above 2/3!
 - c. **DO NOT** place any non-contaminated waste in the sharps container or Biohazard waste!
- 14. Remove PPEs in this order:
 - a. Remove contaminated gloves.
 - b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
 - c. Remove any eye protection.
 - d. Remove liquid impervious/resistant lab coat or apron.
 - e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
- 15. BEFORE allowing the patient/client to leave, take the gauze off the venipuncture site to ensure it has stopped bleeding.
 - a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
 - b. **DO NOT** allow patient to get up from the chair, table, etc. without being physically at the side or in

front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

Specimen Preparation:

- 1. Blood collected in a plain red stopper tube or in a serum separator tube (SST): allow the tube of blood to remain undisturbed in an upright position at room temperature for 20 30 minutes.
 - a. When the specimen has clotted, DO NOT allow the serum to sit on the clot, whether collected in a red tube or SST tube, without separating through centrifugation; then store according to instructions in the Reference Laboratory manual for specimen collection and transport.
 - b. Note: check manufacturer's package insert for maximum time blood can sit on clot BEFORE centrifugation, if using an SST (serum separator tube).
- 2. After a clot has formed, gently loosen the clot at the top; "rim" with a sterile applicator stick, if necessary.
- 3. Centrifuge tubes for 10 15 minutes.
 - a. Since all centrifuges are calibrated by the Instrumentation Department (Facilities Management Division, Public Health Laboratory), the time for most centrifugation needs will be on the instrument.
 - b. CHECK OUT THE CALIBRATED TIME/SPEED ON YOUR CENTRIFUGE!
- 4. Remove the serum carefully with a sterile transfer pipette, and transfer to a clean sterile rubber- stoppered tube or to a screw-top, plastic vial/tube. Avoid transferring any red cells.
- 6. Label tube or plastic vial running up the length of the tube.
 - a. **Do NOT** wrap the label around or "flag" the label by pressing ends together and extending from the tube.
 - b. This includes ALL vacuum tubes for chemistry, hematology and serology; red top, SST, or purple (EDTA) top tubes would be the common ones.
- 7. Store tubes of labeled serum in a refrigerator until the specimens are ready to ship to the clinic laboratory or the Public Health Laboratory.

Special Procedural Notes:

- 1. If sending whole blood in a vacuum tube, omit steps 2 and 4 (see page III-6).
- 2. If using serum separator tubes (gel in the bottom of the tube, SST) omit steps 2 and 4 above. Be sure the gel forms a distinct barrier between serum and clot.
- 3. During the summer months, pack all SST specimens with a cold pack since the gel can possibly breakdown at temperatures experienced during the summer months. The breakdown of the gel allows the red blood cells to "leak" into the serum contaminating the specimen and possibly rendering the specimen unacceptable for testing.
- 4. Always refer to the Public Health Laboratory Services Guide for complete instructions for specimen collection, specimen preparation, specimen storage and specimen transport for the specific laboratory test(s). Note: use current edition only.

- 5. Never use a gauge needle size smaller than a 23: this can cause hemolysis!
- 6. Always allow the blood to flow into a vacuum tube without adding additional pressure.
- 7. DO NOT take disposable tourniquet off until you have collected ALL of the tubes and the tubes are filled: when you take the tourniquet off once you are inside you run the risk of slow blood flow and/or short draws and/or insufficient blood volume.

Specimen Collection: Fingerstick Procedure for Patients Greater Than 1 Year Old

Hemoglobin or General Laboratory Procedures

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

- 1. Retractable safety lancets: see Clinical Formulary on the intranet for approved lancets for adults and pediatrics
- 2. 70% isopropyl alcohol pads or benzylkonium chloride pads
- 3. Sterile gauze pads (NO COTTON BALLS!)
- 4. Band-aids (optional)
- 5. Sharps disposal container (with stand or wall mounted)
- 6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommended if wear contact lens)
- 3. Liquid resistant lab coat or apron (required during collection)
- 4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a fingerstick without direct supervision.

- 1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
 - a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
 - b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.
- 2. Have all supplies within easy reach and all materials ready to use before performing the fingerstick procedure.
- 3. Place the sharps disposal container and waste container so you DO NOT have to cross over the patient or yourself when discarding contaminated items.
- 4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on disposable gloves.
- 5. Instruct the patient to rest his/her arm downward position for about 30 seconds to allow blood flow to the fingertips. If the patient's hand is cold, warm the hand:
 - a. Gently massage the finger a few times from the base to the tip of the finger.
 - b. Stroke the arm with gentle downward motion from the forearm to the hand.
 - c. Ask the patient to briskly rub both hands together.
 - d. Use a warm (not more than 105 degrees F.), moist towel on the hand for a couple of minutes.
 - e. Ask the patient to wash his/her hands with warm water.

- 6. Select the middle or ring finger for puncture on the hand used least often.
- 7. **Do NOT** choose a puncture site on a fingertip that is callused, purple, scarred, swollen, or injured.
- 8. Use the less painful, fleshy area of the fingertip, just off center to the finger pad, slightly to the side.
- 9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
 - a. Wipe in one direction ONLY!
 - b. Allow the alcohol or benzylkonium chloride to evaporate.
 - c. Do NOT blow on the finger or fan the area.
- 10. **Do NOT** saturate the site with alcohol. Note: Discard the used alcohol pad and wrapper in the regular trash can.
- 11. Allow the site to air dry completely.
- 12. Firmly hold the patient's finger, palm side up, between your thumb and index finger.
- 13. Puncture the site and dispose of the used lancet in the sharps container.a. Note: Puncture the finger with the lancet PERPENDICULAR to the ridge swirls on the finger.b. Place the lancet FIRMLY on the finger pad site BEFORE triggering the lancet.
- 14. Wipe away the first 2-3 drops of blood with the sterile gauze.
- 15. Apply gentle pressure every few seconds, about $\frac{1}{2}$ inches from the puncture site.
- 16. Collect specimen in a microtube (bullet), or for dried blood spots, or a hemoglobin cuvette.
- 17. Have patient apply pressure on the site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired.
 - a. Ask the patient/or parent to hold the gauze on the finger.
 - b. If the patient cannot do this, hold the finger for them.
- 18. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen goes on the requisition/lab form.
 - d. Note: if you use a HemoCue microcuvette, the frosted edge needs to have patient's last name at least and the date.
- 19. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335-OE.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Test required
 - e. Type of specimen
 - f. Ordering physician, APRN, RN, DIS
 - g. Test(s) requested

- h. Sender Address or Sender code number
- i. Any specimen instructions or other important information
- j. Note: if you use a computer label, just add time and initials of person collecting specimen.
- k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
- 1. You will send the original top copy of the DHEC 1332/1335-OE with the specimen(s)
- m. Retain the third copy for your files in the County Health laboratory.
- 20. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during fingerstick.
 - a. Place all blood soaked material in the contaminated waste bag (Biohazard).
 - b. Place all sharps in the sharps container and DO NOT fill above 2/3!
 - c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!
- 21. Remove PPEs in this order:
 - a. Remove contaminated gloves.
 - b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
 - c. Remove any eye protection.
 - d. Remove liquid impervious/resistant lab coat or apron.
 - e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
- 22. BEFORE allowing the patient/client to leave, take the gauze off of the fingerstick site to ensure it has stopped bleeding.
 - a. DO NOT wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
 - b. DO NOT allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!

Specimen Collection: Fingerstick for Patients Greater Than 1 Year Old

Dried Blood Spots Collection

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

The filter paper to be used in the collection of dried blood spots is attached to the DHEC form 1339 for HEMOGLOBIN ELECTROPHORESIS or the DHEC form 1327 for PKU MONITORING. Envelopes for mailing specimen are also available.

Sufficient blood MUST be obtained from the fingerstick puncture to fill each preprinted, dashed circle by making a single application of blood to the filter paper. The filter paper should touch only the drop of blood and should not be pressed against the skin around the puncture. Be sure that the filter paper is saturated through with blood. DO NOT layer blood drops! This leads to inaccurate results. It is very important to fill each circle with <u>ONE</u> <u>LARGE</u> blood drop.

Supplies:

- 1. Retractable safety lancets for infant or pediatric: see Clinical Formulary listings on the intranet for approved lancets
- 2. 70% isopropyl alcohol or benzylkonium chloride pads
- 3. Sterile gauze pads (NO COTTON BALLS!)
- 4. Band-aids (optional)
- 5. Sharps disposal container (with stand or wall mounted)
- 6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommend if wear contact lens)
- 3. Liquid resistant lab coat or apron (required during collection)
- 4. Additional protection as recommended by OSHA and/or MSDS

Specimen Collection:

- 1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
 - a. BEFORE putting on ANY PPE, wash hands with soap and water or use hand sanitizer with at least 60% alcohol content.
 - b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.
- 2. Have all supplies within easy reach and all materials ready to use before performing the fingerstick procedure.
- 3. Place the sharps disposal container and waste container so you **DO NOT** have to cross over the patient or yourself when discarding contaminated items.
- 4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on disposable gloves.

- 5. Instruct the patient to rest his/her arm downward position for about 30 seconds to allow blood flow to the fingertips. If the patient's hand is cold, warm the hand:
 - a. Gently massage the finger a few times from the base to the tip of the finger.
 - b. Stroke the arm with gentle downward motion from the forearm to the hand.
 - c. Ask the patient to briskly rub both hands together.
 - d. Use a warm (not more than 105 °F.), moist towel on the hand for a couple of minutes.
 - e. Ask the patient to wash their hands with warm water.
- 6. Select the middle or ring finger for puncture on the hand used least often.
- 7. **Do NOT** choose a puncture site on a fingertip that is callused, purple, scarred, swollen, or injured.
- 8. Use the less painful, fleshy area of the fingertip, just off center to the finger pad, slightly to the side.
- 9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
 - a. Wipe in one direction **ONLY**!
 - b. Allow the alcohol or benzylkonium chloride to evaporate.
 - c. **Do NOT** blow on the finger or fan the area.
- 10. **Do NOT** saturate the site with alcohol. Note: Discard the used alcohol pad and wrapper in the regular trash can.
- 11. Allow the site to air dry completely.
- 12. Firmly hold the patient's finger, palm side up, between your thumb and index finger.
- 13. Puncture the site and dispose of the used lancet in the sharps container.
 - a. Note: Puncture the finger/heel with the lancet PERPENDICULAR to the ridge swirls on the finger.
 - b. Place the lancet FIRMLY on the finger pad/heel site BEFORE triggering the lancet.
- 14. Wipe away the first drop of blood with the sterile gauze.
- 15. Apply gentle pressure every few seconds, about ¹/₂ inches from the puncture site.
- 16. Collect specimen onto filter paper for dried blood spots.
- 17. Have patient apply pressure on the site for 2-3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired.
 - a. Ask the patient/or parent to hold the gauze on the finger.
 - b. If the patient cannot do this, hold the finger for them.
- 18. Complete ALL information on the 1327 or 1339 form:
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Ordering physician, APRN, RN, DIS
 - e. Complete submitter and/or physician information
 - f. You will send the original top copy of the DHEC 1327/1339 with the specimen(s).
 - g. Retain the middle copy for your files.

- 19. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during fingerstick.
 - a. Place all blood-soaked material in the contaminated waste bag (Biohazard).
 - b. Place all sharps in the sharps container and **DO NOT** fill above 2/3!
 - c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!
- 20. Remove PPEs in this order:
 - a. Remove contaminated gloves.
 - b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
 - c. Remove any eye protection.
 - d. Remove liquid impervious/resistant lab coat or apron
 - e. Wash hands with soap and water or with hand sanitizer with > 60% alcohol.
- 21. BEFORE allowing the patient/client to leave, take the gauze off of the fingerstick site to ensure it has stopped bleeding.
 - a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
 - b. **DO NOT** allow patient to get up from the chair, table, etc. without being physically at the side or in front of the patient/client: THIS IS A FALL PREVENTION MEASURE!
- 22. Special Procedural Notes for Dried Blood Spots:
 - a. When properly filled, the blood spot will be the same size on both sides of the filter paper.
 - b. **DO NOT** send the specimen if the circles are not completely filled collect a second specimen.
 - c. All the circles are needed. If tests have to be repeated or additional tests need to be run, all 5 circles are required.

Troubleshooting:

- 1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results.
- 2. Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult.
- 3. **DO NOT** lance on previous puncture site.
- 4. Use of a capillary tube is not recommended since application of blood with a capillary tube results in scratching and/or abrading the surface of the filter paper which adversely affects test results.
- 5. Avoid touching area within filter paper circles before blood is applied.
- 6. **DO NOT** place filter paper in the envelope until thoroughly dry.
- 7. INSUFFICIENT DRYING ADVERSELY AFFECTS TEST RESULTS!

Specimen Collection: Heel-stick Procedure for Patients Less Than 1 Year Old

Hemoglobin or General Laboratory Testing or Newborn Screening

Precaution: Wear gloves and liquid resistant lab coat or apron while collecting and preparing blood for shipment.

Supplies: see Clinical Formulary on the intranet for approved supplies

- 1. Retractable safety lancets: TenderfootTM or lancet giving 1.0 mm 2.0 mm depth
- 2. 70% isopropyl alcohol or benzylkonium chloride pads
- 3. Sterile gauze pads (**NO COTTON BALLS**!)
- 4. Band-aids (optional)
- 5. Sharps disposal container (with stand or wall mounted)
- 6. Biohazard waste container

Personal Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection; strongly recommend if wear contact lens)
- 3. Liquid resistant lab coat or apron (required during collection)
- 4. Additional protection as recommended by OSHA and/or MSDS Personal

Protective Equipment (PPE) Requirements:

- 1. Disposable gloves (required during collection)
- 2. Safety glasses (required if there is any chance of eye/mouth contamination during collection)
- 3. Liquid resistant lab coat or apron (required during collection)
- 4. Closed-toe shoes MUST be worn when collecting ANY blood specimens
- 5. Additional protection as recommended by OSHA and/or safety data sheet (SDS)

Specimen Collection: You MUST have completed a DHEC Workshop and be rated proficient and competent BEFORE you can collect a fingerstick without direct supervision.

- 1. While putting on the appropriate PPE, explain the procedure to the patient and ask the patient to identify themselves or check a picture identification card; if a child, ask parent and/or guardian to state child's name.
 - a. BEFORE putting on ANY PPE, wash hands with soap and water or use a hand sanitizer with at least 60% alcohol content.
 - b. Order for putting on PPE: put eye protection on first (optional), then put on liquid resistant/impervious lab coat/apron, and then put on non-latex gloves.
- 2. Have all supplies within easy reach and all materials ready to use before performing the heel stick procedure.
- 3. Place the sharps disposal container and waste container so you **DO NOT** have to cross over the patient or yourself when discarding contaminated items.
- 4. Wash hands with soap and water or use a hand sanitizer with at least 60% alcohol; put on disposable gloves.

- 5. Instruct the parent/guardian to rest the leg of the infant in a downward position for about 30 seconds to allow blood flow to the foot. If the patient's foot is cold, warm the foot:
 - 1. Gently massage the foot/heel a few times from the base to the tip of the heel.
 - 2. Stroke the heel with gentle downward motion from the ankle to the toes.
 - 3. Ask the patient to briskly rub both hands together.
 - 4. Use a warm (not more than 105 °F.), moist towel on the heel for a couple of minutes.
 - 5. Ask the parent/guardian to wash child's foot/heel with warm water.
- 6. Select the heel for puncture.

Note: Use **ONLY** the lateral or medial sides of the heel.

Note: **DO NOT** use the plantar region of the foot or great toe.

- 7. **Do NOT** choose a puncture site on a heel that is callused, purple, scarred, swollen, or injured.
- 8. Get all microcuvettes ready and LABEL NOW!!! Use a #2 pencil or black Sharpie.
- 9. Clean the puncture site with an alcohol pad or benzylkonium chloride pad.
 - a. Wipe in one direction ONLY!
 - b. Allow the alcohol or benzylkonium chloride to evaporate.
 - c. Do NOT blow on the finger or fan the area.
- 10. Do NOT saturate the site with alcohol.
 - a. Remove excess alcohol with a clean gauze pad.
 - b. Discard the used alcohol pad and wrapper in the regular trash can.
- 11. Allow the site to air dry completely.
- 12. Firmly hold the patient's heel between your thumb and index finger.
- 13. Puncture the site and dispose of the used lancet in the sharps container.
 - a. Note: Puncture the heel with the lancet PERPENDICULAR to the ridge swirls on the heel.
 - b. Place the lancet FIRMLY on the heel site BEFORE triggering the lancet.
- 14. Wipe away the first 2 3 drops of blood with the sterile gauze.
- 15. Apply gentle pressure every few seconds, about ¹/₂ inches from the puncture site.
- 16. Collect specimen in a microtube (bullet), or for dried blood spots, or a hemoglobin cuvette. LABEL NOW!!
- 17. Have patient apply pressure on the site for 2 3 minutes to prevent leakage of blood under the skin and formation of a hematoma. When site is no longer bleeding, a bandage may be applied if desired; elevate the leg higher than the heart.
 - a. Ask the parent to hold the gauze on the puncture site.
 - b. If the parent cannot do this, hold the heel elevated above the heart.
- 18. Label specimen tube (s) with proper patient identification information; if not already done when getting supplies together.
 - a. Name of patient/client (first name and last name).

- b. MCI number or other unique identification number.
- c. Date collected, time collected and initials of person who collected specimen goes on the requisition/lab form.
- d. Note: if you use a HemoCue microcuvette, the frosted edge needs to have patient's last name at least and the date.
- 19. Complete ALL information on the test request/lab requisition form(s): DHEC 1332/1335-OE.
 - a. Name of patient/client (first name and last name).
 - b. MCI number or other unique identification number.
 - c. Date collected, time collected and initials of person who collected specimen.
 - d. Test required
 - e. Type of specimen
 - f. Ordering physician, APRN, RN, DIS
 - g. Test(s) requested
 - h. Sender Address or Sender code number
 - i. Any specimen instructions or other important information
 - j. Note: if you use a computer label, just add time and initials of person collecting specimen.
 - k. Note: if you use a computer label, be sure to place the computer label with all demographic information on copy 1, copy 2 and copy 3.
 - 1. You will send the original top copy of the DHEC 1332/1335-OE with the specimen(s).
 - m. Retain the third copy for your files in the County Health laboratory.
- 20. Properly dispose of lancets (in biohazard puncture proof sharps container) and other contaminated materials used during heelstick.
 - a. Place all blood-soaked material in the contaminated waste bag (Biohazard).
 - b. Place all sharps in the sharps container and **DO NOT** fill above 2/3!
 - c. DO NOT place any non-contaminated waste in the sharps container or Biohazard waste!
- 21. Remove PPEs in this order:
 - a. Remove contaminated gloves.
 - b. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
 - c. Remove any eye protection.
 - d. Remove liquid impervious/resistant lab coat or apron.
 - e. Wash hands with soap and water or with hand sanitizer with >60% alcohol.
- 22. BEFORE allowing the patient/client to leave, take the gauze off of the puncture site to ensure it has stopped bleeding.
 - a. **DO NOT** wipe the area with gauze since this will initiate bleeding again (subcutaneous) and may cause a hematoma (bruise).
 - b. **DO NOT** allow parent/patient to get up from the chair, table, etc. without being physically at the side or in front of the parent/patient: THIS IS A FALL PREVENTION MEASURE!

Special Procedural Notes for Dried Blood Spots:

- 1. When properly filled, the blood spot will be the same size on both sides of the filter paper.
- 2. **DO NOT** send the specimen if the circles are NOT completely filled—collect a second specimen.

3. All the circles are needed. If tests have to be repeated or additional tests need to be run, all 5 circles are required.

Troubleshooting:

- 1. Failure to wipe off alcohol residue may dilute the specimen and adversely affect test results.
- 2. Puncturing the heel on posterior curvature will permit blood to flow away from puncture, making proper spotting difficult.
- 3. **DO NOT** lance on previous puncture site.
- 4. Use of a capillary tube is not recommended since application of blood with a capillary tube results in scratching and/or abrading the surface of the filter paper which adversely affects test results.
- 5. Avoid touching area within filter paper circles before blood is applied.
- 6. **DO NOT** place filter paper in the envelope until thoroughly dry.
- 7. INSUFFICIENT DRYING ADVERSELY AFFECTS TEST RESULTS!

QuantiFERON-TB Gold Plus (QFT-Plus) Collection Procedure

Principle:

To properly collect a blood specimen for QuantiFeron-TB Gold Plus.

Supplies:

- 1. 4 QFT tubes
- 2. DHEC form 1335-OE
- 3. Designated QFT shipper

Collection Procedure:

Precaution: Wear gloves when collecting blood specimens

- 1. For each patient, collect 1mL of blood by venipuncture directly into each of the QFT-Plus blood collection tubes (4 tubes total).
 - a. As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completely filled, to ensure that the correct volume is drawn. *Note: The black mark on the side of the tubes indicates 1mL fill volume. QFT-Plus blood collection tubes have been validated for volumes from 0.8 mL- 1.2 mL. If the level of blood is outside the indicator line, it is recommended to obtain another blood specimen.*
 - b. If a butterfly needle is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus tubes being used.
- 2. Immediately after filling tubes, shake them ten (10) times just firmly enough to ensure the entire inner surface of the tube is coated with blood to dissolve the antigens on the tube walls
 - a. Tube temperature should be between 17-25°C at the time of blood tube filling.
 - b. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.
- 3. Label tubes appropriately.
- 4. The tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain the tubes at room temperature (22°C ± 5°C). Do not refrigerator or freeze the blood specimens. *Note: There are incubators located at specific sites in the regions, or specimens can be placed on courier for incubation, HOWEVER specimens must be received within the acceptable 16 hours post-collection if incubation is to occur at the Public Health Laboratory.* If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation at 37°C.
- 5. Incubate the tubes **UPRIGHT** at $37^{\circ}C \pm 1^{\circ}C$ for 16 24 hours.
- 6. After incubation at 37°C, blood collection tubes may be held between 4 27°C for up to 3 days before further testing. Specimens should be shipped to the Virology laboratory using the courier system in the designated boxes within the 3-day post-incubation time period.

Specimen Handling:

- 1. Use a patient label to properly label each QFT-Plus tube.
- 2. Complete a DHEC 1335-OE. See instructions on back of form for completing. Mark QuantiFeron Gold-Plus and complete incubation start and end time.

Specimen Preservation and Transport:

- 1. Specimens should be shipped and received within 16 h ours of collection if not incubated in regions, or within 3 days post-incubation.
- 2. Place the specimen inside designated QFT-Plus shipper (large white shipper with pink label) labeled to the attention of Virology and ship to maintain tubes in the temperature range of 17 27°C until receipt at the Public Health Laboratory.

Specimen Rejection:

- 1. Universal Rejections, See <u>Section 1</u>
- 2. Use of improper collection techniques and/or under- or over-filled collection tubes.
- 3. Specimen not incubated within the proper incubation period after collection (specimens under- or over-incubated) or specimens requiring incubation at 37°C are not received at the Public Health Laboratory within 16 hours of collection.

ENTERIC PATHOGENS

Purpose:

To properly collect a stool specimen for the isolation of the following enteric pathogens: *E coli 0157, Salmonella, Shigella, Yersinia, Campylobacter, Vibrio, Staphylococcus, Clostridium perfringens and Bacillus cereus.*

Patient Preparation:

No special preparation.

Supplies:

- 1. Wide-mouthed container.
- 2. Enteric kit with Cary-Blair transport media. See <u>Page III-1</u> to order.
- 3. DHEC form 1335-OE

Collection Precautions:

Wear gloves when collecting stool specimens.

Collection Procedure (Stool):

- 1. Collect stool in a clean (not necessarily sterile) wide-mouthed container with a tight-fitting lid. These containers must be free of preservatives and detergents.
- 2. Do not collect specimen from toilet. Avoid contamination with urine.
- 3. Infant specimens may be collected in a disposable diaper with plastic side facing inside.
- 4. Collect a walnut sized piece if stool is formed or 5 10 mL if stool is liquid.

Cary-Blair Transport media

Formed feces: use tongue depressor or spoon inside the lid to transfer walnut size portion of stool. Liquid feces: use pipette to transfer 5 - 10 mL of liquid stool to the transport media. Replace cap on tube and refrigerate until transported.

Specimen Handling:

- 1. Place a patient identification label on the transport medium
- 2. Complete a DHEC form 1335-OE to accompany specimen. See instructions on back of form. Be sure to complete additional test specific information

Specimen Type/Source: Mark X by Feces Date Collected

Organism Suspected: Indicate name of suspected organism

NOTE: Routine culture includes testing for Salmonella, Shigella, Campylobacter, and *E. coli 0157. Request for other specific pathogens must be indicated on the laboratory request form.*

Test Requested: Mark 508 Enteric Culture.

Specimen Preservation and Transport:

- 1. Ship specimens in transport media in cooler with cold packs to be received at the temperature of 2-8°C. Specimen should be received within 48 hours of collection.
- 2. See <u>Section IV</u> for appropriate shipping container, packaging and transport instructions.

Specimen Rejection:

- 1. Specimen too old.
- 2. Use of improper transport media or transport conditions.
- 3. Insufficient quantity
- 4. Universal rejections, See <u>Section I</u>

NEISSERIA GONORRHOEAE

Principle:

To properly collect an eye culture, rectal culture and oropharyngeal culture for the diagnosis of *Neisseria gonorrhoeae*. To properly collect a cervical, urethral and vaginal culture in cases of assault or sexual abuse.

Patient Preparation:

For male urethral culture: The patient should not have voided for at least 1 hour before performing a culture, especially men without a discharge.

Supplies:

- 1. Sterile Dacron or Rayon swab
- 2. Sterile thin, flexible wire with Dacron or Rayon swab (males)
- 3. GC culture kit with Transgrow bottle for *N. gonorrhoeae* See <u>Page III-1</u> to order.
- 4. DHEC form 1335-OE
- 5. Speculum (cervical, vaginal)

Collection Precautions: (All specimens)

Wear disposable gloves and protective eye wear when collecting and handling specimens. Note: Collect all specimens Monday - Wednesday. Do not ship for weekend delivery.

Collection Procedure: (Eye)

- 1. Touch a sterile swab to purulent discharge. If necessary, lower eyelid may be pulled down and the swab touched to the conjunctival mucosa.
- 2. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium

Collection Procedure: (Rectal)

- 1. Have the patient bear down slightly for ease in insertion of swab.
- 2. Insert a sterile swab approximately 3 cm into the anal canal using lateral pressure to avoid entering any fecal mass. If gross fecal contamination of the swab occurs, it should be discarded into a biohazard container and a repeat specimen obtained.
- 3. Rotate the swab to specimen crypts just inside the anal ring and allow the swab to remain in the anal area for several seconds for better absorption onto the swab.
- 4. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Oropharyngeal [Throat])

- 1. Using a tongue blade to hold the tongue down, take a specimen directly from the back of the throat, carefully avoiding contact with teeth, cheeks, gums or tongue when inserting or removing the swab.
- 2. Rub a sterile swab over the back wall of the throat and tonsillar crypts.
- 3. Inoculate Transgrow bottles as described under Inoculation of Transgrow Medium.

Collection Procedure: (Cervical)

- 1. Obtain the cervical specimen with the aid of a speculum that has been moistened with water. Other lubricants may contain antibacterial agents.
- 2. Insert the speculum and if unable to visualize the cervical os, remove excess mucus with swab.
- 3. Insert another sterile swab into the endocervical canal approximately 2 3 cm. Move the swab in a rotary motion for a few seconds to permit absorption of the exudate. If the patient is pregnant, and there has been no vaginal bleeding, insert swab into the endocervix only until the tip is no longer visible and rotate gently for a few seconds).
- 4. Inoculate Transgrow bottles as described under inoculation of Transgrow medium.

Collection Procedure: (Vaginal) for Children and Hysterectomy Patients Only

- 1. Insert the speculum.
- 2. With a sterile swab obtain the specimen from the posterior vaginal vault.
- 3. Allow a few seconds for absorption of material.
- 4. If the hymen is intact, a swab of the vaginal orifice will suffice.
- 5. Inoculate Transgrow bottles as described under Inoculation of Transgrow medium.

Collection Procedure: (Urethral Culture - Females)

- 1. Massage the urethra against the pubic symphysis from vagina to orifice to express discharge.
- 2. If no discharge is evident, insert a sterile flexible thin wire swab approximately 2 cm into the urethra and rotate for several seconds.
- 3. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow

Collection Procedure: (Urethral - Males)

- 1. Insert a sterile flexible swab with a thin wire shaft 2 4 cm into the urethra.
- 2. Once inserted, rotate the swab gently to ensure contact with all urethral surfaces.
- 3. Leave inserted for 2 3 seconds for better absorption of material.
- 4. Withdraw swab and inoculate Transgrow bottle as described under Inoculation of Transgrow.

Inoculation of Transgrow Medium

- 1. Have Transgrow at room temperature; check the expiration date before inoculation.
- 2. Hold the bottle in an upright position. Remove the cap only when ready to inoculate.
- 3. Soak up excess moisture in the bottle with the specimen swab and roll the swab from side to side over the entire surface of the medium starting at the bottom of the bottle.
- 4. Remove swab from bottle and discard into a biohazard container.
- 5. Recap the bottle tightly.

Specimen Handling:

- 1. Place label with patient's name on back of Transgrow bottle where chocolate colored medium is layered. **Do not place label on clear side of bottle**. This window is needed to observe growth.
- 2. Complete a DHEC form 1335-OE to accompany specimen. See instructions on back of form. Be sure to complete test specific information.
 - Specimen: Mark X by the appropriate type and write in the site.
 - Was Culture Incubated Before Transport?: mark X in the appropriate space(s).
 - Test Requested: Mark X in the appropriate space.

Specimen Preservation and Transport:

- 1. Place the Transgrow bottle in an upright position in an incubator set at 35°C as soon as possible after inoculation. Never refrigerate the medium after inoculation as cold temperature will rapidly kill gonococci. Incubate until ready to ship,
- 2. If an incubator is not available, make sure culture is shipped on the same day as collected.
- 3. If the specimen is collected on Friday and cannot be shipped until Monday, incubate over the weekend, but remove first thing Monday morning to prevent contaminant overgrowth.
- 4. Note: Do not ship for weekend delivery.
- 5. Ship to be maintained at 15-25°C until received at the Public Health Laboratory.

Specimen Rejection:

- 1. Transgrow media not used or Transgrow media expired.
- 2. Specimen in transit for more than 5 days.
- 3. Universal rejections, See Section I.

DIPHTHERIA

Principle:

To properly collect a throat swab for the culture of C. diphtheria

Patient Preparation:

No special preparation

Supplies:

- 1. Culturette swab kit containing Stuart's medium. Use form 1323 to order and indicate culturette in blank space on form.
- 2. DHEC form 1335-OE

Collection Procedure for Throat Swab:

- 1. Shine a bright light, if possible, over the shoulder of the specimen collector into the oral cavity of the patient so that the swab can be guided to the posterior pharynx.
- 2. The patient is instructed to tilt his/her head back and breathe deeply.
- 3. Depress the tongue with a tongue depressor to help visualize the posterior pharynx. Use culturette kit. Do not use calcium alginate swabs.
- 4. Extend the swab to the back of the throat between the tonsillar pillars and behind the uvula.
- 5. Have the patient phonate a long aah which will lift the uvula and help to prevent gagging.
- 6. The tonsillar areas and posterior pharynx should be firmly rubbed with the swab.
- 7. Care should be taken not to touch the teeth, cheeks, gums or tongue when inserting or removing the swab to minimize contamination with normal mouth flora.
- 8. After collection, place the swab back into the culturette and break or squeeze the ampule. Note: Notify the DHEC PHL Clinical Microbiology Section (803-896-0803) when a diphtheria specimen is to be collected so that special isolation media can be prepared.

Specimen Handling

- 1. Place a patient label on a culturette swab kit.
- 2. Organism suspected: Indicate Corynebacterium diphtheriae.

Specimen Preservation and Transport

- 1. Store and ship culturette at room temperature. Note: Transport within 24 hours. Do not ship for weekend delivery.
- 2. See <u>Section IV</u> for appropriate shipping container, packaging and transport instructions.

Specimen Rejection

- 1. Ampule in culturette not crushed.
- 2. Universal rejections, See <u>Section I</u>.

MYCOBACTERIUM (TB)

Principle:

To properly collect a sputum or urine specimen for the diagnosing and monitoring of tuberculosis and other mycobacterial infections.

Supplies:

- (a) Mycobacteriology collection kit (50 mL plastic sputum collection tube) See <u>Page III-1</u> to order.
 (b) Sterile screw cap container with a round opening of at least 2 inches for urine
- 2. DHEC form 1335-OE
- 3. Particulate respirator (PR)

Collection Procedure: (All Specimens) Wear Disposable Gloves and a Particulate Respirator When Collecting Specimens

Patient Preparation: (Sputum)

- 1. Explain to patient the importance of how to collect and handle a sputum specimen. Give the patient the sputum collection kit and COLLECTION OF SPUTUM SPECIMENS FOR MYCOBACTERIA (TB) sheet.
- 2. If the nurse must remain with the patient while he/she is coughing, the nurse should wear a particulate respirator.
- 3. Have the patient collect an early morning sputum specimen.
- 4. Ask the patient to breathe deeply, exhale, and then cough deeply. Steam from a hot shower or a boiling kettle may help to stimulate the flow of secretions. Also, drinking several cups nonalcoholic liquids will assist in raising sputum.
- 5. Patient should brush their teeth and/or rinse with water, not an antiseptic solution before obtaining the sputum specimen to reduce the overgrowth of mouth flora,
- 6. The patient should submit a series of three (3) sputum specimens over a period of three days (one/day), if specimens are being collected for initial diagnosis.

Collection Procedure (Sputum)

- 1. Remove the cap from the sterile container without touching the inside of the container. This will avoid contamination of the specimen which results in having to submit another specimen.
- 2. Patient is instructed to take a deep breath, hold it momentarily and cough deeply from the deepest part of the chest. Saliva and nasal secretions which contain few acid-fast bacteria are not to be collected.
- 3. Instruct the patient to spit the sputum into the appropriate sterile container until at least 5 mL or 1 teaspoon is obtained. Replace cap on the container. A minimum of 5 mL is needed for culture.
- 4. Avoid soiling the outside of the container. If soiling does occur, wipe with a clean cloth wet with alcohol soap and water, or 1/10 bleach solution, and then wash hands.
- 5. Sputum specimens should be free of food particles and other extraneous material.
- 6. Place the cap on plastic tube or sterile container and screw to close tightly.

If patient is to collect sputum in the home, give patient sputum collection and mailing containers and instruction sheet on how to obtain a sputum specimen.

Collection Procedure: (Urine)

The patient should submit a series of three (3) urine specimens over a period of three days (one/day) if specimens are being collected for initial diagnosis.

Female- midstream voided:

- 1. Have patient thoroughly clean the urethral area with soap and water.
- 2. Instruct patient to sit on toilet, and to manually separate labia minora with one hand and keep them separated while voiding the first portion of urine into the toilet.
- 3. After several mL have passed, have patient collect the midstream portion into the specimen container without stopping the flow of urine. Try to avoid touching the lip or inside of the container with the hand.
- 4. Have the patient finish voiding into the toilet.
- 5. Amount of urine needed is 10 mL. Screw cap on plastic container to close tightly.

Male-midstream voided:

- 1. Clean the glans with soap and water.
- 2. While holding foreskin retracted, begin voiding.
- 3. After several mL have passed collect the midstream portion into the appropriate container without stopping flow of urine.
- 4. Have the patient finish voiding into the toilet.
- 5. Amount of urine needed is 10 mL. Screw cap on plastic tube to close tightly.

For collection procedures on other specimens see chart on Collection and Shipment of Mycobacterial Specimens.

Specimen Handling:

- 1. Place a patient identification label on the 50 mL screw capped tube.
- 2. Complete a DHEC form 1335-OE to accompany specimen See instructions on back of form. Be sure to complete test specific information:

Agent suspected: Enter the suspected agent

Specimen source: Mark "X" by the appropriate source.

Date & Time Collected:

NOTE: <u>All clinical specimens</u> should be ordered using Test Code 601. Test Code 602 is reserved exclusively for laboratories that have isolated Mycobacteria and need them identified. Do not request drug susceptibility testing (Test Code 604) when submitting specimens from suspected new cases of tuberculosis. <u>All</u> initial isolates of M. tuberculosis will be tested for susceptibility to INH, rifampin, ethambutol, streptomycin and pyrazinamide.

Specimen Preservation and Transport: Sputum:

- 1. Refrigerate specimens if shipping is delayed over 24 hours. This will decrease overgrowth of other microorganisms which delay culture results.
- 2. Ensure that the cap is tightly closed, secure and not cross threaded. Be sure plastic tube is not soiled with sputum or urine.
- 3. Place the completed DHEC 1335-OE laboratory form into the side pocket of the biohazard bag. Specimen goes into the large opening of the biohazard bag. If the laboratory form is soiled, the laboratory must autoclave it before it can be handled. Be sure the date the specimen was collected is on the form.
- 4. Ship to maintain specimens within the range of 2-30°C until received at the Public Health Laboratory

Specimen Preservation and Transport Urine.

- 1. If specimen is urine, ship cold with frozen cold packs in shipper to maintain specimen at 2-8°C until received at the Public Health Laboratory.
- 2. Label outside of cooler as Urine for TB testing

Specimen Rejection:

- 1. Specimen broken or leaked in transit. Sterile body fluids may be processed with the approval of the Supervisor or Division Director.
- 2. Specimen > 5 days old.
- 3. Universal rejections, See <u>Section I</u>

SPECIMEN TYPE	TIME	AMOUNT	NUMBER	SPECIAL PROCEDURE
Sputum	Early AM On Waking	5-10 mL	Series of 3 One/Day	Sputum-material coughed up from deep in lungs-not saliva
Urine	Early AM	Entire specimen, centrifuge 10 mL	Series of 3 One/Day	Voided midstream specimen collected as aseptically as possible. Transport to lab immediately.
Gastric Washing	Early AM	10 mL	1 or more as needed	No food after midnight. Pass 20-50 mL. sterile distilled water through stomach tube and draw off specimen in sterile tube.
Biopsy				
Feces		Formed-send walnut sized portion Liquid- send 10 mL	1 or more as needed	No fixative or preservatives (saline only)
Sterile body fluids other than blood		10 mL	1 or more as needed	
Swabs of drainage or other material				Use small amt of sterile saline to keep swab moist. Do not use transport media. Swabs are not usually productive specimens for mycobacteria.

SPECIMEN COLLECTION FOR CULTURE OF MYCOBACTERIA (TB)

Use a Mycobacteriology (TB) collection kit for all specimen types

CHLAMYDIA/GC & TRICHOMONAS VAGINALIS by GEN-PROBE APTIMA (Endocervical, Male Urethral, Male/Female Rectal, Pharyngeal, Vaginal, Urine Specimens)

Principle:

To collect and appropriately handle specimens for nucleic acid amplification testing for Chlamydia, Gonorrhoeae, and Trichomonas vaginalis.

Patient Preparation:

See collection procedures below.

Supplies:

- GC/ Chlamydia/Trichomonas Gen-Probe supplies See <u>Page III-1</u> to order. For Unisex Collection Kit, the blue swab is the specimen collection swab for both male and female specimens.
- 2. DHEC form 1332

Collection Procedure for Endocervical Swab Specimens (FOR GC/CT/TRICH TESTING):

- 1. The clinician collects the specimen from the cervical and endocervical area using the <u>APTIMA Unisex Swab</u> (green printing) designed to collect endocervical and urethral specimens for the APTIMA Combo 2 Assay. **Please** use the blue shaft swab for collection.
- 2. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft in package with red printing). **Discard this swab!!!**
- 3. Insert specimen collection swab (blue shaft) into endocervical canal.
- 4. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
- 5. Withdraw swab carefully; avoid any contract with vaginal mucosa.
- 6. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
- 7. Break off the swab at the scoreline. Use care to avoid splashing contents.
- 8. Re-cap swab specimen transport tube tightly.
- 9. Place a label with patient name, date taken, and anatomic site (cervical, Cx) on the tube.
- 10. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (cervical, Cx) indicated on the form.
- 11. Specimens can be stored in the refrigerator or at room temperature, between 2-30° C, prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
- 12. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
- 13. The specimen is good for 60 days.
- 14. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.



Collection Procedure for Vaginal Specimens (FOR GC/CT/TRICH TESTING):

- 1. The clinician collects the specimen from the vaginal area using the <u>APTIMA MTS (Multitest) Swab</u> (orange label, previously known as vaginal swab) designed to collect specimens for the APTIMA Combo 2 Assay. **Please use the pink shaft swab for collection.**
- 2. Carefully insert the swab into vagina about 2 inches inside the opening of the vagina and gently rotate swab 10-30 seconds.
- 3. Make sure the swab touches the walls of the vagina so that the moisture is absorbed by the swab and then withdraw the swab without touching the skin.
- 4. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
- 5. Break off the swab at the scoreline.
- 6. Tightly screw the cap onto the tube.
- 7. Place a label with patient name, date taken, and anatomic site (vaginal, vag) on the tube.
- 8. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (vaginal, vag) indicated on the form.
- 9. Specimens can be stored in the refrigerator or at room temperature, between 2-30° C, prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
- 10. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
- 11. The specimen is good for 60 days.
- 12. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.

Collection Procedure for Male Urethral Specimens (FOR GC/CT TESTING ONLY):

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

- 1. The clinician collects the specimen from the urethral area using the <u>APTIMA Unisex Swab</u> (green printing) designed to collect endocervical and urethral specimens for the APTIMA Combo 2 Assay. **Please use the blue shaft swab for collection.**
- 2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
- 3. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
- 4. Withdraw the swab carefully.
- 5. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
- 6. Carefully break off the swab at the scoreline. Use care to avoid splashing contents.
- 7. Re-cap the swab specimen transport tightly.
- 8. Place a label with patient name, date taken, and anatomic site (male urethral) on the tube.
- 9. Complete a laboratory test requisition (DHEC 1332) for each specimen with the test(s) requested and the appropriate anatomic site (male urethral) indicated on the form.
- 10. Specimens can be stored in the refrigerator or at room temperature, between 2-30° C, prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
- 11. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
- 12. The specimen is good for 60 days.
- 13. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months after collection.

Collection Procedure for Pharyngeal Specimens (FOR GC/CT TESTING ONLY):

Since this collection kit is designed to collect endocervical specimens, included is a white shaft "cleaning" swab which is NOT to be used for pharyngeal or rectal specimen collection.

- 1. The clinician collects the specimen from the pharyngeal area using the <u>APTIMA Unisex Swab</u> (green printing) designed to collect endocervical and urethral specimens for the APTIMA Combo 2 Assay. **Please use the blue shaft swab for collection.**
- 2. Swab area between the tonsillar pillars and the region posterior to the pillars.

- 3. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
- 4. Break off the swab at the scoreline.
- 5. Place a label with patient name, date taken, and anatomic site (throat) on the tube.
- 6. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (throat) indicated on the DHEC Form 1332.
- 7. Specimens can be stored in the refrigerator or at room temperature, between 4-30° C, prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
- 8. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
- 9. The specimen is good for 60 days.

Collection Procedure for Male/Female Rectal Specimens (FOR GC/CT TESTING ONLY):

Since this collection kit is designed to collect endocervical specimens, included is a white shaft "cleaning" swab which is NOT to be used for pharyngeal or rectal specimen collection.

- 1. The clinician collects the specimen from the rectal area using the <u>APTIMA Unisex Swab</u> (green printing) designed to collect endocervical and urethral specimens for the APTIMA Combo 2 Assay. **Please use the blue shaft swab for collection.**
- 2. **Asymptomatic and/or Symptomatic Males/Females:** moisten swab with sterile saline/tap water and insert into anus and rectum approximately 2-5 cm (1 to 2 inches) and rotate 3-8 times. **NOTE: it is ok to have some fecal contamination that appears as a brown discoloration but NO frank fecal material.**
- 3. Remove foil cap from swab specimen transport tube and immediately place specimen collection swab into the transport tube.
- 4. Break off the swab at the scoreline.
- 5. Place a label with patient name, date taken, and anatomic site (rectal, rec) on the tube.
- 6. Complete a laboratory test requisition for each specimen with the test(s) requested and the appropriate anatomic site (rectal, rec) indicated on the form.
- 7. Specimens can be stored in the refrigerator or at room temperature, between 4-30° C, prior to transport to the Public Health Laboratory, 8231 Parklane Road, Columbia, SC 29223.
- 8. Specimens need to be stored in an upright position in a rack so that the buffer is in contact with the swab.
- 9. The specimen is good for 60 days.

Collection Procedure for Male and Female Urine Specimens (FOR GC/CT/TRICH TESTING):

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



- 1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.
- 2. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
- 3. Re-cap urine specimen transport tube tightly. This is now known as the "processed urine specimen."
- 4. See Specimen Transport and Storage below.

Specimen Handling:

Complete DHEC form 1332 to accompany specimen See instructions on back for completing. Be sure to complete test specific information.

Specimen Preservation and Transport

A. Swab

- 1. After Collection, transport and store swab in swab specimen transport tube at 2°C to 30°C until tested.
- 2. Specimens must be assayed within 60 days of collection. If longer storage is needed,
- freeze at -20°C to -70°C for up to 12 months after collection.

B. Urine

- 1. After collection, transport the processed urine specimens in the GEN-PROBE Aptima Assay urine specimen transport tube at 2°C to 30°C and store at 2°C to 30°C until tested. Processed urine specimens should be assayed with the APTIMA Assay within 30 days of collection. If longer storage is needed, freeze at -20°C -or-70°C for up to 90 days after collection.
- Urine specimens that are still in primary collection container must be transported to lab at 2°C to 30°C. Transfer urine specimen into APTIMA Assay urine specimen transport tube within 24 hours of collection. Store at 2°C to 30°C and test within 30 days.
- 3. See <u>Section IV</u> for appropriate shipping container, packaging and transport instructions.

Specimen Rejection:

- 1. No swab in tube, 2 swabs in tube, or improper (non-blue) swab used.
- 2. Universal rejections, See <u>Section I</u>.
- 3. Note: specimens collected with this system cannot be used for culture.

References:

- 1. Probetec Swab Specimen Collection and Handling by Campbell, D., SFDPH Micro Lab and Engelman, J., M.D., City Clinic, 1/2002.
- 2. APTIMA Swab Specimen Collection Guide; Gen-Probe Incorporated, San Diego, CA 92121.
- 3. City and County of San Francisco, Dept. of Public Health, City Clinic Branch Laboratory, revised 10/09.

HERPES SIMPLEX 1 & 2 ASSAY (ANOGENITAL LESION SWAB SPECIMEN COLLECTION)

Principle:

To properly collect specimens for nucleic acid amplification testing for Herpes Simplex 1 & 2 from an anogenital lesion using the Aptima Multitest Swab Specimen Collection kit.

Patient Preparation:

Do not use disinfectants or cleaners on the lesion before the specimen is collected.

Supplies:

- 1. Aptima Multitest Swab Specimen Collection Kit (Orange Tube). Store collection kit at 15-30°C until needed.
- **2.** DHEC form 1335-OE

Collection Procedure for Anogenital Lesion Swab Specimens:

- 1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection kit.
- 2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
- 3. If needed, expose the base of the lesion to access fluid.
- 4. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.
- 5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection kit.
- 6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
- 7. Carefully break the swab shaft at the score line against the side of the tube.
- 8. Discard the top portion of the swab shaft.
- 9. Tightly screw the cap onto the tube.

Specimen Handling:

- 1. Place a patient identification label on the tube.
- 2. Complete a DHEC form 1335-OE to accompany specimen. See instructions on back for completing. Be sure to complete test specific information:

Specimen Preservation and Transport

- 1. Store and ship specimens within one week of collection to maintain specimens at 2-30°C until received at the Public Health Laboratory.
- 2. See <u>Transporting and Shipping Infectious Substances in Section IV</u> for appropriate shipping container, packaging and transport instructions.

Specimen Rejection

- 1. Collection site NOT from an anogenital lesion.
- 2. Improper swab used.
- 3. Specimens received at the improper temperature.
- 4. Universal rejections, See <u>Section I</u>.

Section IV

Transporting and Shipping Infectious Substances

A. Introduction

Patient specimens from most of the SC Health Departments and many of the SC hospitals are transported to the SC DHEC Public Health Laboratory through a DHEC contracted courier system. This courier system picks up and delivers courier mail to over 60 DHEC health departments and locations throughout the state every evening for arrival at the Public Health Laboratory the next morning.

For the protection of employees and the public, patient specimens and infectious substances <u>must</u> <u>be properly packaged and labeled</u>. As packages delivered using this courier system are transported in commerce, they must be packaged to meet all DOT requirements for shipping infectious substances. <u>Failure to follow these regulations can result in injury, exposure, and/or fines</u>.

B. <u>Regulatory Requirements</u>

There are three regulatory entities regarding the shipping of hazardous materials; the International Air Transporters Association (IATA), the United States Department of Transportation (USDOT), and the United States Postal Service (USPS). According to regulations, it is the **shipper's responsibility** to properly package shipments of infectious substances and hazardous materials.

The International Air Transporters Association (IATA) is a private organization whose regulations only apply to air transport by IATA member airlines. All major airlines are members of IATA and follow the IATA *Dangerous Goods Regulations* taken from the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.

The United States Department of Transportation (US DOT) is a <u>government</u> agency that regulates <u>commercial</u> transport. Commercial transport takes place when money is exchanged for a good or service. All modes of transportation, ground, air, and water, fall under DOT regulations. US DOT regulations are located in the Code of Federal Regulations 49 CFR 173. Updates to these regulations require congressional approval and are not frequently updated.

The United States Postal Service (USPS), has their own regulations found in the domestic mail manual. As one federal agency cannot regulate another federal agency, the USPS is not required to follow US DOT regulations. As an example, the Postal Service can transport cylindrical shippers while a private courier, like Fedex, cannot.

In addition to these regulations, private couriers can have additional regulations. As an example, Federal Express requires that a shippers declaration for Dangerous Goods be typed and not hand written.

The US Department of Transportation (DOT) and the US Postal Service (USPS) <u>harmonized their</u> regulations with the International Air Transporter Association (IATA) regulations in 2006. Therefore, if infectious substance is packaged and labeled to meet the IATA regulations, the package will meet or exceed the requirements for US DOT and the US Postal Service. In addition to providing uniformity, this harmonization allowed the regulations to be more adaptive. As IATA is a private organization, it has the ability to change its regulations without congressional approval.

C. <u>Training Requirements</u>

All employees who are a part of any step of classifying, packaging, labeling, marking, completing the paperwork, or transporting the specimen must be properly trained to package and ship infectious substances. Training records must be retained for a <u>minimum of thirty-six months</u>. Retraining must be completed <u>every two years</u> from the date of completion for IATA regulations and every three years for DOT regulations.

The training must include:

- An overview of the regulatory requirements
- Security awareness training
- Function specific training on the activities the employee will be responsible for, such as classification of infectious substances, packaging, labeling the outside container and completing shipping documentation.
- Safety training to include understanding the hazards of the infectious agent, safe handling and emergency response procedures.

The employer must certify the employees training as adequate and maintain a record of training which includes:

- The individual's name
- The most recent training completion date
- A description, copy or reference to training materials used
- The name and address of the organization providing the training
- A test, which was completed satisfactorily, to verify the employee understood the training.

D. <u>Exemptions</u>

Exempted Materials

The following items are exempt from the shipping regulations for infectious substances, but must be packaged to avoid leaking during shipping and may require a special label.

- Specimens/samples in which all pathogens have been neutralized or inactivated
- Specimens/samples **known** to not contain infectious substances
- Specimens/samples which only contain micro-organisms which are non-pathogenic for humans and animals
- Dried blood spots and fecal occult blood samples
- Environmental samples (food and water) that are not considered to pose a significant health risk
- Organs for transplant and blood for transfusion

Private Courier Exemptions

An exemption called the "materials of trade exemption," located at 49 CFR 173.6, is commonly used by hospital and DHEC employees. This exemption has multiple parts, but the part most useful for the transport of infectious substances is the following: "a hazardous material transported on a motor vehicle, by a private carrier in direct support of a principle means of business that is other than transportation by motor vehicle." This exemption does not apply to all hazard classes and there are quantity limits to those materials that are allowed. For infectious substances, this exemption only applies to category B samples.

So, a hospital courier or DHEC employee that transports samples to the health department, can use this exemption, because their principle business is not the transportation of samples but the care and treatment of patients or the community. Therefore, these regulations listed above do not apply to the transport of category B infectious substances transported by a hospital courier or DHEC employee transporting samples to a health department.

However, in order to protect the safety of the employee and the public, DHEC employees and other entities shipping specimens through the DHEC contracted courier must follow all of the regulations for proper shipping described in further pages. Additionally, secure the package in the vehicle as far away as possible from the driver as possible, preferably in the trunk if available. If there is an accident, emergency responders need to know that infectious substances are in the package.

E. <u>Definitions:</u>

BIOLOGICAL PRODUCTS: Are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

CARBON DIOXIDE, SOLID (DRY ICE): Carbon dioxide, solid (dry ice) is produced by expanding liquid carbon dioxide to vapor and "snow" in presses that compact the product into blocks. It is used primarily for cooling and due to its very low temperature (about -79 C) can cause server burns to skin upon direct contact. When Carbon dioxide, solid (dry ice) converts (sublimates) directly to gaseous carbon dioxide it takes in heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing Carbon dioxide, solid (dry ice) must be designed and constructed so as to prevent build-up of pressure due to the release of carbon dioxide gas.

CONSIGNEE: Any person, organization or government which is entitled to take delivery of a consignment.

CULTURES: Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in 3.6.2.1.4.

DANGEROUS GOODS: Articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in these Regulations or which are classified according to the Regulations.

EXCEPTION: A provision in these Regulations which excludes a specific item of dangerous goods from the requirements normally applicable to that item.

EXEMPTION: Authorization issued by an appropriate national authority of all States concerned providing relief from the provisions of these Regulations.

INFECTIOUS SUBSTANCES: are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

INNER RECEPTACLE: Are receptacles which require an outer packaging in order to perform their containment function.

OVERPACK: An enclosure used by a single shipper to contain one or more packages and to form one handling unit for convenience of handling and stowage. Dangerous goods packages contained in the overpack must be properly packed, marked, labeled and in proper condition as required by these Regulations. For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of Packing Instruction 954. (A Unit Load Device is not included in this definition.)

PACKAGE: (Non-Radioactive Material). The complete product of the packing operation consisting of the packaging and contents prepared for transport.

PACKAGING: (Non-Radioactive Material). Receptacles and any other components or materials necessary for the receptacle to perform its containment function and to ensure compliance with the minimum packing requirements of these Regulations.

PACKING: The art and operation by which articles or substances are enveloped in wrappings and/or enclosed in packaging or otherwise secured.

PATIENT SPECIMENS are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

PROPER SHIPPING NAME: The name to be used to describe a particular article or substance in all shipping documents and notifications and, where appropriate, on packaging.

RECEPTACLE: A containment vessel, including closures, for receiving and holding substances or articles.

SELECT AGENT: microorganisms or toxins, identified by a panel of experts, which could be used for bioterrorism. A complete list of select agents and toxins may be found on the Select Agent Program's web page <u>http://www.cdc.gov/od/sap/docs/salist.pdf</u>

SHIPMENT: The specific movement of a consignment from origin to destination.

UN NUMBER: The four digit number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods to identify a substance or a particular group of substances. (The prefix "UN" must always be used in conjunction with these numbers.)

F. Instructions for Packaging Infection Substances

Step 1: Classifying Infectious Substances

Infectious substances are divided into 2 categories – A and B. If you need assistance with classifying the materials you are shipping, please call the testing section which performs the test you are requesting.

Category A

An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing <u>permanent disability</u>, <u>life-threatening or fatal disease</u> in otherwise healthy humans or animals.

Indicative examples of substances that meet these criteria are given in Table 3.6.D from the IATA Dangerous Goods Regulation (see next page). This table is not exhaustive. New or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.

In this table, organisms listed with the words "cultures only" indicate that clinical specimens known to contain that organism can be shipped as category B. As an example, Ebola is not listed with "cultures only." Therefore specimens known to contain Ebola must be shipped as Category A.

Other Examples of Category A infectious substances:

- Known culture of a Select Agent
- Known culture of *Escherichia coli* (toxigenic)
- Known culture of Neisseria meningitidis
- Known culture of *Mycobacterium tuberculosis*
- Samples or cultures suspected to be Select Agents or BSL-3 organisms. (As an additional precaution and requested by the PHL)

Category B

An infectious substance which does not meet the criteria for inclusion in Category A.

Examples of Category B infectious substances:

- Most cultures and patient specimens shipped to the Public Health Laboratory
- A swab placed in a genprobe bottle (would not meet the IATA definition of a culture)

Table 3.6.D from IATA Dangerous Goods RegulationsIndicative Examples of Infectious Substances Included in Category A in Any FormUnless Otherwise Indicted (January 2021)[NOTE: "Select Agents or Toxins" are shown in red font]				
 Bacillus anthracis (cultures only) Brucella abortus (cultures only) Brucella suis (cultures only) Burkholderia mallei - Pseudomonas mallei - Glanders (cultures only) Burkholderia pseudomallei - Pseudomonas pseudomallei (cultures only) Chlamydia psittaci - avian strains (cultures only) Chlamydia psittaci - avian strains (cultures only) Clostridium botulinum (cultures only) Coccidioides immitis (cultures only) Coxiella burnetii (cultures only) Corimean-Congo hemorthagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) Escherichia coli, verotoxigenic (cultures only) Escherichia coli, verotoxigenic (cultures only) Ebola virus Flexal virus Flexal virus Hantaan virus Hantavirus causing hemorthagic fever with renal syndrome Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (HIV) (cultures only) Highly pathogenic avian influenza virus (cultures only) 	 Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Monkeypox virus Mycobacterium tuberculosis (cultures only) Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus (cultures only) Rickettsia prowazekii (cultures only) Rickettsia rickettsii (cultures only) Rickettsia rickettsii (cultures only) Rift Valley fever virus (cultures only) Risian spring-summer encephalitis virus (cultures only) Sabia virus Shigella dysenteriae type 1 (cultures only) Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) Yellow fever virus (cultures only) Yersinia pestis (cultures only) 			

Examples of Classifying Infectious Substances

Material	Category A	Category B
Culture of Mycobacterium tuberculosis	X	
Sputum from a person infected with <i>Mycobacterium tuberculosis</i>		X
Known culture of Salmonella spp.		Х
Known culture of Bacillus anthracis	X	
Suspected culture of Bacillus anthracis	Safer Choice	Technically Correct
Tube of blood from a person <u>known</u> to be infected with <i>Bacillus anthracis</i>	Safer Choice	Technically Correct
Tube of blood drawn from patient infected with Ebola virus	X	
Animal head shipped for rabies testing		Х

Step 2: Proper Shipping Names and UN Numbers

Once the proper category is determined, use the corresponding UN number and proper shipping name for your package. Both of these items are required on the outer packaging and are used in later steps. The proper shipping name must be spelled exactly as seen here.

Classification	Proper shipping name	UN number
Infectious substance, Category A	"Infectious substance, affecting humans" (technical name)	UN 2814
Infectious substance, Category B	"Biological substance, Category B"	UN 3373

For category A, notice the parenthesis at the end. In these parentheses, a technical name must be entered. Abbreviations and non-standard formatting are not allowed. So, no italics for scientific names. Examples could include; "Escherichia coli" and "Neisseria meningitidis".

If you are shipping a sample suspected, but not confirmed, to be a category A infectious substance, and have elected to ship the material as a category A as an additional safety measure, the packing name must use the text "Infectious Substance, Affecting Humans (suspected category A infectious substance)."

Step 3: Packing Selection and Requirements

Caution: shipping requirements for your specimen may have recently changed. Check the test section in the *Public Health Laboratory Services Guide* to ensure proper shipping conditions and see page IV-15 for temperature controlled packaging instructions.

1. Packaging Selection

Package Construction

Not all packages are acceptable for shipping infectious substances. Packages must follow strict DOT and IATA regulations regarding their size, shape, construction materials, and markings. Approved packaging configurations and requirements are defined by the DOT in 49 CFR 172 and 173, and by IATA in the dangerous goods regulations, section 5, packaging instructions 620 and 650.

Package Performance Testing

Additionally, packages must follow strict manufacturing standards and performance. Performance tests simulate the potential conditions the package may encounter during transit and test the package's ability to contain the hazardous material while enduring stresses like drops, leaks, pressurized atmospheres, and stacking loads. Standards for specific performance tests are located in 49 CFR 178 for the DOT and in the Dangerous Goods Regulations, Section 6 for IATA. Performance tests must be documented and the records must be made available to inspectors upon request.

Packaging Options

Performance packaging accepted by the DHEC contracted courier system, also known as a shipper, falls into three general categories: UN certified shippers, PHL approved shippers, and sender verified packaging. Do not mix and match parts of packages. The package has been certified as a unit. Mixing and matching parts invalidates the UN certification.

1. **UN certified shippers** have been tested by the manufacturer and certified to meet all performance requirements for IATA and DOT. This certification mark (seen right) indicates that the package is UN certified.

UN certified shippers are not certified for all hazardous materials. After the UN mark will be a series of letters and numbers. As an example, 4G / CLASS 6.2 / 20 USA /. Pay



special attention to the second set of information. In this example "CLASS 6.2." Class 6.2 is the class which contains infectious substances. If a box said "3" or "8" in this location, the box would not be appropriate for shipping infectious substances.

A UN certified shipper is <u>certified for both Category A and B infectious substances</u>. UN certified shippers, also meet all of the requirements for <u>air transportation</u>, and are universally accepted by national commercial carriers like FedEx or UPS.



Berlin – HMS-69110

- UN certified for Category A and B shipping.
- Can go by ground or air transport.
- See page IV-15 for temperature controlled packaging instructions.

Infecon 5500

- UN certified for Category A and B shipping.
- Can go by ground or air transport.
- See page IV-15 for temperature controlled packaging instructions.



Infecon 5000

- UN certified for Category A and B shipping.
- Can go by ground or air transport.
- See page IV-15 for temperature controlled packaging instructions.
- 2. **PHL approved shippers**, indicated by the mark to the right, are shippers provided by the PHL, for which the PHL has conducted performance testing. However, the Public Health Laboratory has only conducted the testing needed for ground transportation of Category B infectious substances. Do not use them for Category A shipments and do not offer this package to a national commercial carrier like FedEx or UPS as it has not met all the requirements for air transportation.





<u>ThermoSafe – Sonoco #311</u>

- PHL approved for Category B shipping.
- Ground transport only.
- See page IV-15 for temperature controlled packaging instructions.



Uline – Uline #S-7359

- PHL approved for Category B shipping.
- Ground transport only.
- See page IV-15 for temperature controlled packaging instructions.
- 3. Sender Verified Packaging may be used if the shipper meets all DOT / IATA regulations and/or has been performance tested by your entity or by the manufacturer. If this option is selected, your entity will be responsible for providing USDOT inspectors with performance test results and/or a statement from the manufacturer.

b. Triple Packaging

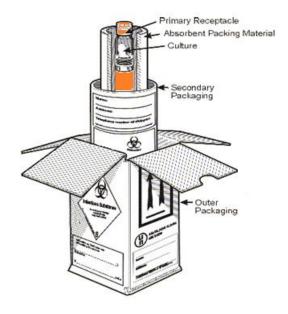
The safe transport of infectious substances is based on "triple-packing." As an example, a primary sample container, in a secondary container, in an outer shipper, offering three layers of protection.

Primary Receptacle

- Is the container (e.g., tube vial, bottle) that holds the specimen.
- Must be securely sealed and leak proof (screw top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit).
- Must be surrounded by absorbent material capable of taking up the entire liquid contents.

NOTE: Remember, there must always be adequate absorbent materials next to the primary receptacle to contain all liquid contents should the container leak. The PHL provided absorbent pads are rated to absorb 50ml.

• Must be packed in the secondary receptacle in such a way that it will not break.



Secondary Packaging

- Is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.
- Must be leak proof and securely sealed.
- Must be placed in the outer packaging so that it does not move.
- Must have a biohazard symbol.
- <u>Never put dry ice inside a secondary container</u>. The container may rupture because of trapped gasses.
- Never put paperwork inside the secondary container.

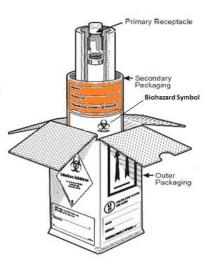
Note: For PHL approved containers, a ziplock biohazard bag may serve as the <u>secondary receptacle</u> for a patient specimen if transport is by ground with the DHEC courier system.

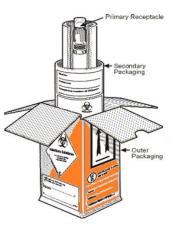
Outer Packaging

- Is the receptacle into which the secondary receptacle, along with cushioning materials, is placed.
- Must be rigid.
- Bears all required markings and labels.
- At least one surface of the outer packaging must have a minimum dimension of 4 inches x 4 inches.
- Itemized list of contents, requisition forms, and other paperwork is placed here next to the secondary container.
- Dry ice and cool pack are placed here next to the secondary container.
- Seal the package with clear shipping tape. Do NOT use excessive tape to close the outside container.
- Use caution when opening outer packages. Cut the tape instead of pulling the tape to open the package. Pulling the tape can rip or tear reusable package. Also be careful not to cut the box, specifically cardboard closing tabs.

Over Packaging

- Is not required for all packages.
- Is a larger box containing one, or more, smaller completely packaged and labeled shippers.
- Must bear <u>all the same marks and labels</u> required by the contents of the shippers it contains and the word "Overpack."
- Over packs may be needed if more, surface area is needed on a shipper to accommodate the required marks and labels.





Closure Instructions

When using a UN certified or PHL approved shipper, you must follow the manufacturer's instructions for closing the package. If the closure instructions specify an order to close the flaps of the box, that order must be followed. Failure to follow the manufacture's closure instructions can result in a DOT fine. It is important to retain a copy of these instructions both for reference as needed and if requested by a DOT inspector.

Quantity Limits

For Category B infectious substances, regulations allow:

- Up to 1 liter per primary receptacle
- Up to 4 liters per outer packaging.

For Category A infectious substances, regulations allow:

- Up to 50ml or 50g per shipper on a passenger aircraft.
- Up to 4 liters per shipper on a cargo aircraft.

c. Shipping at Controlled Temperatures

Caution: Shipping requirements for your specimen may have recently changed. Check the test section in the Public Health Laboratory Services Guide to ensure proper shipping conditions and specimen integrity.

Generally, only three controlled shipping temperatures are used to transport specimens to the Public Health Laboratory. Samples are shipped "frozen" ($\leq -20^{\circ}$ C), "refrigerated" (2-8°C), or at controlled room temperature (CRT) (15-25°C). <u>Specimens received outside of appropriate ranges may be rejected for testing</u>. Please carefully follow the instructions below to ensure sample integrity by following proper controlled temperature shipping.

Caution: It is the shipper's responsibility to ensure proper temperature control of samples during transit where necessary. Guidance provided below is intended to assist shippers with the selection and use of materials provided through the PHL. The use of equivalent materials is acceptable. Please see, <u>Ordering Supplies/Forms/Shipping Containers, Section III, p. 1</u>, for information on receiving free shipping materials to submit specimens to the PHL.

General Instructions

Shipping Frozen (≤ -20°C)

- Follow all infectious substance shipping instructions.
- With UN certified shippers, do not alter the shippers packaging instructions to accommodate dry ice._
- Place dry ice between the secondary container and the outer packaging.
- Never place dry ice inside a secondary container.
- Generally, 6 pounds is sufficient for 24 hour shipments.

Refrigerated Shipping (2-8°C)

- Follow all infectious substance shipping instructions.
- With UN certified shippers, do not alter the shippers packaging instructions to accommodate temperature control materials packs.
- The use of phase changing materials (PCM) is preferred over water based gel packs. This avoids the need for preconditioning (aka "bench time") to prevent freezing the sample at the beginning of transit (aka "cold shock").
- DO NOT USE WET ICE.
- Gel packs should be frozen flat and allowed to equilibrate for 24 hours before use.
- Pre-condition water based gel packs by allowing them to sit at room temperature ("bench time") until their contents begin to become fluid or they begin to sweat. This prevents "cold shocking" and freezing the sample in the beginning of transit.
- The sender will need to determine the number of packs and configurations of materials needed. See instructions below for shipper configurations for PHL provided materials.





Controlled Room Temperature (CRT) (15-25°C)

- Follow all infectious substance shipping instructions.
- With UN certified shippers, do not alter the shippers packaging instructions to accommodate temperature control materials packs.
- The use of phase changing materials (PCM) is preferred over water based gel packs. This avoids the need for pre-conditioning (aka "bench time") to prevent freezing the sample at the beginning of transit (aka "cold shock").
- Gel packs should be frozen flat and allowed to equilibrate for 24 hours before use.
- Pre-condition water based gel packs by allowing them to sit at room temperature ("bench time") until their contents begin to become fluid or they begin to sweat. This prevents "cold shocking" and freezing the sample in the beginning of transit.
- Controlled Room temperature (CRT) gel packs should be allowed to equilibrate to room temperature for 24 hours before use.
- The sender will need to determine the number of packs and configurations of materials needed. See instructions below for shipper configurations for PHL provided materials.

Instructions for Using Shippers and Temperature Control Materials Provided by the PHL

Shipper Name	Frozen <-20oC	Refrigerated 2-8oC	CRT 15-25oC	
Sonoco ThermoSafe #311	24 hours	24 hours	24 hours	
''Head Box''	Year Round	Summer only	Summer only	
Uline	24 hours	24 hours	24 hours	
#S-7359	Year Round	Summer only	Summer only	
Berlin (UN Certified)	24 hours	Do Not Use	Do Not Use	
#HMS-69110	Year Round	Do Not Ose	Do Not Use	
Infecon 5000	24 hours	24 hours	24 hours	
(UN Certified)	Year Round	Summer only	Summer only	
Infecon 5500	24 hours	24 hours	24 hours	
(UN Certified)	Year Round	Summer only	Summer only	

1. Select an appropriate shipper for your situation then follow the packing instructions below.

Shipping Configurations - Sonoco ThermoSafe





Shipping Frozen (<u><</u> -20°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place the secondary container on the dry ice.

Refrigerated Shipping (2-8°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 4 Frozen 24oz packs (one on each side)



- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 2 Frozen 24oz packs on the bottom
 - 2 CRT 24oz packs on top of those
 - 6 CRT 24oz packs on the sides
 - 1 CRT 24oz pack on the top

<u>Shipping Configurations – Uline</u>



Shipping Frozen (<u><</u> -20°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place the secondary container on the dry ice.



Refrigerated Shipping (2-8°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 1 frozen 24oz pack on the bottom
 - 2 frozen 24oz packs, one on each long side



- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 1 Frozen 24oz pack on the bottom
 - 1 CRT 24oz pack on top of that
 - 4 CRT 24oz packs of the sizes
 - 1 CRT 24oz pack on the top

Shipping Configurations – Infecon 5000







Shipping Frozen (\leq -20°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place dry ice around the secondary container.

Refrigerated Shipping (2-8°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - Place the cardboard insert in first
 - Insert the secondary container
 - 2 frozen 24oz packs, one on each long side
 - 1 frozen 24oz pack on the top

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 1 Frozen 24oz pack on the bottom
 - 1 CRT 24oz pack on top of that.
 - Place the secondary container and cardboard insert next.
 - 4 CRT 24oz packs on the sides
 - 1 CRT 24oz pack on the top

Shipping Configurations – Infecon 5500







Shipping Frozen (\leq -20°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place dry ice around the secondary container.

Refrigerated Shipping (2-8°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - Place the cardboard insert in first
 - Insert the secondary container
 - 2 frozen 24oz packs, in an L-shape around the sides
 - 1 frozen 24oz pack on the top

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place temperature controlled materials as follows:
 - 1 Frozen 24oz pack on the bottom
 - 1 CRT 24oz pack on top of that.
 - Place the secondary container and cardboard insert next.
 - 4 CRT 24oz packs on the sides
 - 1 CRT 24oz pack on the top

Shipping Configurations – Berlin



Shipping Frozen (< -20°C)

- Follow all infectious substance shipping instructions and...
- See section for general instructions for shipping items at this temperature on the previous page.
- Place dry ice around the secondary container.



Shipping Refrigerated (2-8°C)

- Do not use for 2-8°C Shipping.
- Cannot sustain temperature for 24 hours.

- Do not use for 15-25°C Shipping.
- Cannot sustain temperature for 24 hours.

Step 4: Shipping Paperwork

The following papers must accompany each package containing infectious substances:

- Itemized list of contents
- Paperwork related to sample testing (requisition forms, results, etc.)
- Declaration of Dangerous Goods (for shipments of Category A or dry ice)

Itemized list of Contents

All packages must be accompanied by an itemized list of contents. This document contains:

- To and From Address
- An Emergency Contact Name and Telephone
- The kind of specimens with a brief description
- The number and total volume of the samples
- The proper shipping classification for the hazards

Itemized List Used by the Public Health Laboratory

Shipped to:

Shipping Temperature

Next day delivery required

- Controlled Room Temperature (15-25°C) Refrigerated (2-8°C) Frozen / Dry Ice (< -20°C)
- ____No ____Yes

Specimen or Culture Examples – culture slant of Salmonella	Number of tubes or plates	Volume in each tube or plate	Total volume	Proper shipping classification (circle only one)
				Infectious substance, category A or Infectious substance, category B

Shippers Declaration for Dangerous Goods

- Required for packages containing a <u>Category A</u> infectious substance and/or <u>dry ice</u>.
- This is a legal document that declares to the courier the hazardous contents in the package.
- A pdf fillable version of this document is available at www.iata.org/whatwedo/cargo/dgr/Documents /Shippers-Declaration-Open-Format-Fillable.pdf
- Small amounts (≤ 30ml) of sample preservative which are classified as Class 3 (flammable) and/or Class 8 (corrosive) materials are not required to be listed on the declaration.
- Use the proper shipping name and UN number as determined in previous steps.
- The document must be attached to the outside (usually the top) of the package in a document pouch. The entire pouch must fit flat on one side of the package.

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- The document must be completed in **triplicate**, each as an original, with the red stripe down each side of the paper. Two copies are given to the transporter and one copy is kept for your files.
- These documents must be kept by the sender for a minimum of <u>two years</u> from the date of the shipment.

NOTE - Federal Express does not accept hand written Shipper's Declarations. Refer to <u>www.fedex.com/us</u> for details regarding acceptable electronic methods to prepare this form.

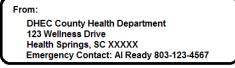
Step 5: Marks and Labels

The following marks and labels must be present, complete, and unobstructed for proper shipping. Any marks or labels which are defaced, altered, or covered up in any way are invalid.

Secondary Packaging

• Address of the sender (with emergency contact information)

• Biohazard Symbol (not required if the symbols is present on the secondary container)





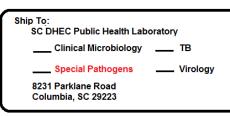
Outside Packaging

- Address of the sender (with emergency contact information)
- Address of the intended recipient

 Mark the intended laboratory



DHEC County Health Department 123 Wellness Drive Health Springs, SC XXXXX Emergency Contact: Al Ready 803-123-4567



• Class 6.2 Hazard Diamond



Category B

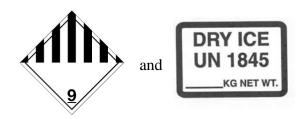
Category A

- UN number and proper shipping name(s)
 - Must be within 6 inches of the 6.2 hazard diamond and on the same side of the box

Category A	"UN 2814 Infectious Substance, Affecting Humans" (technical name)
Category B	"UN 3373 Biological Substance, Category B"
Dry Ice	"UN 1845 Dry Ice"

Outside Packaging (Situational)

- If Dry Ice was used,
 - A class 9 hazard diamond
 - Must be within 6 inches of the 6.2 hazard diamond and on the same side of the box
 - Mark the weight of dry ice, in kilograms. One pound = 2.2 kg
- "Overpack" (if an overpack was used)



Overpack

• Orientation Arrows (if the specimen is liquid)



Emergency Contact Information

- The outside packaging and the secondary container must be marked with an emergency contact name and telephone number for a point of contact of the sender.
- This person must be knowledgeable about the contents of the shipment and be able to provide guidance to first responders who call in case of a spill.
- This number must be immediately answered by the knowledgeable person. An answering service or voicemail is not acceptable.
- An outside contractor that provides this type of service may be used if you have an agreement in place.

G. Special Situations

Newborn Screening Blood Spots

- 1. Allow blood spots to **AIR DRY** thoroughly on a level non-absorbent surface such as a plastic coated test tube rack at least 4 hours at room temperature.
- 2. Place **dried** filter paper form(s) into the provided mailing envelope after filling out sender's information. The mailing address is already provided on the envelope. Mail the specimen within 24 hours. The dried blood spots cannot leak or spill and are exempt from the dangerous goods/hazardous materials shipping regulations. The envelopes provided to ship dried blood spots should not be used to ship any other type of patient specimen.
- 3. Overnight shipping is recommended. Mailing postage and shipping costs are the responsibility of the sender and **will not** be covered by the Public Health Laboratory (PHL).

Suspected Bioterrorism Specimens and Cultures

<u>Prior notification is requested</u> for specimens and/or cultures being sent for "rule out/rule in" testing for bioterrorism agents. Please notify: The Special Pathogens Supervisor, **Amanda Moore, 803-896-0777** <u>before</u> shipping these specimens or cultures. Alternate: Megan Davis, 803-896-0870

<u>Use only UN certified packaging</u>. UN certified shippers specific to the special pathogens program are available upon request. See the section on Requesting Shipping Supplies.

Classification of the infectious substance is the shipper's responsibility and should be based on the available information. We encourage shipping suspected bioterrorism samples as Category A infectious substances as an additional precaution.

If you are shipping a sample suspected, but not confirmed, to be a category A infectious substance, and have elected to ship the material as a category A as an additional safety measure, the packing name must use the text "Infectious Substance, Affecting Humans (suspected category A infectious substance)."

To ensure that the sample is routed to the correct laboratory. <u>Please verify that the Special Pathogens</u> <u>Laboratory has been marked</u> on the "To" shipping label.

Ship To: SC DHEC Public Health Lab	oratory
Clinical Microbiology	TB Virology
8231 Parklane Road Columbia, SC 29223	

[NOTE] Special Pathogens pre-labeled shippers may be obtained by calling 803-896-0777 / 803-896-0773 (limit 2 per laboratory).

H. Contact Information and Support

Public Health Laboratory Shipping Address

Public Health Laboratory 8231 Parklane Road Columbia, SC 29223 Business hours are 8:00 AM to 4:00 PM Monday through Friday, except for state holidays

Public Health Laboratory Contact Information

24/7 telephone number: 803-896-0800

Safety Office: 803-896-0956

Requesting Shipping Supplies: Email: PHL-Supply@dhec.sc.gov

Requesting Shipping and Specimen Collection Supplies

Shipping supplies are available without charge to support DHEC programs. Supplies include:

- Shippers
- Mark and Label Stickers (hazard diamonds, UN numbers, etc.)
- Biohazard bags
- Absorbent materials
- Requisition forms

To request materials, please contact by email at PHL-Supply@dhec.sc.gov.

References for Information in This Document:

IATA *Dangerous Goods Regulations*, 61st edition, effective January 1, 2020 to December 31, 2020

Code of Federal Regulations, 49 CFR Parts 171-180, (US Department of Transportation's Hazardous Materials Regulations)

United States Postal Service, Domestic Mail Manual

Code of Federal Regulations, 42 CFR Part 73, (Select Agent Regulations)

Centers for Disease Control and Prevention, *Guidelines for the* Shipment of Dried Blood Spot Specimen

SECTION V

TEST FEE POLICY

The Public Health Laboratory is only partially supported by legislative appropriations from State Funds. Therefore, we have been authorized to charge fees under certain conditions.

TEST FEES:

A fee is charged for those tests which benefit only the individual patient or which are readily available from private sources.

Exempt from charges:

- A. Test (s) that is not reasonably available from qualified private laboratories.
- B. Test (s) whose result is primarily of epidemiologic or public health significance.
- C. Test (s) performed as a matter of lab policy which is not requested by the physician.
- D. When the patient is medically indigent. In this case, the physician will be billed, but may deduct the charges before remitting. See billing procedures.
- E. Repeat Tests for Newborn Screening. If the Repeat Test was requested by the Public Health Laboratory, i.e., Initial Test was invalid due to early dismissal, or improperly collected specimen or insufficient quantity or other reason, there is no charge for the Repeat Test. *All initial and second tests are subject to the full fee.*

BILLING PROCEDURE

Clients/Customers will be billed monthly by an itemized invoice that includes the patient's name, medical record number, specimen number, date mailed, test(s) performed, and the test fees for each specimen. Billing invoices are generated by Sender and/or Billing numbers. Please note that the Public Health Laboratory **does not** bill Medicaid or any private insurance companies.

Payments:

- 1. Do not send payment with the specimen. Pay only when you receive a billing invoice. Note: Please do not send cash payments.
- 2. The billing invoice will consist of two copies: The remittance copy must be returned with your payment for proper crediting of your account. Please retain the provider copy for your records. On the left side of the billing invoice there is a column headed "Eligible for NON payment." Please place an "X" in this column beside the name of any patient listed who is considered to be unable to pay for the test, i.e. indigent. Place the total charges for patients eligible for non-payment in the indicated space at the upper right-hand corner of the billing invoice and deduct this amount from the total charges. Please indicate the amount remitted on the line designated on the billing invoice. Please make check payable to South Carolina Department of Health and Environmental Control (SCDHEC) and remit to the Attention of: Bureau of Financial Management, PO Box 100103, Columbia, South Carolina 29202-3103. If you have any questions pertaining to your account, please notify the Public Health Laboratory immediately at (803) 896-0800.