



S.C. Department of Health and  
Environmental Control

# Public Health Laboratory

## Guide to Laboratory Services

**SC DHEC Public Health Laboratory**

James A Hayne Building

8231 Parklane Road

Columbia, SC 29223

May 2024

# Guide to Laboratory Services

## Table of Contents

### Section I. Administration

Purpose, Mission Statement, Laboratory Certification.....	I-1
General Information.....	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.....	I-4
Specimen Labeling.....	I-4
Specimen Rejection Policies	
No Specimen Received / No Request Form Received.....	I-5
No Name on Specimen / No Name on Request Form.....	I-5
No Test Requested / Other Missing Information .....	I-5
Mismatched Information.....	I-5
Specimen Broken or Leaked in Transit.....	I-6
Incorrect or Unsatisfactory Specimens Received.....	I-6
Results Reporting Policies.....	
Disease Reporting.....	I-8

### Section II. Alphabetical Test Directory.....II-1

### Section III. Ordering Supplies and Specimen Collection

Ordering Supplies	
Collection Kits.....	III-1
Transport Medium.....	III-1
Shipping Containers.....	III-1
Test Request Forms.....	III-2
County Codes / Sender Numbers / Program Numbers.....	III-9
Specimen Collection Procedures	
QuantiFERON-TB Gold Plus (QFT-Plus) Collection Procedure.....	III-10
Specimen Collection for Culture and ID	
Enteric Pathogens.....	III-12
<i>Neisseria gonorrhoeae</i> .....	III-13
Diphtheria.....	III-15
Mycobacterium (TB).....	III-16
Specimen Collection for Other Tests and Procedures	
<i>Chlamydia/GC &amp; Trichomonas vaginalis</i> by Aptima.....	III-19
Herpes Simplex 1 & 2 Assay.....	III-23

**Section 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.....IV-11  
        c) Shipping at Controlled Temperatures.....IV-14  
    4. Step 4: Shipping Paperwork.....IV-21  
    5. Step 5: Marks and Labels.....IV-23  
Special Situations.....IV-25  
Contact Information and Support.....IV-26

**Section V. Fees and Billing Procedures**

Test Fee Policy and Billing Procedure.....V-1

## **Section I. Administration**

### **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.

### **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.

### **General Information**

#### **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 4:30 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 admin.sc.gov website at:

<https://admin.sc.gov/services/state-human-resources/benefits-leave/holiday-leave>

#### **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 at 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. Holiday and Saturday delivery of Newborn Screening specimens from a hospital or 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.....	(803) 896-4777
Complaints.....	(803) 896-3897 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 request 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.

### Specimen Referral to CDC for Testing

Laboratories wishing to send specimens to the CDC should contact the appropriate division below.

- Microbiology Division at (803)896-0870
- Virology, Serology, and Advanced Molecular Detection (VSA) Division at (803)896-7709

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. The CDC's test directory is available at the link below.

<https://www.cdc.gov/laboratory/specimen-submission/list.html>

### 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 if the sender states clearly what is needed, dates, and signs the report. The patient's record will be updated to reflect the change.

**Specimen Labeling**

Specimens must be labeled with the following information.

1. Patient's name or a unique patient identifier
2. Patient's ID number or date of birth
3. Date and time of collection
4. Specimen source, if applicable

It is strongly recommended and good laboratory practice for the person collecting the specimen to write their initials on the specimen label.

## Specimen Rejection Policies

The following rejection criteria are considered universal, as they apply to all specimens submitted for testing. Specific test related rejections are listed in the Alphabetical Test Directory (Section II) and the Specimen 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 Request 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 request form. After seven days, blood specimens are discarded. Aptima swab specimens are discarded after 60 days and the Aptima urine specimens are discarded after 30 days.

If a specimen is received without a request form and the sender **can be identified** from the specimen label, notification to the sender will be made about the specimen and the need for a request form. The laboratory will complete a request form using all information that is provided from the specimen and assign an accession number to the specimen to allow for a laboratory report to be generated. The report will state that a request form was not received and to please submit one. Specimens are held until either the request form is received, or seven days have passed for blood specimens, 60 days for Aptima swab specimens, and 30 days for Aptima urine specimens.

### **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 Request Form**

When a request 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 request form. The specimen will be tested **ONLY** after the corrected lab request form is received.

### **No Test Requested**

When a specimen is received and there is no test marked on the lab request form, notification will be made to the sender, informing them that no test was requested. The specimen will be tested **ONLY** after the corrected lab request form is received.

### **Other Missing Information**

If other necessary information is missing, all time-critical specimens 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 (i.e. John Doe on request form and J. Doe on specimen tube) with other identifiers and information on the request form matching the specimen. The name on the tube is documented on the request form, the test is performed, and a note is added on the electronic record. 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 laboratory 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, icteric, lipemic, 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 improperly spun in Serum Separator Tubes
- Specimen is nonviable, or decomposed
- Specimen quantity insufficient
- **Specimen for any Aptima Nucleic Acid Amplification Test (NAAT) with more than one patient per biohazard transport bag. Refer to Section II, Alphabetical Test Listing.**

\*Hemolyzed, icteric, or lipemic specimens will be tested if the degree 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). Results will NOT be left on voice mail. A message to call the Public Health Laboratory for results will be left.

### Copies of Test Reports

**Newborn Screening:** Laboratory reports are available 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. To request access, click the link below, complete and sign the DHEC 3268 form, and submit it by mail, fax or electronic scan. Instructions are on page 3 of this form.

<https://scdhec.gov/sites/default/files/media/document/D-3268.pdf>

**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 request form, or to the provider, upon request. To request access to the OpenELIS web portal, click the link below, complete and sign the DHEC 3952 form, and submit it by mail, fax or electronic scan. Instructions are on page 3 of this form.

<https://scdhec.gov/sites/default/files/Library/D-3952.pdf>

### Remailing of Test Reports

If a physician or clinic to which the patient has been referred requests a copy of a test result, 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 at <https://scdhec.gov/sites/default/files/Library/CR-009025.pdf>.

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

## Section II. Alphabetical Test Directory

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 request form 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 <i>Bacillus anthracis</i> .
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 request form 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:	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 abortus</i> , <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 <i>Brucella</i> 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 request form 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 <a href="#">Section I</a> .
Availability:	As needed
Results and Interpretations:	<ul style="list-style-type: none"> <li>- A single serum titer of 1:160 or higher is suggestive of exposure to Brucella at some time. Titer results <math>\geq</math> 1:160 will automatically reflex to a repeat test with the "reduced" serum for acute/convalescence determination.</li> <li>- Cross-reactions may occur between <i>Brucella</i> and <i>F. tularensis</i> antigens and antisera.</li> <li>- 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.</li> </ul>
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 request form 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:	<i>Burkholderia mallei</i> is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Burkholderia mallei</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. 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 request form 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:	<i>Burkholderia pseudomallei</i> is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Burkholderia pseudomallei</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>Burkholderia pseudomallei</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 labeled with patient's full name, and a second patient identifier such as DOB, Specimen #, etc. DHEC request form must be completed in full.
Specimen Volume (optimum):	> 1 mL
Specimen Volume (minimum):	500 $\mu$ L
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
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 Criteria:	Clotted blood, insufficient quantity (QNS), improper temperature. For universal rejections, See <a href="#">Section I</a> .
Availability:	Monday – Friday
Results and Interpretations:	<p>Blood lead levels in children under the age of 16 are considered elevated at or above 3.5 <math>\mu</math>g/dL and chelation treatment should be considered at confirmed blood lead levels of 45 <math>\mu</math>g/dL. The Occupational Safety and Health Administration regulations use a blood lead level of 40 <math>\mu</math>g/dL as cause for written notification and a medical exam, and a blood lead level of 60 <math>\mu</math>g/dL as cause for medical removal from exposure.</p> <p>Levels of concern for cadmium in blood is &gt; 5 <math>\mu</math>g/L.</p> <p>The American Conference of Governmental Industrial Hygienists has a biological exposure index (BEI) of 15 <math>\mu</math>g/L for inorganic mercury in blood.</p>
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 labeled 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 request form 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>For optimal recovery, store stool preserved in transport media in refrigerator at 2-8°C. Ship ALL specimens on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL within 3 days of collection. Ship isolates at 2-30°C.</b>
Specimen Rejection Criteria:	<b>Quantity insufficient, specimen too old, improper transport media or conditions, temperature outside the range of 2-30°C.</b> <b>For universal rejections, See <a href="#">Section I.</a></b>
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:	<b>Important – For optimal recovery, 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. While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>

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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	Specimen – send a 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 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a>
Transport Conditions:	<b>For optimal recovery, store the stool preserved in transport media in refrigerator at 2-8°C. Ship ALL specimens 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.</b>
Specimen Rejection Criteria:	<b>Quantity insufficient, specimen too old, improper transport media or conditions, temperature outside the range of 2-30°C</b> <b>For universal rejections, See <a href="#">Section I</a>.</b>
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.
Purpose of Test:	SC Disease Reportable Conditions required submission, isolate Campylobacter from culture
Method:	bioMerieux VITEK MS
Interfering Substances:	None
Comment:	<b>Important – For optimal recovery, 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. While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>

Test	CANDIDA AURIS	
Synonym:	Candida not Candida albicans, Candida unable to speciate	
Lab Section/Phone:	Clinical Microbiology 803-896-0805	
Days Performed:	Monday – Friday	
Turnaround Time:	10 Business days	
Specimen Required:	Isolate submission on slant	
	<b>Submitter Identification Method</b>	<b>Isolates to Submit</b>
	No identification	A random subset of isolates
	Germ tube only	Germ tube-negative isolates
	Chromagar only	Isolates that are <b>NOT</b> green or blue (so no <i>C. albicans</i> or <i>C. tropicalis</i> or <i>C. dubliniensis</i> )
	API 20C or API 32C	Isolates that are <b>NOT</b> <i>C. albicans</i> or <i>C. tropicalis</i> or <i>C. dubliniensis</i>
	VITEK 2, MicroScan, Phoenix	Isolates that are <b>NOT</b> <i>C. albicans</i> or <i>C. tropicalis</i> or <i>C. dubliniensis</i>
MALDI-TOF or molecular identification	Isolates that are <b>NOT</b> <i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. lusitaniae</i> , <i>C. dubliniensis</i> or <i>C. krusei</i>	
Specimen Identification:	Isolates must be labeled 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 request form must be completed in full.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Isolate of Candida possible auris on slant. See chart below.	
Form:	DHEC 1335-OE - mark “Organism for ID”	
Special Instructions:	Write on form any testing performed	
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>	
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.	
Specimen Rejection Criteria:	Isolate mixed, isolate not a Candida species, improper temperature; For universal rejections, See <a href="#">Section I</a>	
Availability:	Monday – Friday	
Results and Interpretations:	Candida species identified	
Additional Information:	N/A	
Purpose of Test:	To identify possible Candida auris, or other rare newly emerging Candida species.	
Method:	bioMerieux VITEK MS	
Interfering Substances:	N/A	
Comment:	N/A	

Test	CHLAMYDIA (CT)
Synonym:	C. trachomatis Amplified Nucleic Acid Probe, Chlamydia rRNA, CT Aptima <sup>®</sup>
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Monday-Friday
Turnaround Time:	3 - 5 Business Days
Specimen Required:	<p><b>Swab specimen (for patients ≥ 14)</b> : Endocervical, rectal and pharyngeal swab, and/or male urethral specimens collected using the Aptima<sup>®</sup> Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Purple label/Blue collection swab).</p> <p><b>Vaginal specimens (for patients ≥14)</b>: Vaginal specimens collected using the Aptima<sup>®</sup> Multitest Swab Specimen Collection kit. (Orange label/ Pink collection swab).</p> <p><b>Urine specimen</b>: 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<sup>®</sup> Urine Specimen Transport tube (Yellow label) with the provided pipet so that the urine level falls within the two lines on the transport tube labeled: “fill area”. Urine must be transferred to the Urine Collection Tubes within 24 hours. See .</p>
Specimen Identification:	Specimens must be labeled with patient’s first and last name, and a second patient identifier such as DOB, MCI #, or Specimen #. DHEC request form must be completed.
Specimen Volume (minimum/optimum):	Urine should be collected up to fall within the “fill area” lines. Swab collection kits should contain an adequate amount of transport media for testing.
Collect:	See specimen requirements.
Form:	DHEC 1332, Test – GC and CT rRNA, Test- Chlamydia rRNA only, Test- GC/Chlamydia/Trich. Vaginalis rRNA
Special Instructions:	<p>Only use Aptima<sup>®</sup> specimen collection kit (Unisex swab, Multitest swab, or urine).</p> <p><b>Must pack only one patient’s specimen(s) per biohazard transport bag to avoid cross-contamination.</b></p>
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>Ship only one patient’s specimen(s) per biohazard transport bag.</b> 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 ≤ -20 °C and ship on dry ice to maintain at a temperature of ≤20°C until received at the PHL.
Specimen Rejection Criteria:	<p>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; swab specimen for patients &lt;14 years old.</p> <p><b>**Specimen with more than one patient’s specimen(s) per biohazard transport bag.**</b></p> <p>For universal rejections, See <a href="#">Section I.</a></p>
Availability:	Monday - Friday
Results and Interpretations:	<p>Positive: C. trachomatis rRNA detected.</p> <p>Negative: C. trachomatis rRNA not detected.</p> <p>Indeterminate: Inconclusive for the presence of C. trachomatis rRNA.</p>
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:	<b>For patients &lt; 14 years old urine is the only acceptable specimen.</b>

Test	CORYNEBACTERIUM DIPHTHERIAE, CULTURE & ID
Synonym:	<i>C. diphtheriae</i>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 Criteria:	Transport swab not used or ampule in transport swab not crushed. Culture: must be received within 24 hours of collection unless submitted on Loeffler's medium. Specimens received at improper temperature. For universal rejections, see <a href="#">Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
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:	Upper respiratory specimens (nasopharyngeal (NP), oropharyngeal, anterior nasal, and mid-turbinate nasal swabs, nasopharyngeal aspirate) and bronchoalveolar lavage (BALS) specimens																		
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.																		
Specimen Volume (optimum):	Swab in 2 - 3 mL of viral or universal transport media formulated for viral collection.																		
Specimen Volume (minimum):	Swab in 1 mL of viral or universal transport media formulated for viral collection .																		
Collect:	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. Place swabs immediately into sterile tubes containing 2 - 3 mL of viral or universal transport media formulated for viral collection.																		
Form:	DHEC 1335-OE																		
Special Instructions:	N/A																		
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> if needed.																		
Transport Conditions:	Store specimens at 2 - 8°C for up to 72 hours after collection. If specimens will ship without delay, ship overnight on frozen cold packs to maintain 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 ship specimens on dry ice to maintain temperature until received at the PHL.																		
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I</a> .																		
Availability:	5 days/week																		
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;"><b>Hologic Panther Fusion SARS-CoV-2 Assay</b></td> </tr> <tr> <td>Detected</td> <td>SARS-CoV-2 detected</td> </tr> <tr> <td>Not Detected</td> <td>SARS-CoV-2 not detected</td> </tr> <tr> <td>Invalid</td> <td>Recollect specimen</td> </tr> <tr> <td colspan="2" style="text-align: center;"><b>ThermoFisher COVID-19 Real Time PCR Assay Multiplex, ThermoFisher TaqPath</b></td> </tr> <tr> <td>Detected</td> <td>Positive SARS-CoV-2</td> </tr> <tr> <td>Not Detected</td> <td>SARS-CoV-2 not detected</td> </tr> <tr> <td>Inconclusive</td> <td>Recollect specimen</td> </tr> </tbody> </table>	Result	Interpretation	<b>Hologic Panther Fusion SARS-CoV-2 Assay</b>		Detected	SARS-CoV-2 detected	Not Detected	SARS-CoV-2 not detected	Invalid	Recollect specimen	<b>ThermoFisher COVID-19 Real Time PCR Assay Multiplex, ThermoFisher TaqPath</b>		Detected	Positive SARS-CoV-2	Not Detected	SARS-CoV-2 not detected	Inconclusive	Recollect specimen
Result	Interpretation																		
<b>Hologic Panther Fusion SARS-CoV-2 Assay</b>																			
Detected	SARS-CoV-2 detected																		
Not Detected	SARS-CoV-2 not detected																		
Invalid	Recollect specimen																		
<b>ThermoFisher COVID-19 Real Time PCR Assay Multiplex, ThermoFisher TaqPath</b>																			
Detected	Positive SARS-CoV-2																		
Not Detected	SARS-CoV-2 not detected																		
Inconclusive	Recollect specimen																		
Additional Information:	Fact Sheets for this emergency use authorized (EUA) assay for patients and providers can be accessed at the following link: <a href="https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2">https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2</a>																		
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).																		
Method:	<ul style="list-style-type: none"> <li>ThermoFisher COVID-19 Real Time PCR Assay Multiplex, ThermoFisher TaqPath</li> <li>Hologic Panther Fusion SARS-CoV-2 Assay</li> </ul>																		
Interfering Substances:	N/A																		
Comment:	N/A																		

Test	CRE, CRPA, CRAB
Synonym:	<p><b>CRE = Carbapenem-resistant Enterobacterial</b> (former Enterobacteriaceae), Ship All, Do Not send duplicates. Only one isolate per patient regardless of source. Includes the following: <i>E.coli</i>, <i>Enterobacter</i>, <i>Klebsiella</i>, <i>Proteus</i>, <i>Providencia</i>, <i>Serratia</i>, and <i>Morganella</i>. (With the exceptions of <i>Serratia</i> which are both resistant to carbapenems and sensitive to a 3<sup>rd</sup> generation cephalosporin and <i>Enterobacter</i> 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.</p> <p>CRPA = Carbapenem resistant <i>Pseudomonas aeruginosa</i> <b>Send all non-mucoid <i>P. aeruginosa</i> resistant to imipenem, meropenem, or doripenem AND Not Susceptible to cefepime or ceftazidime.</b> Do not send duplicates.</p> <p>CRAB = <b>Carbapenem resistant Acinetobacter baumannii complex</b> Send in all pan-resistant <i>Acinetobacter</i> spp.</p>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
Collect:	Carbapenem-resistant Enterobacteriaceae and <i>Acinetobacter baumannii</i> from all specimen types are required to be submitted.
Form:	DHEC request form 1335-OE, check "CRE/CRPA/CRAB"
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> 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 <a href="#">Section I</a>
Availability:	Monday - Friday
Results and Interpretations:	Organism identification will be confirmed and reported, mCIM test will be set up and reported, all Positive and indeterminate 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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
Collect:	N/A
Form:	DHEC request form 1335-OE
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> , 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 Criteria:	<b>Specimen preserved in PVA</b> , improper labeling, improper temperature. For universal rejections, see <a href="#">Section I</a> .
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 parvum</i> 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	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 (minimum):	Communicated during consultation.
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 request form 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:	<b>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 <i>List of Reportable Conditions</i>. 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.</b>
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:	<ul style="list-style-type: none"> <li>- Final results are verbally communicated to the sender to ensure correct interpretation. Final reports are provided via fax or e-mail.</li> <li>- The definitive identification of Ebola virus requires additional testing to be performed by CDC.</li> <li>- Negative results do not preclude Ebola virus infection and should not be used as the sole basis for patient management decisions.</li> </ul>
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:	<p><b>GI Panel, GI Outbreak</b></p> <p><b>Bacteria:</b> <i>Campylobacter</i>, <i>Clostridium difficile</i> toxin A/B, <i>Plesiomonas shigelloides</i>, <i>Salmonella</i>, <i>Vibrio species</i>, <i>Vibrio cholerae</i>, <i>Yersinia enterocolitica</i>;</p> <p><b>Diarrheagenic E. coli/Shigella:</b> <i>Enteroaggregative E. coli (EAEC)</i>, <i>Enteropathogenic E. coli (EPEC)</i>, <i>Enterotoxigenic E. coli (ETEC) lt/st</i>. Shiga-like producing <i>E. coli (STEC) stx1/stx2</i>, <i>E. coli O157</i>, <i>Shigella/Enteroinvasive E. coli (EIEC)</i>;</p> <p><b>Parasites:</b> <i>Cyclospora cayetanensis</i>, <i>Cryptosporidium</i>, <i>Entamoeba histolytica</i>, <i>Giardia lamblia</i>;</p> <p><b>Viruses:</b> Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus</p>
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 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 request form.
Specimen Volume (optimum):	Walnut sized portion of 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 4 days of collection.
Specimen Rejection Criteria:	Unpreserved stool and specimen preserved in PVA, improper temperature; For universal rejections, see <a href="#">Specimen Rejection Policies Criteria in Section I</a> .
Availability:	N/A
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	To detect the presence of enteric pathogens in a GI outbreak situation.
Method:	FilmArray GI panel (PCR)
Interfering Substances:	N/A
Comment:	N/A

Test	ENTERIC PATHOGENS CULTURE
Synonym:	Fecal culture, stool culture, enteric culture, <i>Salmonella</i> culture, <i>Shigella</i> culture, <i>E coli 0157</i> culture, <i>Campylobacter</i> culture, <i>Vibrio</i> culture, toxin culture for <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , and <i>Clostridium perfringens</i> .
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum/minimum):	N/A
Collect:	Use stool transport such as Cary Blair or ParaPak
Form:	DHEC request form 1335-OE, check "Enteric Culture"
Special Instructions:	Specimen must be maintained at 2-8°C.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>For optimal recovery, 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.</b>
Specimen Rejection Criteria:	<b>Quantity insufficient; specimen too old; improper transport media or conditions, temperature outside the range of 2-30°C</b> <b>For universal rejections, refer to <a href="#">Section I.</a></b>
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	N/A
Purpose of Test:	Culture and identification of the following pathogens: <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , <i>Vibrio</i> , Shiga-toxin producing <i>Escherichia coli</i> , <i>Aeromonas</i> , <i>Yersinia enterocolitica</i> , <i>Plesiomonas shigelloides</i> , <i>Staphylococcus aureus</i> , <i>Bacillus cereus</i> , <i>Clostridium perfringens</i> .
Method:	Traditional culture, conventional biochemicals, serotyping, bioMerieux VITEK MS
Interfering Substances:	Do not use PVA
Comment:	<b>Enteric Pathogen culture testing is available for outbreaks as determined by the SC DHEC DADE (Division of Acute Disease Epidemiology). Epidemiology to note on request form which pathogens are suspected. For optimal recovery, maintain specimen at 2-8°C and ship to be received at the PHL in the temperature range of 2-8°C. While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>

Test	ENTERIC PATHOGENS submitted by 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 <i>Escherichia coli</i> .
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 labeled 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 request form 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 request form 1335-OE, check "Enteric Culture"
Special Instructions:	Specimen must be maintained at 2-8°C.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>For optimal recovery, 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.</b>
Specimen Rejection Criteria:	<b>Quantity insufficient; specimen too old; improper transport media or conditions, temperature outside the range of 2-30°C</b> <b>For universal rejections, see <a href="#">Section I.</a></b>
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: <i>Salmonella</i> , <i>Shigella</i> , <i>Campylobacter</i> , <i>Vibrio</i> , Shiga-toxin producing <i>Escherichia coli</i> , <i>Aeromonas</i> , <i>Yersinia enterocolitica</i> , <i>Plesiomonas shigelloides</i> .
Method:	Traditional culture, conventional biochemicals, serotyping, bioMerieux VITEK MS
Interfering Substances:	Do not use PVA
Comment:	<b>Important – For optimal recovery, 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. While not ideal, specimens received with a temperature range of 2-30°C will be accepted.</b>

Test	ESCHERICIA COLI – SHIGA-TOXIN PRODUCING
Synonym:	<i>E. coli</i> O157:H7, <i>E. coli</i> 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 labeled 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 request form must be completed in full.
Specimen Volume (optimum/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 <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
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 <a href="#">Section I.</a>
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 <i>E. coli</i>
Method:	Immunochemical 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 <a href="#">Food Protection in the county health department</a> . <b>The laboratory does not accept specimens from patients.</b>

<b>Test</b>	<b>FRANCISELLA TULARENSIS</b>
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 (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>F. tularemia</i> " for "Suspect Agent." DHEC request form 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:	<i>Francisella tularensis</i> is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Francisella tularensis</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>F. tularensis</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	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 labeled 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 request form must be completed in full.
Specimen Volume (min. and optimum):	N/A
Collect:	N/A
Form:	DHEC request form 1335-OE, check “Cryptosporidium Antigen”
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 Criteria:	<b>Specimen preserved in PVA</b> , improper labeling, improper temperature; For universal rejections, refer to <a href="#">Section I</a> .
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 parvum</i> 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:	<b>Giardia antigen testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology (DADE).</b>



Test	GI OUTBREAK							
Synonym:	Norwalk Virus, Norovirus PCR, Enteric Outbreak, GI Panel							
Lab Section/Phone:	Virology & Rabies, 803-896-0819							
Days Performed:	Monday - Friday							
Turnaround Time:	N/A							
Specimen Required:	<p>Two separate collections are required:</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. For Enteric Pathogens Culture and GI Panel by FilmArray, a 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.</li> </ol>							
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on both specimens and request form.							
Specimen Volume (optimum):	N/A							
Specimen Volume (minimum):	<ol style="list-style-type: none"> <li>1. For Norovirus Detection by Real-Time PCR, a peanut-sized or tablespoon volume of fresh diarrheal stool.</li> <li>2. For Enteric Pathogens Culture and GI Panel by FilmArray, a walnut sized portion of feces or 5 - 10 mL of liquid stool in stool transport.</li> </ol>							
Collect:	<ol style="list-style-type: none"> <li>1. For stool for Norovirus Detection by Real-Time PCR, use a sterile, screw capped, leak-proof, 50 mL conical tube or urine container.</li> <li>2. For <a href="#">Enteric Pathogens Culture</a> and GI Panel by FilmArray, use transport tube with Cary-Blair medium included in Enteric Kit provided by the Public Health Laboratory</li> </ol>							
Form:	DHEC 1335-OE; When ordering this test panel, please write GI Outbreak on the submission form.							
Special Instructions:	Use of this test is restricted to Epidemiological 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .							
Transport Conditions:	Store and ship to be maintained at 2-8°C until received at the PHL.							
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies Criteria in Section I</a> .							
Availability:	N/A							
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>Detected</td> <td>Organism detected</td> </tr> <tr> <td>Not detected</td> <td>No organism detected</td> </tr> </tbody> </table>	Result	Interpretation	Detected	Organism detected	Not detected	No organism detected	
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 <i>Salmonella</i> , <i>E. coli</i> O157:H7 or <i>Shigella</i> are suspected, please specify.							
Purpose of Test:	<i>GI Outbreak testing is available for outbreaks as determined by the SC DHEC Division of Acute Disease Epidemiology.</i>							
Method:	<ol style="list-style-type: none"> <li>1. Norovirus: Real-time reverse transcriptase polymerase chain reaction (real-time RT-PCR)</li> <li>2. BioFire GI Panel: Multiplex PCR Panel</li> <li>3. Enteric Pathogens Culture: Traditional culture, conventional biochemicals, serotyping, bioMerieux VITEK MS</li> </ol>							
Interfering Substances:	N/A							
Comment:	N/A							

Test	GONOCOCCAL (GONORRHEA) CULTURE
Synonym:	GC culture, <i>Neisseria gonorrhoeae</i> 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 labeled 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 request form must be completed in full. <b>Do Not place label over clear glass viewing area, layer patient label over existing label.</b>
Specimen Volume (optimum):	See <a href="#">N. gonorrhoeae Collection Procedure, Section III.</a>
Specimen Volume (minimum):	N/A
Collect:	Bring transgrow bottle to room temperature before inoculating. <u>Hold bottle 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:	<b>Collect specimens Monday thru Wednesday ONLY.</b>
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a> 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. <b>DO NOT REFRIGERATE AFTER INOCULATION.</b>
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 <a href="#">Section I.</a>
Availability:	Monday - Wednesday
Results and Interpretations:	<i>Neisseria gonorrhoeae</i> isolated or not isolated.
Additional Information:	<b>If Drug Treatment failure is expected, notate this on DHEC request form. If <i>Neisseria gonorrhoeae</i> is isolated, isolate will be sent out for Antimicrobial Susceptibility Testing (AST).</b>
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:	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:	<p><b>Swab specimen:</b> Endocervical, rectal and pharyngeal swab, and/or male urethral specimens in Aptima® Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Purple Label/blue collection swab).</p> <p><b>Vaginal specimens:</b> Vaginal specimens are collected using the Aptima® Multitest Swab Specimen Collection kit. (Orange label/ Pink collection swab).</p> <p><b>Urine specimens:</b> 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 (yellow label) with the provided pipet 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.</p>
Specimen Identification:	Specimens must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, or Specimen #. DHEC request form 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 Required above.
Form:	DHEC 1332 Test-GC/CT rRNA, Test-GC rRNA only, Test-GC/Chlamydia/Trich. vaginalis rRNA
Special Instructions:	Only use Aptima specimen collection kit (Unisex swab, Multitest swab, or urine). <b>Must pack only one patient's specimen(s) per biohazard transport bag to avoid cross-contamination.</b>
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>Ship only one patient's specimen(s) per biohazard transport bag.</b> 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 ≤ -20 °C and ship on dry ice to maintain at temperature of ≤ -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; swab specimen for a patient < 14. <b>**Specimen with more than one patient's specimen(s) per biohazard transport bag.**</b> For universal rejections, See <a href="#">Section I.</a>
Availability:	Monday - Friday
Results and Interpretations:	Positive: N. gonorrhoeae rRNA detected. Negative: N. gonorrhoeae rRNA not detected. Indeterminate: Inconclusive for the presence of N. gonorrhoeae rRNA.
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
Interfering Substances:	N/A
Comment:	<b>For patients &lt; 14 years old urine is the only acceptable specimen.</b>

Test	HAEMOPHILUS INFLUENZAE
Synonym:	<i>H. influenzae</i>
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 labeled 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 request form 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 request 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Section I</a> .
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 <i>Haemophilus influenzae</i> and serotype.
Method:	bioMerieux VITEK MS, serotyping
Interfering Substances:	N/A
Comment:	N/A

<b>Test</b>	<b>HEMOGLOBIN (Hgb) ELECTROPHORESIS</b>
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
Method:	Iso-electric focusing and/or High-Performance Liquid Chromatography
Interfering Substances:	N/A
Comment:	N/A

Test	HEPATITIS A SEROLOGY (IgG & IgM)
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
Turnaround Time:	1 - 5 Business Days
Specimen Required:	Serum
Specimen Identification:	Specimens must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
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 (803-896-7709) 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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; 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 <a href="#">Specimen Rejection Policies</a> .
Availability:	Testing performed as needed.
Results and Interpretations:	Reactive: HAV IgG antibodies detected Nonreactive: HAV IgG antibodies not detected. Reactive: HAV IgM antibodies detected. Nonreactive: HAV IgM antibodies not detected. Grayzone: Borderline for the presence of HAV IgM antibodies.
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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332, Test- Hepatitis B Core IgM Antibody
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
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 <a href="#">Specimen Rejection Policies.</a>
Availability:	As needed
Results and Interpretations:	Reactive: HBc IgM antibodies detected. Nonreactive: HBc IgM antibodies not detected. Grayzone: Borderline for the presence of HBc IgM antibodies.
Additional Information:	*Test automatically performed on patients with reactive anti-HBc total antibody in absence of reactive HBsAg or anti-HBs on Diagnostic Profile ; automatically performed on patients with reactive Hepatitis B surface antigen on Diagnostic Test Panel.
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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332, Test - Hepatitis B Anti-Core
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.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies</a> .
Availability:	As needed
Results and Interpretations:	Reactive: HBc antibodies detected. Nonreactive: HBc antibodies not detected.
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; anti-core IgM 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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form must be completed in full.
Specimen Volume (optimum):	2 mL of serum
Specimen Volume (minimum):	2 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.
Form:	DHEC 1332, Test- Hepatitis B Diagnostic Profile
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.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies</a> .
Availability:	As needed
Results and Interpretations:	See results and interpretations for HBsAg, anti-HBs, and anti-HBc.
Additional Information:	Includes tests for HBsAg, anti-HBs and anti-HBc; 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; 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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332, Test- Hepatitis B Immune Status/Post-Immune
Special Instructions:	Tests include Anti-HBs and Anti-HBc
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies</a> .
Availability:	As needed
Results and Interpretations:	See results and interpretations for anti-HBs and anti-HBc.
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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332, Test- Hepatitis B Surface Antibody
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies</a> .
Availability:	Monday-Friday
Results and Interpretations:	Reactive: HBs antibodies detected. Non Reactive: HBs antibodies not detected.
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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332, Test- Hepatitis B Surface Antigen
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies</a> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive: HBsAg Qualitative Confirmatory Assay to follow. Non Reactive: HBs Ag not detected.
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 labeled with the patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form must be completed in full.
Specimen Volume (optimum):	3 mL of serum
Specimen Volume (minimum):	0.25 mL of serum (if reactive, a total of 2.25 mL serum needs to be collected 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.
Form:	DHEC 1332, Hepatitis C Antibody (HCV)
Special Instructions:	To allow reflex testing of Positive and Grayzone Hepatitis C Ab results, collect blood in a serum separator tube, spin down within 6 hours of collection. See Hepatitis C Quantitation by PCR (RNA).
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 ; 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 <a href="#">Specimen Rejection Policies</a> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive: HCV antibodies detected; Viral load to follow. Non Reactive: HCV antibodies not detected. Grayzone: Borderline for the presence of HCV antibodies. Viral load to follow.
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 Aptima HCV Quant Dx Viral Load test, provided proper storage conditions and special instructions are followed.

Test	HEPATITIS C QUANTITATION BY PCR (RNA)																							
Synonym:	HCV RNA 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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.																							
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. 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 and arrive at the PHL within 5 days of collection.																							
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .																							
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 <a href="#">Specimen Rejection Policies</a> .																							
Availability:	Monday - Friday																							
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> <th>IU/ML</th> <th>Log 10</th> </tr> </thead> <tbody> <tr> <td>Not Detected</td> <td>HCV not detected</td> <td>N/A</td> <td>N/A</td> </tr> <tr> <td>Detected</td> <td>HCV RNA detected below the lower limit of quantification of the assay.</td> <td>&lt;10</td> <td>&lt;1.00</td> </tr> <tr> <td>Detected</td> <td>HCV RNA detected</td> <td>10-10,000,000</td> <td>1.00-7.00</td> </tr> <tr> <td>Detected</td> <td>HCV RNA detected above the upper limit of quantification of the assay.</td> <td>&gt;10,000,000</td> <td>&gt;7.00</td> </tr> </tbody> </table>				Result	Interpretation	IU/ML	Log 10	Not Detected	HCV not detected	N/A	N/A	Detected	HCV RNA detected below the lower limit of quantification of the assay.	<10	<1.00	Detected	HCV RNA detected	10-10,000,000	1.00-7.00	Detected	HCV RNA detected above the upper limit of quantification of the assay.	>10,000,000	>7.00
Result	Interpretation	IU/ML	Log 10																					
Not Detected	HCV not detected	N/A	N/A																					
Detected	HCV RNA detected below the lower limit of quantification of the assay.	<10	<1.00																					
Detected	HCV RNA detected	10-10,000,000	1.00-7.00																					
Detected	HCV RNA detected above the upper limit of quantification of the assay.	>10,000,000	>7.00																					
Additional Information:	N/A																							
Purpose of Test:	Used to aid in the detection and quantitation of HCV infections																							
Method:	Nucleic acid amplification test (RT-TMA)																							
Interfering Substances:	N/A																							
Comment:	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:	Multitest swab specimens from anogenital lesions ONLY, placed in the Aptima <sup>®</sup> Multitest Swab Specimen Collection Kit (Orange Tube). See <a href="#">Ordering Supplies in Section III, p.1</a>		
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.		
Specimen Volume (optimum):	N/A		
Specimen Volume (minimum):	N/A		
Collect:	Multitest swab specimens from anogenital lesions ONLY placed in Aptima Multitest Swab Specimen Collection Kit (Orange Tube). See <a href="#">Specimen Collection Procedure on p.III-23.</a>		
Form:	DHEC 1335-OE		
Special Instructions:	<b>Must pack only one patient's specimen(s) per biohazard transport bag to avoid cross-contamination.</b>		
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>		
Transport Conditions:	<b>Ship only one patient's specimen(s) per biohazard transport bag.</b> Store and ship within one week of collection; maintain specimen at 2-30°C until received at the PHL.		
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I.</a> <b>**Specimen with more than one patient's specimen(s) per biohazard transport bag.**</b>		
Availability:	Monday - Friday		
Results and Interpretations:	<b>HSV-1 Result</b>	<b>HSV-2 Result</b>	<b>Interpretation</b>
	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 the anogenital region.		
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)		
Interfering Substances:	N/A		
Comment:	N/A		

Test	HIV-1 PCR QUANTITATIVE (RNA)
Synonym:	HIV-1 RNA Viral Load Test
Lab Section/Phone:	Diagnostic Serology, 803-896-0811
Days Performed:	Twice weekly
Turnaround Time:	1 - 5 Business Days
Specimen Required:	<p>Minimum 2.0 mL EDTA anticoagulated plasma. 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.</p> <p>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.</p>
Specimen Identification:	Specimens must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form must be completed in full.
Specimen Volume (optimum):	2.0 mL of plasma
Specimen Volume (min.):	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, Test- HIV-1 Quant. RNA, Test-HIV Viral Load
Special Instructions:	The specimen MUST BE kept at 2-8 °C. Label outside of shipping container as "HIV-1". Make sure the label will not come off. Please check with the laboratory during a holiday to ensure that it will arrive to the testing laboratory within 3 days of collection or freeze the specimen at ≤ - 20°C. Ship on dry ice to maintain specimen at ≤ - 20°C until received at the PHL.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 ≤ - 20°C and then ship on dry ice to maintain specimen at ≤ - 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 <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	As needed



Test	HIV-1 PCR QUANTITATIVE (RNA) continued			
Results and Interpretations:	Result	Interpretation	copies/mL	Log 10
	Not Detected	HIV-1 RNA not detected.	N/A	N/A
	Detected	HIV-1 RNA detected, but not quantified. HIV-1 RNA concentration is below the lower limit of quantification of the assay.	<30	<1.47
	Detected	HIV-1 RNA is detected.	1.47-10,000,000	1.47-7.00
	Detected	HIV-1 RNA detected above the upper limit of quantification of the assay.	>10,000,000	>7.00
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 Identification:	Specimens must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form must be completed in full.
Specimen Volume (optimum):	1.5 mL of serum
Specimen Volume (minimum):	1 mL of serum
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.
Form:	DHEC 1332, Test- HIV-1/HIV-2, HIV
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive: Reactive for HIV Ag/Ab. Reflex supplemental assay to follow. Nonreactive: Nonreactive for HIV Ag/Ab.
Additional Information:	Repeatedly reactive specimens are confirmed by Geenius HIV 1 /2. Repeatedly reactive specimens not confirmed by Geenius HIV 1/2 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:	HIV NAT testing is performed by a reference laboratory.

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 (optimum):	Determined during Special Pathogen notification.
Specimen Volume (minimum):	Determined during Special Pathogen notification.
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 <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 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 <i>Influenza A:H5N1</i> 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 <i>Influenza A:H5N1</i> 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 (optimum):	Determined during Special Pathogen notification.
Specimen Volume (minimum):	Determined during Special Pathogen notification.
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 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 <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 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 <i>Influenza A:H7N9</i> virus requires additional testing to be performed by CDC.
Additional Information:	Testing for <i>Influenza A: H5N1</i> will be concurrent with <i>Influenza A:H7N9</i> testing
Purpose of Test:	To presumptively detect <i>Influenza A:H7</i> 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 or universal transport media formulated for viral collection media.
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.
Specimen Volume (optimum):	Swab specimen (see above) placed in 2 - 3 mL viral or universal transport media formulated for viral collection.
Specimen Volume (min):	N/A
Collect:	Screw-capped tube of viral or universal transport media formulated for viral collection.
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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 ≤ -20°C and ship on dry ice to maintain the temperature of ≤ -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. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
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
Comment:	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:	<p>1 mL whole blood collected from venipuncture; 500 µL 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.</p> <p><b>Venous Specimens:</b> 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. <b>Capillary Specimens:</b> 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.</p>
Specimen Identification:	Specimen container must be labeled with patient's full name, and a second patient identifier such as DOB, Specimen #, etc. DHEC request form 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
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	<p>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.</p> <p>Action levels for blood Pb in children and adults print on result reports. Screening (finger stick/heel stick) levels <math>\geq 3.5</math> µg/dL requires venipuncture confirmation.</p>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	1 mL
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 request form 1335-OE form, check "Legionella Urine Antigen"
Special Instructions:	N/A
Packing and Shipping*:	Urine is considered an Infectious substance. See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	<b>Negative Test:</b> 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 <i>Legionella pneumophila</i> . <b>Positive Test:</b> 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 <i>Legionella pneumophila</i> 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 <i>Legionella pneumophila</i> serogroup 1 infection. A negative result does not preclude infection with <i>Legionella pneumophila</i> 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:	<i>Listeria monocytogenes</i>
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 labeled 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 request form 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 request form, check "Organism for ID"
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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:	Culture non-viable; culture mixed; improper temperature. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	<i>Listeria monocytogenes</i> isolated or not isolated.
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



<b>Test</b>	<b>MALARIA ANTIGEN TEST (BINAXNOW)</b>
Synonym:	<i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium ovale</i> , <i>Plasmodium malariae</i>
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 (optimum):	3 - 5 mL
Specimen Volume (minimum):	3 mL
Collect:	N/A
Form:	Form 1335-OE; In "Serological Testing" box, check "Malaria" DHEC request form 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 <b>THIS TEST IS REFERRED TO AND PERFORMED BY the CDC.</b>
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):	<b>Blood smears:</b> 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 request form 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
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 <a href="#">Specimen Rejection Policies in Section I.</a>
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 or universal transport media formulated for viral collection for storage and shipment.											
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.											
Specimen Volume (optimum):	N/A											
Specimen Volume (minimum):	N/A											
Collect:	Sterile, leak-proof, screw-cap tube containing viral or universal transport media formulated for viral collection.											
Form:	DHEC 1335-OE											
Special Instructions:	All submissions require prior notification to the Virology & Rabies Laboratory at (803)896-0819 before shipment..											
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .											
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 <b>Rejection</b> 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 viral or universal transport media formulated for viral collection; non-frozen specimens received more than 72 hours after collection. Specimens received at improper temperature.; See <a href="#">Specimen Rejection Policies in Section I</a> .											
Availability:	Monday - Friday, weekend and holiday testing approved on a case-by-case basis											
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>Detected</td> <td>Measles RNA detected by RT-PCR</td> </tr> <tr> <td>Not Detected</td> <td>Unable to detect Measles RNA by RT-PCR</td> </tr> <tr> <td>Inconclusive</td> <td>Indeterminant: Unable to rule out the presence of Measles RNA</td> </tr> <tr> <td>Unable to detect Human DNA. Results suggest sub-optimal specimen collection, transport, and/or storage conditions.</td> <td>Recollect specimen</td> </tr> </tbody> </table>	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	
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:	Only specimens submitted as part of an epidemiological investigation will be accepted											
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											
Comment:	N/A											

Test	MEASLES (Rubeola) VIRUS SEROLOGY-IMMUNE STATUS/DIAGNOSTIC	
Synonym:	Measles Serology IgG	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	N/A	
Turnaround Time:	IgG: 10 days	
Specimen Required:	Serum	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.	
Specimen Volume (optimum):	2 mL serum	
Specimen Volume (minimum):	1 mL serum	
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. different container/tube). Please follow manufacturer's guidelines.	
Form:	DHEC 1332	
Special Instructions:	Rubeola IgG does not require notification.	
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .	
Transport Conditions:	Store at 2 - 8°C and ship within 36 hours of collection to maintain specimen at 2 - 8°C until received by the PHL. If shipment is delayed longer than 36 hours, store specimen at ≤ -20°C and ship on dry ice to maintain at temperature of ≤ -20°C until received at the PHL.	
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I</a> .	
Availability:	IgG: As requested	
Results and Interpretations:	<b>Result</b>	<b>Interpretation</b>
	<b>Measles IgG</b>	
	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.	
Method:	EIA (Enzyme Immunoassay)	
Interfering Substances:	N/A	
Comment:	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 labeled with patient's full name, and a second patient identifier such as DOB, Specimen #, etc. DHEC request form must be completed in full.
Specimen Volume (optimum):	2 - 5 mL
Specimen Volume (minimum):	500 $\mu$ L
Collect:	Sterile urine cups
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	Urine specimens stored at $\leq -20^{\circ}\text{C}$ and transported frozen by packing on dry ice to maintain $\leq -20^{\circ}\text{C}$ temperature until received at the PHL is preferred, when possible. Urine may also be stored at $2-8^{\circ}\text{C}$ and shipped on frozen cold packs to maintain specimens at $2-8^{\circ}\text{C}$ until receipt at the PHL. Urines stored and shipped at $2-8^{\circ}\text{C}$ must be received at the PHL within 10 days of collection.
Specimen Rejection Criteria:	Insufficient quantity (QNS); improper collection container; improper temperature. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I.</a>
Availability:	Monday – Friday
Results and Interpretations:	N/A
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 request form 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 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 request form 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:	<b>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.</b>
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.

<b>Test</b>	<b>MUMPS RNA DETECTION BY REAL-TIME RT PCR</b>	
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 occur within 3 days of symptom onset. Use swabs with polyester or nylon tips and aluminum or plastic shafts. DO NOT USE cotton, wood, or calcium alginate swabs. Place swab in viral or universal transport media formulated for viral collection for storage and shipment.	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.	
Specimen Volume (optimum):	N/A	
Specimen Volume (minimum):	N/A	
Collect:	Buccal swab placed in a sterile, leak-proof, screw-cap tube containing viral or universal transport media formulated for viral collection.	
Form:	DHEC 1335-OE	
Special Instructions:	All submissions require prior notification to the Virology & Rabies laboratory (803) 896-0819 before specimen submission. Only specimens submitted as part of an epidemiological investigation will be accepted.	
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .	
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:	Swabs with cotton or calcium alginate tips or wooden shafts; Specimens collected more than 14 days after symptom onset; Specimens shipped without viral or universal transport media formulated for viral collection; non-frozen specimens received more than 72 hours after collection. Specimens received at the improper temperature. See <a href="#">Specimen Rejection Policies in Section I</a> .	
Availability:	Monday - Friday, weekend and holiday testing approved on a case-by-case basis	
Results and Interpretations:	<b>Result</b>	<b>Interpretation</b>
	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 Mumps RNA
	Unable to detect Human DNA. Results suggest sub-optimal specimen collection, transport, or storage conditions.	Recollect specimen
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	



<b>Test</b>	<b>MUMPS VIRUS SEROLOGY IgG</b>													
Synonym:	Parotitis Epidemica antibodies													
Lab Section/Phone:	Virology & Rabies, 803-896-0819													
Days Performed:	Per request													
Turnaround Time:	IgG: 10 days													
Specimen Required:	Serum													
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.													
Specimen Volume (optimum):	2 mL serum													
Specimen Volume (minimum):	1 mL serum													
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.													
Form:	DHEC 1332													
Special Instructions:	None													
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .													
Transport Conditions:	Store at 2-8°C and ship within 36 hours of collection to maintain specimen at 2-8°C until received by the PHL. If shipment is delayed longer than 36 hours, store specimen at ≤ -20°C and ship on dry ice to maintain the temperature of ≤ -20°C until received by the PHL.													
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I</a> .													
Availability:	Mumps IgG once/week													
Results and Interpretations:	Mumps IgG immune status reported as positive, negative, or equivocal.													
Additional Information:	<table border="1"> <thead> <tr> <th>Results</th> <th>Interpretations</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;"><b>Mumps IgG</b></td> </tr> <tr> <td>Positive</td> <td>IgG antibodies to the Mumps virus were detected. A positive test indicates a current or past infection, or prior vaccination against the Mumps virus.</td> </tr> <tr> <td>Negative</td> <td>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.</td> </tr> <tr> <td>Equivocal</td> <td>Re-evaluate by collecting and testing another specimen after 14 days.</td> </tr> <tr> <td></td> <td></td> </tr> </tbody> </table>		Results	Interpretations	<b>Mumps IgG</b>		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.		
	Results	Interpretations												
	<b>Mumps IgG</b>													
	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.												
Purpose of Test:	Mumps IgG: To detect Mumps IgG antibodies for determining immune status.													
Method:	EIA for Mumps IgG													
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 request form 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 <a href="#">Section IV, Transporting and Shipping Infectious Substances</a> .
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 Criteria:	For universal rejections, See <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
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 request form must be completed in full.
Specimen Volume (optimum):	5 - 10 mL sputum, and other body fluids; 10 mL urine or gastric washings, walnut sized portion of feces or 10 mL liquid stool. Tissue (biopsy) add just enough liquid to keep the sample wet. SHOULD NOT be floating in saline. See <a href="#">Mycobacterium Culture Collection Procedure</a> .
Specimen Volume (minimum):	N/A
Collect:	Screw cap 50 mL polypropylene conical tube with conical shaped bottom
Form:	DHEC 1335-OE
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 Criteria:	Specimen > 5 days old when received (Sputum and Urine). Specimens received at the improper temperature. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
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 request form 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 <a href="#">Section IV, Transporting and Shipping Infectious Substances</a> .
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
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 labeled 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 re 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 <sub>2</sub> .
Form:	DHEC 1335-OE request form, check "Organism for ID"
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	Store in a 35°C CO <sub>2</sub> 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 <a href="#">Specimen Rejection &amp; Policies in Section I.</a>
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: <ul style="list-style-type: none"> <li>• Amino Acid Disorders</li> <li>• Organic Acid Conditions</li> <li>• Fatty Acid Disorders</li> <li>• Biotinidase Deficiency</li> <li>• Classic Galactosemia</li> <li>• Cystic Fibrosis</li> <li>• Certain Hemoglobinopathies</li> <li>• Primary Congenital Hypothyroidism</li> <li>• Congenital Adrenal Hyperplasia</li> <li>• Severe Combined Immunodeficiencies</li> <li>• Pompe Disease</li> <li>• Mucopolysaccharidosis Type I (MPS-I)</li> <li>• Spinal Muscular Atrophy Type I (SMA-I)</li> <li>• Krabbe Disease</li> <li>• X-linked Adrenoleukodystrophy (X-ALD)</li> </ul>
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 any repeat testing is needed
Collect:	Heel stick; Follow your facility's heel stick collection procedure. Refer to Newborn Screening Manual at <a href="https://scdhec.gov/health-professionals/health-services-facilities/lab-certification-services/newborn-screening/newborn-metabolic-screening-manual">https://scdhec.gov/health-professionals/health-services-facilities/lab-certification-services/newborn-screening/newborn-metabolic-screening-manual</a> and CLSI video <a href="https://www.youtube.com/watch?v=S51Y9ShD6HI">https://www.youtube.com/watch?v=S51Y9ShD6HI</a> for additional resources.
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
Purpose of Test:	Identifies newborns that may be at an increased risk of having a certain serious condition
Method:	<ul style="list-style-type: none"> <li>• <b>Tandem Mass Spectrometry:</b> Amino Acid Disorders, Organic Acid Conditions, Fatty Acid Disorders</li> <li>• <b>Enzymatic &amp; Fluorescence:</b> Biotinidase Deficiency, Classic Galactosemia</li> <li>• <b>Fluorimmuno assay and/or PCR:</b> Cystic Fibrosis</li> <li>• <b>High Performance Liquid Chromatography and/or Iso-electric focusing:</b> Certain Hemoglobinopathies</li> <li>• <b>Fluorimmuno assay:</b> Primary Congenital Hypothyroidism, Congenital Adrenal Hyperplasia</li> <li>• <b>PCR:</b> Severe Combined Immunodeficiency, SMA-I</li> <li>• <b>Flow Injection Analysis Tandem Mass Spectrometry:</b> Pompe, MPS-I, Krabbe</li> <li>• <b>LC-Tandem Mass Spectrometry:</b> X-linked Adrenoleukodystrophy</li> </ul>
Interfering Substances:	N/A

Test	NOROVIRUS DETECTION BY REAL TIME RT PCR
Synonym:	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 request form.
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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	Store at 2 - 8°C and ship to maintain specimen at 2 - 8°C until received by the PHL.
Specimen Rejection Criteria:	Specimens placed in any type of media. Specimen more than 10 days old when received. Specimens received at the improper temperature. See <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday; Availability of this test is restricted to epidemiological investigations.
Results and Interpretations:	Results are reported as negative or positive for the presence of genogroup I or genogroup II Norovirus.
Additional Information:	N/A
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

<b>Test</b>	<b>ORGANISM for IDENTIFICATION</b>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
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 request form, check "Organism for ID"
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	Ship according to directions listed under specific organism.
Specimen Rejection Criteria:	Mixed isolate. Specimens received at the improper temperature. For universal rejections, See <a href="#">Specimen Rejection Policies in Section I.</a>
Availability:	Monday – Friday unless otherwise noted for specific organism.
Results and Interpretations:	Organism identification confirmed or not. Serotyping and serogrouping 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 Gold 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 QFT-Plus blood collection tubes									
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.									
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: <ul style="list-style-type: none"> <li>• Nil antigen (Grey cap)</li> <li>• TB 1 antigen (Green cap)</li> <li>• TB 2 antigen (Yellow cap)</li> <li>• Mitogen (Purple cap)</li> </ul> Specific collection requirements are needed. For detailed collection procedure, see <a href="#">QuantiFERON-TB Gold Plus (QFT-Plus) Collection Procedure in Section III.</a>									
Form:	DHEC 1335-OE; be sure to write the incubation start and end times on this form.									
Special Instructions:	QFT-Plus Blood Collection Tubes should be at 17-25°C at time of blood collection.									
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>									
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 tubes in the temperature range of 4-27°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 lines on tube labels; 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 <a href="#">Specimen Rejection Policies in Section I.</a>									
Availability:	Monday - Friday									
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>Positive</td> <td><i>M. tuberculosis</i> infection likely</td> </tr> <tr> <td>Negative</td> <td><i>M. tuberculosis</i> infection not likely</td> </tr> <tr> <td>Indeterminate</td> <td>Likelihood of <i>M. tuberculosis</i> infection cannot be determined</td> </tr> </tbody> </table>		Result	Interpretation	Positive	<i>M. tuberculosis</i> infection likely	Negative	<i>M. tuberculosis</i> infection not likely	Indeterminate	Likelihood of <i>M. tuberculosis</i> infection cannot be determined
Result	Interpretation									
Positive	<i>M. tuberculosis</i> infection likely									
Negative	<i>M. tuberculosis</i> 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 <i>Mycobacterium tuberculosis</i> (TB) infection									
Method:	Detection of interferon-γ 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. <b>Weekend and Holiday testing only performed with prior approval from Rabies Control Central Office and the Virology Supervisor.</b>
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 <b>only</b> submitted by DHEC Rabies Control Staff.
Form:	DHEC 1308
Special Instructions:	Contact the <a href="#">local county health department</a> for the information on specimen collection and shipping instructions. <b>Confirmation is a postmortem procedure;</b> 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 <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 <a href="#">Specimen Rejection Policies in Section I</a> .
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 2.1 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); SARS-CoV-2; Bordetella pertussis; Bordetella parapertussis; Chlamydomphila 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 or universal transport media formulated for viral collection.
Specimen Identification:	Patient’s full name and patient ID # (or other unique identifier) is required on the specimen and request form.
Specimen Volume (optimum):	1 - 3 mL of viral or universal transport media formulated for viral collection 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 or universal transport media formulated for viral collection. 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.
Form:	DHEC 1335-OE; Request BioFire FilmArray RP2.1 Panel
Special Instructions:	Call Virology at 803-896-0819
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 ≤ -15°C and ship on dry ice to maintain specimen at temperature of ≤ -15°C until received at the PHL. Specimen frozen at ≤ -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 <a href="#">Specimen Rejection Policies in Section I</a> .
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); SARS-CoV-2; Bordetella pertussis; Bordetella parapertussis; Chlamydomphila 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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332 All specimens submitted to the PHL will undergo the reverse-algorithm unless otherwise indicated. Test- Syphilis RPR (Special requests for Syphilis RPR should be in writing on the form under special instructions.)
Special Instructions:	All specimens submitted to the PHL will undergo the reverse-algorithm unless otherwise indicated.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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 Criteria:	Plasma specimen; received after 5 days not maintained at -20° C or colder; received at the improper temperature. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive, titer endpoint Non Reactive
Additional Information:	Reflex test for reactive and equivocal Syphilis TPs; 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 SEROLOGY- IgG											
Synonym:	German Measles antibody, Rubella immune screen, Rubella IgG											
Lab Section/Phone:	Virology & Rabies, 803-896-0819											
Days Performed:	N/A											
Turnaround Time:	IgG: 10 days											
Specimen Required:	Serum											
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.											
Specimen Volume (optimum):	2 mL serum											
Specimen Volume (minimum):	1 mL serum											
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.											
Form:	DHEC 1332											
Special Instructions:	Rubella IgG does not require notification.											
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>											
Transport Conditions:	Store at 2 - 8°C and ship within 36 hours of collection to maintain specimen at 2 - 8°C until received by the PHL. If shipment is delayed longer than 36 hours, specimen should be stored at ≤ -20°C and shipped on dry ice to maintain the temperature of ≤ -20°C until received by the PHL.											
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I.</a>											
Availability:	IgG: As requested											
Results and Interpretations:	<table border="1"> <thead> <tr> <th>Result</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;"><b>Rubella IgG</b></td> </tr> <tr> <td>Positive</td> <td>Indicates a current or previous infection with Rubella virus, or prior vaccination against Rubella virus.</td> </tr> <tr> <td>Equivocal</td> <td>Collect and test another specimen.</td> </tr> <tr> <td>Negative</td> <td>No detectable IgG antibodies to the Rubella virus. A non-reactive result indicates no current or previous infection with Rubella virus. Such patients are presumed to be susceptible to a primary infection. However, specimens taken too early during a primary infection may not have detectable levels of IgG antibody. If this is suspected, collect and test another specimen in 8 - 14 days.</td> </tr> </tbody> </table>		Result	Interpretation	<b>Rubella IgG</b>		Positive	Indicates a current or previous infection with Rubella virus, or prior vaccination against Rubella virus.	Equivocal	Collect and test another specimen.	Negative	No detectable IgG antibodies to the Rubella virus. A non-reactive result indicates no current or previous infection with Rubella virus. Such patients are presumed to be susceptible to a primary infection. However, specimens taken too early during a primary infection may not have detectable levels of IgG antibody. If this is suspected, collect and test another specimen in 8 - 14 days.
Result	Interpretation											
<b>Rubella IgG</b>												
Positive	Indicates a current or previous infection with Rubella virus, or prior vaccination against Rubella virus.											
Equivocal	Collect and test another specimen.											
Negative	No detectable IgG antibodies to the Rubella virus. A non-reactive result indicates no current or previous infection with Rubella virus. Such patients are presumed to be susceptible to a primary infection. However, specimens taken too early during a primary infection may not have detectable levels of IgG antibody. If this is suspected, collect and test another specimen in 8 - 14 days.											
Additional Information:	N/A											
Purpose of Test:	IgG: Used to determine immune status of patient.											
Method:	EIA (Enzyme Immunoassay)											
Interfering Substances:	N/A											
Comment:	N/A											

Test	STAPHYLOCOCCUS
Synonym:	Enteric Pathogen Culture, <i>Staphylococcus aureus</i> , for VISA/VRSA confirmation, see <i>Staphylococcus</i> (VISA/VRSA) isolates.
Lab Section/Phone:	Clinical specimens and isolates – Clinical Microbiology, 803-896-0805
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.
Specimen Identification:	Specimen container and Isolates must be labeled 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 request form must be completed in full.
Specimen Volume (optimum/minimum):	N/A
Collect:	N/A
Form:	DHEC request form 1335-OE
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	<b>Ship isolates in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.</b> <b>For optimal recovery, ship swabs in transport media on frozen cold packs to be maintained in temperature range of 2-8°C until receipt at the PHL.</b>
Specimen Rejection Criteria:	<b>Culture non-viable; culture mixed: temperature outside the range of 2-30°C</b> <b>For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a>.</b>
Availability:	Monday - Friday
Results and Interpretations:	N/A
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:	<b>Important- For optimal recovery, 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 . While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>

Test	STAPHYLOCOCCUS (VISA/VRSA) ISOLATES
Synonym:	Vancomycin Intermediate Staphylococcus aureus, Vancomycin Resistant Staphylococcus aureus <b>Staphylococcus aureus, vancomycin-resistant or intermediate with a VA &gt; 6 MIC.</b>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
Collect:	Be sure to submit a pure bacterial isolate, subbed from an isolated colony.
Form:	DHEC 1335-OE request form, check "Organism for ID"
Special Instructions:	<b>According to CDC and CLSI, only isolates with a commercial instrument MIC or E-test &gt; 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.</b>
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	Ship in approved shippers to maintain temperature within the range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	Culture non-viable, culture mixed, specimens received at the improper temperature. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
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
Comment:	N/A

Test	STREPTOCOCCUS (BETA HEMOLYTIC GROUP A)
Synonym:	Group A Strep, <i>Streptococcus pyrogenes</i>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
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 request 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 (S. Pyrogenes)</i> organisms that are of epidemiologic concern, to be frozen for possible surveillance studies at a later date.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
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 <a href="#">Specimen Rejection Policies in Section I.</a>
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 <i>S. pyogenes</i> is isolated, with permission from the CDC, will be sent to the CDC for further testing.
Purpose of Test:	N/A
Method:	bioMerieux VITEK MS,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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
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 antibiotics according to CLSI for further testing and serotyping.
Form:	DHEC 1335-OE request form, check "Organism for ID"
Special Instructions:	Invasive disease = isolated from normally sterile site. Always specify site of isolate.
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	Store in 35°C CO <sub>2</sub> incubator and ship in approved shippers which will maintain temperature within the range of 15-25°C until received at the PHL.
Specimen Rejection Criteria:	For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	N/A
Additional Information:	Specimen submission to the PHL is required for <i>Streptococcus pneumoniae</i> , 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, T pallidum IgG and IgM 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 labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
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 <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
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 labeled 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:	Specimens received at the improper temperature; specimens received after 5 days not maintained at -20° C or colder. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I.</a>
Availability:	Monday – Friday
Results and Interpretations:	Reactive: Antibodies to Treponemal pallidum detected. Reflex RPR testing to follow. Nonreactive: Antibodies to Treponemal pallidum not detected. Equivocal: Indeterminate for the presence of antibodies to Treponemal pallidum. Reflex RPR testing to follow.
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 labeled with patient’s first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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.
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
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:	Plasma specimen; received after 5 days not maintained at -20° C or colder; Grossly contaminated, grossly lipemic, excessively hemolyzed, or chylous; Specimens received at the improper temperature. For universal rejections, See <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	Reactive: Antibodies to Treponemal pallidum confirmed. Nonreactive: Antibodies to Treponemal pallidum not confirmed. Indeterminate: Indeterminate for the presence of antibodies to Treponemal pallidum. Reflex testing to follow. 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 labeled with patient's full name, and a second patient identifier such as DOB, Specimen #, etc. DHEC request form must be completed in full.
Specimen Volume (optimum):	2 - 5 mL
Specimen Volume (minimum):	500 $\mu$ L
Collect:	Sterile urine cups
Form:	DHEC 1332
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	Urine specimens stored at $\leq -20^{\circ}\text{C}$ and transported frozen by packing on dry ice to maintain $\leq -20^{\circ}\text{C}$ temperature until received at the PHL is preferred, when possible. Urine may also be stored at $2-8^{\circ}\text{C}$ and shipped on frozen cold packs to maintain specimens at $2-8^{\circ}\text{C}$ until receipt at the PHL. Urines stored and shipped at $2-8^{\circ}\text{C}$ must be received at the PHL within 10 days of collection.
Specimen Rejection Criteria:	Insufficient quantity (QNS); improper collection container; specimens received at the improper temperature; For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday – Friday
Results and Interpretations:	N/A
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:	<b>Swab specimen (for patients ≥ 14):</b> Only collect endocervical specimens using the Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens (Purple label/Blue collection swab). <b>Multitest Swab specimens (for patients ≥ 14):</b> Only collect vaginal specimens using the Aptima Multitest Swab Specimen Collection Kit (Orange label/Pink swab). <b>Urine specimen (for patients ≥ 14):</b> Urine from male or female patients.
Specimen Identification:	Specimens must be labeled with patient's first and last name, and a second patient identifier such as DOB, MCI #, Specimen #. DHEC request form 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 Aptima <sup>®</sup> Specimen Collection Kits. See Special Instructions for more information.
Form:	DHEC 1332
Special Instructions:	Only use Aptima <sup>®</sup> 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). Male testing will ONLY be performed on urine specimens. <b>Must pack only one patient's specimen(s) per biohazard transport bag to avoid cross-contamination.</b>
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	<b>Ship only one patient's specimen(s) per biohazard transport bag.</b> 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 ≤ -20 °C and ship on dry ice to maintain at temperature of ≤ -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; <b>**Specimen with more than one patient's specimen(s) per biohazard transport bag.**</b> For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a> .
Availability:	Monday - Friday
Results and Interpretations:	Positive: T. vaginalis rRNA detected. Negative: T. vaginalis rRNA not detected. Indeterminate: Inconclusive for the presence of T. vaginalis rRNA.
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:	Trichomonas vaginalis testing is only performed on patients ≥ 14 years old.

<b>Test</b>	<b>VARICELLA VIRUS SEROLOGY (IgG)</b>	
Synonym:	Chickenpox, Varicella zoster virus	
Lab Section/Phone:	Virology & Rabies, 803-896-0819	
Days Performed:	N/A	
Turnaround Time:	10 days	
Specimen Required:	Serum	
Specimen Identification:	Patient's full name and patient ID # (or other unique identifier) is required on the specimen and request form.	
Specimen Volume (optimum):	2 mL serum	
Specimen Volume (minimum):	1 mL serum	
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 different container/tube). Please follow manufacturer's guidelines.	
Form:	DHEC 1332	
Special Instructions:	N/A	
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .	
Transport Conditions:	Store at 2 - 8°C and ship within 36 hours of collection to maintain specimen at 2 - 8°C until received by the PHL. If shipment is delayed longer than 36 hours, specimen should be stored at ≤ -20°C and shipped on dry ice to maintain the temperature of ≤ -20°C until received by the PHL.	
Specimen Rejection Criteria:	See <a href="#">Specimen Rejection Policies in Section I</a> .	
Availability:	As requested	
Results and Interpretations:	Immune status: Positive, Negative or Equivocal	
Additional Information:	<b>Result</b>	<b>Interpretation</b>
	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 Varicella zoster virus IgG antibodies for determining immune status.	
Method:	EIA (Enzyme Immunoassay)	
Interfering Substances:	N/A	
Comment:	N/A	

Test	VARIOLA
Synonym:	Smallpox
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 request form 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:	<b>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.</b>
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 <i>Variola</i> 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.

<b>Test</b>	<b>VIBRIO, all types, including <i>Vibrio cholerae</i> O1 and O139</b>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
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 request form; check "Organism for ID" for isolates and "Enteric Culture" for stool in transport medium.
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV.</a>
Transport Conditions:	<b>Ship isolates in approved shippers to maintain temperature of specimen within the range of 15-25°C until received at the PHL.</b> <b>For optimal recovery, 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.</b>
Specimen Rejection Criteria:	<b>Received temperature outside the range of 2-30°C.</b> <b>For universal rejections, see <a href="#">Specimen Rejection Policies in Section I.</a></b>
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:	<b>Important- For optimal recovery, 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 . While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>



Test	YERSINIA ENTERCOLITICA
Synonym:	<i>Y. enterocolitica</i>
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 labeled 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 request form must be completed in full.
Specimen Volume (optimum):	N/A
Specimen Volume (minimum):	N/A
Collect:	N/A
Form:	DHEC 1335-OE request form, check "Enteric Culture" or "Organism for ID"
Special Instructions:	N/A
Packing and Shipping*:	See <a href="#">Transporting and Shipping Infectious Substances in Section IV</a> .
Transport Conditions:	<b>Store specimen at 2-8°C. For optimal recovery, 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.</b> <b>Ship slants in approved shippers to maintain the temperature range of 15-25°C until received at the PHL.</b>
Specimen Rejection Criteria:	<b>Quantity insufficient; specimen too old; improper transport media or conditions; specimens received at a temperature outside the range of 2-30°C. For universal rejections, see <a href="#">Specimen Rejection Policies in Section I</a>.</b>
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:	<b>Important- For optimal recovery, 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 . While not ideal, specimens with a temperature of 2-30°C will be accepted.</b>

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 " <i>Yersinia pestis</i> " for "Suspect Agent." DHEC request form 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:	<i>Yersinia pestis</i> is designated as a Tier 1 Select Agent (Select Agent Regulation, 42 CFR, 73, Final Rule). In the event of <i>Yersinia pestis</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>Y. pestis</i> 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**

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 [PHL-Supply@dhec.sc.gov](mailto:PHL-Supply@dhec.sc.gov) to request the 1323 form. An electronic fillable form will be sent by email. Return the completed DHEC 1323 form by email to [PHL-Supply@dhec.sc.gov](mailto:PHL-Supply@dhec.sc.gov). 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 request form. Each kit is to be used for only one specimen.

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

### **Transport Medium**

*(Order request forms and shipping container separately.)*

- GC Culture medium
- Cary Blair Media
- Viral or universal transport media formulated for viral collection

### **Other Supplies**

- Absorbent Packs
- Biohazard Bags
- Envelopes (for Newborn Screening and Hb electrophoresis blood spots)
- GC/Chlamydia/Trichomonas (Nucleic Acid Amplification Test) Unisex swab, MTS (Multitest) swab, also known as the orange/coral vaginal swab), or urine collection kit
- Herpes (Nucleic Acid Amplification Test) MTS (Multitest) swab
- PPT Tubes for Viral Load
- QuantiFERON-TB Gold Plus (QFT 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.

- Thermosafe and Uline
- Infecon 5000
- Infecon 5500
- Category A Cold Shipper
- Rabies Shipper
- QFT Shipper

## Request Forms

The request forms required by the Public Health Laboratory with specimen submissions are listed below. Certain forms are available electronically on the web portal listed below and can be printed with the appropriate sender number, which determines where reports are mailed and/or resulted electronically.

Form #	Test(s)	Web Portal
1308	Rabies	OpenELIS
1323	Request for Laboratory Supplies	N/A: To request this form, email <a href="mailto:PHL-Supply@dhec.sc.gov">PHL-Supply@dhec.sc.gov</a>
1332	HIV/Hepatitis/Syphilis Serology	OpenELIS
1332	GC/CT/Trichomonas	OpenELIS
1332	Immunology	OpenELIS
1332	Lead Analysis	OpenELIS
1335-OE	Clinical Microbiology (Bacteriology/Parasitology)	OpenELIS
1335-OE	Mycobacteriology	OpenELIS
1335-OE	Virology (Virus Detection/Herpes)	OpenELIS
1335-OE	Special Pathogens	OpenELIS
1327	Newborn Screening ( <b>Check expiration date on form</b> )	N/A: These forms are the collection device and are requested by emailing PHL Supply at <a href="mailto:PHL-Supply@dhec.sc.gov">PHL-Supply@dhec.sc.gov</a>
1339	Hemoglobin Electrophoresis ( <b>Check expiration date on form</b> )	



**DHEC 1332 Submission Form**  
 DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL  
 Public Health Laboratory-8231 Parklane Road Columbia, SC 29223  
 (803) 896-0800

**ALIGN BARCODE LABEL  
 TO TOP OF BOX**

CLIA # 42D0658606

Patient's Name (Last)		(First)	(MI)	Sex	Ethnicity	Race	Date of Birth														
Address			City	State	Zip Code	County of Residence															
Phone Number	Country of Birth		MCI Number		Local ID	Clinic ID															
Sender No.	Sender Name			Billing Number	Program Number	Clinic Type															
<b>Reason for Visit</b>					<b>Serology Test Symptoms</b>																
<input type="checkbox"/> Contact <input type="checkbox"/> Contact-Chlamydia <input type="checkbox"/> Contact-Gonorrhea <input type="checkbox"/> Contact-Hepatitis A <input type="checkbox"/> Contact-Hepatitis B <input type="checkbox"/> Contact-Hepatitis C <input type="checkbox"/> Contact-HIV/HD/MD notified <input type="checkbox"/> Contact-HIV Positive <input type="checkbox"/> Contact-HIV/PT notified <input type="checkbox"/> Contact-Syphilis <input type="checkbox"/> Diagnosis <input type="checkbox"/> Family Planning - Annual <input type="checkbox"/> Family Planning - Initial					<input type="checkbox"/> Fast Track Ineligible <input type="checkbox"/> Fast Track Services <input type="checkbox"/> Follow-Up <input type="checkbox"/> Pregnancy Test <input type="checkbox"/> PrEP Testing Services <input type="checkbox"/> Premarital (State _____) <input type="checkbox"/> Prenatal Visit <input type="checkbox"/> Previous HIV Negative <input type="checkbox"/> Previous HIV Positive <input type="checkbox"/> Rapid Test Negative <input type="checkbox"/> Rapid Test Positive <input type="checkbox"/> Referral Agency <input type="checkbox"/> Referred by outreach					<input type="checkbox"/> Referred by Drug Treatment Center <input type="checkbox"/> Referred-Other <input type="checkbox"/> Referred - Self <input type="checkbox"/> Repeat Test/First Test _____ <input type="checkbox"/> Routine Screen <input type="checkbox"/> Self-Report (Date: _____) <input type="checkbox"/> Special Project <input type="checkbox"/> Survey <input type="checkbox"/> Test of Cure <input type="checkbox"/> Unknown <input type="checkbox"/> Volunteer/Medical <input type="checkbox"/> Workplace Exposure <input type="checkbox"/> Other				Date of onset: Fever: Duration: Rash (Type): <input type="checkbox"/> Conjunctivitis <input type="checkbox"/> Constipation <input type="checkbox"/> Cough <input type="checkbox"/> Diarrhea <input type="checkbox"/> Headache <input type="checkbox"/> Muscle Weakness <input type="checkbox"/> Nuchal rigidity				<input type="checkbox"/> Paralysis <input type="checkbox"/> Pericarditis <input type="checkbox"/> Pharyngitis <input type="checkbox"/> Pneumonia <input type="checkbox"/> Rhinitis <input type="checkbox"/> Vomiting			
<b>Specimen Information</b>																					
Collection Date		Collection time		Ordering Physician, Provider and/or Nurse:																	
		<input type="checkbox"/> AM <input type="checkbox"/> PM																			
<b>Specimen Type</b>			<b>Risk History (Past 12 months)</b>																		
<b>Blood</b> <input type="checkbox"/> Clotted <input type="checkbox"/> ETDA-Lavender/Purple <input type="checkbox"/> Finger, Heel <input type="checkbox"/> Plasma <input type="checkbox"/> Serum <input type="checkbox"/> Venipuncture* <b>Other</b> <input type="checkbox"/> CSF <input type="checkbox"/> Urine * for Blood Lead Only			<b>Swab</b> <input type="checkbox"/> Cervical <input type="checkbox"/> Rectal <input type="checkbox"/> Throat <input type="checkbox"/> Unknown <input type="checkbox"/> Urethral <input type="checkbox"/> Vaginal <input type="checkbox"/> Other _____			<b>Client</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 31 <input type="checkbox"/> 32 <input type="checkbox"/> 33 <b>Partner</b> <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30															
<b>Chlamydia Test</b>																					
<b>Pregnancy Status</b>			<b>Symptoms</b>			<b>Risk</b>															
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			<input type="checkbox"/> Multiple partner <input type="checkbox"/> New partner															
<b>Special Instructions and/or Comments:</b>																					
<b>Test Request</b>																					
<b>Virology</b>			<b>Analytical Chemistry</b>			<b>Diagnostic Serology</b>															
<input type="checkbox"/> Mumps IgG <input type="checkbox"/> Mumps IgM <input type="checkbox"/> Rubella IgG <input type="checkbox"/> Rubella IgM <input type="checkbox"/> Rubeola IgG <input type="checkbox"/> Rubeola IgM			<input type="checkbox"/> Chikungunya IgM <input type="checkbox"/> Dengue IgM <input type="checkbox"/> Varicella IgG <input type="checkbox"/> West Nile IgM <input type="checkbox"/> Zika IgM			<input type="checkbox"/> Hg, Pb, Cd screen <input type="checkbox"/> Lead (Blood) Trace Heavy Metals (includes As, Be, Cd, Ba, TI, Pb, and U)*Individual metals upon request <input type="checkbox"/> Biomonitoring-No Demographics			<b>GC/CT Detection</b> <input type="checkbox"/> GC and CT rRNA <b>Trichomonas Detection</b> Trichomonas rRNA Specimen type (Trichomonas): <input type="checkbox"/> Urine <input type="checkbox"/> Cervical <input type="checkbox"/> Vaginal												
<b>Diagnostic Serology</b>																					
<input type="checkbox"/> Hepatitis A IgG <input type="checkbox"/> Hepatitis B ImmuneStatus/post-immune <input type="checkbox"/> HIV <input type="checkbox"/> Hepatitis A IgM <input type="checkbox"/> Hepatitis B Surface Antibody			<input type="checkbox"/> HIV Viral Load <input type="checkbox"/> Hepatitis B Anti-Core <input type="checkbox"/> Hepatitis B Surface Antigen <input type="checkbox"/> HIV/Syphilis <input type="checkbox"/> Hepatitis B Core Antibody IgM			<input type="checkbox"/> Hepatitis B Diagnostic Profile <input type="checkbox"/> Syphilis <input type="checkbox"/> Hepatitis C Antibody <input type="checkbox"/> Hepatitis C Viral Load <input type="checkbox"/> PrEP Panel F/U (HIV, Syphilis, CT/GC) <input type="checkbox"/> PrEP Panel Initial (HIV, Syphilis, CT/GC, Hep C+B)															

DHEC 1332 (10/2020)



### INSTRUCTIONS FOR COMPLETING REQUEST FORM

*(May use printed patient lab label)*

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

A = Asian	B = Black/African American
W = White	I = American Indian/Alaskan Native
P = Native Hawaiian/Other Pacific Islander	O = Other
U = Unknown/Unclassified	
5. Enter date of birth (month, day and year. Example: Enter 03/06/1960 for the birthday March 6, 1960.)
6. Enter the patient address and five-digit zip code.
7. Enter county of residence and the 10-digit telephone number.
8. Enter Country of Birth.
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.
12. Enter billing number if billing number is different from sender number
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.**
18. Check type/source of specimen.
- 19.

Use the codes below to identify client and partner Risk Factors during the **PAST 12 MONTHS**. (Circle all that apply)

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

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 1335 Submission Form**  
 DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL  
 Public Health Laboratory  
 8231 Parklane Road Columbia, SC 29223  
 (803) 896-0800

CLIA#42D0658606

**ALIGN BARCODE LABEL  
 TO TOP OF BOX**

Patient's Name (Last)		(First)	(MI)	Sex	Ethnicity	Race	Date of Birth	
Address			City	State	Zip Code	County of Residence		
Phone Number	Country of Birth		MCI Number		Local ID	Clinic ID		
Sender No.	Sender Name			Billing Number	Program No.	Outbreak Number		
Ordering Physician, Provider and/or Nurse:				Clinical Diagnosis				
Special Instructions and/or Comments:								
<b>Specimen Information</b>				<b>Date of Onset</b>	<b>Agents/Organisms/or Virus Suspected</b>			
Collection Date:	Collection Time:		<input type="checkbox"/> AM <input type="checkbox"/> PM					
<b>Specimen Type/Source</b>								
<input type="checkbox"/> Blood/Serum		<input type="checkbox"/> Throat swab		<input type="checkbox"/> Genital _____		<b>Mycobacteriology Specimens</b>		
<input type="checkbox"/> Bronchial wash		<input type="checkbox"/> Urine		<input type="checkbox"/> Tissue/Biopsy _____		<input type="checkbox"/> Induced sputum		
<input type="checkbox"/> Nasopharyngeal Swab		<input type="checkbox"/> Wound pus drainage		<input type="checkbox"/> Other _____		<input type="checkbox"/> Spontaneous sputum		
<input type="checkbox"/> Smear (Do not mark for TB)		<input type="checkbox"/> BAL				<input type="checkbox"/> Other _____		
<input type="checkbox"/> Stool specimens		<input type="checkbox"/> Swab _____						
<b>Symptoms</b>								
<input type="checkbox"/> Arthralgia/Myalgia		<input type="checkbox"/> Diarrhea		<input type="checkbox"/> Meningitis		<input type="checkbox"/> Rash Type: _____		
<input type="checkbox"/> Asymptomatic		<input type="checkbox"/> Encephalitis		<input type="checkbox"/> Nausea/Vomiting		<input type="checkbox"/> Respiratory		
<input type="checkbox"/> Conjunctivitis		<input type="checkbox"/> Fever		<input type="checkbox"/> Pleurodynia		<input type="checkbox"/> Other		
<b>Test Requested</b>								
<b>Clinical Microbiology (Bacteriology/Parasitology)</b>								
Was culture incubated before transport: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 24 hours <input type="checkbox"/> 48 hours								
<input type="checkbox"/> Broth Specimen for Shiga toxin producing E. coli		<input type="checkbox"/> Culture/Isolate for Shiga toxin producing E. coli		<input type="checkbox"/> Legionella Urine Antigen				
<input type="checkbox"/> CRE/CRPA/CRAB		<input type="checkbox"/> Enteric Culture		<input type="checkbox"/> Non-Enteric Culture and ID				
<input type="checkbox"/> Candida ID		<input type="checkbox"/> GC Culture and ID		<input type="checkbox"/> Organism for ID-Aerobic				
<input type="checkbox"/> Cryptosporidium Antigen				<input type="checkbox"/> Other _____				
<b>Mycobacteriology</b>								
Known TB case? <input type="checkbox"/> Yes <input type="checkbox"/> No		R/O new TB Case? <input type="checkbox"/> Yes <input type="checkbox"/> No		Suspicious hx, s/sx? <input type="checkbox"/> Yes <input type="checkbox"/> No		Current Rx? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/> Clinical Specimen for ID and Smear		<input type="checkbox"/> Drug Susceptibility:		<input type="checkbox"/> Specimen for Genotyping				
<input type="checkbox"/> Isolate for ID <input type="checkbox"/> Blood Culture		<input type="checkbox"/> Clinical Specimen <input type="checkbox"/> Referred Isolate						
<b>Virology</b>								
<input type="checkbox"/> BioFire Respiratory Panel (Outbreak Only)		<input type="checkbox"/> Herpes		COVID RT-PCR		Y	N	U
<input type="checkbox"/> Bordetella (BioFire)		<input type="checkbox"/> Measles RT-PCR		First Test?				Hospitalized?
<input type="checkbox"/> GI Outbreak (Norovirus RT-PCR and/or Biofire GI panel)		<input type="checkbox"/> Mumps RT-PCR		Employed in healthcare?				ICU?
<input type="checkbox"/> Influenza RT-PCR In-patient Out-Patient		<input type="checkbox"/> Triplex RT-PCR		Symptomatic (CDC defined)?				Pregnant?
<input type="checkbox"/> QuantiFeron TB-Gold Plus Incubation Start Time:		End Time:		Resident in a congregate care facility?				
<b>Special Pathogens</b>								
<b>Rule-out Testing</b>		<b>Molecular Testing for Viral Pathogens</b>			<b>Serological Testing</b>			
<input type="checkbox"/> Bacterial Isolate <input type="checkbox"/> Clinical Specimen		<input type="checkbox"/> Avian Influenza		<input type="checkbox"/> Ebola		<input type="checkbox"/> BMAT		
Suspect Agent: _____		<input type="checkbox"/> MERS		<input type="checkbox"/> Other		<input type="checkbox"/> Malaria		

DHEC 1335OE (06/2020)



1335

**INSTRUCTIONS FOR COMPLETING REQUEST FORM  
DHEC 1335**

*(May use printed patient lab label)*

1. Enter patient name.
2. Enter M = Male; F = Female; TX = Transgender M2F (Male to Female); or TY = F2M (Female to Male) in Sex box.
3. Enter ethnicity as follows: H = Hispanic/Latino and N = NonHispanic/Latino.
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.
6. Enter the patient address and five-digit zip code.
7. Enter county of residence and the 10-digit telephone number.
8. Fill in patient MCI ID number (DHEC Clients only).
9. Enter local and clinic ID if applicable. (Private clients must provide a clinic ID)
10. Enter Program number.
11. Enter Country of Birth.
12. Enter billing number if billing number is different from sender number.
13. Enter the Outbreak number.
14. Enter the date and time of collection and initial.
15. Check type/source of specimen.
16. Enter Ordering Physician, Provider and/or Nurse if applicable. **Note: Please print.**
17. Enter in the Special Instructions and/or comments where you vacated (travel history).
18. Enter Date of Onset if applicable.
19. List agents, organisms, or virus suspected.
20. Enter clinical diagnosis.
21. Check symptoms that apply.
22. Mark test requested.
23. Answer the four questions in Mycobacteriology Section.
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.

DHEC 1335OE (06/2020)





SC DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

Public Health Laboratory
8231 Parklane Road Columbia, SC 29223
(803) 896-0800
CLIA # 42D0658606

ALIGN BARCODE LABEL TO TOP OF BOX

Request for Rabies Testing

Form with multiple sections: Animal type (Cat, Dog, Bat, etc.), Date of Submission/Death, Vaccination status, Sender information, Address where animal was found, Reason for testing, Exposure type, Date of exposure, Owner information, HUMAN EXPOSURE section, DOMESTIC ANIMAL EXPOSURE section, and Laboratory results/exception section.



DHEC 1308

1308

**BIOHAZARD**

**dhec** NEWBORN SCREENING  
PUBLIC HEALTH LABORATORY  
SC DEPT. OF HEALTH AND ENVIRONMENTAL CONTROL  
8231 PARKLANE ROAD, COLUMBIA, SC 29223  
803-896-0874

**Use By 2028-11-30**

**DHEC LAB USE ONLY**

BABY'S LAST NAME	BABY'S FIRST NAME	DATE OF BIRTH	TIME OF BIRTH
MOTHER'S LAST NAME	MOTHER'S FIRST NAME	DATE OF COLLECTION	TIME OF COLLECTION
MOTHER'S ADDRESS		COLLECTOR ID / INITIALS	
CITY		SEX	RACE
STATE COUNTY ZIP CODE	PARENT(S) / GUARDIAN'S PHONE NO.	BIRTH WEIGHT IN GRAMS	PRESENT WEIGHT IN GRAMS
MEDICAL RECORD NO.	PRIMARY MD LICENSE NO.	HOSPITAL / SPECIMEN SUBMITTER NO.	
BABY'S PRIMARY PHYSICIAN	HOSPITAL NAME / SUBMITTER NAME	MULTIPLE BIRTHS	
STREET ADDRESS	STREET ADDRESS	IF MULTIPLE: A, B, C, etc.	
CITY, STATE	CITY, STATE, ZIP	LAST TRANSFUSION DATE	
PHONE NUMBER		FEEDING	
<input type="checkbox"/> NBS TEST PANEL REQUESTED		GESTATIONAL AGE	WKS.

**DHEC LAB USE ONLY**

**DHEC 1327 (1/2021)**

DHEC 1327 (1/2021)

LOT 114068 / 31840002

01985001

SENDER COPY

01985001

DO NOT DETACH LAB COPY

**BIOHAZARD**

**dhec** NEWBORN SCREENING  
PUBLIC HEALTH LABORATORY  
SC DEPT. OF HEALTH AND ENVIRONMENTAL CONTROL  
8231 PARKLANE ROAD, COLUMBIA, SC 29223  
803-896-0874

**USE BY 2027-02-28**

**DHEC LAB USE ONLY (DO NOT WRITE HERE)**

CLIA#42DO658606

PATIENT NAME	FIRST NAME	INITIAL	MONTH	DAY	YEAR
LAST NAME	FIRST NAME	INITIAL	BIRTHDATE		
ID / INFORMATION	RACE	SEX	DATE SPECIMEN COLLECTED	MONTH	DAY
COUNTY OF RESIDENCE	COLL TIME	MIL TIME	DATE SPECIMEN COLLECTED	MONTH	DAY
SENDER NUMBER	PATIENT INFORMATION		TEST REQUESTED		
SENDER'S NAME/ADDRESS	TRANSFUSION WITHIN 120 DAYS		HEMOGLOBINOPATHY SCREEN		
	IF CHILD, WRITE MOTHER'S NAME				

**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.

PerkinElmer 226 Ahlstrom DHEC-1339 (REV. 02/2022)

RESULTS HAVE BEEN ADDED IF FORM IS NOT COMPLETELY FILLED OUT  
SEE PAGE 1C HEAT THE LABORATORY GLASS FOR COLLECTION AND MAILING INFORMATION

LOT 114068 / 31840002

### County Codes

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

### Sender Numbers

Sender Numbers are assigned by the Public Health Laboratory. If not known, contact the lab at (803) 896-4777 for assignment.

### 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

## QuantiFERON-TB Gold Plus (QFT-Plus) Specimen Processing Procedure

### Principle:

To properly process 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 refrigerate 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°C ± 1°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 completion. Mark QuantiFeron Gold-Plus and complete incubation start and end time.

**Specimen Preservation and Transport:**

1. Specimens should be shipped and received within 16 hours 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 4 - 27°C until receipt at the Public Health Laboratory.

**Specimen Rejection:**

1. Universal Rejections, See **Section 1**
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 (specimen under- or over-incubated) or specimen requiring incubation at 37°C are not received at the Public Health Laboratory within 16 hours of collection.

## Specimen Collection for Culture and ID

### 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 **Page III-1** 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 of stool or 5 - 10 mL of liquid stool.

#### Cary-Blair Transport media

Solid 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 an X for Stool Specimens

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 an X for Enteric Culture.

#### Specimen Preservation and Transport:

1. For optimal recovery, 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 **Section IV** for appropriate shipping container, packaging and transport instructions.

#### Specimen Rejection:

1. Specimen too old
2. Improper transport media or conditions, temperature outside the range of 2-30 °C
3. Insufficient quantity
4. Universal rejections, See **Section I**

## *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 **Page III-1** 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 [Section IV](#) for appropriate shipping container, packaging and transport instructions.

### Specimen Rejection

1. Ampule in culturette not crushed.
2. Universal rejections, See [Section I](#).

## **Mycobacterium (TB)**

### **Principle:**

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

### **Supplies:**

1. (a) Mycobacteriology collection kit (50 mL plastic sputum collection tube) See **Page III-1** 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.

#### Collection Procedure: Tissue (biopsy)

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. Place the tissue specimen in the tube using sterile forceps without touching the inside of the container.
3. Add enough saline to the sterile container to keep the sample wet until processing. \*\*Note: the specimen should NOT be floating in saline.\*\*
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. Place the cap on plastic tube or sterile container and screw 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: Do not request drug susceptibility testing when submitting specimens from suspected new cases of tuberculosis. All 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 delays 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 **Section I.**

**Specimen Collection for Culture of Mycobacteria (TB)**

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				No fixative or preservatives (saline only)
Feces		Formed-send walnut sized portion Liquid-send 10 mL	1 or more as needed	
Sterile body fluids other than blood		10 mL	1 or more as needed	
Swabs of drainage or other material				Use a small amount of sterile saline to keep swab moist. <b>Do not use transport media. Swabs are not usually productive specimens for mycobacteria.</b>

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

## **Chlamydia/GC & Trichomonas vaginalis by Hologic 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:**

1. GC/ Chlamydia/Trichomonas Aptima supplies See [Page III-1](#) to order.  
For Unisex Collection Kit, the blue swab is the specimen collection swab for both male and female specimens.
2. DHEC form 1332

### **Specimen Handling:**

**\*\*Due to potential cross-contamination in this highly sensitive test, the manufacturer's instructions are clear about proper specimen collection and handling of these Aptima tubes. Ensure that specimen containers do not touch one another during specimen processing. Gloves should be changed between the processing of each patient's specimen(s). Aptima tube specimens must be packaged with only one patient's specimen(s) per bag. The same patient's blood collection tubes may be packaged in the same transport bag, provided the transport requirements are the same.**

### **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 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.
2. 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 [Section IV](#) for appropriate shipping container, packaging and transport instructions.

### **Specimen Rejection:**

1. **More than one patient's specimen(s) in one biohazard transport bag.**
2. No swab in tube, 2 swabs in tube, or improper (non-blue) swab used.
3. Universal rejections, See [Section I](#).
4. Note: specimens collected with this system cannot be used for culture.

### 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 Aptima Unisex Swab (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 contact 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 on the tube.
10. Complete a laboratory test request for each specimen with the test(s) requested and the appropriate anatomic site.
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 APTIMA MTS (Multitest) Swab (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 on the tube.
8. Complete a laboratory test request form for each specimen with the test(s) requested and the appropriate anatomic site.
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 APTIMA Unisex Swab (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 on the tube.
9. Complete a laboratory test request form (DHEC 1332) for each specimen with the test(s) requested and the appropriate anatomic site.
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 APTIMA Unisex Swab (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 on the tube.
6. Complete a laboratory test request form for each specimen with the test(s) requested and the appropriate anatomic site.
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 APTIMA Unisex Swab (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 on the tube.
6. Complete a laboratory test request form for each specimen with the test(s) requested and the appropriate anatomic site.
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.

**References:**

1. Probetec Swab Specimen Collection and Handling by Campbell, D., SFDPH Micro Lab and Engelman, J., M.D., City Clinic, 1/2002.
2. [https://www.hhs.nd.gov/sites/www/files/documents/DOH%20Legacy/Lab\\_Services/Hologic%20Collection%20Devices.pdf](https://www.hhs.nd.gov/sites/www/files/documents/DOH%20Legacy/Lab_Services/Hologic%20Collection%20Devices.pdf)
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

**Specimen Handling:**

**\*\*Due to potential cross-contamination in this highly sensitive test, the manufacturer's instructions are clear about proper specimen collection and handling of these Aptima tubes. Ensure that specimen containers do not touch one another during specimen processing. Gloves should be changed between the processing of each patient's specimen(s). Aptima tube specimens must be packaged with only one patient's specimen(s) per bag. The same patient's blood collection tubes may be packaged in the same transport bag, provided the transport requirements are the same.**

**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 **Transporting and Shipping Infectious Substances in Section IV** for appropriate shipping container, packaging and transport instructions.

**Specimen Rejection (Universal rejections, See [Section I.](#))**

1. **More than one patient's specimen(s) in one biohazard transport bag.**
2. Collection site NOT from an anogenital lesion.
3. Improper swab used.
4. Specimens received at the improper temperature.

**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.
10. Place a patient ID label on the tube.
11. Complete a DHEC 1335-OE form, using instructions on back of form, to send with specimen.

## **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 50 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 must be properly packaged and labeled. As packages delivered using this courier system are transported in commerce, they must be packaged to meet all DOT requirements for shipping infectious substances. Failure to follow these regulations can result in injury, exposure, and/or fines.

### **B. Regulatory Requirements**

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 government agency that regulates commercial 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 shipper's declaration for Dangerous Goods be typed and not handwritten.

The US Department of Transportation (DOT) and the US Postal Service (USPS) harmonized their 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. Training Requirements**

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 minimum of thirty-six months. Retraining must be completed every two years 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. Exemptions**

### 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 principal 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. Definitions:**

**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 severe 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 <http://www.cdc.gov/od/sap/docs/salist.pdf>

**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 Infectious 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 permanent disability, life-threatening or fatal disease 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 an Aptima collection tube (would not meet the IATA definition of a culture)

**Table 3.6.D from IATA Dangerous Goods Regulations**  
**Indicative Examples of Infectious Substances Included in Category A in Any Form**  
**Unless Otherwise Indicted (January 2024)**

[NOTE: “Select Agents or Toxins” are shown in red font]

<ul style="list-style-type: none"> <li>• <i>Bacillus anthracis</i> (cultures only)</li> <li>• <i>Brucella abortus</i> (cultures only)</li> <li>• <i>Brucella melitensis</i> (cultures only)</li> <li>• <i>Brucella suis</i> (cultures only)</li> <li>• <i>Burkholderia mallei</i> - <i>Pseudomonas mallei</i> – Glanders (cultures only)</li> <li>• <i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only)</li> <li>• <i>Chlamydia psittaci</i> - avian strains (cultures only)</li> <li>• <i>Clostridium botulinum</i> (cultures only)</li> <li>• <i>Coccidioides immitis</i> (cultures only)</li> <li>• <i>Coxiella burnetii</i> (cultures only)</li> <li>• <b>Crimean-Congo hemorrhagic fever virus</b></li> <li>• Dengue virus (cultures only)</li> <li>• <b>Eastern equine encephalitis virus</b> (cultures only)</li> <li>• Escherichia coli, verotoxigenic (cultures only)</li> <li>• <b>Ebola virus</b></li> <li>• Flexal virus</li> <li>• <i>Francisella tularensis</i> (cultures only)</li> <li>• Guanarito virus</li> <li>• Hantaan virus</li> <li>• Hantavirus causing hemorrhagic fever with renal syndrome</li> <li>• <b>Hendra virus</b></li> <li>• Hepatitis B virus (cultures only)</li> <li>• Herpes B virus (cultures only)</li> <li>• Human immunodeficiency virus (HIV) (cultures only)</li> <li>• <b>Highly pathogenic avian influenza virus</b> (cultures only)</li> </ul>	<ul style="list-style-type: none"> <li>• Japanese Encephalitis virus (cultures only)</li> <li>• Junin virus</li> <li>• Kyasanur Forest disease virus</li> <li>• <b>Lassa virus</b></li> <li>• Machupo virus</li> <li>• <b>Marburg virus</b></li> <li>• <b>Monkeypox virus</b></li> <li>• <i>Mycobacterium tuberculosis</i> (cultures only)</li> <li>• <b>Nipah virus</b></li> <li>• Omsk hemorrhagic fever virus</li> <li>• Poliovirus (cultures only)</li> <li>• Rabies virus (cultures only)</li> <li>• <i>Rickettsia prowazekii</i> (cultures only)</li> <li>• <i>Rickettsia rickettsii</i> (cultures only)</li> <li>• <b>Rift Valley fever virus</b> (cultures only)</li> <li>• Russian spring-summer encephalitis virus (cultures only)</li> <li>• Sabia virus</li> <li>• <i>Shigella dysenteriae</i> type 1 (cultures only)</li> <li>• <b>Tick-borne encephalitis virus</b> (cultures only)</li> <li>• <b>Variola virus</b></li> <li>• <b>Venezuelan equine encephalitis virus</b> (cultures only)</li> <li>• West Nile virus (cultures only)</li> <li>• Yellow fever virus (cultures only)</li> <li>• <b>Yersinia pestis</b> (cultures only)</li> </ul>
---	--



## Examples of Classifying Infectious Substances

Material	Category A	Category B
Culture of <i>Mycobacterium tuberculosis</i>	<b>X</b>	
Sputum from a person infected with <i>Mycobacterium tuberculosis</i>		<b>X</b>
Known culture of <i>Salmonella spp.</i>		<b>X</b>
<u>Known</u> culture of <i>Bacillus anthracis</i>	<b>X</b>	
<u>Suspected</u> culture of <i>Bacillus anthracis</i>	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	<b>X</b>	
Animal head shipped for rabies testing		<b>X</b>

### **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.

#### **a. 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.

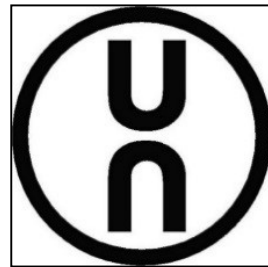
##### Package Performance Testing

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 certified for both Category A and B infectious substances. UN certified shippers also meet all of the requirements for air transportation, 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.



ThermoSafe – Sonoco #311

- 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**

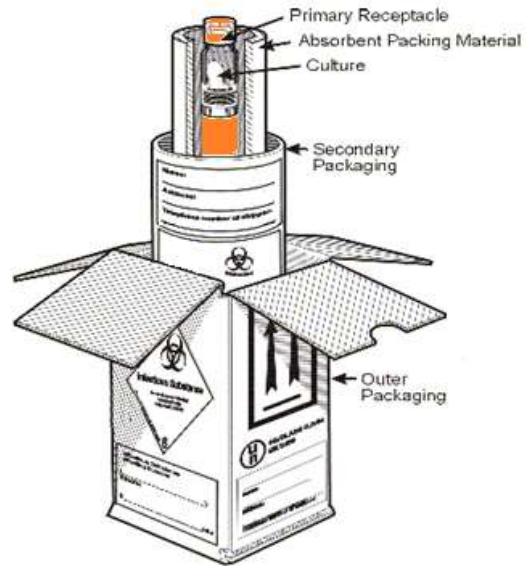
The safe transport of infectious substances is based on “triple-packing.” As an example, a primary sample container, in a secondary container, in an outer shipper, offering three layers of protection.

**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.

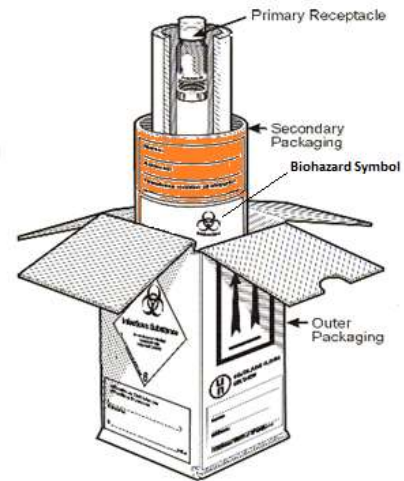
- Must be packed in the secondary receptacle in such a way that it will not break.



### **Secondary Packaging**

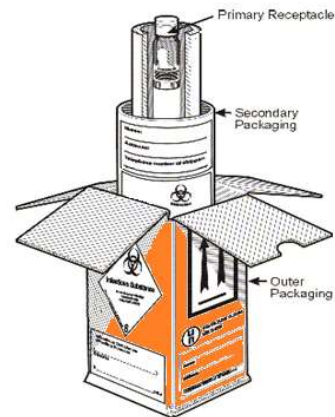
- Is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.
- Must be leak proof and securely sealed.
- Must be placed in the outer packaging so that it does not move.
- Must have a biohazard symbol.
- Never put dry ice inside a secondary container. The container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

*Note: For PHL approved containers, a Ziplock biohazard bag may serve as the secondary receptacle 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, request 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 all the same marks and labels 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 manufacturer'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” ( $\leq -20^{\circ}\text{C}$ ), “refrigerated” ( $2-8^{\circ}\text{C}$ ), or at controlled room temperature (CRT) ( $15-25^{\circ}\text{C}$ ). Specimens received outside of appropriate ranges may be rejected for testing. 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, [Ordering Supplies/Forms/Shipping Containers, Section III, p. 1](#), for information on receiving free shipping materials to submit specimens to the PHL.

#### **General Instructions**

##### **Shipping Frozen ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- Follow all infectious substance shipping instructions.
- With UN certified shippers, do not alter the shippers packaging instructions to accommodate temperature control materials packs.
- 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.
- 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**

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

<b>Shipper Name</b>	<b>Frozen ≤-20°C</b>	<b>Refrigerated 2-8°C</b>	<b>CRT 15-25°C</b>
<b>Sonoco ThermoSafe #311 “Head Box”</b>	<b>24 Hours</b>	<b>24 Hours</b>	<b>24 Hours</b>
<b>Uline #S-7359</b>	<b>24 Hours</b>	<b>24 Hours</b>	<b>24 Hours</b>
<b>Berlin (UN Certified #HMS-69110</b>	<b>24 Hours</b>	<b>DO NOT USE</b>	<b>DO NOT USE</b>
<b>Infecon 5000 (UN Certified)</b>	<b>24 Hours</b>	<b>24 Hours</b>	<b>24 Hours</b>
<b>Infecon 5500 (UN Certified)</b>	<b>24 Hours</b>	<b>24 Hours</b>	<b>24 Hours</b>



## Shipping Configurations - Sonoco ThermoSafe



### **Shipping Frozen ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- 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)



### **Controlled Room Temperature Shipping ( $15-25^{\circ}\text{C}$ )**

- 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:
  - 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



## Shipping Configurations – Uline



### **Shipping Frozen ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- 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



### **Controlled Room Temperature Shipping ( $15-25^{\circ}\text{C}$ )**

- 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
  - 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 ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- 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



### **Controlled Room Temperature Shipping ( $15-25^{\circ}\text{C}$ )**

- 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
  - 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 ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- 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



### **Controlled Room Temperature Shipping ( $15-25^{\circ}\text{C}$ )**

- 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
  - 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 ( $\leq -20^{\circ}\text{C}$ )**

- 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 ( $2-8^{\circ}\text{C}$ )**

- Do not use for  $2-8^{\circ}\text{C}$  Shipping.
- Cannot sustain temperature for 24 hours.

### **Controlled Room Temperature Shipping ( $15-25^{\circ}\text{C}$ )**

- Do not use for  $15-25^{\circ}\text{C}$  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 (request 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 from:** SC DHEC Public Health Laboratory  
 8231 Parklane Road  
 Columbia, SC 29223  
 Emergency Contacts: Andrea Causey  
 Emergency Telephone: (803) 767-8110

**Shipped to:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Shipping Temperature**

\_\_\_ Controlled Room Temperature (15-25°C)  
 \_\_\_ Refrigerated (2-8°C)  
 \_\_\_ Frozen / Dry Ice (≤ -20°C)

**Next day delivery required**

\_\_\_ 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 <b>or</b> Infectious substance, category B

## Shipper's Declaration for Dangerous Goods

- Required for packages containing a Category A infectious substance and/or dry ice.
- 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](http://www.iata.org/whatwedo/cargo/dgr/Documents/Shippers-Declaration-Open-Format-Fillable.pdf)
- Small amounts ( $\leq 30\text{ml}$ ) 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.
- 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 two years from the date of the shipment.

**SHIPPER'S DECLARATION FOR DANGEROUS GOODS** (Provide at least three copies to the airline)

Shipper: \_\_\_\_\_ Air Request No.: \_\_\_\_\_  
 Page: \_\_\_\_\_ of \_\_\_\_\_ Pages  
 Shipper's Reference Number: \_\_\_\_\_

Company: \_\_\_\_\_  
 This shipper's declaration was prepared using a FedEx Express template  
 & must be used ONLY for:  
 \* Class 7 Infectious Substances  
 \* Shipments using an IATA-approved IATA, IATA or IATA-approved  
 \* Shipments originating from a non-IATA location

This certificate and accompanying information must be handed to the operator

**TRANSPORT DETAILS**  
 The document is valid for conditions specified for: \_\_\_\_\_  
 (where not applicable) \_\_\_\_\_  
 Report of Departure: \_\_\_\_\_  
 Report of Distribution: \_\_\_\_\_

**WARNING**  
 Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

**NATURE AND QUANTITY OF DANGEROUS GOODS**

Dangerous Goods Identification				Quantity and type of packaging	Packing and	Additional
UN No.	Proper Shipping Name	Hazard Class	Quantity			

Additional Handling Information: \_\_\_\_\_

I hereby declare that the contents of this declaration are fully and accurately described above to the proper shipping name, and are classified, packaged, marked and labeled/affixed, and are in all respects in proper condition for transport according to applicable International and National Cargo General Regulations. I declare that all of the applicable air transport requirements have been met.

Signature of Shipper: \_\_\_\_\_  
 Name/Title of Shipper: \_\_\_\_\_  
 Place and Date: \_\_\_\_\_  
 Signature and name of carrier: \_\_\_\_\_  
 Operator Reference Number: \_\_\_\_\_

FOR INFORMATION: SHIPPERS ACCEPTING RESPONSIBILITY FOR THE SHIPPER'S DECLARATION MUST BE ADVISED THAT THE SHIPPER'S DECLARATION IS NOT A SUBSTITUTE FOR THE SHIPPER'S OBLIGATIONS UNDER THE IATA DANGEROUS GOODS REGULATIONS.

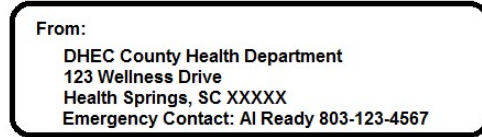
**NOTE** - Federal Express does not accept handwritten Shipper's Declarations. Refer to [www.fedex.com/us](http://www.fedex.com/us) for details regarding acceptable electronic methods to prepare this form.

**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.

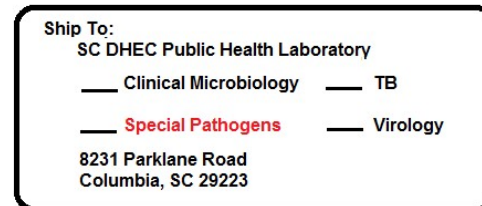
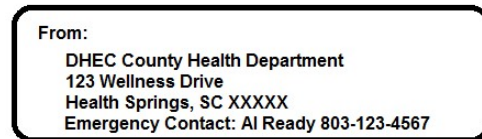
**Secondary Packaging**

- Address of the sender (with emergency contact information)
- Biohazard Symbol (not required if the symbol is present on the secondary container)

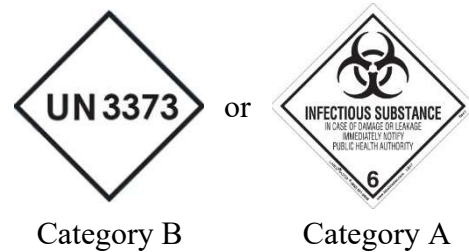


**Outside Packaging**

- Address of the sender (with emergency contact information)
- Address of the intended recipient
  - a. Mark the intended laboratory



- Class 6.2 Hazard Diamond



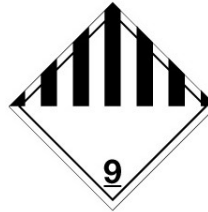
- UN number and proper shipping name(s)
  - Must be within 6 inches of the 6.2 hazard diamond and on the same side of the box

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



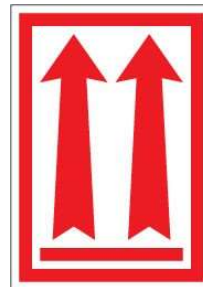
and



- “Overpack”  
(if an overpack was used)



- 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. Specimens being sent from birthing hospitals should be sent with the agency newborn screening courier Sunday through Friday 3 to 4 hours after the specimen has dried, ideally the same day as collection.
3. Specimens sent from midwifery practices, birthing centers, pediatrician offices, etc. should be mailed using overnight delivery services with an 8:30 am arrival time. 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.**
4. Specimens sent from local health departments should be sent in the newborn screening mailing envelope using the agency courier on the same day as collection.

**Note:** Newborn screening specimens should be sent as expeditiously as possible to ensure positive health outcomes. Please contact the newborn screening lab with any questions.

### **Suspected Bioterrorism Specimens and Cultures**

Prior notification is requested 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** before shipping these specimens or cultures. Alternate: Megan Davis, 803-896-0870

Use only UN certified packaging. 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. Please verify that the Special Pathogens Laboratory has been marked on the “To” shipping label.

Ship To:	
SC DHEC Public Health Laboratory	
<input type="checkbox"/> Clinical Microbiology	<input type="checkbox"/> TB
<input checked="" type="checkbox"/> <b>Special Pathogens</b>	<input type="checkbox"/> 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](mailto: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
- Request forms

To request materials, please contact by email at [PHL-Supply@dhec.sc.gov](mailto:PHL-Supply@dhec.sc.gov).

### **References for Information in This Document:**

IATA *Dangerous Goods Regulations*, 65<sup>th</sup> edition, effective  
January 1, 2024 to December 31, 2024

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. Fees and Billing Procedures**

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

### **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 NONpayment." 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. 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.