SCOPE

A Guide To Laboratory Services

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North Carolina State Laboratory of Public Health
NC Department of Health and Human Services

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Public Health
State Laboratory of Public Health

SCOPE

A Guide to Laboratory Services

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North Carolina State Laboratory of Public Health
Division of Public Health
Department of Health and Human Services

October 2026

Josh Stein, Governor
State of North Carolina

Devdutta Sangvai, Secretary
N.C. Department of Health and Human Services

Scott Shone, PhD, HCLD(ABB)
Laboratory Director

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SCOPE, A Guide to Laboratory Services, provides descriptions of testing services, special instructions for specific tests, and explanation of reports, when necessary. It is impossible to address all situations in a guide. Efforts have been made to be concise. For more detailed information, pleases contact the appropriate unit.

Administration	919-733-7834
Customer Service	919-733-3937
Environmental Sciences	919-733-7308
Hemachemistry (Blood Lead)	919-733-3937
Laboratory Improvement	919-733-7186
Laboratory Preparedness	
Bioterrorism & Emerging Pathogens	919-807-8765
Chemical Terrorism	919-807-8571
Microbiology	919-733-7367
Molecular Epidemiology	919-807-8607
Newborn Screening	919-733-3937
Quality Assessment	919-733-7834
Virology/Serology	919-733-3937

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North Carolina State Laboratory of Public Health

Mission

The North Carolina State Laboratory of Public Health (NCSLPH) provides certain medical and environmental laboratory services (testing, consultation, and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.

Administration

Laboratory Director:	Scott Shone, PhD, HCLD(ABB)
Assistant Director - Science and Technology:	
Assistant Director - Infectious Diseases:	William Glover, PhD, D(ABMM), MT(ASCP)
Assistant Director - Quality and Regulatory Compliance:	Susan Orton, PhD, D(ABMLI), MT(ASCP)
Operations Manager:	Jade Stelmach, JD

ADDRESS FOR USPS AND STATE COURIER DELIVERIES
North Carolina State Laboratory of Public Health
1918 Mail Service Center
Raleigh, NC 27699-1918

ADDRESS FOR FEDEX, UPS, AND OTHER COMMERCIAL COURIERS
North Carolina State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607

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CLIA Certificate of Compliance #: 34D0692393

Federal EIN #: 562033116

Main Phone Number: (919) 733-7834

Web Address: https://slph.dph.ncdhhs.gov/

Official Business Hours: 8:00 a.m. to 5:00 p.m., Monday-Friday.

Parking: Parking is available on-site in front of NCSLPH.

NCSLPH Objectives

- Provide high quality laboratory services
- Assist other North Carolina laboratories in developing and strengthening their laboratory services
- Serve as North Carolina's primary Laboratory Response Network (LRN) laboratory in response to acts of bioterrorism, chemical terrorism, and to address emerging public health issues
- Serve the entire state as a reference laboratory for difficult, unusual, or otherwise unavailable laboratory services
- Serve as a resource of information on laboratory practice
- Test human and related animal samples and environmental samples
- Assist in the development, evaluation, and standardization of medical and environmental laboratory testing procedures
- Participate in special studies and research projects
- Provide training, consultation, and information updates to improve and assure quality services in other laboratories
- Certify milk and water laboratories and milk analysts

Delivery of Specimens and Samples

- Postal Services: Daily except Sundays (specimens arriving on weekends are refrigerated, except Newborn Screening (NBS). The laboratory does not accept "POSTAGE DUE" samples.
- UPS, FedEx, and private courier: Monday through Friday and Saturday 8:00-12:00.
- State Courier Service: Daily except Sundays, Mondays, and holidays (specimens arriving on weekends are refrigerated, except NBS).
- Delivery in Person: Monday – Friday, from 6:30 a.m. to 4:00 p.m. NBS samples only are accepted on Saturday 8:30 a.m. – 12:00 p.m.
- Medical Courier: Daily except Saturdays, Sundays and state observed holidays. Courier transported specimens may arrive after hours. After hours deliveries will be place in the vestibule at appropriate holding temperature.
- After normal business hours: Specimens/Samples are delivered to the door to the left of the Loading dock. A sign directs the deliverer to "ring buzzer for after-hours assistance." The buzzer will notify on-site Capital Police for access to the building, and they will respond via the facility intercom.
- Environmental samples for agents of Bioterrorism (BT) must be delivered in person by law enforcement agents. Clinical isolates/specimens are typically delivered by private courier. Bioterrorism and Emerging Pathogens (BTEP) staff will coordinate delivery of clinical specimens with the submitter. Please call the BTEP Unit at 919-807-8600 (24/7 number) prior to submitting/delivering samples.
- For samples or specimens needing examination for agents of Chemical Terrorism (CT), please contact the Chemical Terrorism Laboratory at 919-602-2481 prior to submitting/delivering samples.

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Policies and Limitations

NCSLPH receives consultation on policy matters from the State Health Director, the Epidemiology/Preparedness Liaison Committee of the Association of Local Health Directors, Advisory Committees to Departmental Programs and the Directors of the Departmental Agencies. Public health needs, available resources and whether or not the services are available from other laboratories determine services offered by the State Laboratory. Most public health programs are directed toward prevention of illness and require laboratory support for disease surveillance and diagnosis or monitoring and enforcement of environmental health programs. Some services are available only to Local Health Departments and State-operated health facilities.

All clinical and environmental samples submitted for testing to the NCSLPH must be accompanied by a specimen submission form (test requisition). **Every tube, vial, or other sample container must be labeled with at least two identifiers (e.g., the patient's name and date of birth) that exactly match the identifiers on the submission form.** Unlabeled clinical specimens will be deemed "unsatisfactory for testing", and a new sample requested. The clinical specimen submission form must include the patient's first and last name, patient date of birth, patient demographics (sex and race), date of collection, submitter's EIN and suffix, ICD-10 code, ordering provider name and NPI number, Medicaid number, if applicable, test requested, and any other unit-specific information needed for testing. Use waterproof ink (unless otherwise indicated) to prevent smearing and washing off. Submission forms must be filled out completely and clearly; print legibly if labels are not used. Results may be delayed if all required fields are not completed. Most specimen submission forms are available from the State Laboratory Public Health Website at https://slph.dph.ncdhhs.gov/forms.asp. Do not photocopy forms.

NCSLPH, in collaboration with public health officials, reserves the right to decide whether or not specimens or samples are acceptable for testing. The Laboratory Director or appropriate Laboratory Managers should be contacted before collecting or sending unusual numbers of samples/samples (as in epidemics, investigations, or surveys). This is necessary to determine if the samples can be analyzed and if so, give the lab time to prepare for the increased workload.

Samples must be submitted through a local health department, physician, or other authorized submitter, as defined in the N.C. Administrative Code. * Private citizens are only authorized to submit animals or animal heads for rabies examination. [10A NCAC 42A.0105(b)]

The report of testing results is sent to the authorized submitter of the clinical specimen, as designated on the test requisition. Copies of clinical laboratory results may be furnished to another authorized submitter upon request of the initial authorized submitter. Certain results are furnished to public health programs for follow-up or epidemiologic purposes.

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* "Authorized submitter of clinical samples" [10A NCAC 42A.0102(6)] refers to any individual who, by virtue of a license to practice medicine, dentistry, veterinary medicine, nursing, etc. in the State of North Carolina, is authorized to manipulate a patient for the purpose of collecting blood, spinal fluid, and other body materials for analysis. It may also refer to an agency such as a hospital, local health department, clinic, etc. which employs persons to perform such services under the direction of a licensed individual as described in this subsection. In some cases, this is limited by program guidelines.

The patient or their designated personal representative can request a copy of their completed laboratory testing results. For privacy protection, the laboratory will require proof of identity prior to issuing the test results. This request must be made in writing on a request form available at https://slph.dph.ncdhhs.gov/forms.asp

Consultation

Please direct general or policy questions, comments or suggestions, and feedback on NCSLPH services to the Director's office. Each Unit may be contacted about specific problems or to obtain information concerning specific services or explanation of results, etc. NCSLPH recognizes its special relationship with local health departments. The Laboratory Improvement Unit provides consultation for laboratory services, management and technical operations of local health departments. On-site consultation can be arranged upon request by telephoning (919) 733-7186.

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Quality Assessment

The purpose of the Quality Assessment Unit (QA) is to define and implement the quality tools necessary for monitoring, assessing, and improving the quality of services provided at NCSLPH. The QA unit encompasses the clinical functions at NCSLPH. Functions of the QA unit include: review of Federal Regulations for guidance and compliance; overseeing proficiency testing; monitoring tasks to assess potential problems; developing, evaluating, and standardizing lab procedures and tools; and providing support to all lab areas to ensure quality laboratory testing. Questions may be directed to the QA unit, (919) 733-7834. Quality Assessment of the environmental functions is overseen by the Environmental Sciences Manager.

Specimen and Sample Mailers

Laboratory Mailroom (919) 733-7656

NCSLPH furnishes, either free or at cost, mailers for collection and shipment of laboratory specimens and environmental samples. These mailers are carefully selected by the Laboratory to meet U.S. Postal Service/DOT diagnostic specimen shipping and packaging regulations to minimize problems such as leakage or breakage, and to identify the type of specimen or sample through color-coding. Color-coding speeds up the process of sorting and routing of thousands

of specimens and samples received daily. Therefore, the Laboratory prefers receiving specimens and samples in these mailers. <u>The mailers are provided for shipping specimens and samples only to the State Laboratory and not elsewhere.</u>

Ordering

The NCSLPH Online Supply Ordering System must be used to order supplies. Supplies may be ordered by going through the NCSLPH website, https://slphreporting.ncpublichealth.com/labportal/. Some services of this Laboratory are mandated by the Legislature or other funding source to be provided to both public and private providers. Many services are restricted by the Legislature, Department Programs, or other funding sources to only local health departments and state-operated facilities. The latter does not include federally funded facilities, county facilities that are not part of the health department, or private facilities even if they serve indigent patients. Some services are further restricted to certain patients seen in local health departments, such as pregnant women, children of certain ages, patients with symptoms of certain conditions, etc. Even though a particular testing service may be available to facilities other than local health departments, the same supplies are not available to others. Certain funds are provided to the Laboratory by Department Programs or the Legislature for the purpose of furnishing only to local health departments certain items at no cost or at a very low cost (state contract price and recovery of handling costs only) to support specific tests on particular patients.

Ordering Supplies/Forms

Supplies	Order online, https://slphreporting.ncpublichealth.com/labportal/
Clinical Specimen Submission Forms	Download and print from website, https://slph.dph.ncdhhs.gov/forms.asp *Note: Newborn Screening and Hemoglobinopathy forms which require dried blood spots are not available on the State Lab Web Site and must be ordered same as supplies.*
Environmental Submission Forms	Provided as part of the sample collection kit.

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Biologicals

Rabies Vaccine and Rabies Immune Globulin (RIG) are available to physicians and health departments. These items are very expensive and are not usually stockpiled by the end-user. The person ordering is financially responsible for the cost of the treatment. Once purchased, rabies treatment (vaccine and RIG) may not be returned for credit or refund. Prior to ordering vaccine, consultation with one of the authorized persons in the Communicable Disease Branch (CDB) is highly recommended.

Authorized Personnel/Rabies Treatment

PH Veterinarian, Communicable Disease Branch (919) 733-3419
State Epidemiologist or Medical Consultation Unit (919) 733-3419

The above personnel may be reached at this number after hours, nights, weekends or holidays.

Shipment of rabies treatment is usually made by using UPS or FedEx. In very rare emergency situations, it may be relayed by the State Highway Patrol. This method will not be used unless absolutely necessary.

Botulism Antitoxin

NCSLPH does not supply antitoxin for treatment of botulism. The antitoxin is available only from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA, and is released to physicians after consultation with a state epidemiologist or physician specialist on call to determine the validity of the diagnosis. To obtain antitoxin for treatment of botulism, contact Communicable Disease Branch (CDB) Epidemiology Section at (919) 733-3419. This number is also used after hours, nights, weekends, and holidays to reach the epidemiologist on call.

Payments and Prices

Printed invoices are sent immediately upon shipment of the entire order. Invoices can also be viewed on the NCSLPH website, mailroom ordering portal, while logged in to your account. Prices for all laboratory supplies, specimen containers and biological products are updated as necessary and subject to change without notice.

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SERVICES FROM OTHER LABORATORIES
(Not Performed at NC State Laboratory of Public Health)

Criminal case tests – (919) 662-4500 (Must be referred through law enforcement) 3320 Old Garner Road Raleigh, NC 27610	NC Department of Justice State Bureau of Investigation
Food tests (not associated with human illness) Constable Laboratory – (919) 733-7366 4000 Reedy Creek Road, PO Box 27647 Raleigh, NC 27607	NC Department of Agriculture & Consumer Services
Animal diseases (except Rabies) (919) 733-3986 Rollins Diagnostic Laboratory 2101 Blue Ridge Road, PO Box 12223 Raleigh, NC 27605	NC Department of Agriculture & Consumer Services
Chromosome Studies (Karyotype) (Refer to the Genetic Counseling Program in the Department of Pediatrics at the listed medical centers)	Carolinas Medical Center PO Box 32816 Charlotte, NC 28232 (704) 355-3159 ECU School of Medicine Greenville, NC 27834 (252) 744-2525 UNC School of Medicine Pediatric Genetics and Metabolism Chapel Hill, NC 27599 (919) 966-4202 Wake Forest Baptist Health Department of Pediatrics/Section on Medical Genetics Medical Center Boulevard Winston-Salem, NC 27157 (336) 713-4500
Centers for Disease Control and Prevention (CDC)	NOTE: Submission of specimens to CDC must be sent via the State Laboratory. In special cases the State Laboratory can arrange for direct submission of specimens to CDC.

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Environmental Sciences Unit

(919) 733-7308

Environmental Sciences (ES) provides consultation and laboratory support for environmental and health related programs in the Department of Health and Human Services. ES offers comprehensive analysis of drinking water for local health departments and authorized health care providers. ES is also responsible for accrediting/certifying milk and drinking water laboratories.

Environmental Sciences is organized into five lab areas:

Environmental Inorganic Chemistry
Environmental Organic Chemistry
Environmental Microbiology
Environmental Radiochemistry
Laboratory Certification

The mission of ES is to provide timely and cost effective environmental analytical laboratory services to local health departments and supported programs.

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Environmental Inorganic Chemistry

(919) 733-7308

Introduction

The Environmental Inorganic Chemistry Laboratory analyzes a variety of samples such as water, dust wipes, paint and soils. Water samples from both public (non-compliance) and private water systems are examined for chemical and/or physical parameters.

Inorganic Chemical Analysis

To obtain a chemical analysis, the homeowner must submit samples through the local health department. A full well panel includes: alkalinity, arsenic, barium, cadmium, calcium, chromium, copper, hardness (Total), lead, iron, magnesium, manganese, mercury, nitrate/nitrite, pH, selenium, sodium, silver, sulfate, chloride, fluoride, and zinc. This laboratory also offers testing for hexavalent chromium, uranium and soluble/insoluble iron and manganese. Sampling kits are available for selective testing when the full panel is not required.

Fluoride Analysis

A fluoride analysis can be performed on a private well water sample if submitted through a local health department, a dentist, or a physician. The report form must contain the collection date and the patient's name. Fluoride results are reported to the health department, dentist, or physician.

Nitrate/Nitrite Analyses

Nitrate/Nitrite analyses require a special sample kit. The kit consists of a small Styrofoam cooler with three ice packs. The ice packs must be removed from the kit and placed in a freezer for at least 24 hours prior to collecting the samples. Samples must be cooled to 4° Celsius after collection; therefore, it is recommended that the samples be placed in a cooler containing ice packs or with thermal preservation upon collection and refrigerated until it is placed in the Styrofoam cooler for shipment to the laboratory. Prior to shipment, make certain that the sample is placed between the frozen ice packs inside the Styrofoam cooler. The analysis of the sample must begin within 48 hours of collection (plan collection time and transportation accordingly). Samples received at room temperature or are greater than 48 hours old will be rejected.

Optional Parameters

A private water system can request additional testing, as necessary, for the optional parameters by indicating on the sample submittal form. These include, but may not be limited to: aluminum, antimony, beryllium, cobalt, nickel, potassium, thallium, vanadium, acidity, phosphate, conductivity, settleable solids, total dissolved solids, total suspended solids, and turbidity. The laboratory also offers a full panel for Coal Ash analytes.

Ammonia and cyanide analyses may also be requested but require special sampling kits and preservation. Please contact the lab supervisor to order these sample kits.

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Sample Collection and Identification

All samples must be collected in sampling containers supplied by the laboratory. Complete directions for sample collection and shipment are found on the back of the request form included with each sample kit. Each sample must be properly identified with a completed form. Please write legibly on the form. Place the submitter's name on the first line of the inorganic chemical analysis form. All the information on the form must be complete. Incomplete or illegible information may lead to sample rejection.

Reasons for Sample Rejection by the Laboratory

- Samples submitted without DHHS forms or samples submitted with blank forms.
- Samples submitted without a collection date, collection time, county, or "Report to:" information on the DHHS form.
- Samples collected for nitrate/nitrite analyses that are more than 48 hours old or do not meet temperature requirements.
- Fluoride only samples not submitted by a doctor, dentist, or health department.
- Fluoride samples that exceed the 28 days holding time.

Shipment

Samples should be mailed/transported as soon as possible after collection (See appendix C for local health department specimen transport guidance).

Reporting Procedures and Interpretation

Sample analysis time will vary from one to thirteen days, depending upon the number of parameters requested for the sample. The submitter should receive a copy of the analytical results within three weeks of the date of sample collection. Public and private water systems laboratory reports are held for five to seven years depending on program area, then destroyed.

The laboratory report contains results for each parameter tested followed by a unit of measurement. Most of the analyses are reported in parts per million (ppm) or milligrams per liter (mg/L) that are equivalent. If the laboratory does not detect the parameter in the sample, then the laboratory will report a result preceded by a less than symbol (<). These "less than" results are based on the lowest concentration of the analyte that the laboratory can satisfactorily quantify with the method and the instrumentation in use.

The recommended limits or the maximum contaminant levels (MCLs) listed are for informational purposes only to provide guidance in interpreting an inorganic chemical analysis. These limits have been established for public water systems by the Environmental Protection Agency (EPA) under the Safe Drinking Water Act. If a limit is not listed in this column of the report, neither the EPA or the State has established an MCL for the contaminant. Questions or concerns about the health effects of any of these contaminants should be addressed to the Occupational and Environmental Epidemiology Branch (919-707-5900).

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The EPA and/or State recommended limits or maximum contaminant levels for the primary drinking water inorganic contaminants in public water supplies established by the EPA are as follows:

Antimony – MCL = 0.006 mg/L. Antimony may decrease growth and longevity. Potential sources are industrial discharges or from tin/antimony solder used in plumbing.

Arsenic – MCL = 0.010 mg/L. Carcinogenic properties have been ascribed to arsenic. Its presence may be due to natural deposits, industrial discharges, or pesticides.

Barium – MCL = 2 mg/L. Barium occurs only in trace amounts in drinking water and rarely exceeds 1 mg/L. Sources include discharge from metal refineries and erosion of natural deposits.

Beryllium – MCL = 0.004 mg/L. Beryllium is very poisonous. It may enter a water system through metal refineries and coal-burning factories and discharges from electrical, aerospace and defense industries.

Cadmium – MCL = 0.005 mg/L. Cadmium is toxic and may be carcinogenic. It may enter water as a result of industrial pollution or deterioration of galvanized pipe.

Chromium – MCL = 0.10 mg/L. Chromium salts are used in industrial processes and may enter a water supply through industrial discharge and erosion of natural deposits.

Copper – MCL = 1.3 mg/L. Copper may impart a metallic taste to water and cause greenish stains on faucets and plumbing fixtures, and can lead to both short and long-term health effects. Sources include household plumbing and erosion of natural deposits.

Cyanide – MCL = 0.2 mg/L. Cyanide can cause spleen, brain and liver damage and can lead to thyroid problems. It is used in electroplating, steel processing, plastics, synthetic fibers, fertilizer, and farm products.

Fluoride - MCL = 4.0 mg/L. Fluorides are found mostly in groundwater as a natural constituent. It is added to water to promote strong teeth.

Iron – MCL = 0.3 mg/L. Iron in water can cause staining of laundry and porcelain. It may give the water an astringent taste.

Lead – MCL = 0.015 mg/L. Lead is a cumulative poison and is of special concern for infants and small children where exposure may lead to physical and mental developmental delays. In a water supply it may occur where piping material or pipe joint compound contains lead.

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Manganese – MCL = 0.05 mg/L. Manganese can cause objectionable stains to laundry and fixtures.

Mercury – MCL = 0.002 mg/L. Mercury is very toxic and can lead to kidney damage. Its presence may be associated with industrial water and agricultural applications.

Nitrate – MCL = 10 mg/L (as nitrogen). Serious poisonings in infants have occurred following ingestion of well water containing nitrogen in the form of nitrate at concentrations greater than 10 mg/L. This problem is known as methemoglobinemia (blue-baby syndrome) and is generally confined to infants less than three months old. The presence of nitrates is usually due to animal wastes and fertilizers. Boiling water does not remove nitrates but instead concentrates them.

Nitrite – MCL = 1 mg/L (as nitrogen). Nitrite is the actual etiologic agent of methemoglobinemia. It results from oxidation of ammonia or reduction of nitrates. May occur in natural water or water distribution systems from fertilizer use as well as leaching from septic systems and sewage.

pH – MCL = 6.5 – 8.5. Soft acid water may leach metals from plumbing causing staining problems, metallic tastes, or deleterious health effects.

Selenium – MCL = 0.05 mg/L. Selenium is an essential trace nutrient but may be toxic above trace levels. Natural levels in groundwater may be due to soil types. Selenium may be leached from coal ash and fly ash at electric power plants that burn seleniferous coal.

Thallium – MCL = 0.002 mg/L. Thallium affects the brain, kidneys, and liver. Its presence may be associated with electronics or glass industries.

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The limits listed for the contaminants below are recommended limits that the EPA has established for public water systems. These recommended limits are based on the cosmetic effects (such as skin or tooth discoloration) or the aesthetic effects (such as taste, odor, or color) they have in drinking water and are therefore considered as secondary contaminants.

Aluminum – 0.05 to 0.2 mg/L. Aluminum may cause discoloration of the water and may contribute to scaling or sedimentation in pipes.

Chloride – 250 mg/L. High chloride levels may harm pipes, as well as impart an unpleasant salty taste.

Total Dissolved Solids – 500 mg/L. Waters with high dissolved solids are unpalatable and may be unsuitable for many industrial applications.

Silver – 0.10 mg/L. Exposure to silver in drinking water may cause argyria (a discoloration of the skin). Health effects are only cosmetic.

Sulfate – 250 mg/L. Sulfate may naturally be present in groundwater. Its sodium and magnesium salts exert a cathartic action.

Zinc – 5 mg/L. Zinc may cause a bitter astringent taste and opalescence in alkaline water. It most often enters the water supply through the deterioration of galvanized iron pipes.

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Environmental Microbiology

(919) 733-7308

Introduction

The Environmental Microbiology Lab performs bacteriological analyses on water samples from both public (non-compliance) and private water systems. Samples are examined for the presence of the coliform group of bacteria, including total coliform and *E. coli,* which are indicators of fecal contamination. Water is not examined for pathogenic bacteria, as the prospect of isolating them from water is very remote.

Public water system samples are submitted to this Laboratory by the Public Water Supply Section. Samples from private wells will be analyzed for coliform bacteria only if the sample is submitted through a local health department or other authorized submitter. The well should be inspected at the time the sample is collected by a health department representative. Refer to the water sample collection recommendations found on the NCSLPH website from the DHHS, DPH, Environmental Health Section On-Site Water Protection Branch.

Samples of non-drinking water, such as those from lakes, streams, rivers, and ponds that are submitted by health departments may also be examined for total and fecal coliform bacteria to determine the degree of contamination.

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Sample Collection and Identification

A. Coliform

All samples for coliform analysis must be collected in regulation, sterile bottles supplied by this Laboratory. Complete directions for collecting a proper sample are found on the back of the request form included with each sample kit. Directions must be followed closely to ensure that the sample is not contaminated during collection. Each sample must be properly identified with a completed form. A minimum of 100 mL is required for drinking water samples submitted for testing of total coliforms (fill to or slightly above the first 100-mL line). Most coliform and *E. coli* results are reported as Present or Absent, but enumeration using a Most Probable Number (MPN) method is available upon request.

B. Other Tests

With the exception of the Sulfate Reducing/Sulfur Bacteria and Iron Bacteria tests, please call the Laboratory before submitting samples for the following tests:

1. Heterotrophic Plate Count

   This procedure does not determine a specific organism, but the aerobic bacteria present in a water sample that will grow at the temperature of incubation and on the non-selective media used. Results will be reported as the number of Colony Forming Units (CFUs) per milliliter (mL) of sample.

2. Pseudomonas

This analysis confirms the presence of *Pseudomonas aeruginosa*. An opportunistic pathogen, this organism has been associated with eye, ear, nose, throat, skin, and urinary and intestinal tract infections. Results will be reported as the number of *Pseudomonas aeruginosa* organisms present in 100 mL of sample.

3. Enterococcus

This test detects enterococci in fresh and marine waters. Enterococci are considered a valuable bacterial indicator for determining the extent of fecal contamination of recreational surface waters. Results will be reported as the Most Probable Number (MPN) of enterococci per 100 mL of sample.

4. Sulfate Reducing and Sulfur Bacteria

The presence of Sulfate Reducing and/or Sulfur Bacteria in a water source may cause taste, odor, and pipe corrosion problems. These bacteria are considered "nuisance organisms" and are not pathogenic. Both tests can be performed using the same sample. Results will be reported one calendar month from initiation of sample analysis. Results are reported as either Positive or Negative for each of these bacteria.

5. Legionella

The laboratory has added testing for *Legionella pneumophilia* in water samples to the list of available test options. This test requires a special collection bottle and a 100-ml sample volume and is incubated for a seven-day period. Results are reported as a Most Probable Number (MPN).

6. Microscopics

a. Iron Bacteria

Iron Bacteria may produce taste, odor, and pipe corrosion problems. Results for Iron Bacteria examinations will be reported as Positive or Negative for Iron Bacteria. If there is no visible sediment or particulate matter or reddish tinge in the water, it is unlikely that Iron Bacteria are present.

b. Fungi, Protozoan, and Miscellaneous Materials

Microscopic examinations will be made to identify the material or organism. Samples should be transported to the Laboratory as soon as possible after collection using the same form and bottle used for other microscopics.

c. Giardia and Cryptosporidium

This Lab does not examine water samples for Giardia or Cryptosporidium.

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C. Milk Microbiology

The Environmental Microbiology Unit provides analyses of milk and dairy products on samples received from the Milk Sanitation Branch of the NC Department of Agriculture and Consumer Services. Proper shipping measures must be observed to maintain integrity of samples and to meet the regulatory requirements of the National Conference of Interstate Milk Shippers (NCIMS). Milk/Dairy products and containers may be analyzed for the following:

- Aerobic Bacteria
- Coliform Bacteria
- Inhibitory Substances, including beta-lactam and tetracycline antibiotics
- Somatic Cell Count
- Alkaline Phosphatase – residual, microbial, or reactivated

Sample Shipment:

Note: Samples for coliform analysis must reach this Laboratory and be processed within a maximum of 30 hours after collection. Samples arriving after 30 hours will be rejected as unsuitable for analysis.

Non-drinking water samples should be refrigerated during a maximum transport time of six hours. A special courier may be required to deliver the samples to this Laboratory. Arrangements for these analyses should be made with the Laboratory by telephone at least 24 hours in advance.

Reporting Procedures and Interpretation

Test results for drinking water analyses are sent within three working days after the Laboratory receives the samples. If *E. coli* are present, the water is considered unsafe for drinking purposes. Results are reported as the presence or absence of both Total Coliform and *E. coli* bacteria. An analysis refers only to the sample as received and should not be regarded as a complete report on the water supply. With the exception of Sulfur/Sulfate-reducing bacteria and *Legionella*, non-drinking water sample results are forwarded as soon as complete, typically 4-5 days after receipt of the sample and initiation of testing. Laboratory reports are held for five to seven years and then destroyed. Grade A milk reports are retained for three years.

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Environmental Organic Chemistry

(919) 733-7308

Introduction

The Environmental Organic Chemistry Lab analyzes water for a variety of organic chemicals. Eligible submitters include health departments and certain governmental agencies.

Sample Collection and Identification

In general, all water samples should be taken in a one (1) liter amber bottles, 60-120 mL bottle or 40 mL glass vials supplied by the Laboratory.

A. Petroleum Products and Volatile Organic Compounds (VOC)

Petroleum products fall into two categories: 1) solvents and gasoline; and 2) heavy oils and greases. If the suspected petroleum contaminant is a solvent or gasoline, request a Volatile Organic Compound (VOC) Kit. VOC samples are collected in 40 mL vials; all kits can be ordered on the State Laboratory web site, https://slph.dph.ncdhhs.gov. If the suspected contaminant is a heavy oil or grease, request a Petroleum Kit. Petroleum samples are analyzed for both volatiles and extractables. Petroleum product samples are collected in clean one-liter amber bottles and 40 mL vials. VOC and Petroleum Kits are supplied only to health departments upon request. Follow all instructions on the label or request sheet when sampling. Screw the cap tightly, making sure the cap seals. This analysis is to determine a potential health hazard of the supply by identifying the compound(s) and will not necessarily determine the source of contamination. The person submitting the sample should make note of any odors or possible sources of contamination on the request sheet. Please fill in all blanks on the sample submittal form provided in the kit. Print legibly.

B. Pesticides (Herbicides, Fungicides, Insecticides, etc.)

Samples to be analyzed for the presence of pesticides are sampled in two (2) one-liter amber glass bottles. These bottles/kits are available on the State Laboratory website, https://slph.dph.ncdhhs.gov. The Laboratory is unable to analyze for every pesticide, so before sampling, check with the Laboratory for availability of testing. Carefully fill the bottle with the water sample and seal with Teflon lined cap. Make sure the cap seals completely. Follow all instructions on the label or report sheet when sampling. Mail immediately to the Laboratory so that analysis can be started within the method established holding time. Remember to complete all information on the submission form and print legibly.

Multiple test procedures are used for this class of organic compounds. Chlorinated pesticides, nitrogen-phosphorous pesticides, glyphosate (Round-up®) and herbicides are all analyzed by different procedures and require individual sample collection kits. Refer to the SLPH ordering website and contact the Environmental Sciences laboratory at 919-733-7308 if you have questions.

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Shipment

For results to be valid, it is necessary to ship/transport samples as soon as possible after collection. Samples should be shipped cold using frozen ice packs in Styrofoam mailers. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

Organic analyses are diverse in nature and vary greatly in complexity and analytical requirements. It is difficult to state precisely when a report for a particular test will be completed. Some samples may receive priority treatment because of a critical health concern, an imminent hazard in the workplace, the instability of a particular sample, or other factors. Generally, results are complete within three weeks of the sample collection date. Public and private water system laboratory reports are retained for five to seven years and then destroyed.

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Environmental Radiochemistry

(919) 733-7308

Introduction

The Environmental Radiochemistry Lab analyzes environmental samples submitted by the Radiation Protection Section (Division of Health Service Regulations/DHHS) and other approved sample submitters. Currently, natural and manmade radiation levels in air, water, milk, food and other media, are monitored.

These environmental surveillance programs are outlined below. All parameters are not tested for every sample.

Air Filters
Gross Alpha
Gross Beta
Gamma

Air Cartridges
Gamma

Surface Supplies
Gross Alpha
Gross Beta
Gamma
Tritium
Iodine – 131 (low levels)
Uranium (total)

Ground Supplies (not public)
Gross Alpha
Gross Beta
Tritium
Uranium (total)
Gamma

Silt/Soil
Gross Alpha
Gross Beta
Uranium (total)

Milk
Gamma
Iodine 131 (Low level)

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Edible Products
Same as Silt/Soil

Wipe Samples (Leak Test)
Isotopes as requested

Sample Collection and Identification

Eligible submitters must provide a detailed listing of the sample source and the testing required. Formats will vary depending on the submitting agency.

Shipment

Use the shipment guidelines on the back of the requisition form or contact Environmental Sciences at (919) 733-7308 with any questions.

Reporting Procedures and Interpretation

The variety of sample types, analytical methodologies, and current sample loads make it difficult to predict the time required for reporting. Best estimates, based on the individual situation, can be made at the time of sample submission to the Laboratory.

Crisis samples will receive priority over routine monitoring samples. Radiological laboratory reports are retained for 10 years, and then destroyed.

Note: For radiation contamination problems other than routine monitoring, please contact the DHHS/Radiation Protection Section at (919) 571-4141.

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Laboratory Certification

(919) 733-7308

Introduction

Laboratory Certification evaluates laboratories that analyze water from public water supplies, which are subject to regulation under the North Carolina Drinking Water Act. Laboratories and analysts that test milk under the Grade A Pasteurized Milk Ordinance (PMO) are also evaluated. Certification is granted to qualified laboratories and personnel that meet State and Federal requirements. In addition, Laboratory Certification provides consultation and guidance to Laboratories involved in milk and water testing and offers training through seminars and workshops.

Accreditation of Milk Laboratories

For a milk laboratory to be accredited, the following requirements must be met:

Laboratory facilities must meet the criteria as described in Official Milk Laboratory Evaluation Forms (FD-2400). An on-site evaluation determines compliance. When an accredited laboratory changes location or undergoes substantial remodeling, the Laboratory Evaluation Officer must be notified, and facilities must be re-evaluated within three months. No evaluation of personnel or procedures is required at this time.

The analyst(s) working at the milk laboratory must be certified/approved as outlined below. All official examinations required by the Grade A Pasteurized Milk Ordinance must be performed by a certified/approved analyst.

When a certified analyst resigns from an accredited laboratory, the laboratory certification officer must be notified since the loss of a certified analyst could result in loss of accreditation. For example, a laboratory having only one certified analyst would lose accreditation if that analyst resigns. No official samples could be tested until a new analyst becomes certified.

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Certification or Approval of Milk Analyst

An analyst may be certified to perform analysis of raw or processed milk and milk products to meet the testing requirements of Section 6 of the PMO. Analysts may be approved for screening raw milk for the presence of antibiotic residues.

Full Certification

Three criteria must be achieved for an analyst to become fully certified:

1. The laboratory facilities must meet the requirements.
2. The analyst's performance must be evaluated during an on-site visit at least once every two years.
3. The analyst must participate annually in the split sample program and must demonstrate acceptable performance.

When all three criteria are met, the analyst is fully certified.

Conditional Certification

For initial certification, an analyst not meeting all three criteria may be granted conditional approval to conduct official examinations when 1 and 2 OR 1 and 3 are met.

If a conditionally approved analyst does not perform satisfactorily on split samples or does not meet performance standards during an on-site evaluation, his/her certification status will be revoked.

Provision Certification

A fully certified analyst who (1) fails to satisfactorily participate in the split sample program annually or (2) fails on on-site evaluation will be placed on provisional status. Failure to participate in the next split sample evaluation or to meet satisfactory performance levels on the repeat on-site evaluation will result in withdrawal of certification for that test.

An analyst who loses certification for some or all tests cannot examine official samples using those tests for which certification has been withdrawn.

Reinstatement of Decertified Analyst

An analyst who has lost certification must participate in a training program acceptable to the certifying authority before requesting recertification. Recertification after training is based on the analyst's meeting the three criteria previously described.

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Certification of Water Laboratories

For a water laboratory to be certified, three requirements must be met:

1. Laboratory facilities must meet the criteria as described in the regulations (10A-42D-.0200). An on-site evaluation determines compliance.
2. Performance test (PT) samples must be analyzed for each analyte and by each method for which certification is requested. For chemical parameters, Heterotrophic Plate Count and *E. Coli* enumeration, two of the previous three PT results must be acceptable. For the coliform bacteria group (Total Coliform and *E. coli*), acceptable results must be reported on 90% of the samples in each set.
3. Certification fees must be paid for each analyte group for which certification is desired.

Certification activities for both milk and water can be initiated by contacting:

North Carolina State Laboratory of Public Health
Laboratory Certification - Drinking Water
PO Box 28047
Raleigh, North Carolina 27611-8047.
Phone: 919-807-8879

Blood Lead Testing

(919) 733-3937

Introduction

Childhood lead poisoning is one of the most common pediatric health problems in the United States, even though it is entirely preventable. The persistence of lead poisoning, in light of present knowledge about the sources as well as pathways and prevention of lead exposure, presents a direct challenge to clinicians and public health authorities.

Lead poisoning is widespread and is not solely a problem of inner city or minority children. No socioeconomic group, geographic area, racial or ethnic population is spared its effects.

According to the Centers for Disease Control and Prevention (CDC), there are approximately a half-million children in the United States ages 1-5 with blood lead levels above 3.5 micrograms per deciliter (µg/dL), the reference value at which CDC recommends public health actions be initiated. No safe blood level in children has been identified. Lead exposure can affect nearly every system in the body. Because lead exposure often occurs with no obvious symptoms, it frequently goes unrecognized.

The newest methodology at the North Carolina State Laboratory of Public Health (NCSLPH) includes ICP-MS (Inductively Coupled Plasma Mass Spectrometry). In addition, effective October 2021, a multi-tier approach to follow-up has been adopted with an overall goal of reducing children's blood lead levels below 3.5 µg/dL.

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Who and When to Screen

All children seen at local health departments for health maintenance visits (Well Child and Well Baby Clinics; Early Periodic Screening Diagnosis Treatment (EPSDT) Clinics; Pediatric Supervisory Clinics; WIC Children, etc.) and all children receiving services through private providers are to be screened at least once before the age of six without regard to risk determination.

Ideally, children should be tested at 12 and 24 months of age, or upon their first entry to the health care system at a later age. Children identified as high risk should be rescreened in 12 months. All refugee children 6 months to 16 years of age are to be tested at time of arrival to the United States. For refugee children aged 6 months to 6 years of age Blood Lead testing should be repeated again 3 to 6 months after placement in a permanent residence regardless of initial test results.

The specimen should be collected by the child’s primary care provider.

Screening Test and Methodology

Direct whole blood lead measurement is the screening test of choice. Finger-stick, capillary blood specimens are adequate for the initial screening test, provided that precautions are taken to minimize the risk of contamination. Venous blood specimens should be collected for confirmation of all elevated blood lead results.

The State Laboratory is available to analyze blood specimens collected by local health departments, community clinics, hospitals, and private providers on all children up to 16 years of age.

Sample Identification and Collection

A. Specimens must be accompanied by DHHS form #3707 which is available on the NCSLPH website at https://slph.dph.ncdhhs.gov/Forms/3707-Blood-Lead-Analysis.pdf. This is a scannable form and must be printed on plain white paper from the website.

B. Specimen collection device kits can also be ordered on-line at https://slphreporting.ncpublichealth.com/labportal/.

C. Complete all identification and requested information on DHHS form #3707. It is imperative that all following information be completed:

Two unique patient identifiers, to include:
First and last name of patient
Patient date of birth
Medicaid number if applicable
ICD-10 code (reason for testing)
Patient demographics (sex, race, etc.)
Date of Collection
Type of sample collected
Initial or follow-up blood lead test
Submitter EIN
Ordering provider and National Provider Identifier (NPI)
Patient medical record number or Social Security Number can also be used as a second unique identifier (optional)

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D. Submit a whole blood EDTA (lavender top) capillary or venipuncture tube blood specimen. All specimens must be labeled with at least two identifiers that match exactly with the submission form, such as:

First and last name of patient
Patient Date of Birth
Patient number or Social Security Number
Medicaid number

E. Preparation of Child for Fingerstick Specimen Collection
   a. Wash child's hand with soap and water, using hand brush. Rinse well. Dry.
   b. Grasp the child's hand so that the blood drawer's thumb is across the top of the child's fingers.
   c. Hold the child's hand so that the palm faces up.
   d. Use child's middle or ring finger for specimen collection.
   e. Using an alcohol wipe, briskly scrub area on the child's fingertip for 20 seconds.

f. Use lancet to stick finger slightly left of center.
g. Use dry gauze to wipe off the first drop of blood.

Note: After specimen collection, care of puncture site should be consistent with your institution's procedures.

F. Collection of Blood Specimen:
   a. Continuing to grasp the finger, touch the capillary tip of the collection device to the beaded drop of blood.
   b. The capillary must be held continuously in a horizontal position during specimen collection to prevent air bubbles from forming in the capillary tube.
   c. Dispense the full capillary of blood (150 – 250 µL) into the container.
   d. Turn capillary/tube unit immediately to a vertical position to allow the blood in the capillary to flow into the tube.
   e. Remove capillary with holder at the same time. Close blood container with attached cap.
   f. Agitate the specimen to mix the EDTA through the blood.
   g. Label capillary blood tube with two unique patient identifiers and keep at ambient temperature (15 to 38 ºC).

Laboratory testing will NOT be performed unless the information on the specimen tube **exactly matches information on the collection form.*

Shipment

The Laboratory must test **specimens within 14 days of collection** to ensure specimen integrity and suitability for analysis; however, immediate shipping is recommended to ensure that patients with elevated blood lead levels are rapidly identified and treated. See appendix C for local health department specimen transport guidance.

Children are classified according to the risk for adverse effects of lead based solely on blood lead measurement. The urgency and type of follow-up required are based on a child's risk classification.

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Additional information may be found at:

https://ehs.dph.ncdhhs.gov/hhccehb/cehu/lead/resources.htm

Prenatal Lead Testing

(919) 733-3937

The North Carolina State Laboratory of Public Health (NCSLPH) has established a Prenatal Lead Testing Program in partnership with local public health departments (LHDs) in North Carolina. Since the Centers for Disease Control and Prevention (CDC) does not recommend blood lead testing of all pregnant women in the United States, state or local public health departments should identify populations at increased risk for lead exposure and provide community specific risk factors to guide clinicians in determining the need for population-based blood lead testing.

Routine blood lead testing of pregnant women is only recommended in clinical settings that serve populations with specific risk factors for lead exposure that meet the required criteria assessed using the Lead Risk Assessment Questionnaire. Health care providers serving lower risk communities should consider the possibility of lead exposure in individual pregnant women by evaluating risk factors for exposure as part of a comprehensive occupational, environmental, and lifestyle health risk assessment of the pregnant woman, and perform blood lead testing if a single risk factor is identified.

This test is only available to local public health departments.

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Sample Identification and Collection

A. Specimens must be accompanied by DHHS form #3707 which is available on the NCSLPH website at https://slph.dph.ncdhhs.gov/Forms/3707-Blood-Lead-Analysis.pdf. This is a scannable form and must be printed on plain white paper from the website. Do not photocopy form.

B. Complete all identification and requested information on DHHS form # 3707. It is imperative that all of the following information be completed:
   - First and last name of patient
   - Patient date of birth
   - Medicaid number if applicable
   - ICD-10 code (reason for testing)
   - Patient demographics (sex, race, etc.)
   - Assure that the Prenatal box is checked appropriately
   - Date of collection
   - Type of sample
   - Initial or follow-up blood lead test
   - Submitter EIN
   - Ordering provider name and National Provider Identifier (NPI)

Patient medical record number or Social Security Number (can be used as a second unique patient identifier) (optional)Please be advised that the specimen of choice for this testing is a

whole blood venipuncture specimen (rather than fingerstick) collected in a EDTA (lavender-top) blood collection tube. All specimens must be labeled with at least two identifiers that match with the submission form exactly, such as:

First and last name of patient
Patient Date of Birth
Patient medical record number or Social Security Number
Medicaid number

Shipment

The Laboratory must receive the venipuncture specimen within 14 days of collection to ensure specimen integrity and suitability for analysis; however, immediate shipping is recommended to ensure that patients with elevated blood lead levels are rapidly identified and treated. See appendix C for local health department specimen transport guidance.

Additional information may be found at:

http://epi.publichealth.nc.gov/oee/programs/ables.html

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Laboratory Improvement

(919) 733-7186

Laboratory Improvement conducts and coordinates diverse activities which promote and contribute to the quality-assurance of laboratory services. The general responsibilities of the unit are described below.

Consultation

The Laboratory Improvement consultants have knowledge and experience in many technical areas. Information is provided to local laboratory managers, laboratorians, and nursing staff concerning laboratory management, operations, technical procedures, biosafety, packaging and shipping, and quality assurance guidelines. Consultation is provided to public health programs concerning laboratory services needed to support program objectives. Arrangements for on-site reviews can be made by regional technical consultants upon request to Laboratory Improvement.

Federal mandates have a great impact on the Laboratory Improvement consultant's roles. The consultants assist the local health departments in complying with the Occupational Safety and Health Administration (OSHA) regulations, as well as the Clinical Laboratory Improvement Amendments (CLIA '88) federal regulations. This is achieved through on-site visits as well as identifying and developing new training courses to address the needs of the laboratorian. Continued monitoring of the local health departments is an on-going commitment of this Unit.

Training

Surveys and evaluations to identify training needs are conducted periodically and used to guide the development of workshops and training activities. In addition, training activities may be developed in response to specific requests from individuals and groups. Workshops are presented on clinical, environmental and management topics; they are designed to give "hands-on" experience with methods and techniques. Instructors are selected on the basis of competency, experience, and the ability to communicate with participants. Workshops are announced annually on the NCSLPH website under Lab Improvement Training Workshops tab. Additions to the workshop calendar are announced as they are scheduled; quarterly schedules of upcoming workshops are published in the NCSLPH newsletter, *Lab-Oratory.*

Laboratory Improvement is also an active member of the National Laboratory Training Network (NLTN). The NLTN is a cooperative training agreement between the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC). The purpose of the network is to address the need for effective laboratory information and management systems to assist state health agencies to develop, promote, and deliver quality laboratory training. The network functions as a training service delivery program that utilizes available resources and conducts regionalized training based on documented needs.

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Laboratory Advisor to the Gonorrhea Control Program

Training consultation and quality control related to the statewide gonorrhea control program are provided. For information about laboratory methods and available workshops in this program contact Laboratory Improvement.

Control Cultures

Microbiological cultures useful in quality control of media and reagents are available on a limited basis. To order control cultures, use the "Stock Culture Order Form" on the NCSLPH public website. This form is found in the "Forms" section of the "Forms, Newsletters & Bulletins" tab under Lab Improvement on the home page.

Regional Laboratory Consultants

Regional Laboratory Improvement consultants are assigned to four regional areas:

Yancey County
Phone: (828) 289-8519

Davie County
Phone: (336) 306-4302

Wilson County
Phone: (910) 322-8120

Pitt County
Phone: (252) 414-3078

The Regional Consultants are available Monday through Friday of each week for phone consultation or site visits at local health department laboratories in their respective areas.

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Laboratory Preparedness

Bioterrorism and Emerging Pathogens (919-807-8600)
Chemical Terrorism (919-807-8571)

The Laboratory Preparedness Unit houses both biological and chemical labs that test for agents of terrorism. Both labs are members of the Laboratory Response Network (LRN). The LRN was established by the US Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC). The LRN founding partners are the Federal Bureau of Investigation (FBI), the Association of Public Health Laboratories (APHL) and the CDC. The objective for establishing the LRN was to ensure an effective laboratory response to bioterrorism by helping to improve the nation's public health infrastructure. Today, the LRN maintains an integrated network of state and local public health, federal, military, and international laboratories that can respond to bioterrorism, chemical terrorism and other public health emergencies. The CDC provides to all LRN members validated protocols for the testing of agents of terrorism.

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Bioterrorism and Emerging Pathogens

24/7 Duty Phone: (919) 807-8600

Introduction

The mission of Bioterrorism and Emerging Pathogens (BTEP) is to maintain laboratory capacity for the detection of biological weapons and emerging infectious diseases and to strengthen crisis response within the Division of Public Health. BTEP is an Advanced Reference Lab within the Laboratory Response Network (LRN-B) and a member of the Food Emergency Response Network (FERN). The LRN and FERN provide standardized protocols for the testing of biothreat agents and emerging pathogens in clinical, environmental and food samples. BTEP functions as a referral laboratory for all labs and agencies in NC for possible Select Agent viruses, bacteria, and some toxins. BTEP also accepts environmental samples and food from law enforcement agencies where a biothreat agent or toxin is suspected or a credible threat is identified in environmental situations. BTEP is also a Variola (Smallpox) testing laboratory for the CDC.

The BTEP Unit may be contacted for emergency situations by:

Duty Phone (24/7): 919-807-8600 or
BT Pager (24/7): 919-310-4243

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Specimen Collection and Submission

NOTE: All submission forms are located on the NCSLPH web site, https://slph.dph.ncdhhs.gov/forms.asp under Bioterrorism Information.

Currently, three types of specimens may be submitted for analysis:

A. Suspicious Substances – These are often environmental samples and must be submitted through a law enforcement agency or through the Public Health Preparedness and Response (PHPR) Branch. Untrained individuals should NOT attempt collection. Suspicious substances are generally transported to the State Laboratory under ambient conditions by the submitting law enforcement agency using Chain of Custody documentation. All samples should be field screened for radioactive, chemical, and explosive substances. Samples are triple packaged in a rigid outer container (no paint cans) for transport to the state lab. Notify BTEP prior to submission by phoning first the duty phone followed by the 24/7 backup pager if needed. An environmental submission form must be completed for each sample. If multiple samples are submitted, be prepared to prioritize samples for testing. Also include chain of custody paperwork. BTEP will initiate an in-house chain of custody form once the sample arrives and BTEP takes possession of the sample(s). See **Table 1** in **Appendix A** for further sample guidance.

B. Clinical Samples – **Prior to submission,** call 919-807-8600 (BTEP Duty Phone) for guidance on collection, packaging, transport of samples, and labeling of packages. Acceptable clinical isolates/samples include those from a hospital or other public or private clinical lab in North Carolina. Isolates/samples are submitted to BTEP if available microbiological

methods used in the submitting lab are unable to safely rule out a possible bio-threat or Select Agent. Primary specimens must be collected aseptically and placed into leak-proof containers. Isolated bacterial or viral organisms should be pure isolates and must be shipped on media or using conditions that will support the transport of the isolate. Isolates and/or specimens are packaged as suspected Category A infectious substances and packaged by lab staff that are certified in Pack and Ship procedures. Bacterial isolates should NEVER be sent on plated medium. All submitters of samples should include 24/7 contact information. Submitters should call BTEP for guidance on the appropriate samples and collection for testing. Transport all samples immediately or as soon as possible to the lab. Samples for bacterial testing should be sent at ambient temperatures; samples for viral testing should be sent on cold packs. Call for transportation requirements for toxins. See **Table 2** in **Appendix A** for further sample guidance.

For known Select Agents all submitters are required to first complete the transfer forms found in the Code of Federal Regulations (see regulations 7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16) and receive approval from the Select Agent Program and the NCSLPH prior to transfer.

C. Food – If food items are suspected of containing bio-threat Select Agents or toxins, contact BTEP immediately. If botulism is suspected, contact CDB at (919) 733-3419. No food samples can be submitted to the NCSLPH unless received through a law enforcement agency, the Public Health Preparedness and Response Branch (PHP&R) or by special request from the State Department of Agriculture. Transport the samples using Chain of Custody documentation. Complete and submit a 'Suspicious Package or Bioterrorism Sample' environmental submission form for each food item submitted. All food items must be collected aseptically and placed into leak-proof containers, being careful not to touch the food items with hands. Collect at least 50 grams of solid food sample and at least 50 mL of liquid food sample (See table 3 for more details). All samples should be promptly refrigerated and transported on cold packs in insulated containers. DO NOT FREEZE samples. If samples are already frozen, keep frozen during transport. See **Table 3** in **Appendix A** for further sample guidance.

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Reporting Procedure and Interpretation

A. Suspicious Substances – Presumptive and final test results are phoned to the submitter at the 24/7 contact number listed on the submission form. Final reports are sent to the submitter. Final reports on BTEP environmental samples are NOT available on the NCSLPH LIMS secure web site. Requests for additional copies of reports must be made directly to BTEP. All samples received from a law enforcement agency are handled as evidence and stored in secure areas until released to the submitters or destroyed. An internal Chain of Custody form is maintained, and copies are given to the submitter when the completed sample is released. Upon request, digital photos of the materials submitted, or threat letters contained within the samples can be attempted and electronically mailed to the submitting agency. After all testing is completed; the

submitting agency may claim their samples by appointment only between the hours of 8 a.m. to 5 p.m., Monday-Friday. All sample material is securely stored for at least 60 days. After 60 days and without further notice, BTEP periodically destroys unclaimed samples.

B. Clinical specimens – All positive results are called immediately to the submitter, the NCSLPH Laboratory Director and the Medical Consultation Unit (MCU)/Epidemiology Section. Negative results are called to the submitter. Final reports are sent to the submitter. Results are reported to CDC.

C. Food – Presumptive and final test results are phoned to the submitter. Final reports are sent to the submitter at the address listed on the submission form. Final reports are NOT available on the NCSLPH LIMS secure web site. Requests for additional copies must be made to the BTEP section. Food samples submitted to BTEP are treated as environmental samples and subject to the same Chain of Custody, and storage and release requirements.

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CHEMICAL TERRORISM

(919) 807-8571

Introduction

The Chemical Terrorism and Threat lab (CTAT) is part of the Laboratory Preparedness Unit at the NC State Laboratory of Public Health and is a Laboratory Response Network (LRN) level 2 laboratory. The CTAT Unit serves as a surge capacity laboratory for other state LRN-C laboratories and for the CDC in qualified methodology. The CTAT Unit was created in 2002 to respond to chemical acts of terrorism by testing potentially exposed persons for cyanide and metals. The unit has expanded this role to currently respond to acts of terrorism, accidental exposures, occupational exposures, and the identification of unknown substances.

In the event of a chemical exposure, the NCSLPH laboratory will be able to provide instruction for and assistance with the proper collection, packaging and shipping of clinical specimens either to CDC, the NCSLPH or another state LRN-C laboratory. The current menu provides analyses of clinical and environmental samples for:

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Toxic Metals in Urine

- Beryllium
- Barium
- Cadmium
- Thallium
- Lead
- Uranium
- Arsenic
- Mercury

Toxic Metals in Whole Blood

- Lead
- Mercury
- Cadmium

Cyanide in Whole Blood

Tetramine in Urine

Tetramethylenedisulfotetramine (TET, Tetramine)

Volatile Organic Compounds in Whole Blood

Chloroform, 1,2-dichloroethane, Benzene, Carbon Tetrachloride, Toluene, Tetrachloroethane, Ethylene, Xylenes, and Styrene

HNPAA in Urine

Determines the exposure to Tetranitromethane (TNM) by measuring 4-Hydroxy 3-Nitrophenylacetic Acid (HNPAA)

Nerve Agent Metabolites in Urine and Serum

Determines the exposure to: GB (Sarin), GF (cyclohexylsarin), GD (Soman), VX, and Russian VX.

Ricinine and Abrine in Urine

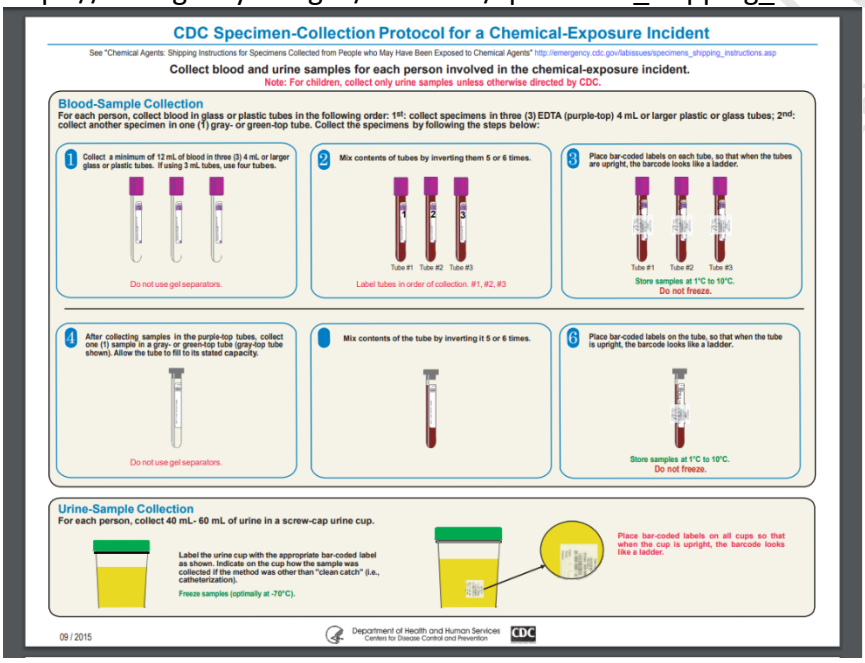
Determines the exposure to Ricin and Abrin.

CT staff may be contacted 24/7 by:

Contact Number for CTAT Coordinator:	919-807-8878
24-hour contact number:	919-602-2481

Clinical Sample Collection and Identification:

https://emergency.cdc.gov/labissues/specimens_shipping_instructions.asp



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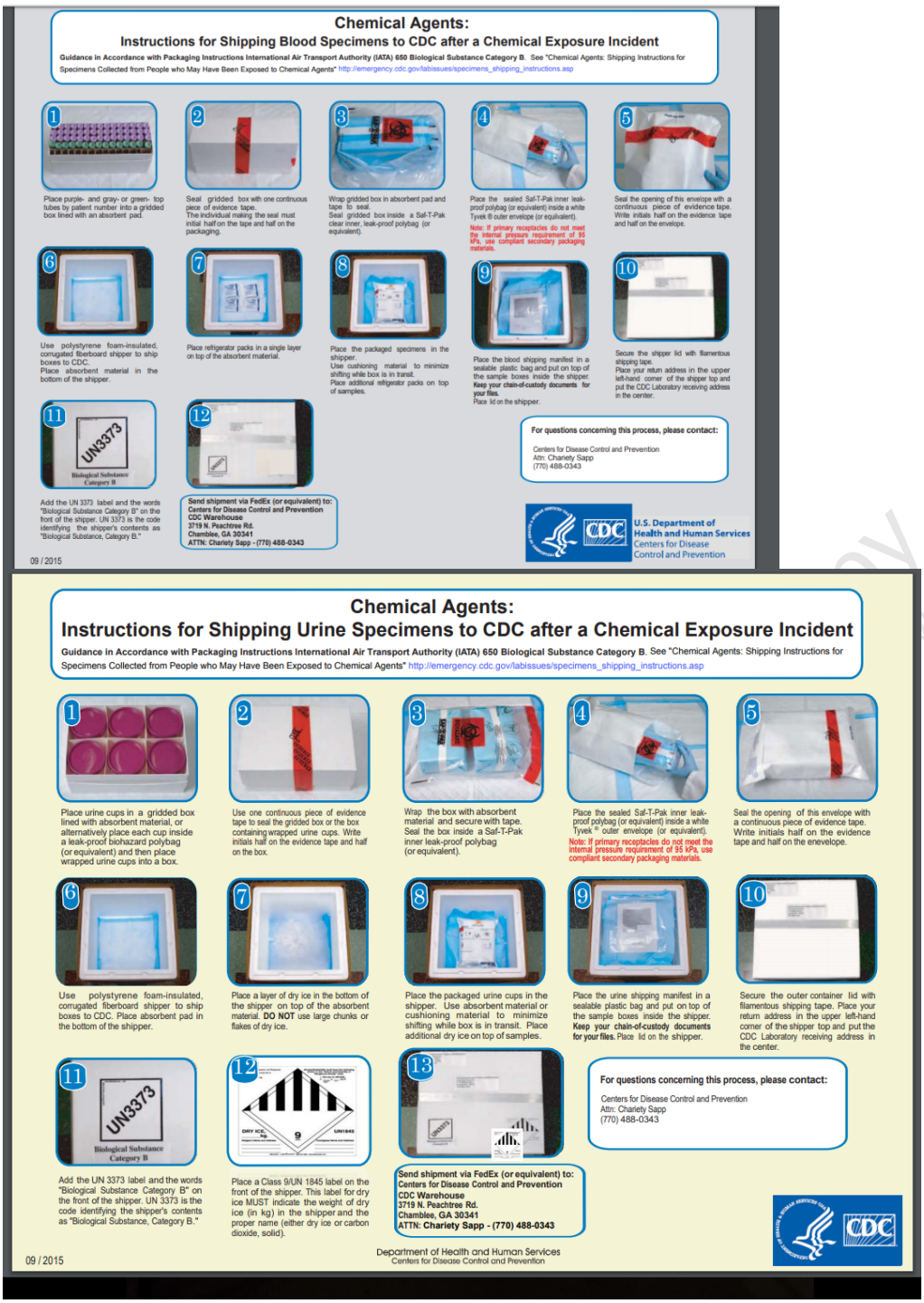

Chemical Agents:
Instructions for Shipping Blood Specimens to CDC after a Chemical Exposure Incident

Guidance in Accordance with Packaging Instructions International Air Transport Authority (IATA) 650 Biological Substance Category B. See "Chemical Agents: Shipping Instructions for Specimens Collected from People who May Have Been Exposed to Chemical Agents" http://emergency.cdc.gov/labissues/specimens_shipping_instructions.asp

1. Place purple- and gray- or green- top tubes by patient number into a gridded box lined with an absorbent pad.
2. Seal gridded box with one continuous piece of evidence tape. The individual making the seal must initial half on the tape and half on the packaging.
3. Wrap gridded box in absorbent pad and tape to seal. Seal gridded box inside a Saf-T-Pak clear inner, leak-proof polybag (or equivalent).
4. Place the sealed Saf-T-Pak inner leak-proof polybag (or equivalent) inside a white Tyvek ® outer envelope (or equivalent). Note: If primary receptacles do not meet the internal pressure requirement of 95 kPa, use compliant secondary packaging materials.
5. Seal the opening of this envelope with a continuous piece of evidence tape. Write initials half on the evidence tape and half on the envelope.
6. Use polystyrene foam-insulated, corrugated fiberboard shipper to ship boxes to CDC. Place absorbent material in the bottom of the shipper.
7. Place refrigerator packs in a single layer on top of the absorbent material.
8. Place the packaged specimens in the shipper. Use cushioning material to minimize shifting while box is in transit. Place additional refrigerator packs on top of samples.
9. Place the blood shipping manifest in a sealable plastic bag and put on top of the sample boxes inside the shipper. **Keep your chain-of-custody documents for your files.** Place lid on the shipper.
10. Secure the shipper lid with filamentous shipping tape. Place your return address in the upper left-hand corner of the shipper top and put the CDC Laboratory receiving address in the center.
11. UN3373 Biological Substance Category B — Add the UN 3373 label and the words "Biological Substance Category B" on the front of the shipper. UN 3373 is the code identifying the shipper's contents as "Biological Substance, Category B."
12. Send shipment via FedEx (or equivalent) to: Centers for Disease Control and Prevention, CDC Warehouse, 3719 N. Peachtree Rd., Chamblee, GA 30341, ATTN: Chariety Sapp - (770) 488-0343

For questions concerning this process, please contact:
Centers for Disease Control and Prevention
Attn: Chariety Sapp
(770) 488-0343

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Chemical Agents:
Instructions for Shipping Urine Specimens to CDC after a Chemical Exposure Incident

Guidance in Accordance with Packaging Instructions International Air Transport Authority (IATA) 650 Biological Substance Category B. See "Chemical Agents: Shipping Instructions for Specimens Collected from People who May Have Been Exposed to Chemical Agents" http://emergency.cdc.gov/labissues/specimens_shipping_instructions.asp

1. Place urine cups in a gridded box lined with absorbent material, or alternatively place each cup inside a leak-proof biohazard polybag (or equivalent) and then place wrapped urine cups into a box.
2. Use one continuous piece of evidence tape to seal the gridded box or the box containing wrapped urine cups. Write initials half on the evidence tape and half on the box.
3. Wrap the box with absorbent material and secure with tape. Seal the box inside a Saf-T-Pak inner leak-proof polybag (or equivalent).
4. Place the sealed Saf-T-Pak inner leak-proof polybag (or equivalent) inside a white Tyvek ® outer envelope (or equivalent). Note: If primary receptacles do not meet the internal pressure requirement of 95 kPa, use compliant secondary packaging materials.
5. Seal the opening of this envelope with a continuous piece of evidence tape. Write initials half on the evidence tape and half on the enevelope.
6. Use polystyrene foam-insulated, corrugated fiberboard shipper to ship boxes to CDC. Place absorbent pad in the bottom of the shipper.
7. Place a layer of dry ice in the bottom of the shipper on top of the absorbent material. **DO NOT** use large chunks or flakes of dry ice.
8. Place the packaged urine cups in the shipper. Use absorbent material or cushioning material to minimize shifting while box is in transit. Place additional dry ice on top of samples.
9. Place the urine shipping manifest in a sealable plastic bag and put on top of the sample boxes inside the shipper. **Keep your chain-of-custody documents for your files.** Place lid on the shipper.
10. Secure the outer container lid with filamentous shipping tape. Place your return address in the upper left-hand corner of the shipper top and put the CDC Laboratory receiving address in the center.
11. UN3373 Biological Substance Category B — Add the UN 3373 label and the words "Biological Substance Category B" on the front of the shipper. UN 3373 is the code identifying the shipper's contents as "Biological Substance, Category B."
12. DRY ICE 9 UN1845 — Place a Class 9/UN 1845 label on the front of the shipper. This label for dry ice MUST indicate the weight of dry ice (in kg) in the shipper and the proper name (either dry ice or carbon dioxide, solid).
13. Send shipment via FedEx (or equivalent) to: Centers for Disease Control and Prevention, CDC Warehouse, 3719 N. Peachtree Rd., Chamblee, GA 30341, ATTN: Chariety Sapp - (770) 488-0343

For questions concerning this process, please contact:
Centers for Disease Control and Prevention
Attn: Chariety Sapp
(770) 488-0343

Department of Health and Human Services
Centers for Disease Control and Prevention

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All specimens submitted **must** have a chain of custody accompanying them to preserve the integrity of potential evidence because all acts of terrorism are a federal offense and are subject to litigation. Specimens must be evidence taped and initialed according to CDC guidelines. Proper evidence preservation is critical. The samples also must follow CDC protocol for collection, packaging, and shipping.

Environmental Samples:
All environmental samples will be screened first through the Bioterrorism Unit following the NCSLPH All-hazards approach. Please see the Bioterrorism and Emerging Pathogens (BTEP) Unit information for further information.

Shipment
Submission forms, chain of custody forms, and sample manifest forms are obtainable from the NCSLPH CT Lab website: https://slph.dph.ncdhhs.gov/chemical/contact.asp

Reporting Procedure and Interpretation
Results are reported to the NCSLPH Laboratory Director, to CDC via the LRN, and to the submitter by phone or mail.

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MICROBIOLOGY

(919)-733-7367

The mission of the Microbiology Unit is to provide clinical and reference microbiological services to public and private laboratories in North Carolina. A wide variety of specimen types are examined. Many of the services performed here are available only at the NCSLPH and the Centers for Disease Control and Prevention (CDC) in Atlanta, GA.

The Microbiology Unit is organized into five labs:

- Bacteriology (includes Atypical Bacteriology, Special Bacteriology, and Enteric Bacteriology)
- Mycobacteriology
- Mycology
- Parasitology
- Bacterial Sexually Transmitted Diseases (STD) (includes Chlamydia/Gonorrhea, Syphilis Serology)

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Anaerobic Bacteriology

(919) 733-7367

Laboratory services in anaerobic bacteriology are not available at the NCSLPH.

Botulism (*Clostridium botulinum)*

The NCSLPH **does not** perform *Clostridium botulinum*-related testing.

Cases of suspected botulism constitute a health emergency and are handled according to protocols of the Epidemiology Section and the CDC. The patient's physician MUST FIRST contact the Communicable Disease Branch (CDB), Epidemiology Section of the Division of Public Health at (919) 733-3419. This telephone number provides assistance on a 24-hour basis and includes recorded instructions for after-hours emergencies.

An epidemiologist in this Section must discuss the case with the patient's physician. If botulism is a probable diagnosis, the State Epidemiologist will then contact the CDC to arrange shipment of botulism antitoxin to the patient's physician. Clinical specimens also may be forwarded to the CDC for culture or toxin testing. These test results may be delayed, although they can confirm the diagnosis.

Recommended specimens for botulism examination include fresh stool specimens (25g), serum (15 ml) and any implicated food items shipped cold on frozen ice packs (1-8°C) in an insulated container.

Botulism-related specimens may be submitted to the CDC only after approval by the CDB and the CDC. Instructions for shipping specimens will be provided at that time.

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Bordetella Pertussis

(919) 807-8603

Introduction

Specimens for isolation of *Bordetella pertussis* and *B. parapertussis* in suspected cases of whooping cough are accepted from public and private health care providers. PCR screening is available for *Bordetella pertussis and Bordetella parapertussis*. Only symptomatic contacts of diagnosed cases of pertussis are recommended for Bordetella examination, since a carrier state in asymptomatic persons has not been demonstrated as an important source of transmission. Reference cultures are accepted for confirmation of Bordetella pertussis*, B.parapertussis, B.bronchiseptica, and B. holmesii*. Consultation and bench training are provided upon request.

Specimen Collection and Identification

Nasopharyngeal swabs in Copan ESwab Liquid Amies transport medium should be collected as soon as possible after onset of symptoms, and prior to antibiotic treatment. There is a greater likelihood of positive cultures and/or PCR in the first two weeks of symptomatic infection than during later weeks of illness. However, PCR may detect organisms for a prolonged period of time regardless of viability.

Mailers containing materials and instructions necessary for collecting and shipping nasopharyngeal specimens are available from the Laboratory Mailroom. Orders may be placed online at https://slph.dph.ncdhhs.gov/. The Copan ESwab Liquid Amies transport medium in the mailer has a shelf life of approximately six (6) months. **Notify the Microbiology Unit before submitting large numbers of specimens (e.g., outbreaks, clusters).** The Copan ESwab Liquid Amies transport medium included in the mailer must be labeled with two patient identifiers: patient's name and either date of birth, medical record number or Social Security number accompanied by a completed DHHS Form #4121. **Please do not place adhesive labels on the microcentrifuge tube**. Unlabeled specimens will not be tested. Follow collection instructions included in the mailer. The following additional clinical information should be entered on the **back of the form**: nature of symptoms, date of onset, immunization history, contact with other cases of whooping cough, any antibiotic therapy prior to specimen collection and other pertinent information.

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Note: Specimens received without the **submitter's return address** are subject to rejection.

Fill out DHHS#4121 Form with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of Collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested

Isolated organisms for identification should be subcultured to appropriate media and incubated until growth is apparent before shipping. Bordet-Gengou or Regan-Lowe Agar is recommended for

B. pertussis; blood, chocolate or heart infusion agar is satisfactory for other bordetellae. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. Growth from culture plates also may be suspended in Copan ESwab Liquid Amies transport medium for shipment.

Shipment of Specimens

Specimens should be shipped as soon as possible after collection (See appendix C for local health department specimen transport guidance).Friday shipments are not recommended as specimens should be kept cold. Refer to the **Microbiology section in Appendix A** for Bordetella specimen and shipment requirements. Contact SLPH if further guidance is needed.

It is essential for clinical culture specimens to be kept cold after collection and during transit to the Laboratory. Copan ESwabs or culture isolates should be packed in the return mailer, along with a completed DHHS 4121 Form.

Reference isolates may be shipped in a microbiology reference mailer with a completed DHHS 4121 Form. Plates should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof, crush-proof container. Label "Pertussis" on the outside of the package. When shipping by U.S. Mail, use first-class postage. Be sure to place **return address** on the outside of the container, regardless of shipping method.

Reporting Procedures and Interpretation

PCR tests are generally batched twice per week and positive results are telephoned to the submitter on the day of completion, usually within 1 -3 days of sample receipt. If needed, priority requests can be accommodated with laboratory pre-approval. Positive culture results will also be called to the submitter; negatives will be held for 7 days before reporting. Positive PCR and culture results are reported to the Epidemiology Section, Division of Public Health, for surveillance purposes. **All results are available via the website.**

PCR results are presumptive for the presence of *Bordetella pertussis* or Bordetella parapertussis while culture is considered the gold standard. However, culture can be less sensitive than PCR, since PCR is not dependent on viability and has higher sensitivity (can detect fewer numbers of organisms) compared to culture. Subsequently, discrepant PCR and culture reports may occur. Low numbers of organisms may be detected by PCR but may be overgrown by normal flora or non-viable in culture. This PCR has been known to cross-react with *Bordetella holmesii*.

Both culture and PCR may fail to detect *B. pertussis or B. parapertussis*. Positive PCR are valuable for early diagnosis of pertussis but should be accompanied by culture since culture is the recommended diagnostic method. As the disease process may continue for weeks or months after viable organisms no longer remain in the nasopharynx, a negative culture does not rule out infection, especially if specimens were collected late in the course of illness. Organisms present in low numbers may be difficult to detect by either method. Prior antibiotic therapy, overgrowth of contaminants or failure to keep specimens cold after collection and during transit may result in a negative culture. Cultures performed at the local level using commercial agar plates may be negative due to insufficient moisture in the medium. Accuracy in both tests is dependent on correctly collected specimens.

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Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. Copies of reports are retained at the NCSLPH. The submitting agency is responsible for maintaining reports in the patient's file.

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Chlamydia/Gonorrhea Detection

(919) 733-3937

Introduction

Chlamydia trachomatis and *Neisseria gonorrhoeae* infections are two of the most common sexually transmitted infections worldwide. In 2021, a total of 1,644,416 cases of chlamydia infection and a total of 710,151 cases of gonorrhea infection were reported to the CDC, making them the first and second most common notifiable sexually transmitted infections in the United States for that year.

Chlamydia are nonmotile, gram-negative, obligate intracellular bacteria. The *C. trachomatis* species consists of a group of 15 different serovars that can cause disease in humans. The serovars D through K are the major cause of genital chlamydial infections in men and women. *C. trachomatis* can cause assorted urogenital infections in addition to asymptomatic infection, which if undiagnosed could lead to pelvic inflammatory disease (PID), ectopic pregnancy, and infertility in women. Children born to infected mothers are at significantly higher risk for inclusion conjunctivitis and chlamydial pneumonia.

N. gonorrhoeae is the causative agent of gonorrheal disease. *N. gonorrhoeae* are non-motile, gram-negative diplococci. The majority of gonorrheal infections are uncomplicated lower genital tract infections and may be asymptomatic. However, if left untreated in women, infections can ascend and cause PID. PID can manifest as endometritis, salpingitis, pelvic peritonitis, and tubo-ovarian abscesses. A smaller percentage of persons with gonococcal infections may develop Disseminated Gonococcal Infection (DGI).

The diagnostic testing for *C. trachomatis* and *N. gonorrhoeae* at the NC State Laboratory of Public Health is a nucleic acid amplification test (NAAT) that dually detects the presence of *C. trachomatis* RNA and/or *N. gonorrhoeae* RNA on a single specimen. Chlamydia cell culture is not performed at the NC State Laboratory of Public Health but is available from commercial reference laboratories.

The vaginal swab is the CDC preferred collection method, however extragenital swab and urine specimen testing for C. trachomatis and N. gonorrhoeae is available on a limited basis to pre-approved, select sites. Diagnostic testing is the same as for vaginal swab specimens.

Sample Collection and Identification

In addition to the instructions below, an instructional presentation “Chlamydia/Gonorrhea Specimen Collection and Form Training” can be accessed and viewed at the NC State Laboratory website:(https://slph.dph.ncdhhs.gov/labimprovement/labtraining.asp). The purpose of the presentation is to assist in training people who collect and submit samples to the NCSLPH for Chlamydia/Gonorrhea testing. Following the instructions should result in optimal quality of test samples and the expeditious reporting of test results. The presentation may be reviewed for guidance or continuing education.

All specimens must be labeled with patient first and last name and at least one other unique identifier that matches with data on the submission form. Clearly label each tube of chlamydia/gonorrhea detection transport medium with the patient’s name (first and last) and either the date of birth, Social Security number, or other unique identifier. Complete submission form

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DHHS Form #4011 “Chlamydia/Gonorrhea Detection”. The DHHS #4011 form is available on this website. Forms should be printed on white paper only.

A. Vaginal swab specimens (clinician-collected) are obtained by the following procedure:

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

4. 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.

5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.

6. Carefully break the swab shaft at the score line against the side of the tube.

7. Immediately discard the top portion of the swab shaft.

8. Tightly screw the cap onto the tube

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B. Patients who wish to collect their own vaginal swab specimens (in clinic) should be instructed as follows:

Note: For patient-collected vaginal swab specimen collection, ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

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, request 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. Carefully insert the swab into your vagina about 2 inches (5 cm) inside the opening of the vagina and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab

touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.

4. 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, request a new Aptima Multitest Swab Specimen Collection Kit.

5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.

6. Carefully break the swab shaft at the score line against the side of the tube. .

7. Immediately discard the top portion of the swab shaft.

8. Tightly screw the cap onto the tube. Return the tube as instructed by your doctor, nurse, or healthcare-provider.

C. Urine specimens are obtained by the following procedure:

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

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

3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.

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

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Note*:* *Chlamydia trachomatis/Neisseria gonorrhoeae* laboratory services are subject to the following guidelines which have been developed to ensure proper patient management and efficient utilization of limited resources. Information regarding health care provider eligibility and patient selection is stated below. Specimens submitted to the Microbiology laboratory must be accompanied by a fully completed submission form DHHS Form #4011. Failure to supply the requested patient information may result in significantly delayed specimen testing or in specimen rejection. Specimens for diagnostic testing not labeled with correct patient identification information will not be tested. Minimal patient specimen identification includes two identifiers: full first and last name and either the date of birth, Social Security number or other unique identifier. Specimens received more than 28 days from collection, or for any reason deemed unsuitable or inappropriate for diagnostic testing will not be tested. Rejected specimens will be properly stored for three days pending verbal and/or written notification of the submitter. Unless

alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

Eligible Health Care Providers: Local Health Departments.

NOTE: The performance of the Aptima Combo 2 assay for Chlamydia/Gonorrhea detection has not been evaluated in adolescents less than 14 years of age. Samples received by NCSLPH for patients aged 10 to less than 14 years of age will be forwarded to LabCorp for testing. Testing for CT/GC on patients <10 years of age and medicolegal testing for CT/GC are not available through NCSLPH.

Vaginal Specimen Acceptance Policy
Chlamydia trachomatis/Neisseria gonorrhoeae laboratory services are subject to the following guidelines which have been developed to ensure proper patient management and efficient utilization of limited resources. Only the following specimens will be accepted from local health departments:

1. Vaginal swab specimens from women with syndromes compatible with *C. trachomatis* and/or *N. gonorrhoeae* infection.
2. Vaginal swab specimens from pregnant females.
3. Vaginal swab specimens from asymptomatic women, 25 years old and younger seen in either Family Planning or Sexually Transmitted Disease clinics.
4. Vaginal swab specimens from women for retest for Chlamydia/Gonorrhea at three months post-treatment.
5. Vaginal swab specimens from women due to sex partner referral.
6. Vaginal swab specimens from women with high-risk history (i.e. new partner, multiple partners, etc.)
7. Vaginal swab specimens for Chlamydia testing prior to IUD insertion.

Extragenital/Male Urine Specimen Acceptance Policy
Only the following specimens will be accepted from local health departments:

1. Asymptomatic MSM or transgender who has had sexual exposure at an extragenital site within the preceding 60 days
2. Symptomatic MSM or transgender, regardless of stated date of last exposure
3. Symptomatic female who reports rectal and/or oropharyngeal exposures
4. Any individual being initiated on or receiving HIV pre-exposure prophylaxis (PrEP)
5. Individual who would normally be cultured but requires molecular testing due to culture media supply issues

Shipment
Refer to the **Microbiology section of Appendix A** for CT/GC specimen and shipment requirements. CT/GC specimens are acceptable for testing up to 28 days after collection and storage at 2-30°C; however, it is advisable to ship as soon as possible to avoid delays in turn-around time of test results. If longer storage is needed, freeze specimens in the Aptima specimen transport tube within 7 days of collection at -20°C to -70°C to allow testing up to 60 days after collection for extragenital swab samples and up to 12 months after collection for vaginal swab and urine samples.

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See **Appendix C** for local health department specimen transport guidance.

Reporting Procedures and Interpretation

The Chlamydia/Gonorrhea NAAT test methodology performed at the NCSLPH is a dual detection assay, therefore, both test results will be reported for each clinical specimen. Specimens in which C. trachomatis RNA is detected are determined to be positive for C. trachomatis and will be reported as “Chlamydia Positive”. Specimens in which C. trachomatis RNA is not detected are presumed negative for C. trachomatis and will be reported as “Chlamydia Negative”. Specimens in which N. gonorrhoeae RNA is detected are determined to be positive for N. gonorrhoeae and will be reported as “Gonorrhea Positive”. Specimens in which N. gonorrhoeae RNA is not detected are presumed negative for N. gonorrhoeae and will be reported as “Gonorrhea Negative”. If the test result for either agent is determined to be equivocal or invalid, that result will be reported as “Indeterminate, please submit another sample for testing”; in these cases, another specimen should be properly collected and submitted to resolve the status of the patient. Turn-around time for test results is three working days. Results should be interpreted in conjunction with patient history and clinical findings.

Data indicates that both the sensitivity and specificity of the nucleic acid amplification test (NAAT) approach 100%. Although these values are quite impressive for laboratory tests, it must be remembered that the results of this test are not 100% predictive of every patient’s true infected status, and that both false negative and false positive results are a possibility.

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Cholera *(Vibrio cholerae)*

(919) 807-8608

Strains of *Vibrio cholerae* possessing the somatic 01 or 0139 antigen (*"V. cholerae:01" or "V.cholerae: 0139"*) are associated with epidemic cholera, while those lacking this antigen (*"V. cholerae non-01"*, "non-cholera vibrio*"),* cause sporadic diarrheal disease and do not present a public health threat. Although cholera is not endemic in the U.S., cases may be imported by travelers returning from countries where the disease is prevalent. Sporadic cases of non-cholera gastroenteritis are associated with saltwater exposure or consumption of raw or insufficiently cooked contaminated seafood.

Please telephone the Enteric Lab before submitting food specimens when cholera or other *Vibro*-associated diarrheal disease is suspected.

Ship refrigerated but not frozen food samples as quickly as possible after collection in an insulated container cold on frozen ice packs (1-8°C)with a completed DHHS Form #1814 (Food/Environmental Sample Collection Report). Submit preserved stool specimens ambient in Enteric culture mailers with a completed DHHS Form #3390. Indicate on the Form that *Vibrio* is suspected.

Note: Direct reference isolates of *Vibrio* spp. to the Atypical Bacteriology Lab with a completed DHHS Form #4121.

Isolates of *V. cholerae* are tested in the Atypical Bacteriology Lab at the SLPH for the presence of the 01 and O139 antigens; those presumptively identified as *V. cholerae* 01 or O139 are forwarded to the CDC for definitive identification and toxin testing. The Foodborne Disease Epidemiologist in the Communicable Disease Branch is notified of potential cholera cases. Confirmed isolates of non-*V.cholerae* are also sent to CDC and epidemiologically investigated.

Fill out form DHHS#4121 or DHHS# 3390 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of Collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested

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Diphtheria (*Corynebacterium diphtheriae*)

(919) 807-8606

Introduction

Diphtheria is an upper respiratory tract illness caused by Corynebacterium diphtheriae, a facultative anaerobic, Gram-positive bacterium. Diphtheria is a contagious disease spread by direct physical contact or breathing the aerosolized secretions of infected individuals. Historically quite common, diphtheria has largely been eradicated in industrialized nations through widespread vaccination. The diphtheria-pertussis-tetanus (DPT) vaccine is recommended for all school-age children in the U.S., and boosters of the vaccine are recommended for adults, since the benefits of the vaccine decrease with age without constant re-exposure; they are particularly recommended for those traveling to areas where the disease has not been eradicated.

The diagnosis of Diphtheria is primarily a clinical one; a thorough evaluation of the patient history should be made before deciding to culture and submit to the NC State Laboratory of Public Health for analysis. Often the patient has thrush, which can mimic the signs of Diphtheria; therefore, it is recommended that a routine bacteriological culture be performed initially.

All confirmed cases of Diphtheria must be reported to the Communicable Disease Branch at 919-733-3419.

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Specimen collection and Identification

At the local level:

- Specimen collection - swabs of the nasopharynx, throat, wound or membranes.
- Transport – use Amies, Stuarts, or other readily available transport medium.
- Culture – set up on blood agar and, if available, on cystine blood tellurite (CBT) agar, and if possible, a Loeffler's slant for production of polar bodies. Incubate cultures at 35-37°C preferably in CO_2 for 18-24 hours and examine the plates for predominant coryneform-like colonies.
- On CBT agar, *C.diphtheriae* forms small, dark "gunmetal"-gray opaque colonies with a pronounced garlic odor. On blood and other plates, colony morphology is not distinctive.
- Verify morphology by gram stain and, if possible, by the Loeffler methylene blue stain. (Apply methylene blue stain for 30-60 seconds, rinse, dry, and examine slides for unusually pleomorphic, beaded rods with swollen ends and reddish-purple metachromatic granules.)

  Note: Look for beta strep and yeast as well, to rule out these organisms as the pathogen.

  Gram stain – *C. diphtheriae* is typically extremely pleomorphic. Cells may exhibit elongated and exaggerated "dumbbell" shapes that usually appear beaded or barred in the central area. (This morphology is exhibited best by methylene blue stain of organisms grown on serum-containing media such as Loeffler or Pai Egg Yolk agar).

- After the gram stain, either perform biochemical screening tests for identification, or subculture an isolate(s) and forward to the NC State Laboratory of Public Health. If isolate appears to be *C. diphtheriae*, it is advisable to send to the NC State Laboratory for confirmation.

At the NC State Laboratory:

- Telephone the Atypical Bacteriology Laboratory at 919-807-8606 **prior** to submitting diphtheria specimens. Please include the patient's clinical history when submitting suspected diphtheria specimens to the NCSLPH.

At the CDC:

- CDC does not perform PCR to rule out diphtheria unless diphtheria anti-toxin (DAT) has been requested to treat the patient.
- Toxigenicity testing – available at the CDC – suspect isolates from a fresh pure culture may be sent on blood, or tryptic soy agar slants. Other readily available transport media may also be used. Isolates should be shipped at room temperature.
- All specimens sent to CDC must be accompanied by a CDC Form DASH.
- NOTE: For confirmed cases, physicians can acquire anti-toxin (DAT) directly from the CDC. The earlier this is given, the more favorable the outcome for the patient. Clinicians can obtain DAT by calling 770-488-7100, CDC Emergency Operations Center.

Shipment of Specimens to the NC State Lab of Public Health

Submit swab specimens to the NC State Lab as soon as possible after collection in a swab transport system such as Culturette®. Alternatively, place swabs in a sterile screw-capped tube in a few drops of sterile broth or saline. Seal in plastic bag, cushion with paper towels, and place in a box or other closed container.

Submit reference isolates preferably on Loeffler agar slants; infusion, blood trypticase, or chocolate is satisfactory. Package tightly capped slant (may also seal cap with Parafilm®) wrapped in paper towels inside a metal tube placed inside a second metal tube (Microbiology Reference Culture Container available from the NCSLPH mailroom (919-733-7656). Forward to the NCSLPH either by courier or mail with a DHHS Form #4121 for Special Bacteriology:
https://slph.dph.ncdhhs.gov/Forms/4121-Special-Atypical-Bacteriology.pdf

Refer to Scope "Specimens Requiring Special Handling" section for C. diphtheriae specimen and shipping requirements. See appendix C for local health department specimen transport guidance.

****Avoid shipping packages to arrive over the weekend****.

Fill out DHHS Form #4121 with the following required information:

First and last name of patient
Patient date of birth
Patient demographics (sex, race, etc.)
Patient number or Social Security Number (optional)
Date and time of Collection
Submitter EIN
ICD-10 code (reason for testing)

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Ordering provider and National Provider Identifier (NPI)
Medicaid number if patient has Medicaid
Test requested

Reporting Results and Interpretations

Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. The submitting agency is responsible for maintaining reports in the patient's file.

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Enteric Bacteriology

(919) 807-8608

Introduction

Clinical specimens for the isolation of enteric microorganisms are accepted only from public health care providers. Fecal specimens are examined for the presence of enteric pathogens including *Aeromonas*, *Campylobacter, Escherichia coli* (*E. coli*) 0157:H7 and other Shiga-toxin producing *E. coli* (STEC) *Salmonella typhi*, other *Salmonella* serotypes, *Shigella, Vibrio, and Yersinia.* Reference isolates are accepted from public and private health care providers for identification, serotyping, and/or whole-genome sequencing (WGS). The NCSLPH is the North Carolina serotyping center for *Salmonella, Shigella* and *E. coli* 0157:H7 and participates in the national surveillance programs of the CDC.

Please Note: The North Carolina Communicable Disease Control rules (10A NCAC 41A.0209) state that laboratories culturing stool from a person with bloody diarrhea should culture for Shiga-toxin producing *Escherichia coli* or send the specimen to the State Public Health Laboratory for Shiga-toxin testing after consultation with the Enterics Lab at 919-807-8608.

Feces and food specimens associated with food-borne illness, see Foodborne illness section below.

Consultation and bench training are provided upon request.

Please telephone the Enteric Bacteriology Lab to discuss outbreak-related specimens or to coordinate specimen handling in unusual circumstances. The Communicable Disease Control Nurse for your county should also be contacted.

Sample Collection and Identification

Each specimen must be clearly labeled with the patient's name and a second unique identifier and accompanied by DHHS Form #3390. Unlabeled specimens will not be tested. Specimens should be collected early in the course of enteric disease and before antimicrobial therapy is begun. **Please indicate if the patient has bloody diarrhea** and if a specific disease agent is suspected. Cary-Blair transport media for collection of feces or rectal swabs is available from the laboratory mailroom on-line at https://slphreporting.ncpublichealth.com/labportal/.

Fill out form DHHS #3390 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

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Note: Specimens received without submitter return address are subject to rejection!

A. Fecal Specimens

Collect specimen so that feces are free of foreign matter, following instructions in Enteric Culture mailer or equivalent. (Do not use the Parasitology mailer: it contains formalin which kills bacteria.) Using the scoop, place feces in the vial of transport medium until the level of liquid reaches the fill line marked on the label. Do not overfill vial. Break up any large pieces with the scoop. Stir well; replace the top tightly on the vial. Label with two patient identifiers: patient's name and either date of birth, medical record number or Social Security number.

B. Rectal Swabs (2) **Note: FECAL SPECIMENS PREFERRED**

Collect specimens by inserting two sterile swabs into rectum (best results are obtained if fecal material is observed on swab), avoiding contact with skin of perianal area. Use Enteric Culture mailer or equivalent. Place swabs in the vial of transport medium and break or cut off ends so that swabs fit into vial. Label with two identifiers: patient's name and either date of birth or Social Security number.

C. Blood Cultures

Following incubation and subculture, isolates may be forwarded for reference identification.

D. Reference Cultures

Reference cultures for further identification should meet the following criteria for inclusion in the order Enterobacterales: Gram-negative non-spore forming rods which grow aerobically and anaerobically, grow on MacConkey agar, ferment glucose, reduce nitrates, are oxidase negative, do not require NaCl and are catalase positive.

Use the Microbiology Reference mailer or equivalent to ship pure cultures. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. On the form, indicate preliminary test results or presumptive identification and patient clinical information.

Note: Reference cultures of nonfermentative gram-negative organisms as well as fermenters NOT INCLUDED in the order Enterobacterales (ex: *Pasteurella, Aeromonas, Actinobacillus, Vibrio*) should be directed to the Atypical Bacteriology Unit and should be accompanied by Special/Atypical Bacteriology DHHS Form #4121.

Shipment

Mailers for submitting fecal specimens and reference cultures are available on-line at https://slphreporting.ncpublichealth.com/labportal/. To submit specimens:

1. Write patient's name and second unique identifier on specimen tube. Unlabeled specimens will NOT be tested.
2. Place completed Enteric Bacteriology DHHS Form #3390 (one form for each specimen) in outer container to avoid contamination in case of breakage or leakage.

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3. Use double-walled or equivalent shipping containers that meet safety requirements. Multiple tubes or specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof container. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. Mailers should be clearly labeled "Enteric Bacteriology" on the outside of the container.
4. Ship clinical specimens as soon as possible after collection. Refer to the **Microbiology section of Appendix A** for Enteric specimen and shipment requirements. Refrigeration is recommended for Enteric Culture mailers, particularly specimens submitted for isolation of *E. coli* 0157:H7 and other STEC. See appendix C for local health department specimen transport guidance.
5. When shipping by U.S. mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method.
6. Telephone the Enteric Bacteriology Lab before shipping large numbers of specimens, such as in an outbreak situation, or those requiring urgent attention.

Reporting Procedures and Interpretation

Negative culture results are reported within one to three workdays after receipt of the specimen. Serotyping and biochemical identification results usually are reported within four to ten workdays. Final results on isolates referred to the CDC for further testing may be delayed up to several months.

Recommendations for diagnosis and follow-up of cases of disease caused by Salmonella, Shigella, *E. coli* 0157:H7 or other Shiga-toxin producing *E. coli* (STEC), and Campylobacter are outlined in Control of Communicable Diseases in Man. Questions concerning epidemiological investigation of these illnesses should be directed to the Epidemiology and Communicable Disease Section at (919)733-3419.

The NCSLPH reports all confirmed *Salmonella, Shiqella, Campylobacter. Vibrio.* and *E.coli* 0157:H7 isolates to the Communicable Disease Branch of the Epidemiology Section for surveillance purposes.

Results are reported on computer-generated forms which are returned to the submitting agency. Bacteriology DHHS form #3390 accompanying specimens are retained in the Unit for 5 years. Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. The submitting agency is responsible for maintaining records in patient files.

Note: Local health departments should telephone the Communicable Disease Branch at (919) 733-3419 when enteric disease outbreaks are suspected in a day care center, nursing home or restaurant. In addition, the Food Protection Program of the Environmental Health Section should be notified at (919) 707-5854 when restaurant or institution- associated illness is suspected.

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A. *Salmonella*

Salmonella species are reported according to the following designations:

- *Salmonella typhi* -- includes only this agent of typhoid fever.
- *Salmonella choleraesuis* -- includes *S. choleraesuis* and *S. choleraesuis* bioserotype Kunzendorf.
- Other Salmonella serotypes -- all other serotypes are reported using the traditional designation (ex.: *Salmonella typhimurium, Salmonella heidelberg*, etc.) or by antigenic formula if monophasic (ex.: I 4,[5],12: i:-) or belonging to a subspecies other than subspecies I (*subsp. enterica*).

Note: All species of *Salmonella* can cause enteric disease (salmonellosis).

B. *Shigella*

Species of the genus *Shigella* are reported as follows:

- *Shigella dysenteriae* or subgroup A (12 serotypes)
- *Shigella flexneri* or subgroup B (6 serotypes)
- *Shigella boydii* or subgroup C (18 serotypes)
- *Shigella sonnei* or subgroup D (2 serotypes)

Note: All species of *Shigella* can cause enteric disease (shigellosis).

C. *E. coli* O157:H7/STEC

Shiga Toxin producing E. coli (STEC) like E.coli O157:H7 (sorbitol negative) are associated with hemorrhagic colitis and hemolytic Uremic Syndrome (HUS). Stool samples and isolates sent to SLPH are tested for Shiga toxin. If positive, we will look for E. coli O157 and the top 6 Non-O157 serotypes (O26, O103, O121, O45, and O145). Stool specimens should be collected and then preserved in Enteric transport media culture containers and should be refrigerated after collection and during **transport with frozen ice packs (1-8ºC) in an insulated container**. Indicate on the Enteric Bacteriology, DHHS form # 3390, that examination for *E. coli* O157/STEC is requested. Please telephone the Enteric Bacteriology Lab at (919) 807-8608 prior to submitting specimens associated with outbreaks. Contact the Epidemiology and Communicable Disease Section at (919) 733-3419 for epidemiology assistance. Clinical stool samples submitted for diagnostic STEC testing must be received within 72 hours of collection. SLPH also accepts clinical fecal samples in enteric transport media from positive culture independent tests (CIDT) reflexed for specific pathogen confirmation/surveillance. These stool samples must be received within 7 days of collection.

D. Other Enterobacterales

Members of other genera in the order Enterobacterales are reported using genus and species designations consistent with descriptions in the Manual of Clinical Microbiology, or in accordance with the International Code of Nomenclature of Bacteria.

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Foodborne Illness

(919) 807-8608

Introduction

Food samples are not currently tested at SLPH. The N.C. Department of Agriculture and Consumer Services and CDC test food samples forwarded by SLPH, as needed. Contact the Communicable Disease Branch (CDB) at (919) 733-3419 for assistance in investigating foodborne disease. Consumer complaints, foods suspected of adulteration or those not associated with illness are referred to the Food and Drug Administration through the N.C. Department of Agriculture and Consumer Services (919-733-7366). Upon approval, food samples should be submitted through the local health department. The local health department should always be notified of suspected foodborne illness so that an epidemiological investigation can be conducted. Stool and other specimens related to foodborne disease also are accepted.

Sample Collection and Identification

Each food item should be clearly labeled; different batches should be individually identified. Environmental samples should be labeled as to individual source. Fecal or other specimens should be clearly labeled with the patient's name; requisition forms should indicate their association with foodborne illness.

A. Food and Related Environmental Samples

Collect food samples aseptically taking care not to touch the food items with the hands or non-sterile equipment. Samples should be placed in sterilized jars or sealable plastic bags and promptly refrigerated. Packaging and shipping methods should maintain the integrity of the food sample as closely as possible to its condition when sampled. Use a separate DHHS form #1814 for each food item; when submitting multiple samples at least one form should be completed with all requested information.

If botulism is suspected immediately contact the Communicable Disease Branch at (919) 733-3419.

B. Food Handlers

To culture potential carriers of *Staphylococcus,* carefully rub sterile swab over infected area, avoiding contact with adjacent skin, or swab anterior nasal membranes. Use DHHS form #4121, SPECIAL BACTERIOLOGY.

C. Fecal Specimens

See **Enteric Bacteriology**, for instructions for collecting specimens for bacteriological culture. See **Virus Culture**, for collecting specimens for viral culture.

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Shipment

Place food samples in a waterproof container inside an insulated shipping container with cold packs (do not use wet ice) and send to the NCSLPH as quickly as possible after collection. Notify the Microbiology Unit of the expected arrival time. Outbreak-associated fecal specimens may be shipped separately in Enteric Culture Mailers with DHHS form # 3390.

Reporting Procedures and Interpretation

. Foods are implicated as vehicles of disease transmission under one or more of the following circumstances:

- confirmation of the same pathogen or toxin in ill patients' specimens and in the epidemiologically implicated food
- confirmation of the presence of bacterial toxin in the food in the absence of patient clinical specimens
- confirmation of the presence of certain enteric pathogens such as *Salmonella* in the food
- food-specific attack rates significantly higher in persons who have consumed the food compared to those who have not

Note: Local health departments should notify the Communicable Disease Branch (919) 733-3419 when enteric disease outbreaks are suspected in a daycare center, nursing home or restaurant. Additionally, the Food Protection Program of the Environmental Health Section should be notified at (919) 707-5854 when foodborne illness is suspected in a restaurant or institution.

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Collection and Shipment of Specimens for Foodborne Illness

Sample	Collection and Preservation	Packing and Shipping
Solid food > 25 grams	Cut or separate portions of food with sterile knife or other implement. Aseptically collect a representative sample; transfer to sealable plastic bag or sterile jar and refrigerate.	Label; pack in insulated container cold on frozen ice packs (1-8°C). Seal forms in waterproof bag. Take or ship to the NCSLPH.
Liquid food > 25 grams	Stir or shake. Use sterile implement or pour representative sample into sterile container and refrigerate.	Same as above.
Dehydrated food > 25 grams	Use sterile implement to transfer representative sample to sterile jar or sealable plastic bag.	Same as above.
Environmental or equipment surface swab	Preferably use commercially available swab collection/transport system. Or moisten swab with sterile water, rub environmental or equipment surfaces and place swab in sterile jar, plastic tube or sealable plastic bag.	Same as above.
Frozen food >25 grams	Place frozen food in sterile jars or sealable plastic bag or use sterile implement to chip food and transfer chips to container.	Keep frozen (≤-20°C) if possible with dry ice or frozen ice packs as listed above.

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Note: Most local health departments maintain a supply of sputum mailers for tuberculosis testing. These mailers contain sterile screw-capped plastic centrifuge tubes which also are suitable containers for food samples or environmental swabs.

Legionella

(919) 807-8603

Introduction

Legionella infection is diagnosed by a combination of culture, direct fluorescent antibody (DFA) staining, serum serologic testing (performed as a send-out by the Virology/Serology Unit) and other techniques in conjunction with the patient's clinical history. Culture is the recommended diagnostic procedure and should be attempted along with other methodologies. The Bacteriology Laboratory offers culture and DFA staining of clinical specimens and reference cultures to public and private health care providers. Urinary antigen detection and DNA probe procedures are NOT available in this Laboratory. Environmental specimens are not currently tested. Consultation and bench training are available upon request.

Sample Collection and Identification

Recommended specimens for culture include respiratory tract secretions, tissues, fluids such as sputum, pleural fluid, transtracheal aspirates, bronchial washings, and lung biopsies. Saline is not recommended to collect or dilute specimens for *Legionella* culture as it may inhibit growth; use sterile broth or sterile distilled water. If saline must be used to collect specimens, it may be centrifuged, and the pellet resuspended in sterile distilled water or broth.

Collect specimens aseptically and place in a sterile screw-capped plastic centrifuge tube (such as those in NCSLPH sputum mailers); seal containers securely to prevent leakage. Flexible "in-house" suction tube collection cups are not acceptable for shipping specimens. DFA smears should be air dried, heat fixed, and 10% formalin fixed before packaging or mailing. A minimum of three smears are necessary for clinical specimens.

Each specimen must be clearly labeled with two unique patient identifiers and accompanied by a completed DHHS Form #4121. Two forms are required for paired serum specimens.

Fill out form DHHS Form #4121 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

Note: Specimens received without submitter return address are subject to rejection!

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Isolated cultures for identification of *Legionella* sp. should be grown on charcoal yeast extract agar slants or plates.

Shipment

Clinical specimens for *Legionella* culture should be shipped as soon as possible after collection. Refer to the **Microbiology section of Appendix A** for Legionella specimen and shipment requirements. Identification forms should be enclosed in sealed plastic bags to prevent wetting or contamination. Formalinized smears should be shipped in rigid slide mailers to prevent crushing. Formalinized tissue for DFA staining should be shipped in screw-capped containers and should be labeled as formalinized specimens. Sputum mailers are available online at http://slph.ncpublichealth.gov.

Reference cultures of *Legionella* should be shipped in the Microbiology Reference Culture mailer or equivalent container that meets safety requirements. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags, and securely packaged in a **crush-proof** container.

When shipping by U.S. Mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method, and plainly label "*Legionella*" on the outside of the container. Prior to shipping large numbers of specimens, telephone the Microbiology Unit at (919) 807-8603.

See appendix C for local health department specimen transport guidance.

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Reporting Procedures and Interpretation

Legionella is identified from culture and smears by specific DFA staining. At least 33 species of legionellae have been described; approximately half of human infections are associated with *L. pneumophila* serogroup 1. This Laboratory examines smears for *L. pneumophila* serogroups 1-14 and for 25 other species. DFA staining is a presumptive test. Cross-reactivity may occur among legionellae. Negative cultures will be held for 14 days after inoculation.

Neither a negative DFA stain nor a negative culture rules out *Legionella* infection. Low numbers of organisms, improper specimen/smear handling and/or previous antimicrobial therapy can influence test results.

Legionella isolates requiring definitive identification are forwarded to the CDC.

Smears are reported according to the number of strongly fluorescing cells with typical morphology seen. The CDC criteria for reporting the results of DFA staining are as follows:

- Smears from lung tissue: 25 or more organisms per smear = DFA positive
- Smears from other respiratory specimens: five or more organisms per smear = DFA positive

If the number of fluorescing cells seen is fewer than the minimum needed for a positive DFA report, the number of cells seen is reported. The results of serologic and culture tests along with the patient's clinical history may be useful in interpreting the DFA stain report. All positive DFAs are reported to Epidemiology.

Results of DFA examinations are available on the day of testing or the next workday and can be accessed via the secure web page for results and are followed by a computer-generated report. Positive cultures are reported by telephone and by mail as soon as growth is identified. Cultures are held for three weeks before being reported as negative. All positive cultures are reported to Epidemiology.

Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. The submitting agency is responsible for maintaining reports in the patient's file.

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Mycobacteriology

(919) 807-8620

Introduction

Specimens for isolation and identification of all *Mycobacteria* species (including *Mycobacterium tuberculosis* (TB) complex and other nontuberculous mycobacteria) are accepted from public and private health care providers. Positive isolations or identifications of *M. tuberculosis* must be reported by the submitter to the NC Tuberculosis Control program in the Communicable Disease Branch (CDB) in accordance with State Law. (Refer to NC TB Policy Manual for guidance.)

Respiratory specimens and specimens from other sources are concentrated and stained with fluorochrome stain and cultured for the isolation and identification of mycobacteria. Blood or bone marrow specimens will be set up for culture and identification. No smears will be performed on blood or bone marrow specimens.

Real-time polymerase chain reaction (PCR) testing for *Mycobacterium tuberculosis* (TB) complex on selected samples is offered (see **Mycobacteriology PCR** for additional information). Real-time PCR is designed to supplement, not replace, standard mycobacterial culture for confirmation of diagnosis and the test is not suitable for all specimens. PCR is performed on digested decontaminated primary sputa specimens.

Species identification is accomplished using nucleic acid probe tests or are forwarded to CDC. Reference specimens for confirmation, identification, and/or susceptibility testing are also accepted. Consultation and bench training are provided upon request.

All isolates of *Mycobacterium tuberculosis* complex are tested for susceptibility to five primary drugs: isoniazid, ethambutol, rifampin, pyrazinamide, and moxifloxacin. If resistance is found in first-line testing, second-line drug testing will be initiated, unless the second-line drug testing is already being performed by the CDC through the Molecular Detection of Drug Resistance (MDDR) test.

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Specimen Collection and Submission

Specimens should be shipped as soon as possible after collection. Blood, CSF, and bone marrow aspirates received >3 days after collection will not be tested. Specimens other than blood, CSF, or bone marrow apirates received >7 days after collection will not be tested. To ensure proper patient/specimen identification and ensure accurate results reporting, specimen containers must be labeled with two unique patient identifiers: the patient's first and last name and date of birth. This information must match the requisition form. A local medical record number may also be used on the specimen and requisition for one of the identifiers. Any specimens without two unique identifiers will be rejected and discarded. The following data items are essential to our laboratory information management system: patient name, date of birth, submitter Federal Tax Number, Medicaid number, if eligible, submitter return address and phone number, county code,

provider name and NPI (National Provider Identifier), specimen collection date (CLIA requirement) and specimen source. Without these data, a report of results cannot be printed. Other data are required for follow-up and for statistical purposes. For more information, contact the Mycobacteriology Laboratory at (919) 807-8620 or refer to the NC Tuberculosis Policy Manual at https://epi.dph.ncdhhs.gov/cd/lhds/manuals/tb/toc.html. See Appendix A for additional specimen requirements.

A. Sputum

A series of three specimens is recommended. Collect in the early morning on consecutive days. A volume of 5 mL is recommended for each specimen. A negative result may be less reliable if the specimen volume is less than 5 mL. Induced (or nebulized) sputum specimens are usually very watery, and unless indicated on the requisition form, may be mistaken for saliva, which is an inappropriate specimen. Sputum swabs are unsatisfactory. Do not use any transport medium. Use Sputum Mailer or equivalent that meets safety requirements.

B. Bronchoalveolar Lavage Fluids and Bronchial Washings

Collect at least 5 mL in a sterile container. Avoid contaminating bronchoscope with tap water. Saprophytic mycobacteria may produce false-positive culture or smear results. Frequently, bronchoscopy causes the patient to produce sputum naturally for several days after the procedure, and specimens collected a day or two after bronchoscopy enhance detection of mycobacteria. Do not use any transport medium. Use Sputum Mailer or equivalent that meets safety requirements.

C. Gastric lavage

Collect 5 to 10 mL of fluid in a sterile container without a preservative, either early in the morning or eight hours after eating or drug therapy. A series of three specimens is recommended. Neutralize as soon as possible with 100 mg of sodium carbonate powder (Na_2CO_3). Do not use any transport medium. Use Sputum Mailer or equivalent that meets safety requirements.

D. Tissue

Collect 1g of tissue, if possible, aseptically. Select a caseous portion, if available. Do not immerse the specimen in saline (or other fluid) or wrap in gauze. Freezing decreases yield. A sterile container with a small amount of sterile water or sterile saline (to keep the specimen moist) is acceptable. Do not use any transport medium, preservative or fixative. Use Sputum Mailer or equivalent that meets safety requirements.

E. Urine

Collect catheterized or midstream urine voided in early morning. A minimum of 40mL is recommended. Submit a series of three specimens, taken on three different days. Twenty-four-hour cumulative specimens are unsatisfactory. Do not use any transport medium. Use Sputum Mailer or equivalent that meets safety requirements.

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F. Blood and Bone Marrow

Collect 5-10 mL for blood and as much as possible for bone marrow in a sterile tube containing heparin (green top) or sodium polyanetholsulfonate (SPS-yellow top). These specimens will be rejected if not submitted in the green or yellow tubes. Blood collected in EDTA or blood that is coagulated is not acceptable. Use Sputum Mailer or equivalent that meets safety requirements.

G. Stools

NCSLPH will only accept stools for suspected gastrointestinal tuberculosis (GI-TB). Prior approval from the Mycobacteriology Laboratory is <u>required</u> for all stool samples. Any stool specimen received without prior approval will be rejected and discarded. Stool is not a recommended specimen for identification of disseminated *Mycobacterium avium complex* and has a poor recovery rate. Therefore, we will only accept stools from patients with highly suspect GI-TB.

H. Body Fluids (CSF, pleural, peritoneal, pericardial, etc.)

Collect aseptically following proper procedure for type of specimen; collect as much as possible (10-15 mL) in a sterile container. The recommendation for CSF is at least 2 mL. Bloody specimens may be anticoagulated with SPS or heparin. Please phone prior to submission if you have any questions. <u>Do not use any transport medium</u>. Use Sputum Mailer or equivalent that meets safety requirements.

I. Abscess Contents, Aspirated Fluid, Skin Lesions, Wounds

Aspirate as much material as possible into a syringe with a luer tip cap. If the volume is insufficient for aspiration by syringe, collect the specimen on a swab and place in transport medium (Amies or Stuart's). For cutaneous lesions, aspirate material from under the margin of the lesion. Dry swabs are not acceptable. Use Sputum Mailer or equivalent that meets safety requirements.

J. Reference Specimens

Select organisms or subcultures which show good growth and appear in **<u>pure</u> <u>culture.</u>** If a laboratory is unable to isolate the colonies, contact the NCSLPH for guidance (919-807-8620). Any culture received that is mixed with yeast or other bacteria will be rejected. Label the media with two patient identifiers and wrap carefully, securing screw cap. If liquid media is used, pack with enough absorbent material to absorb the entire contents in case of breakage or leakage. Do not seal cap with paraffin, as it may contaminate culture and interfere with processing. Do not wrap DHHS Form #1247 around culture tube, but place in outer container of culture mailer. Use Microbiology Culture Mailer or equivalent that meets safety requirements. Note: Any ***known Mycobacterium tuberculosis complex*** samples, identified by the submitter, **must be shipped Category A.** This is a federal regulation.

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Specimens should be submitted in double-walled mailing containers. Glass tubes should be wrapped in absorbent cushioning material before they are inserted in mailing containers. Mailers for submitting clinical specimens and for reference cultures are available from the Laboratory mailroom. Do not reuse damaged shipper tubes or screw capped lids nor, corroded screw capped lids. To facilitate safe handling, the following general suggestions are made:

1. Label specimen with two identifiers: patient's first and last name and date of birth. The same identifiers must be included on the requisition. Unlabeled specimens will not be tested; they will be discarded.

2. Screw caps on tubes tightly. This is especially important with the plastic-capped centrifuge tubes in the Sputum Mailer. These plastic caps must be turned to the point of total resistance to prevent leakage. If caps are sufficiently tightened, sealing with separate material, such as tape (never use paraffin, as it interferes with processing) will not be necessary. If tube appears to be leaking after cap is tightened, transfer to another tube. For safety reasons, leaking and broken specimens will not be tested.

3. Place properly completed DHHS Form #1247, for each specimen or isolate in the outer container to avoid contamination in case of breakage or leakage. Screw cap on properly. Do not use any kind of tape to secure cap.

4. When shipping by U.S. mail; use first-class postage and place return address of submitting agency on the outside of the container. Do not write any patient information on the outside of the container.

5. Do not affix any patient information on the outside of either shipping containers. Do not reuse damaged shipper tubes or screw capped lids, nor corroded screw capped lids

6. Mail specimens as soon as possible after collection to avoid overgrowth of possible contaminants. CDC recommends sending specimens to the lab within 24 hours of collection. **Refer to the Microbiology section of Appendix A** for Mycobacterium specimen and shipment requirements, and contact SLPH for additional guidance if needed.

Do not submit subcultures until good growth occurs. Do not send mixed or contaminated cultures. **Use the Orange Labeled cans for TB/Mycobacteriology Specimens for shipment. These are available from the NCSLPH mailroom and may be ordered on-line at** https://slph.ncpublichealth.gov/forms.asp#mailroom. See appendix C for local health department specimen transport guidance.

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Specimen Testing and Reporting

Results and interpretations are reported to the submitting agency via U.S. Mail. Results are also available on the NCSLPH website, https://slph.dph.ncdhhs.gov/. Duplicate reports for appropriate notification of results are the responsibility of the agency submitting the specimen. Refer to the NC TB Policy Manual for reporting regulations.

A. **Fluorochrome (AFB) Smear**

A smear is used as a rapid test to detect mycobacteria and many *Nocardia spp*. that may be causing an infection. A smear of the concentrated clinical specimen is examined and reported within 24 hours of receipt in the laboratory. Smears are not performed on blood or bone marrow specimens.

Reporting:

Positive, Grade, Per Field - indicates the presence of acid-fast organisms in the smear, the smear grade and the approximate number of acid-fast- organisms seen per microscopic field.

Not Found - indicates the absence of acid-fast- organisms in the smear.

B. **MTB/RIF PCR (GeneXpert)**

Real-time PCR is performed using the Cepheid GeneXpert® directly from digested decontaminated clinical sputum specimens only. Accurate PCR results depend on proper specimen collection and transport. PCR testing is performed based on fluorochrome (AFB) smear results:

a. AFB smear positive sample – GeneXpert PCR will be performed on the first AFB smear positive sample for each patient; unless the patient has a recent GeneXpert detected result from a hospital.

i. Positive PCR result - PCR will not be performed on subsequent samples. Positive PCR results are called to the submitting agency for each first time PCR positive patient. The sample will be cultured and TB isolates tested for drug susceptibility.

ii. Negative PCR result - One additional positive AFB sample will be tested using real-time PCR, for a total of two samples tested.

b. AFB smear negative samples will be performed from patients who are at increased risk of tuberculosis and who demonstrate signs of symptoms consistent with pulmonary tuberculosis, with prior approval from the Mycobacteriology Supervisor or Manager. No more than three (3) smear negative specimens will be tested per patient.

Reporting:

M. tuberculosis complex DNA DETECTED; Rifampin resistance DETECTED – indicates the presence of MTB complex in the DNA sample and Rif resistance was detected. Sample will be reflexed to send to the CDC for MDDR testing to confirm Rifampin mutation.

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M. tuberculosis complex DNA DETECTED; Rifampin resistance NOT DETECTED - indicates the presence of MTB complex in the DNA sample and Rif resistance was not detected.
M. tuberculosis complex DNA DETECTED; Rifampin resistance INDETERMINATE - indicates the presence of MTB complex in the DNA sample. However, Rif resistance could not be determined. Sample will be reflexed to send to the CDC for MDDR testing to confirm or rule out Rifampin mutation.
M. tuberculosis complex DNA NOT DETECTED - indicates that MTB complex was not detected in the sample. Negative results do not indicate the absence of disease.
Inconclusive – There was potential inhibition in the sample used for MTB/RIF PCR. A second sample meeting MTB/RIF PCR criteria will be tested if available. If another sample is not available, submitter should recollect from patient.

The following disclaimer for MTB/RIF PCR tests will be included on all NC SLPH Mycobacteriology Laboratory reports:
The GeneXpert MTB/RIF PCR Assay is a qualitative, nested real-time PCR assay that has been approved by the FDA for the detection of M. tuberculosis complex and presumptive rifampin resistance associated mutations in raw sputum, or concentrated sputum sediment from induced or expectorated sputum. Patients should have not received antituberculosis therapy or have had more than three days of therapy. **Results should not be used as the sole basis for diagnosis and patient management.**

C. **MTBC/MAC real-time PCR**
This NC SLPH laboratory developed multiplex real-time PCR assay is for the detection of *Mycobacterium tuberculosis* complex and *Mycobacterium avium-intracellulare* complex (MAC). This assay is performed on growth from solid media (Middlebrook 7H10 and Lowenstein-Jensen slants) and BD BACTEC™ MGIT™ mycobacterial growth indicator tubes that are between 1-7 days from date of flagged positivity on the MGIT 960 instrument.

Reporting:
M. tuberculosis complex DNA
DETECTED
M. avium-intracellulare complex DNA
NOT DETECTED
Indicates the presence of MTB complex in the sample and MAC was not detected in the sample. A culture result of Mycobacterium tuberculosis complex will be reported and positive PCR results are called to the submitting agency for each first time PCR positive patient with MTB complex identified.

M. tuberculosis complex DNA
NOT DETECTED
M. avium-intracellulare complex DNA
DETECTED
Indicates the presence of MAC in the sample and MTB complex was not detected in the

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sample. A culture result of Mycobacterium avium-intracellulare complex will be reported.

M. tuberculosis complex DNA
DETECTED
M. avium-intracellulare complex DNA
DETECTED
Indicates the presence of both MTB complex and MAC in the sample. A culture result of Mycobacterium tuberculosis complex and Mycobacterium avium-intracellulare complex will be reported and positive PCR results are called to the submitting agency for each first time PCR positive patient with MTB complex identified.

M. tuberculosis complex DNA
NOT DETECTED
M. avium-intracellulare complex DNA
NOT DETECTED
Indicates that both MTB complex and MAC were not detected in the sample. A preliminary report will be sent with a "Suggestive of a Non-tuberculous Mycobacterium" preliminary identification**.** Culture will be monitored for mycobacteria growth and identified.

Inconclusive
Indicates MTBC/MAC DNA could not be detected due to inhibition during the amplification process. Culture will be monitored for growth and MTBC/MAC PCR will be repeated from the solid media or the sample will be reflex to MALDI-TOF.

The following disclaimer for MTBC/MAC real-time PCR tests will be included on all NC SLPH Mycobacteriology Laboratory reports:
The MTBC/MAC real-time PCR assay was developed by the Wadsworth Center and its performance characteristics were determined and validated at NC SLPH. It has not been cleared or approved by the FDA.

The following disclaimer for MTBC/MAC real-time PCR tests will be included on all NC SLPH Mycobacteriology Laboratory reports with a DETECTED result for either M. tuberculosis complex DNA or M. avium-intracellulare complex DNA:
A detected real-time PCR result indicates that the DNA of *Mycobacterium tuberculosis complex* (MTBC) or *Mycobacterium avium-intracellulare complex* (MAC) is present. However, this does not necessarily indicate an active infection. A detected result may also occur if there are non-viable organisms or residual cellular DNA present.

The following disclaimer for MTBC/MAC real-time PCR tests will be included on all NC SLPH Mycobacteriology Laboratory reports with an Inconclusive result:
An inconclusive result indicates MTBC/MAC DNA could not be detected due to inhibition during the amplification process.

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D**. Drug Susceptibility Test**

Indirect drug susceptibility tests for *M. tuberculosis* complex are performed on clinical and reference samples using five primary drugs; ethambutol, isoniazid, rifampin, pyrazinamide, and moxifloxacin. Second line drugs are tested when resistance is seen in first-line testing. Reporting is the same for both first- and second-line drug susceptibility test results.

Reporting:

Pending – a preliminary result. Drug susceptibility test results are pending completion.

Susceptible – final result. *M. tuberculosis* from patient sample is susceptible to tested drug.

Resistant – final result. M. tuberculosis from patient sample is resistant to tested drug. All resistant results all called to the submitter. If resistance is found in first-line testing, second-line drug testing will be initiated. All resistance is performed twice for confirmation, causing a slight delay in reporting final results. If Rifampin resistance is found, the sample is automatically forwarded to the CDC for MDDR confirmation testing.

Culture/Final Report

Cultures are incubated for a maximum of six weeks (42 days). If growth occurs, organisms are identified by nucleic acid probes or are forwarded to the CDC as applicable. Identification of some organisms may necessitate susceptibility testing which may require up to several additional weeks.

A report of "no growth" indicates that no acid-fast organisms have grown by the end of six weeks. If “growth resembling mycobacteria” is observed, identification testing is performed as quickly as possible. If there is overgrowth of other bacteria, the specimen is reported "Contaminated." Reports of "no growth" require six weeks from receipt of the specimen.

Final identification reports (including susceptibility results, where appropriate) may require three to twelve weeks for all tests to be completed. If isolates are submitted to the CDC for further testing or confirmation, additional time will be required.

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Mycobacteriology PCR

Real-time PCR** will be performed on digested decontaminated primary clinical sputa specimens only.

1. PCR will be performed on the first AFB smear-positive specimen for each patient.

2. PCR will be performed on smear-negative specimens from patients who are at increased risk of tuberculosis and who demonstrate signs or symptoms consistent with pulmonary TB, with prior approval from the Mycobacteriology Supervisor or Manager. **No more than three (3) smear negative specimens will be tested per patient.**

The NCSLPH Mycobacteriology Laboratory will determine which specimens qualify for testing using the criteria outlined below. It is imperative that all fields on the Mycobacteriology (TB) submission form, DHHS Form #1247, are completed accurately, and includes all information specifically related to:

1. "Previously Diagnosed"
2. "Current Condition/Pertinent Date"
3. "Drug Therapy", *and*
4. "Source of Specimen"
5. "Previous testing by Xpert MTB/Rif"

If tuberculosis is suspected, indicate on the Mycobacteriology (TB) submission form, DHHS Form #1247, which signs or symptoms are present and which risk factors apply to the patient. **If this information is not supplied, Real TimePCR will not be run if the sample is AFB smear negative.**

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Signs/Symptoms *(At least 2 must be present)*	**Risk Factors**
Cough	HIV infection
Fever, chills or night sweats	Cough present for more than 2 weeks
Significant weight loss	Immigrant from high-incident country
Hemoptysis	Immunosuppressive medications (includes TNF alpha inhibitors)
	Contact with known TB case in last 2 years
	Leukemia, lymphoma, or cancer of the head and neck or lung
	Diabetes mellitus

Silicosis

Gastrectomy or jejunoileal bypass

Injection drug use

Also, include the following information:

1. Is patient in respiration isolation?
2. Is patient currently on TB medication? If so, which drugs and for how long?
3. Previously diagnoses:
    a. TB – date: _____
    b. Other mycobacterium – Which: _____ When: _____

The following disclaimer for MTBC/RIF PCR tests will be included on all SLPH Mycobacteriology Laboratory reports:

****The Xpert MTB/RIF Assay is a qualitative, nested real-time PCR assay that has been approved by the FDA for the detection of *M. tuberculosis* complex and presumptive rifampin-resistance associated mutations in raw sputum, or concentrated sputum sediment from induced or expectorated sputum. Patients should have not received antituberculosis therapy or have had more than three days of therapy. Results should not be used as the sole basis for diagnosis and patient management.**

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Mycology

(919) 807-8605

Introduction

Clinical specimens for isolation and identification of medically important fungi from body tissues and fluids are accepted from public and private health care providers but must be limited to those actually implicated in fungal disease. Reference cultures are also accepted for identification of yeasts, molds, and aerobic actinomycetes. Antimicrobial susceptibility testing is not performed in this laboratory. Consultation and bench training in mycology are provided upon request.

Sample Collection and Identification

Specimens should be inoculated to isolation media within 24 hours of collection. Viability of most fungal pathogens decreases significantly with delay in processing specimens; for example, viability of *Histoplasma capsulatum* is lost after 24 hours regardless of how the specimen is handled. For this reason, it is preferable to initiate primary isolation at the local level. It is not recommended, however, that primary isolation of systemic fungi be attempted without using a biological safety cabinet for specimen processing. Appropriate culture media are available commercially; consult reference manuals for recommended isolation methods.

Blood, bone marrow, spinal fluid, biopsy material, aspirates, and other clinical specimens should be collected aseptically. Sputum for fungus culture should be an early morning specimen collected after rinsing the mouth with water. Bronchial washings and brushings and other body fluids should be submitted in the centrifuge tubes found in the sputum mailer for TB. Tissue from fungal lesions should be obtained from the center and the wall of the lesion. Skin, hair, and nail clinical samples are no longer accepted.

Label specimen with two unique patient identifiers that include: patient's name, and date of birth, Social Security number, or the local laboratory number. Unlabeled specimens will not be tested. It is particularly important that pertinent clinical information be sent with each specimen since it is used in selecting appropriate isolation procedures. For safety reasons, please do not submit a single clinical specimen for primary isolation of both fungi and *Mycobacterium tuberculosis*; however, please indicate if tuberculosis is suspected in addition to fungal disease.

Place properly completed DHHS Form #2010 (one form for each specimen) in the outer container of the shipping packaged, this helps to avoid contamination in case of breakage or leakage. Place caps on tightly and secure with tape to avoid leakage. Leaking specimens constitute a biological hazard and may not be tested.

To submit reference cultures, isolated pure colonies from primary culture media should be subcultured to fresh media slants and incubated until visible growth appears before shipment. Upon visible growth, ship the pure isolate at ambient temperature. If necessary, initial cultures believed to be clinically significant may be submitted on primary isolation slants. Specimens will be rejected if SLPH cannot subculture and obtain a viable isolate. **Culture plates should not be submitted.** Each specimen should be clearly labeled with two patient identifiers and

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accompanied by DHHS Form #2010. **Note: Specimens received without the submitter's return address are subject to rejection!**

Shipment

Always use double walled shipping containers, or equivalents that meet safety and current USPS shipping requirements. Several types are available from the Laboratory Mailroom at https://slphreporting.ncpublichealth.com/labportal/. Multiple tubes or specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leakproof container. Mailers or packages not supplied by the State Laboratory should have "Mycology" plainly marked on the outside of the package. This ensures that packages and mail will be delivered directly to the Mycology Laboratory, eliminating needless and possibly hazardous exposure of nontechnical staff.

Ship specimens as soon as possible after collection. **Refer to the Microbiology section of Appendix A** for Mycology specimen and shipment requirements. Use first-class postage on U.S. Mail. Be sure to place return address on the outside of the container, regardless of shipping method. When outbreak associated specimens, unusual specimens, or potentially hazardous specimens are being submitted, telephone the Microbiology Unit at (919) 807-8605 or 919-733-7367 prior to shipping. See appendix C for local health department specimen transport guidance.

Reference cultures may be submitted on any appropriate fungal culture medium slants after growth is visible, and pure isolates should be shipped ambient. Specimens will be rejected if a viable culture cannot be obtained by the lab. Use Microbiology Reference Culture mailer or equivalent for shipping. Please telephone the Microbiology Unit before mailing clinical material or cultures of *Histoplasma capsulatum, Blastomyces dermatitidis,* or *Coccidioides immitis*. **Known cultures of these organisms must be shipped according to Federal Regulations for Diagnostic or Infectious substances.**

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Fill out form DHHS Form #2010 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

Note: Specimens received without submitter return address are subject to rejection!

Reporting Procedures and Interpretation

Yeasts and some other fungi may be identified and reported within three to ten working days, while others may require longer time. Cultures are held four weeks before being reported as negative. Preliminary reports are sent out on all clinical specimens.

Most medically important fungi are identified to the species level (e.g., *Microsporum gypseum, Trichophyton mentagrophytes*). Most saprophytic fungi are identified to genus level only.

Computer generated final reports are returned to the submitting agency only; therefore, the submitter is responsible for sending copies and/or making reports to any other agency. The submitting agency is responsible for maintaining reports in the patient's file.

Results are also available via the website, at https://celr.dph.ncdhhs.gov**.**

Collection and Shipment of Mycology Specimens

Specimen	**Collection**	**Isolation Medium and/or Container***
Subcutaneous and systemic mycoses		
Blood	Aseptic, blood culture venipuncture. Collect with heparin anticoagulant.	Sabouraud Agar or other isolation medium.
Bone marrow	Collect aseptically	Same as above or sterile container or TB mailer.
Bronchial washings and aspirates	Collect through bronchoscopy procedure	Same as above.
Pus or exudates	Aspirate with sterile syringe	Same as above.
Spinal fluid	Routine spinal tap	Same as above.
Sputum, early morning	Allow patient to cough up and discard drainage accumulated during the night, then collect specimen in sterile container. May be obtained following inhalation of saline aerosol.	Same as above.
Yeast Infections	Collect as for bacteriological specimens, using aseptic technique.	Isolate on Sabouraud Agar or submit in TB sputum mailer.
Reference Cultures		
All except *Nocardia* sp.	Select and subculture colonies from isolation medium which show good growth and are in pure culture. Incubate until growth appears.	Sabouraud Agar slant or other fungus isolation medium.
Nocardia sp.	Select pure colony, as above. Incubate until growth appears	Sabouraud agar, LJ, 7H10 or 7H11 agar.

* Reference cultures should be mailed in Microbiology Reference Culture Mailer or equivalent.

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Neisseria Gonorrhoeae and Neisseria Species

(919) 807-8606

Introduction

Clinical specimens such as cervical, rectal or throat swabs are not accepted by the NCSLPH for primary isolation of *Neisseria gonorrhoeae* (GC). Primary culture is available through the local health department Sexually Transmitted Disease (HIV/STD) Program. Reference cultures are accepted from public and private health care providers for confirmation. State Laboratory of Public Health also offers antimicrobial susceptibility testing for Neisseria gonorrhoeae. The minimum inhibitory concentrations for the following drugs are tested and reported: Ceftriaxone, Cefixime, Ciprofloxacin, and Azithromycin.

Suspected cultures of GC should be confirmed in the following instances: 1) cultures from anatomic sources other than urogenital sites in symptomatic patients, 2) rectal cultures in homosexual males, 3) cases involving children, 4) any other legal case, 5) if there is any question regarding the local laboratory's interpretation of biochemical or microscopic test results, or 6) if a genital culture has been resulted as 'presumptive positive for N. gonorrhoeae' and the laboratory does not have a means to confirm the identification.

Sample Collection and Identification

To submit reference cultures, transfer a **well-isolated** colony from the primary isolation plate to a fresh Thayer-Martin plate (see also SHIPMENT OF SPECIMENS, below). Martin-Lewis, JEMBEC, GC-Lect® and Chocolate agar slants or plates are also satisfactory. Isolates of *Neisseria* other than gonococci may be submitted on blood, chocolate, or infusion agar.

All Neisseria gonorrhoeae which are isolated/confirmed at SLPH are frozen and held in case antimicrobial susceptibility testing is requested.

Clearly label each specimen with the patient's name and either date of birth or Social Security number; submit with a Special Bacteriology DHHS Form #4121. Unlabeled specimens will not be tested. Please indicate if a specimen is a legal case.

Fill out form DHHS #4121 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of Collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

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Note: Specimens received **without submitter return address** are subject to rejection!

Shipment of Specimens

Cultures should be incubated overnight or until growth is visible before shipment. Slant cultures should be overlaid with sterile broth (such as infusion broth) to within one inch of the top of the tube, sealed with tape and placed in a leak-proof container before shipping to help preserve organism viability. The submitting laboratory should maintain an additional viable isolate in the event the organism does not survive shipment. Do not ship on Fridays, holidays, or weekends.

Thayer Martin Modified agar or other commercially available media for gonococci are suitable for submitting cultures to the NCSLPH for confirmation. Health department STD clinics may obtain mailers for gonococcal culture media plates from the NCSLPH, Laboratory Improvement by telephoning (919) 733-7186. Cultures must be maintained in a CO_2 atmosphere during shipment. Plate cultures in the CO_2 environmental transport system should be shipped at room temperature and cushioned against breakage. Use Microbiology Reference Culture mailer for isolates submitted on tubed media; use double-walled or equivalent containers that meet safety requirements.

Place completed identification DHHS Form #4121 in the outer container, or in a sealed plastic bag to prevent wetting and contamination in case of leakage. Multiple specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof container, crush-proof container.

Plainly label "*Neisseria gonorrhoeae*," or "GC culture" and "DO NOT REFRIGERATE" on the outside of the package, and address to "Atypical Bacteriology". Every effort should be made to protect cultures from temperature extremes during shipment; cultures should never be refrigerated. Shipment should be timed so that cultures do not arrive on Fridays or weekends.

Ship specimens as soon as possible after growth is present on the plate. Please note: *Neisseria* species die easily and should be freshly subbed to a chocolate slant or transport media such as the MTM plate and incubated overnight before shipping. **Refer to the Microbiology section of Appendix A** for Neisseria gonorrhoeae specimen and shipment requirements. See appendix C for local health department specimen transport guidance. Please note: if shipment is delayed, cultures with growth should be subcultured by the submitter every 2-3 days to maintain viability. When shipping by U.S. Mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method. Label "Atypical" and "DO NOT REFRIGERATE" on the outside of the package. Telephone the Microbiology Unit prior to shipping large numbers of specimens (e.g., outbreaks, clusters) or those requiring urgent attention.

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Reporting Procedures and Interpretation

Positive Gonococcal cultures are reported as "Culture positive for Neisseria gonorrhoeae. " Non-gonococcal neisseriae are reported as “No *Neisseria gonorrhoeae* isolated” and may be identified to the genus or species level as appropriate. Results usually are reported within one to three workdays unless difficulty is encountered in growing the organism or isolating it from a mixed culture. Results can be accessed via the secure web page for results.

Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. The submitting agency is responsible for maintaining reports in the patient's file.

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Parasitology

(919) 807-8609

Introduction

Diagnostic specimens for examination for the presence of human parasites are accepted from public health care providers only, and only from symptomatic patients. Reference specimens for confirmation of parasite identity or further identification, with the exception of blood, are accepted from all laboratories.

Feces and other specimens are examined for eggs, cysts and larvae of the intestinal parasitic worms and protozoa.

Arthropods are referred to the Entomology Department at NC State University through the Insect and Plant Disease Clinic (919-515-9530) for identification for a fee of $30. Submitter should contact the clinic directly to arrange testing.

Testing for *Cryptosporidium* and *Cyclospora* are offered upon request; testing for *Microsporidium* is NOT available at this time. Testing for Blood Parasites is available from the Centers for Disease Control and Prevention (CDC).

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Specimen Collection and Identification

Clearly label each specimen with patient's name and date of birth and fill out DHHS Form #1245 completely. Unlabeled specimens will NOT be examined.

Fill out form DHHS Form #1245 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of Collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

Note: Specimens received **without submitter return address** are subject to rejection!

Intestinal Parasites

Fecal Specimens: Collect specimen following instructions in the Parasitology mailer supplied by this Laboratory, by ordering online at https://slphreporting.ncpublichealth.com/labportal/ or in any commercially available

parasite collection kit containing 10% formalin as a preservative. Do not contaminate with dirt, urine, or paper. Place feces in a vial of 10% formalin, such as provided in the kits available from the NCSLPH Mailroom. Break up any large pieces by shaking or stirring well. **Do Not Overfill**. Specimens will be rejected if not received in 10% formalin, or if the sample plus the preservative exceeds the fill line. Place caps on securely to avoid leakage. Leaking specimens constitute a biological hazard and will not be tested. Label tube with two identifiers. Three specimens collected on alternate days are recommended, e.g., Monday, Wednesday and Friday. If three (3) specimens are collected, mail all three at the same time.

Other Clinical Materials: Collect specimen aseptically following proper procedure for type of specimen. Place in sterile container; label with two identifiers, name and date of birth.

Whole Worms or Proglottids: Whole worms should be preserved in 70% alcohol, if possible. Place in plastic or glass container; label with two patient identifiers. Proglottids may be preserved in 10% formalin or placed in saline or 70% alcohol. Parasitology mailer may be used if it is large enough, as it contains 10% formalin.

Arthropods: Arthropods are referred to the Entomology Department at NC State University through the Insect and Plant Disease Clinic (919-515-9530) for identification for a fee of $30. Submitter should contact the clinic directly to arrange testing.

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Shipment of Specimens

Always use double-walled shipping containers that meet DOT and USPS requirements. Mailers for submitting formalin preserved specimens are available on-line at https://slphreporting.ncpublichealth.com/labportal/. Specimens should be submitted for testing as soon as possible. Refer to Appendix A, **Microbiology _ Parasitology** for specimen and shipment requirements. See appendix C for local health department specimen transport guidance.

Multiple tubes or specimens should be packaged individually in leak-proof containers so as not to contaminate the requisitions. Mailers or packages should have "Parasitology" plainly marked on the outside of the package. This ensures that packages and mail will be delivered directly to the proper unit and eliminates needless and possibly hazardous exposure of non-technical staff, as well as lost or delayed samples. To facilitate handling, the following general suggestions are made:

1. Write patient's name and date of birth on specimen vial or slide. Unlabeled specimens will NOT be tested.

2. Place sealed primary container (specimen tube) inside secondary container (metal silver can) with absorbent material. Seal.

3. Place properly completed identification DHHS Form #1245 (found at https://slph.dph.ncdhhs.gov/Forms/1245-Parasitology.pdf) around sealed secondary container to avoid contamination in case of breakage or leakage.

4. Place secondary container into outer mailing container. Please place return address on mailing container.

6. When using U.S. Mail, use first-class postage, and place return address on the outside of the container.

7. When unusually large numbers of specimens are anticipated (as an outbreak), the Microbiology Unit should be alerted by telephone at (919) 733-7367 so that preparations may be made.

Reporting Procedures and Interpretation

Specimen results are usually reported within two to three days of receipt. Reference specimens submitted to the CDC may require several weeks for analysis.

An estimate of few, moderate, or many will be reported only with certain organisms where quantity may have a correlation with worm burden (such as *Ascaris*, Trichuris, and hookworms) or be an indicator for treatment (such as *Blastocystis hominis*).

A report of *Entamoeba coli* is not to be confused with *E. histolytica*. *E. coli* is a non-pathogenic commensal amoeba often found in the human gastrointestinal tract and is reported only as an indication of unsanitary conditions relating to the patient, such as poor personal hygiene.

Reports are returned to the submitting agency only; therefore, the submitter is responsible for sending copies and/or making reports to any other agency. The submitting agency is responsible for maintaining reports in the patient's file. Results can be accessed via the secure webpage at https://celr.dph.ncdhhs.gov/.

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Special and Atypical Bacteriology

Special Bacteriology (919) 807-8603

The Special Bacteriology lab serves primarily as a referral laboratory for bacteria that are unusual or difficult to identify. In this context, "Special Bacteriology" refers to the examination of a variety of microorganisms including the following: *Bordetella, Legionella,* and gram-positive cocci. Certain clinical specimens are accepted for primary isolation; otherwise, pure isolates are required for identification or serotyping. Specimens are accepted from public and private health care providers. Cultures from animal or environmental sources must be associated with human illness. Anaerobic culture and antimicrobial susceptibility testing are not performed in this laboratory. Consultation and bench training are provided upon request.

Services available in the Special Bacteriology lab include:

- PCR testing for *Bordetella pertussis and B. parapertussis*
- culture for *Bordetella pertussis* and *B. parapertussis*
- culture and DFA staining for *Legionella*
- grouping of beta hemolytic streptococci and identification of clinically significant isolates of other gram-positive cocci
- confirmation of suspected Vancomycin resistant or intermediate isolates of *Staphylococcus aureus*

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Streptococcus pneumoniae typing:
Isolates are sent from SLPH to the Wisconsin State Laboratory of Hygiene (WSLH). Isolates should be submitted on a chocolate slant with a completed DHHS Form #4121 (Special/Atypical Bacteriology). Please write in "Strep. Pneumoniae for typing" as the test order. For questions, contact the Special Bacteriology lab at (919) 807-8603.

Vancomycin Intermediate and Vancomycin Resistant *Staph aureus* (VISA/VRSA):
These isolates should be sent to the NCSLPH for minimum inhibitory concentrations (MICs) and resistant organisms will then be sent to the CDC for final confirmation. VISA and VRSA are reportable to both the CDC and the State of North Carolina through the Communicable Disease Branch at 919-733-3419. Subculture and save a copy of the isolate in-house.

Atypical Bacteriology (919) 807-8606

The Atypical Bacteriology lab serves primarily as a referral laboratory for bacteria that are unusual or difficult to identify. In this context, "Atypical Bacteriology" refers to the examination of a wide variety of microorganisms including the following: *Bacillus, Corynebacterium, Haemophilus, Neisseria, Pasteurella, Pseudomonas* and similar organisms and "unclassified" bacteria. Pure isolates are required for identification or serotyping. Specimens are accepted from public and private health care providers. Culture from animal or environmental sources must be associated

with human illness. Anaerobic cultures are not performed in this laboratory. General antimicrobial susceptibility testing, other that for Neisseria gonorrhoeae, is not performed in this laboratory. Consultation and bench training are provided upon request.

Services available in the Atypical Bacteriology Lab include:

- confirmation and serotyping of *Neisseria meningitidis* and *Haemophilus influenza* from sterile body sites **(see note below)**
- confirmation of *Neisseria gonorrhoeae*
- *Antimicrobial susceptibility testing for Neisseria gonorrhoeae*
- confirmation of *Listeria monocytogenes*
- identification of non-fermentative gram-negative bacilli
- identification of gram-negative fermentative bacilli not included in the order Enterobacterales
- identification of gram-positive *Bacillus sp*. and coryneform rods
- identification or referral of cultures which are unidentifiable at the local level due to special growth requirements, atypical test results or misidentification from automated systems. Hazardous suspected organisms such as *Brucella* should be directed to the Bioterrorism Unit.

Please Note: The North Carolina Communicable Disease Control rules (10A NCAC 41A.0209) state that laboratories isolating *Neisseria meningitidis* and *Haemophilus influenzae* from a normally sterile site, shall test the organism for specific serogroup or send the isolate to the NC State Laboratory of Public Health for serogrouping.

*The hazardous nature of certain suspected organisms such as *Francisella tularensis, Bacillus anthracis, Yersinia pestis, Burkholderia mallei, Burkholderia pseudomallei and Brucella spp.* require submission to the Bioterrorism and Emerging Pathogens Unit (BTEP). Please call the BTEP Unit at 919-807-8600 if one of these organisms is to be submitted.

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Specimen Collection and Identification

Specimens should be collected aseptically and cultured at the local laboratory. Only pure cultures should be submitted; mixed cultures are subject to rejection. To assure purity, isolates should be subcultured onto appropriate media before referral to the NCSLPH. Specimen in which a subculture or a viable isolate cannot be obtained upon arrival at the SLPH lab will be rejected. Each specimen should be clearly labeled with the patient's name and either date of birth or Social Security number accompanied by a completed Special/Atypical Bacteriology requisition DHHS Form #4121. Use separate forms for individual specimens. Unlabeled specimens will not be tested. Place forms in the outer container to avoid contamination in case of specimen leakage.

Note: Specimens received without **submitter return address** are subject to rejection!

Fill out form DHHS Form #4121 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date and time of collection
- Submitter EIN
- ICD-10 code (reason for testing)
- Ordering provider and National Provider Identifier (NPI)
- Medicaid number if patient has Medicaid
- Test requested
- Specimen source

On the form indicate presumptive identification or preliminary test results and patient clinical information.

Telephone the Microbiology Laboratory at (919) 733-7367 of outbreak situations, to make special arrangements in urgent or unusual circumstances, or before submitting large numbers of isolates or highly infectious organisms.

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Shipment of Specimens

Isolated organisms other than those requiring special handling preferably should be submitted on carbohydrate-free agar slants such as infusion, nutrient, trypticase soy, blood or chocolate. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. Use the Microbiology Reference Mailer for agar slant cultures. Use double-walled or equivalent containers; pure isolates of the organism should be shipped ambient. When submitting large numbers of isolates, tubes should be wrapped individually in absorbent cushioning material and packaged together, securing against breakage. Refer to **the Microbiology section of Appendix A** for Special and Atypical bacteriology specimen and shipment requirements. See appendix C for local health department specimen transport guidance.

Plainly label "Special/Atypical Bacteriology" on the outside of all mailers. Ship specimens as soon as possible after collection. When shipping by U.S. Mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method.

Reporting Procedures and Interpretation

Most culture identifications are reported within five to ten workdays; mixed cultures or fastidious bacteria may require longer for identification. Reports on isolates referred to the CDC may be delayed up to several months.

Organisms are identified to a genus and species level only when cultural, morphological and biochemical test results indicate a good species correlation. Some organisms can be identified accurately only to the genus level. Organisms normally encountered as contaminants or those lacking clinical significance also may be reported only to the genus level. Test reactions of atypical organisms may fail to correlate with those of known cultures. Reports reflect any similarity to characterized bacterial strains.

Organisms reported as "unidentified" do not correspond to recognized genera and/or species. These cultures are not routinely forwarded to the CDC unless 1) the nature of the isolate, source and/or patient clinical history warrant further study, or 2) a special request is made for referral. The submitting laboratory may need to clear this request with CDC staff prior to forwarding the isolate to the NCSLPH for referral to the CDC.

Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. Copies of reports are maintained in this Laboratory. The submitting agency is responsible for maintaining reports in the patient's file. Reports of *Haemophilus influenzae* and *Neisseria meningitidis* from cases of invasive disease are forwarded electronically to the Communicable Disease Branch.

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NC DEPARTMENT OF
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HUMAN SERVICES
Division of Public Health
State Laboratory of Public Health

Syphilis Serology

(919) 733-3937

Introduction

Syphilis, a disease caused by infection with the bacterium *Treponema pallidum*, can be readily diagnosed by serologic methods. Serologic assays used to screen patients for syphilis are non-treponemal tests. The nontreponemal test performed in this laboratory is the Rapid Plasma Reagin (RPR). Confirmation of reactive screening test results (RPR) is obtained through the use of specific treponemal tests for syphilis. The SYPHILIS TP CMIA test is performed in this laboratory to confirm syphilis screening test results when appropriate. The Venereal Disease Research Laboratory (VDRL) and the Fluorescent Treponema Antibody Absorption (FTA-ABS) assays are not performed at the NC State Laboratory of Public Health but are available from commercial reference laboratories.

Sample Collection and Identification

The non-treponemal test for syphilis (RPR) performed on serum is available only to local health departments and state-operated health facilities. Although the specific treponemal test for syphilis (SYPHILIS TP CMIA) is available to all health care providers, it is not designed to be a screening procedure and thus is only performed when required for proper patient management.

Submit 2-3 mL of serum in a plastic screw-capped vial. Hemolyzed, icteric, or lipemic serum is unacceptable for syphilis serologic assays. Clearly label each vial of serum with the patient's name (first and last), and either date of birth or Social Security number. Refer to **Appendix C** for requirements regarding specimen storage after collection and prior to shipment.

Recommended Tests for the Different Stages of Syphilis

Disease Stage	Specimen	Test to Request
Screening	Serum	RPR
Primary	Serum	RPR
Secondary	Serum	RPR
Latent	Serum	RPR, SYPHILIS TP CMIA
Late Neurosyphilis	Serum	RPR, SYPHILIS TP CMIA
Congenital CNS Involvement	Serum	RPR, SYPHILIS TP CMIA

All screening tests performed in this laboratory which are determined to be reactive will be confirmed by the SYPHILIS TP CMIA test, unless a previous positive SYPHILIS TP CMIA or other confirmatory test result is on file at the laboratory. In those cases, only the screening test results will be reported.

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A request to this laboratory for a SYPHILIS TP CMIA test **must** be accompanied by a quantitative screening test result, i.e., the submitter must provide a titer. This request will yield only a qualitative SYPHILIS TP CMIA test result without performing a screening test. If a previous positive SYPHILIS TP CMIA or other confirmatory test result is on file at the laboratory, no testing will be performed.

For the purposes of evaluating patients suspected of having late syphilis, the SYPHILIS TP CMIA test will be performed in this laboratory on serum regardless of the screening test result. Under these circumstances, the submitter must specifically request a SYPHILIS TP CMIA test, state the quantitative screening test result/titer, and indicate that late syphilis is suspected.

Note: North Carolina law no longer requires a premarital serologic test for syphilis. Any other states requiring a premarital syphilis test will accept test results from the State Laboratory of Public Health.

Note: North Carolina Public Health Law 10A NCAC 41A.0204 requires all pregnant women to be screened at the first prenatal visit, between 28-30 weeks gestation, and at delivery.

Specimens submitted to the Microbiology Unit must be accompanied by a fully completed DHHS Form #3446 request form.

- Check "RPR (Titer and Confirmatory if Reactive)" for screening purposes. All specimens testing Reactive on the screening RPR will be automatically reflexed to a quantitative RPR (titer) and syphilis confirmatory test (SYPHILIS TP CMIA).
- Check "*Treponema pallidum* confirmatory serology" only if requesting follow-up confirmatory testing on a previously Reactive screening test; please provide screening test (RPR/TRUST) quantitative titer results.
- When requesting both an RPR and a confirmatory test (even if the RPR is Nonreactive) because latent or late syphilis is suspected, write in this reason for testing in the "Other" section under Reason for Testing.

Failure to supply the requested patient information may result in significantly delayed specimen testing.

Only serum may be submitted for primary serologic syphilis testing. Specimens submitted for diagnostic testing not labeled with correct patient identification information will not be tested and will be discarded. Patient specimen identification includes full first and last name and either date of birth, Social Security number, or another unique identifier. Specimens received more than 5 days from the collection, not received cold (2-8°C) on frozen ice packs or frozen (≤-20°C) on dry ice, or for any other reason deemed unsuitable or inappropriate for diagnostic testing will not be tested and will be discarded. Specimens received without a test requisition will be properly stored no longer than 3 business days pending verbal and/or written notification of the submitter. Unless a test requisition is received, the specimen will be discarded at the end of the holding period.

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Shipment

Refer to the **Microbiology section of Appendix A** for Syphilis specimen and shipment requirements and contact the laboratory if additional guidance is needed. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

Results of nontreponemal tests for syphilis (RPR) performed on serum are available within three working days after receipt of the specimen. Treponemal specific tests (SYPHILIS TP CMIA) performed on serum are available within four working days after receipt of specimen.

Patients with primary syphilis may have a non-reactive RPR and/or SYPHILIS TP CMIA when first seen; however, these tests will usually become reactive soon thereafter. Most patients treated for primary syphilis will have a reversion of nontreponemal tests to non-reactive within 2-3 years. The SYPHILIS TP CMIA test will usually remain reactive after treatment. Non-reactive serologic tests and normal clinical evaluations do not exclude incubating syphilis.

Syphilis Serology Test Results and Interpretations

RPR Results	SYPHILIS TP CMIA	Interpretation
Reactive	Positive	Usually indicates syphilis.
Reactive	Negative	"Biologic False Positive" reaction in reagin tests may be caused by infection, immunizations, inflammatory disease, immunity abnormalities, drug addiction, pregnancy, or aging. Tests should be repeated on a follow-up specimen if doubt exists.
Non-Reactive	Not Done	Treponemal tests are not indicated unless late syphilis is suspected according to clinical data.
Non-Reactive	Positive	Usually indicates previously treated syphilis or late syphilis (untreated).

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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Public Health
State Laboratory of Public Health

Specimens Requiring Special Handling

Organism or Disease	Collection Instructions	Shipping Requirements	Special Requirements
Bacillus anthracis	See Section: Bioterrorism and Emerging Pathogens		
Bordetella pertussis (whooping cough)	See separate listing		
Brucella spp.	See Section: Bioterrorism and Emerging Pathogens		
Burkholderia mallei	See Section: Bioterrorism and Emerging Pathogens		
Burkholderia pseudomallei	See Section: Bioterrorism and Emerging Pathogens		
Corynebacterium diphtheriae	Culture: Collect throat or skin lesion swabs (2 preferred); place in swab transport system (e.g. Amies or Stuarts) or subculture to Loeffler or other agar slants. If PCR is desired, it is forwarded to CDC. Contact Atpical Bacteriology (919-807-8606) prior to specimen submission for specimen acceptance, collection, storage and preservation requirements.	Microbiology Reference mailer for isolates or swab transport system.	Notify Unit Atypical Bacteriology (919-807-8606) prior to shipping. Toxigenicity testing performed at the CDC.
Francisella tularensis	See Section: Bioterrorism and Emerging Pathogens		
Haemophilus ducreyi (chancroid)	NOTE: Culture is seldom successful; diagnosis usually is made by clinical evidence and exclusion of other STD agents associated with lesions.		
	Collect specimens from lesions of inguinal bubo and inoculate onto chocolate agar (CA) or CA + vancomycin; incubate at 33-35º in 5-10% CO_2	Reference culture of heavy growth from CA on sterile swabs stabbed into CA Microbiology Reference mailer	*Primary culture recommended at local level*
	PCR testing performed at CDC; contact Section for information (919-733-7367) or (919-807-8606)		
Legionella	See separate listing		
Leptospira	Note: PCR and serological testing at the CDC is available; refer to Virology/Serology		
Staphylococcus aureus	Isolates of coagulase positive staphylococci from documented outbreaks.	Microbiology Reference mailer.	Notify Unit prior to shipping. Referred to CDC
Yersinia pestis	See Section: Bioterrorism and Emerging Pathogens		

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* Federal regulations require that these organisms must be shipped by a system that allows tracking and prompt location of packages and notification of receipt, such as certified or registered mail. Biohazard labeling is required on the outside of the container

Turnaround Times for NCSLPH Bacteriology The turn-around times for in-house testing are general guidelines and vary by the individual test:

TEST	TURNAROUND TIME
Bordetella PCR	Batched twice a week; usually 1-3 working day TAT
Bordetella culture	7 days after receipt
Legionella DFA	Day of receipt or next work day
Legionella culture	2 weeks after receipt
Special Reference identifications	~5-10 work days
Enteric Reference identifications	~7-10 work days
Enteric Clinical Cultures	~7-10 work days
Neisseria gonorrhoeae confirmations	1-3 work days after receipt
Atypical Reference identifications	~5-10 work days
Yeast identifications	~2 weeks
Mold identifications	~5-8 weeks
Actinomycetes identifications	6-8 weeks
Ova & protozoa concentrations	3-5 work days
Mixed, fastidious, or particularly difficult to identify isolates may take longer.	
Identifications referred to CDC may take several months.	
TEST	**TURNAROUND TIME**
M. tuberculosis PCR	Testing: Mon, Wed, Fri (TAT 24-48 hrs.)
Fluorochrome Acid Fast staining	24 hrs. from receipt of specimen
M. tuberculosis identification	Goal TAT 14-21 days from receipt Mixed/contaminated cultures may cause delays
Liquid (1st Line) Drug Susceptibility testing for *Mtb*	Goal TAT 17 days from positive identification of M. tuberculosis. Mixed or contaminated cultures may cause delays.
Conventional (2nd Line) Drug Susceptibility testing for *Mtb* (agar proportion)	21 days from drug set up
Mycobacterium sp. (NTM) identification	7-42 days from receipt
Culture Negative (No Growths)	42 days
Mtb isolates sent to Michigan Department of Community Health (CDC GIMS Program)	7-10 days
Mixed, fastidious, or particularly difficult to identify isolates may take longer.	
Identifications referred to CDC may take several months.	

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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Public Health
State Laboratory of Public Health

NC Antimicrobial Resistance Laboratory Network (ARLN) Laboratory

(919) 807-8607

Carbapenemase-producing organisms (CPO)
Candida auris identification
Neisseria gonorrhoeae Antimicrobial Susceptibility Testing
Expanded Antimicrobial Susceptibility Testing (ExAST)
Carbapenemase-producing organisms and *C. auris* Screenings
Staphylococcus aureus (VISA/VRSA) Screenings

slph.arln@dhhs.nc.gov

The CDC's Antimicrobial Resistance Laboratory Network (ARLN) is an effort between U.S. healthcare facility laboratories, public health laboratories, regional laboratories, and the CDC. The AR Lab network is the first network in the nation providing comprehensive antimicrobial resistance testing of healthcare-associated infections (HAIs), community-associated infections, fungal disease, sexually transmitted diseases, and drug-resistant *Mycobacterium tuberculosis*.

The NCSLPH is a part of CDC's AR Lab Network. NC ARLN laboratory testing is performed across the Microbiology and Molecular Epidemiology units. NC ARLN performs moderate and high complexity testing to determine the presence of genes that produce carbapenemases in bacteria, confirm the identification of *Candida* auris in reference cultures, determine the antibiotic susceptibility pattern in *Neisseria gonorrhoeae* reference cultures, and detect vancomycin resistant *Staphylococcus aureus* (VRSA) in contact screening samples.

The NC ARLN Lab utilizes the Maryland Public Health Laboratory (MDPHL) for additional testing when necessary. This testing includes colonization screening for carbapenemase producing organisms (CPO), colonization screening for *Candida auris*, antifungal susceptibility (AFST) testing for *Candida auris*, and expanded antimicrobial susceptibility testing (ExAST) for Enterobacterales.

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Characterization of Carbapenemase-producing Organisms (CPO)

Introduction

Isolate submission of carbapenem-resistant Enterobacterales (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) and *Acinetobacter baumannii* (CRAB) to the NCSLPH supports statewide efforts to prevent the spread of multidrug-resistant organisms (MDROs) and facilitate coordination between clinical and public health partners; it is not to confirm the results of completed clinical testing. Isolates are examined for the presence of genes that produce carbapenemases which break down carbapenem antibiotics. These bacteria are referred to as carbapenemase-producing organisms (CPO). These genes can easily be transferred to other

bacteria. The most common CP genes of concern include *Klebsiella pneumoniae* carbapenemase (KPC), New Delhi metallo-β-lactamase (NDM), oxacillinase-48 (OXA-48), Verona integron encoded metallo-β-lactamase (VIM), and imipenemase metallo-β-lactamase (IMP). The NCSLPH receives isolates from healthcare facilities and clinical laboratories for the characterization of CRE, CRPA, and CRAB.

Testing Methodology:

Testing of CPOs is performed using various test methodologies. Identification of bacterial isolates is performed using matrix-assisted laser desorption/ionization time of flight (MALDI-TOF). Detection of carbapenemase enzyme production is performed using the modified Carbapenem Inactivation Method (mCIM) and NG-Test CARBA 5, lateral flow immunoassay. Gene detection is performed using real-time polymerase chain reaction (PCR).

Isolate submission guidelines

*Submit when criteria are met

Enterobacterales (CRE)* - Resistant to meropenem, imipenem, or ertapenem

- Positive phenotypic or PCR test
- Phenotypic test not performed
- Discrepant results between phenotypic and PCR tests

***P. aeruginosa* (CRPA) -** Resistant to meropenem or imipenem.

- Positive phenotypic or PCR test
- Phenotypic test not performed
- Discrepant results between phenotypic and PCR tests

If you're unable to perform carbapenemase production (CP) testing on CRPA to comply with the new NC CPO reporting rule change, NCSLPH can perform testing at no cost. If you can perform CP testing, then NCSLPH requests that you send CRPA isolates that are meropenem and/or imipenem resistant and have shown to harbor a carbapenemase enzyme and/or gene. CDC requests non-mucoid and non-cystic fibrosis CRPA isolates.

***A. baumannii* (CRAB) -** Resistant to any carbapenem

- Resistant to any carbapenem
- Molecular detection of a carbapenemase(s)

***** Elevated minimum inhibitory concentrations (MICs) to imipenem in *Morganella* spp., *Proteus* spp., and *Providencia* spp. are frequently due to mechanisms other than carbapenamases. Therefore, we request the submission of *Morganella* spp., *Proteus* spp., and *Providencia* spp. only if they also exhibit resistance to other carbapenems.

Isolate shipment guidelines

All CRE, CRPA, and CRAB testing and shipping is free through NCSLPH. Please ship isolates via FedEx to the following address:

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HEALTH AND
HUMAN SERVICES
Division of Public Health
State Laboratory of Public Health

NCSLPH ARLN
North Carolina State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607

Alternatively, laboratories can work with their Local Health Department to ship through the NC DOA Medical Courier.

Isolate submission steps:

1. If shipping materials are needed, including TSA slant media and FedEx labels, please contact the NCSLPH ARLN team at slph.arln@dhhs.nc.gov.
2. Complete the NCSLPH Enteric Bacteriology (Enterobacterales) Form DHHS 3390.
3. For “Specimen Type” select “Reference isolate”.
4. In the “Microbiology Test request/Pathogen(s) identified” section, mark “ARLN Panel” box and provide the identification of the organism beside “ARLN Panel”.
5. Submission of CRE, CRPA, or CRAB on TSA slant is preferred.
6. Label slant with two patient identifiers. Place completed DHHS form 3390 (one form per isolate slant) in outer container to avoid contamination in case of breakage or leakage.
7. All isolates must be packaged as UN3373 Category B, Biological Substance and shipped at ambient temperatures.

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Acceptance criteria

- Pure bacterial isolates that have been determined to exhibit carbapenem resistance carbapenem-resistant *Enterobacterales* (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB) by clinical microbiology laboratories should be received on agar slants.
- Agar slants that support growth are preferred. Agar plates are discouraged. However, if necessary, plates must be sealed with tape or parafilm, enclosed in a leak-proof bag and securely packaged in a crush-proof container.

Rejection criteria

- Non-viable cultures
- Mixed cultures will be deemed unsatisfactory and resubmission will be requested from the submitter.
- Unlabeled specimens
- Requisition or specimen label missing two identifiers
- Discrepancy between patient identifiers on the test requisition and the specimen label
- Unacceptable specimen type
- Broken, leaking, or grossly contaminated specimen

Results Reporting
Results are sent to the submitter via StarLIMS electronic reporting.

Turnaround time

5-7 working days. Certain situations (i.e. mixed cultures, holidays, or severe weather) may extend testing turnaround.

Candida auris Identification

Introduction
Candida auris is an emerging multidrug-resistant yeast that can cause invasive infections and is associated with high mortality. Some strains of *C. auris* are resistant to the three major classes of antifungals, severely limiting treatment options. Isolate submission from any specimen site of either suspected *C. auris* or yeasts that could not be identified to the NCSLPH supports statewide efforts to prevent the spread of *C. auris* and facilitate coordination between clinical and public health partners. Isolates are confirmed for the presence of *C. auris* and then sent to Maryland Public Health Laboratory (MDPHL) for antifungal susceptibility testing (AFST).

Test Methodology
Yeast isolates submitted to NC ARLN Lab are subcultured to selective and differential media for the isolation of yeast. Isolated yeast colonies are identified using matrix-assisted laser Desorption/Ionization time of flight (MALDI-TOF).

C. auris isolates are forwarded to MDPHL for AFST.

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Isolate shipment guidelines

All *C. auris* testing and shipping is free through NCSLPH. Please ship isolates via FedEx to the following address:

NCSLPH ARLN
North Carolina State Laboratory of Public Health
4312 District Drive
Raleigh, NC 27607

Alternatively, laboratories can work with their Local Health Department to ship through the NC DOA Medical Courier.

Isolate submission steps:

1. If shipping materials or FedEx labels are needed, please contact the NCSLPH ARLN team at

slph.arln@dhhs.nc.gov.

2. Complete the NCSLPH Mycology (Fungus) Form DHHS #2010.
3. For "Specimen Type" select "Isolated Organism" and fill in the "*(describe) section with further information about the organism.
4. In the "Examine For" section, mark "Yeast".
5. Submission of yeast isolates on agar slant media is required.
6. Label slant with two patient identifiers. Place completed DHHS form #2010 (one form per isolate slant) in outer container to avoid contamination in case of breakage or leakage.
7. All isolates must be packaged as UN3373 Category B, Biological Substance

Acceptance criteria

Pure isolate of yeast, *Candida species,* or *Candida auris* sub-cultured to agar slant and incubated until visible growth appears.

Agar plates should **not** be submitted.

Rejection criteria

- Non-viable culture
- Mixed cultures will be deemed unsatisfactory, and resubmission will be requested from the submitter
- Unlabeled specimens
- Requisition or specimen label missing two identifiers
  - Discrepancy between patient identifiers on the test requisition and the specimen label
  - Unacceptable specimen type
  - Broken, leaking, or grossly contaminated specimen

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Results Reporting

Results are sent to the submitter via StarLIMS electronic reporting.

Turnaround time

3-5 working days for *C. auris* identification confirmation and 2-8 weeks for AFST, which is performed by MDPHL. Certain situations (i.e. mixed cultures, holidays, or severe weather) may extend testing turnaround.

Neisseria Gonorrhoeae Antimicrobial Susceptibly testing

For further information, please see the "Neisseria Gonorrhoeae and Neisseria Species" section in Microbiology.

VISA/VRSA Screen

For further information, please see the "Special and Atypical Bacteriology" section in Microbiology. **Please hyperlink to current page: 87**

Maryland Public Health Laboratory (MDPHL)

The NC ARLN laboratory utilizes MDPHL as our regional AR Lab Network laboratory. Colonization screening testing for CPOs and *C. auris* make up the bulk of reference testing performed by MDPHL.

Expanded Antimicrobial Susceptibility Testing (ExAST)

The CDC ExAST program helps clinical labs and clinicians decide if a new antibiotic can effectively treat highly resistant infections. Highly resistant Enterobacterales isolates that carry metallo-beta lactamases (MBLs) qualify for ExAST by request.

Please contact the NC ARLN Lab for further information at (919) 807-8607 and slph.arln@dhhs.nc.gov.

Candida auris Antifungal Susceptibility Testing (AFST)

Candida auris isolates identified and confirmed by the NC ARLN Lab are forwarded to MDPHL for AFST. Results will be made available electronically upon test completion by the NC ARLN Lab. Expected turnaround times are 2 to 8 weeks.

Carbapenemase Producing Organism (CPO) Colonization Screening

Colonization testing and materials are provided by the AR Lab Network and coordinated by the Epidemiology section of the North Carolina Department of Health. For further information please contact either the NC AR Lab network at slph.arln@dhhs.nc.gov or NC Epidemiology at nchai@dhhs.nc.gov.

Candida auris Colonization Screening

Colonization testing and materials are provided by the AR Lab Network and coordinated by the Epidemiology section of the North Carolina Department of Health

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Molecular Diagnostics and Epidemiology

Norovirus Outbreaks
(919) 807-8607

Introduction

To ensure that the event is eligible for outbreak investigation and norovirus testing, contact the Communicable Disease Branch (CDB) epidemiologists (919-733-3419) for approval.

Testing for norovirus using real-time reverse-transcription polymerase chain reaction (RT-PCR) is available for outbreak situations only and is for surveillance purposes rather than diagnosing individual patients. Requests for norovirus testing on outbreaks with five or more specimens must be approved prior to submission. After approval by the CDB epidemiologists, submit one stool specimen for each patient from at least five, but no more than ten outbreak associated patients and request norovirus testing. Stool specimens should be submitted in commercially available enteric transport medium such as Cary-Blair Transport Medium, ETM™, or Para-Pak® Enteric Plus Transport System. Stools in transport medium are to be kept refrigerated (not frozen) until shipping. Facilities are to hold shipment of specimens to the State Lab until at least five stool samples have been collected. Testing will not occur until at least five stools are received from the outbreak. Specimens for norovirus testing must be accompanied by requisitions filled out appropriately, with the name on sample matching name on requisition and requesting that norovirus testing be performed.

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Sample Collection and Identification

Each specimen must be clearly labeled with the patient's name and a 2nd identifier and accompanied by Enteric Bacteriology DHHS Form #3390. Unlabeled specimens will not be tested. Cary-Blair transport media for collection of feces is available from the laboratory mailroom on-line at https://slphreporting.ncpublichealth.com/labportal/.

Fill out form DHHS Form #3390 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date of Collection
- Test requested
- Specimen source
- Select "Norovirus (outbreak-associated)" under "Molecular Test request/Pathogen(s) identified"

Collect specimen so that feces are free of foreign matter, following instructions in Enteric Culture mailer or equivalent. (Do not use the Parasitology mailer.) Using the scoop, place feces in the vial of transport medium until the level of liquid reaches the fill line marked on the label. Do not overfill vial. Break up any large pieces with the scoop. Stir well; replace the top tightly on the vial. Label with two identifiers: patient's name and either date of birth or Social Security number.

Acceptance criteria

•Prior approval by the NC Communicable Disease Branch (CDB) epidemiologists.
•A minimum of five (5) stools are required to be submitted per suspected outbreak.
•Stool specimens must be submitted in commercially available enteric transport medium such as Cary-Blair Transport Medium, ETM™, or Para-Pak® Enteric Plus Transport System
•Stools must be shipped with freezer packs in an insulated container.

Rejection criteria

•Stools receive without approval by the CDB epidemiologists
•Less than five (5) stools submitted. All untested stools will be discarded after a month.
•Stools received without freezer packs
•Unlabeled specimens
•Requisition or specimen label missing two identifiers
•Discrepancy between the patient identification on the test requisition and the specimen label
•Inappropriate specimen type (e.g., form stool or vomitus)
•Broken, leaking, or grossly contaminated specimen

Shipment

Mailers for submitting stool samples are available on-line at https://slphreporting.ncpublichealth.com/labportal/. To submit specimens:

1. Write patient's name and other identifier on specimen tube. Unlabeled specimens will NOT be tested.
2. Place completed Enteric Bacteriology DHHS Form #3390 (one form for each specimen) in outer container to avoid contamination in case of breakage or leakage.
3. Use double-walled or equivalent shipping containers that meet safety requirements. Multiple tubes or specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof insulated container. Shipping Containers should be clearly labeled "Enteric Bacteriology" on the outside of the container.
4. When shipping by U.S. Mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method. See appendix C for local health department specimen transport guidance.

Reporting Procedures Results for norovirus real-time RT PCR will be provided to the CBD Epidemiologists and the local health department. Norovirus testing is for surveillance and not diagnostic purposes. Therefore, only results that are provided are the ratio of positive to

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negative results for epidemiological purposes only. Individual patient results will not be provided.

Real-time PCR for the detection of *stx1* and *stx2* virulence genes in Shiga toxin producing *E. coli*
(919) 807-8607

Introduction

Enterohemorrhagic *Escherichia coli* (EHEC, *E. coli*) have been isolated from patients who have hemorrhagic colitis and hemolytic-uremic syndrome (HUS). One virulence trait of all EHEC strains is the ability to produce cytotoxin(s) called Shiga toxin (ST) or verotoxin (VT). Shiga toxin 1 (*stx1*) and Shiga toxin 2 (*stx2*) are the two most common toxins. EHEC strains can produce one or both, in varying quantities. A probe-based real-time PCR assay developed by CDC is performed for the detection of *stx1* and *stx2* virulence genes in Shiga toxin producing *E. coli* (STEC).

Clinical specimens for the isolation of *Escherichia coli* (*E. coli*) 0157:H7 and other Shiga-toxin producing *E. coli* (STEC) are accepted only from public health care providers. Fecal specimens are examined for the presents of suspected STEC colonies, are run by real-time PCR for the detection of *stx1* and *stx2*. Reference isolates are accepted from public and private health care providers for identification, serotyping, and/or whole-genome sequencing (WGS).

Please Note: The North Carolina Communicable Disease Control rules (10A NCAC 41A.0209) state that laboratories culturing stool from a person with bloody diarrhea should culture for Shiga-toxin producing *Escherichia coli* or send the specimen to the State Public Health Laboratory for Shiga-toxin testing after consultation with the Enterics Lab at 919-807-8608.

Sample Collection and Identification

Specimens for identification and serotyping of STEC are submitted through the Microbiology Enteric Bacteriology lab. Each specimen must be clearly labeled with the patient's name and a 2nd identifier and accompanied by Enteric Bacteriology DHHS form #3390. Unlabeled specimens will not be tested. Cary-Blair transport media for collection of feces is available from the laboratory mailroom on-line at https://slphreporting.ncpublichealth.com/labportal/.

Fill out form DHHS #3390 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date of Collection
- Test requested
- Specimen source

Collect specimen so that feces is free of foreign matter, following instructions in Enteric Culture mailer or equivalent. (Do not use the Parasitology mailer.) Using the scoop, place feces in the

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vial of transport medium until the level of liquid reaches the fill line marked on the label. Do not overfill vial. Break up any large pieces with the scoop. Stir well; replace the top tightly on the vial. Label with two identifiers: patient's name and either date of birth or Social Security number. Please see the Microbiology Enteric Bacteriology section for additional requirements and details.

Shipment

Mailers for submitting stool samples are available on-line at https://slphreporting.ncpublichealth.com/labportal/. To submit specimens:

1. Write patient's name and other identifier on specimen tube. Unlabeled specimens will NOT be tested.
2. Place completed Enteric Bacteriology DHHS form #3390 (one form for each specimen) in outer container to avoid contamination in case of breakage or leakage.
3. Use double-walled or equivalent shipping containers that meet safety requirements. Multiple tubes or specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof container. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. Mailers should be clearly labeled "Enteric Bacteriology" on the outside of the container.
4. When shipping by U.S. mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

Real-time PCR results for the detection of *stx1* and *stx2* STEC are included on the Enteric Report. Results will be reported as:

stx1 gene (Real-time PCR) * DETECTED / NOT DETECTED
stx2 gene (Real-time PCR) * DETECTED / NOT DETECTED

*** Comment(s):** This Real-time PCR test was developed, and its performance characteristics determined by the North Carolina State Laboratory of Public Health. It has not been cleared by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary.

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Whole Genome Sequencing (WGS)
(919) 807-8607

Introduction

Whole Genome sequencing (WGS) is a procedure that allow for the sequencing of an organism's entire genome. The information obtained from WGS can tell you everything about the organism, such as genetic relatedness, serotype, resistance, and virulence factors. Therefore, this technology allows for better identification, characterization, and improved surveillance. WGS is performed on all shiga-toxin producing *E. coli*, *Salmonella*, and *Listeria monocytogenes*, for the purposes of reporting *Salmonella* serotypes to submitters, as well for foodborne disease surveillance. As a CDC PulseNet participating laboratory, this data is uploaded to a national database to aid the molecular characterization, identification, and surveillance of foodborne disease.

When the NCSLPH Enterics lab identifies an isolate as *Salmonella* it is forwarded to the Molecular Unit for WGS. A unique software platform is utilized to perform bioinformatic analysis to obtain genetic information about the organism, including *Salmonella* serotype.

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Sample Collection and Identification

Specimens for identification and serotyping of *Salmonella* are submitted through the Microbiology Enteric Bacteriology lab. Each specimen must be clearly labeled with the patient's name and a 2nd identifier and accompanied by Enteric Bacteriology DHHS form #3390. Unlabeled specimens will not be tested. Cary-Blair transport media for collection of feces is available from the laboratory mailroom on-line at https://slphreporting.ncpublichealth.com/labportal/.
Fill out form DHHS #3390 with the following required information:

- First and last name of patient
- Patient date of birth
- Patient demographics (sex, race, etc.)
- Patient number or Social Security Number (optional)
- Date of Collection
- Test requested
- Specimen source

Collect specimen so that feces is free of foreign matter, following instructions in Enteric Culture mailer or equivalent. (Do not use the Parasitology mailer.) Using the scoop, place feces in the vial of transport medium until the level of liquid reaches the fill line marked on the label. Do not overfill vial. Break up any large pieces with the scoop. Stir well; replace the top tightly on the vial. Label with two identifiers: patient's name and either date of birth or Social Security number. Please see the Microbiology Enteric Bacteriology section for additional details and requirements.

Shipment

Mailers for submitting stool samples are available on-line at https://slphreporting.ncpublichealth.com/labportal/. To submit specimens:

1. Write patient's name and other identifier on specimen tube. Unlabeled specimens will NOT be tested.
2. Place completed Enteric Bacteriology DHHS form #3390 (one form for each specimen) in outer container to avoid contamination in case of breakage or leakage.
3. Use double-walled or equivalent shipping containers that meet safety requirements. Multiple tubes or specimens should be wrapped individually in absorbent cushioning material and securely packaged in a leak-proof container. Agar slants are preferred. Plates are discouraged, but if necessary, may be used if they are taped closed, sealed in leak-proof bags and securely packaged in a **crush-proof** container. Mailers should be clearly labeled "Enteric Bacteriology" on the outside of the container.
4. When shipping by U.S. mail, use first-class postage. Be sure to place return address on outside of container, regardless of shipping method. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

Salmonella serotyping results usually are reported within four to ten workdays. Results are reported on computer-generated forms which are returned to the submitting agency and available online through the NCSLPH Clinical and Environmental Lab Reports portal. Bacteriology DHHS form #3390 accompanying specimens are retained for 5 years. Reports are returned only to the submitting agency; the submitter is responsible for sending copies to any other agency. The submitting agency is responsible for maintaining records in patient files.

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NEWBORN SCREENING

(919) 733-3937

NCSLPH offers a Newborn Screening program for babies born in North Carolina. Briefly, the sample used to perform NBS consists of an aliquot of the sample submitted from a dried blood spot (DBS) specimen collected from the baby. This program includes screening for conditions on the NC Newborn Screening Panel.
Newborn Screening is performed in three laboratories:

MS/MS: A DBS aliquot is extracted in a solvent containing known amounts of internal standards for each analyte of interest. The extract is analyzed using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS) to detect analytes of interest (e.g., amino acids and acylcarnitines). The results are evaluated by a set of rules to correlate the analyte's concentration to metabolic disorders such as Amino Acid Disorders, Fatty Acid Oxidation Disorders, Organic Acid Disorders, and X-Linked Adrenoleukodystrophy.

FIA-SC: Fluoroimmunoassays and enzymatic assays are performed to detect analytes used in screening for conditions, Congenital Adrenal Hyperplasia, Congenital Hypothyroidism, Galactosemia, Biotinidase Deficiency, and Cystic Fibrosis. Hemoglobinopathies are determined by High Performance Liquid Chromatography and Isoelectric Focusing.

NBS Molecular: Screen for Severe Combined Immunodeficiency (SCID) using real-time PCR, Galactosemia using Amplification Refractory Mutation System-PCR and Cystic Fibrosis using NextGen Sequencing.

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Newborn Screening

(919) 733-3937

Introduction

NCSLPH offers Newborn Screening testing to all babies born in North Carolina. These tests are performed on a filter paper blood spot sample (DBS) collected from the newborn baby. This sample is screened for conditions that may cause intellectual or physical disabilities, or other health complications, if untreated. To prevent early effects of conditions, the sample should be drawn during the infant's first 24 to 48 hours of life. Present protocol includes testing for:

- Primary Hypothyroidism: Analytes thyroxine (T4) and thyroid-stimulating hormone (TSH) are measured by time-resolved fluoroimmunoassay (FIA).

- Hemoglobinopathies: The specimen is analyzed by high performance liquid chromatography (HPLC) for the presence of abnormal hemoglobins. The abnormal hemoglobins are confirmed by isoelectric focusing (IEF).

- Galactosemia: Total Galactose and galactose-1-phosphate are measured, total galactose by a fluorescent galactose oxidase method. Galactose-1-phosphate uridyl transferase (GALT) activity is determined by measuring its reaction produced over time. Both assays are performed on all specimens. GALT Polymerase Chain Reaction (PCR) is a reflex test performed on low level Galactosemia Newborn Screening blood spots using a conventional PCR method for mutation detection (Tetra-prime Amplification Refractory Mutation System PCR (ARMS-PCR) or if the total galactose is $\geq$ 7.3 mg/dl and the patient is transfused.

- Congenital Adrenal Hyperplasia (CAH): 17-alpha Hydroxy Progesterone (17-OH-P) is measured by time-resolved FIA.

Amino Acid Disorders: Amino acids (Phenylalanine, Tyrosine, Valine, Leucine\Isoleucine\Hydroxyproline, Methionine, Succinylacteone, Citrulline, Arginine and Arginoinosuccinic Acid) are measured using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS).

- Fatty Acid Oxidation Disorders: Carnitines, to include Free Carnitine(C0), Butyrlcarnitine (C4), Isovalerylcarnitine (C5), Octanoylcarnitine (C8), Tetradecenoylcarnitine (C14:1), 3-Hydroxy-hexadecanoylcarnitine (C16OH), 3-Hydroxy-octadecanoylcarnitine (C18OH), Hexadecanoylcarnitine (C16), Octadecenoylcarnitine (Oleylcarnitine) (C18:1), and Malonylcarnitine\3-Hydroxy-butyrylcarnitine (C3DC+C4OH), are measured using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS).

- Organic Acid Disorders: Carnitines, to include Proprionylcarnitine (C3), Butyrlcarnitine (C4), Isovalerylcarnitine (C5), Methylmalonyl\3-Hydroxy-isovalerylcarnitine

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(C4DC+C5OH), Glutarylcarnitine\3-Hydroxy-hexanoylcarnitine (C5DC+C6OH), Tiglylcarnitine (C5:1), Malonylcarnitine\3-Hydroxy-butyrylcarnitine (C3DC+C4OH) are measured using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS).

- Biotinidase Deficiency: Biotinidase enzyme activity is measured by time-resolved FIA.

- Cystic Fibrosis (CF): Immunoreactive trypsinogen (IRT) is measured by time-resolved FIA. The daily top 4% of specimens with the highest IRT values and patients with meconium ileus undergo DNA testing using a panel of over 139 common CF mutations.

- Severe Combined Immunodeficiency (SCID) and Spinal Muscular Atrophy due to homozygous deletion of exon 7 in SMN1 (SMA): SMA testing is performed by measuring the Homozygous Deletion of Exon 7 in SMN1 using real time PCR.

- X-Linked Adrenoleukodystrophy (X-ALD): X-ALD testing is performed by measuring C26:0-LPC using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS).

- Mucopolysaccharidosis Type I (MPS I): MPS I testing is performed by measuring α-L-iduronidase (IDUA) enzyme activity using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS). When decreased IDUA enzyme activity is detected, dried blood spot specimens are further tested including quantitation of a MPS I marker (small, non-reducing end GAG fragment) measured by MS/MS. When abnormal MPS I marker results are obtained, sequencing analysis of the *IDUA* gene is performed.

- Glycogen Storage Disease Type II (Pompe): Pompe testing is performed by measuring acid-α-glucosidase (GAA) enzyme activity using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS). When decreased GAA enzyme activity is detected, dried blood spot specimens are further tested including quantitation of creatine (Cre), creatinine (Crn), acid-α-glucosidase (GAA) by MS/MS and the calculation of Cre/Crn/GAA ratios. When abnormal Cre/Crn/acid-α-glucosidase (GAA) ratios are obtained, sequencing analysis of the GAA gene is performed.

- **Mucopolysaccharidosis Type II (MPS II)**: MPS II testing is performed by measuring iduronate-2-sulfatase (I2S) enzyme using ultra-high performance liquid chromatography (UHPLC) coupled with tandem mass spectrometry (MS/MS). When decreased I2S enzyme activity is detected, dried blood spot specimens are further tested including quantitation of an MPS II marker (small, non-reducing end GAG fragment) measured by

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MS/MS. When abnormal MPS II marker results are obtained, sequencing analysis of the I2S gene is performed.

Sample Collection and Identification

A. Newborn Screening Specimen collection form DHHS Form #3105 can be ordered on-line at https://slphreporting.ncpublichealth.com/labportal/

B. Training in specimen collection and form completion is available from the laboratory's website at https://slph.dph.ncdhhs.gov/newborn/resourcesupdates.asp#formtraining

C. Time of Collection

1) A blood spot specimen (heel stick) should be obtained from every infant prior to discharge or transfer to another hospital, regardless of age. In instances where a specimen was not collected prior to discharge or transfer, submit a filter form with completed demographics and without sample to the NCSLPH to document the infant in the database. Should a parent refuse screening, document internally and submit a filter form with completed demographics and without sample, to the testing laboratory to document the infant in the database. The number or type of feedings (breast or formula) will not affect this rule. Optimum time for specimen collection is 24-48 hours of age.

2) The specimen should be collected 24 hours after birth. Optimum time for specimen collection is 24-48 hours of age. If the specimen is collected prior to 24 hours of age a repeat screening specimen should be collected by one week of age. It is the responsibility of the provider whose name is listed on the form to obtain this second specimen in a timely manner. Parents should be informed that the infant is being retested because of early sample collection, not because the infant has an increased risk for a disorder.

3) The specimen should be collected pre-transfusion. If the initial specimen was collected post-transfusion, a second specimen should be collected 120 days after the last transfusion. Note that infants greater than 6 months of age at collection are no longer considered newborns and are only eligible for hemoglobinopathies testing (refer to section C5 Note).

4) Premature (gestational age less than 37 weeks or low birth weight of < 2300 grams) or ill infants receiving parenteral feeding should be screened upon admittance to the special care baby unit, regardless of age, medical condition, or status of feedings. If the first specimen is collected at less than 24 hours of age or the infant had a birthweight of < 2000 grams, a second screen should be collected between 48-72 hours of age. At the 28th day of after birth or upon discharge, whichever is first, a third specimen should be collected on those infants whose birthweight was < 2000 grams. Premature or ill infants

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or infants receiving parenteral feeding should be screened between 24-72 hours of age. The status of feedings will not affect this policy. The sample should not be obtained [f] from a central line when an amino acid solution is being infused.

5) All infants less than or equal to 1500 grams (Very Low Birthweight) shall have a repeat specimen collected at 4-6 weeks of age. If the infant is discharged prior to this time, a repeat specimen shall be collected at the time of discharge, with an additional repeat specimen collected at 4-6 weeks of age.

Note: Limits for blood spot specimen submission are based on the baby's age at specimen collection. MS/MS and CF and FIA/GAL/BIO are limited to babies less than 6 months of age at the time of collection. Only Sickle Cell testing can be done on babies greater than six months of age by submitting a blood spot sample on DHHS form #1859, Hemoglobin Electrophoresis form (See Hemoglobinopathies). Do not submit a sample for hemoglobin electrophoresis on DHHS Form # 3105.

D. Identification and Collection of Newborn Screening Specimen. The recommended method of collection is from a heel stick; collection into a capillary or other device is not the recommended method of collection. Anticoagulants interfere with laboratory testing. Collection and transport instruction follow. Refer to online training https://slph.dph.ncdhhs.gov/newborn/resourcesupdates.asp#formtraining for a tutorial of these processes.

E. Complete all information and identification on Newborn Screening Form #3105. It is imperative that all demographic fields are complete when submitting the filter form, even if the sample submitted is a repeat.

1) Do not contaminate filter paper circles by allowing the circles to come in contact with spillage or by touching before or after blood collection.

2) "Keep for your records" portion of the form should be retained by the hospital/submitter for documentation purposes.

3) Warm heel with a soft cloth, moistened with warm water up to 41° Celsius, for three to five minutes or use an approved commercial warmer according to manufacturer's instructions. Position the infant with the leg dependent for optimal venous flow.

4) Cleanse site with 70% isopropyl alcohol prep pad. Wipe site dry with sterile gauze pad.

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5) Puncture heel with lancet and wipe away first blood drop with another sterile gauze pad. Allow another LARGE blood drop to form.

6) Lightly touch filter paper circle to the LARGE blood drop. Allow blood to soak through and completely fill circle with SINGLE application of the LARGE blood drop. Only apply blood once to one side of filter paper. Fill remaining circles in the same manner, with additional blood drops. Care of puncture site should be consistent with your institution's procedures.

7) Allow blood spots to air-dry thoroughly for a minimum of three hours at room temperature on a flat non-absorbent surface. Keep away from direct sunlight and heat.

Transport Blood Spots for the Laboratory

A. After drying, send completed forms (both first tests and repeats) to the NCSLPH for *delivery* within 24 hours of collection, using an overnight transport method. **DO NOT HOLD OR BATCH SAMPLES FOR ANY REASON, INCLUDING COMPLETION OF HEARING SCREENING**. Overnight delivery preserves the integrity of the sample, decreases transit time, and allows for earlier diagnosis and treatment of an affected infant.

B. **Do not package blood spot collection forms in plastic bags for mailing.** Heat and humidity build up and can deteriorate the dried blood spot specimen.

See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation In all cases where a repeat sample is requested, it should be collected as soon as possible and transported to the NCSLPH within 24 hours of collection unless a specified time of repeat collection is indicated on the NBS report. Do not wait until the next well-baby visit for collection.

A. **Primary Hypothyroidism**: Thyroid results are reported as normal, borderline, or abnormal. For borderline results, a repeat filter specimen is requested by confirmation mail. For abnormal results, the infant's healthcare provider is contacted by Follow-up. For abnormal values, it is recommended that serum testing be performed by the provider or approved laboratory. NCSLPH does not perform serum testing.

B. **Galactosemia**: Galactose results are reported as normal, Elevated Risk, or Urgent. Both total galactose and Galactose-1-phosphate uridyl transferase (GALT) activity levels are determined. Specimens with low GALT activity are screened to detect three common GALT mutations (Q188R, S135L, and N314D). For elevated risk results, a repeat filter specimen is requested by confirmation mail. All urgent results are reported to the Follow-up program who will contact the baby's health care provider with further recommendations.

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C. **Congenital Adrenal Hyperplasia (CAH):** 17-OH-Progesterone results are reported as normal, borderline, inconclusive, or abnormal. For Inconclusive and borderline results, a repeat filter specimen is requested by confirmation mail. For abnormal results, Follow-up will contact the baby's health care provider with further recommendations.

D. **Hemoglobinopathies (Sickle Cell):** Hemoglobinopathy results are reported as normal if no abnormal hemoglobin is detected. Identification of heterozygotes with S, C, D and E are reported as trait. Abnormal hemoglobin disease states are reported to the North Carolina Sickle Cell Syndrome Program who will contact the baby's health care provider. Appropriate follow-up is requested which includes additional testing using EDTA whole blood specimens from the infant and biological parents.

E. **Tandem Mass Spectrometry (MS/MS) screening**: Screening results for each analyte of interest (e.g., amino acids profile and acylcarnitine profiles) are evaluated by a set of rules that correlates the analyte concentration to metabolic disorders including Amino Acid Disorders, Fatty Acid Oxidation Disorders and Organic Acid Disorders. Screening results are reported as normal, borderline or abnormal. For borderline results, a repeat blood spot specimen is requested by confirmation mail to be collected and submitted by the baby's health care provider. Abnormal and repeat Borderline results (for the same condition) are referred to the Follow-up program that contacts the baby's health care provider to arrange for clinical evaluation.

F. **Biotinodase deficiency**: Biotinidase activity is reported as normal, borderline, inconclusive, or abnormal. For borderline or inconclusive results, a repeat filter specimen is requested by confirmation mail. For abnormal results, the Follow-up program will contact the infant's healthcare provider with further recommendations.

G. **Cystic Fibrosis (CF):** CF testing is performed with a two-tier screening process. Specimens are first tested to measure levels of immunoreactive trypsinogen (IRT). The top 4% of specimens with the highest IRT values and patients with meconium ileus are reflexed to a second tier DNA test that detects 139 characterized variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. When these variants are not detected, results are reported as no variants detected. This suggests there is minimal risk for CF; however, the IRT value reported may be indicative of CF in the presence of one or more variants that are not identified in the panel used. Results with one variant detected are suggestive of a carrier status; however, further testing to detect other variants not included in the panel is recommended. All specimens with two variants detected are reported as abnormal for CF. Abnormal results will contain the actual IRT value and the specific mutations detected. All abnormal results are called to the CF Follow-up Coordinator who contacts the infant's health care provider to arrange for sweat chloride testing at an accredited CF center.

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H**. Severe Combined Immunodeficiencies (SCID):** The results will be reported as normal, borderline, abnormal or inconclusive. For all abnormal and borderline results from Gestational Age ≥35 weeks, the healthcare provider will be contacted by the Follow-up program to provide further recommendations. Inconclusive results are obtained when the DNA in the specimen is of poor quality or limited quantity. Therefore, another specimen will need to be collected and submitted for analysis.

I. **Spinal Muscular Atrophy due to homogenous deletion of exon 7 in SMN1 (SMA):** The results will be reported as normal, abnormal, or inconclusive. For all abnormal results, the healthcare provider will be contacted by Follow-up with further recommendations. Inconclusive results are obtained when the DNA in the specimen is of poor quality or limited quantity. Therefore, another specimen will need to be collected and submitted.

J. **X-Linked Adrenoleukodystrophy (X-ALD):** The results will be reported as normal, abnormal, or inconclusive. For all abnormal results, the healthcare provider will be contacted by Follow-up with further recommendations. For Inconclusive results, another specimen will need to be collected and submitted.

K. **Mucopolysaccharidosis Type I (MPS I)**: The results will be reported as normal, decreased activity, or inconclusive. For inconclusive results, another specimen will need to be collected and submitted. For all decreased activity results, second-tier MPS I Marker concentrations will be measured and reported as normal or positive. For all MPS I Marker positive results, third-tier *IDUA* sequencing will be performed and the healthcare provider will be contacted by the Follow-up program with further recommendations.

L. **Glycogen Storage Disease Type II (Pompe)**: The results will be reported as normal, decreased activity, abnormal-decreased activity or inconclusive. For inconclusive results, another specimen will need to be collected and submitted. For all decreased activity results, creatine (Cre), creatinine (Crn), acid-α-glucosidase (GAA) by MS/MS and Cre/Crn/GAA ratios are calculated. When abnormal Cre/Crn/GAA ratios are obtained, sequencing analysis of the *GAA* gene is performed. Healthcare providers will be contacted by the Follow-up program with further recommendations. For all abnormal-decreased activity results, second-tier Cre/Crn/GAA ratios and GAA gene sequencing are conducted simultaneously and the healthcare provider will be contacted by the Follow-up program with further recommendations.

M. **Mucopolysacchardosis Type II (MPS II):** The result will be reported as normal or decreased activity. For all decreased activity results, second-tier MPS II Marker concentrations will be measured and reported as normal or positive. For all MPS II Marker positive results, third-tier I2S sequencing will be performed, and the healthcare provider will be contacted by the Follow-up program with further recommendations.

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N. **Insufficient or Unsatisfactory Specimens**: A letter is sent to the baby's health care provider and submitter (as listed on the filter form) to request a specimen recollection and submission. The integrity of the infant's newborn screening results is dependent upon the timely collection and quality of application of a blood specimen on the filter paper form. DO NOT DETATCH and re-attach the filter portion of the form. Taking the time to accurately complete the information and identification on the filter form, preparing the site for blood collection, and properly applying the blood specimen on the filter form saves time, resources, and the need for a repeat blood spot collection. Specimens collected on expired filter paper cards are unsatisfactory. Insufficient and unsatisfactory specimen submissions can be avoided if proper collection protocol is followed.

A. Records of laboratory results are filed by date of birth and baby's name. Records are retained for five (5) years in the Newborn Screening computer database.

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Hemoglobinopathies

(919) 733-3937

Introduction

Newborn Screening includes a screening test for abnormal hemoglobins S, C, D, and E and is performed only on infants six months of age or younger.

Hemoglobinopathy testing is offered as a follow-up test on specimens reported as abnormal by Newborn Screening and on infants greater than six months of age. It tests only for hemoglobin identification. This test is also used to screen blood samples from individuals and family studies for hemoglobin S (sickle cell) and other hemoglobinopathies. Isoelectric focusing electrophoresis (IEF) and high performance liquid chromatography (HPLC) are utilized in the testing process. These services are available to public and private providers for the purposes of prenatal screening, family studies and follow-up testing. **The laboratory does not have the capacity to perform sickle cell trait testing for the purposes of school and college athletics**.

Specimen Identification, Collection and Shipment for Filter Paper Spots

A. A hemoglobin electrophoresis filter paper collection DHHS Form #1859 can be ordered online at https://slph.dph.ncdhhs.gov/.

B. Complete the entire identification section on the DHHS Form #1859 with ballpoint pen, making sure all copies are legible. It is imperative that the following information is given: patient's name or unique identifier, patient number, address, sex, race, birth date, blood specimen collection date, transfusion information, Medicaid number, provider name and NPI#, complete name and address of submitter, and EIN #.

C. Follow your institution's procedures for performing heel or finger punctures. After skin is cleansed with alcohol, puncture heel or finger with sterile lancet.

D. Fill each circle on the form with blood, making sure it soaks completely through the paper.

E. Allow the sample to dry for 3-4 hours at room temperature on a flat non-absorbent surface before mailing. DHHS Form #1859, newborn screening filter form, requires 3-4 hours' drying time. Do not expose the sample to temperature extremes (heating or freezing), as this will render the sample unsatisfactory for use in the testing procedures.

F. Dried blood spot (DBS) specimens should be shipped within 24 hours of collection using overnight delivery. Write return address on the package. Do not ship specimens in biohazard or plastic bags.

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G. DBS specimens received >14 days post collection will be rejected.

Note: Filter paper specimens should not be submitted for detecting β-thalassemia. An EDTA whole blood specimen is required when β-thalassemia is suspected. (Please follow whole blood testing guidelines).

Whole Blood Specimen Submission and Testing

A. The laboratory may request an EDTA whole blood sample in order to perform follow-up testing for certain previously reported hemoglobin screening results. Samples from the patient and/or both of the patient's biological parents are necessary in order to provide definitive results.

B. Listed below are the conditions by which whole blood family study and/or follow-up testing may be requested:

- Hemoglobin Disease states
- FA+ Variant or A+ Variant
- Not Definitive results
- Trait patients who are pregnant. Whole blood testing on the partners can be requested.
- Abnormal results on original patient. Whole blood testing may be requested by physician when sibling/parent studies are needed.
- Suspected Beta Thalassemia due to family history (Please add requesting physician's name to form.)

C. The EDTA whole blood methodology requires a longer time for completion than that of blood spot testing. Please allow a MINIMUM of 14 business days, from the time of receipt in the lab, before expecting patient results.

D. Complete a DHHS Form #1859WB for each specimen collected. Include patient name, patient number, address, birth date, race, sex, Medicaid number, patient phone number, date specimen collected, blood transfusion information (if applicable), provider name and NPI#, complete name and address of submitter, NPI and EIN#. For family study specimen submission, provide the original laboratory reference number, original name as submitted for newborn screening and date of birth of the infant. This information will allow the laboratory personnel to reference and link the family study results to each other. It is IMPERATIVE that the forms are filled out completely. Any missing information could result in longer turn-around time or unsatisfactory reports.

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E. Submit 5-7 mL of well-mixed blood collected in EDTA (lavender top) specimen collection tube. If the patient is an infant or young child, submit 0.5- 1 mL of blood collected in EDTA (lavender top) microtainer specimen collection device. Write patient name and date specimen collected on the specimen tube label. If using an adhesive label, do not cover up the tube expiration date or obscure view of the specimen because laboratory personnel must assess specimen integrity before testing. Clotted blood is unsatisfactory for use. EDTA whole blood must be refrigerated following collection and shipped on fully frozen ice packs within 6 days of collection. Specimens received after 7 days after collection will be rejected. EDTA whole blood submitted in expired EDTA tubes is unacceptable.

   See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretations

A. Normal results on blood spot specimens are reported within 1 week after receipt in the Laboratory. Abnormal results are reported after further testing. A copy of each diseased patient report is sent to the Sickle Cell Program and Regional Counselors for follow-up.

B. The whole blood methodology requires a longer time for completion than that of blood spot testing. Please allow a minimum of 14 business days after specimen receipt in the lab, before expecting patient results.

C. There are testing limitations with respect to the identification of some hemoglobin variants. In these instances, the lab suggests referrals to a local hematologist.

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Known Phenylketonuria (PKU) Specimens

(919) 733-3937

Introduction

Newborn Screening includes a screening test for abnormal amino acid and acylcarnitine concentrations performed only on infants six months of age or younger by the MS/MS Lab.

Specimen Identification, Collection and Shipment for Filter Paper Spots

A. Specimens are collected on DHHS Form #3105, newborn screening filter form, by the patients themselves or their health care provider. These forms are ordered by patients or their health care provider on an as-needed basis from the NCSLPH Mail Room (919) 733-7656.

B. Complete the identification sections on the DHHS Form #3105 with ballpoint pen, making sure all copies are legible. It is imperative that the following information is given: patient's name, birth date, and blood specimen collection date.

C. Patients are provided with the procedures for performing blood collection by their metabolic specialist.

D. It is not necessary to fill each circle on the form with blood. There should be enough to cut one 3.2mm size spot that is completely soaked through the paper.

E. Allow the sample to dry for 3-4 hours at room temperature on a flat non-absorbent surface before mailing. DHHS #3105, newborn screening filter form, requires 3-4 hours' drying time. Do not expose the sample to temperature extremes (heating or freezing), as this will render the sample unsatisfactory for use in the testing procedures.

F. Mail specimen within 24 hours of collection. Write return address on envelope. Do not mail specimens in biohazard or plastic bags. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretations

A. Results on blood spot specimens are reported within 2-3 days after receipt in the Laboratory. A paper copy of each patient report is sent to patients who elect to receive them and reported to metabolic specialists.

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Virology/Serology

(919) 733-3937 or (919) 733-7544

Virology/Serology (VS) performs highly complex laboratory tests to identify infections due to a variety of bacterial and viral pathogens of public health significance. The majority of reports generated by this unit are used by state and local health officials in the diagnosis, treatment, surveillance, and control of communicable disease.

Virology/Serology is organized into four laboratory areas:

- Serology
- Special Serology
- Rabies
- Molecular Virology

The mission of VS is to provide quality-assured laboratory services to public and private health provider organizations and to assist other Public Health program partners responsible for communicable disease prevention and control.

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Arbovirus

(919) 733-3937

Introduction

Diagnostic serologic assays are performed on serum and cerebrospinal fluid (CSF) suspected for Arbovirus infections. The Arbovirus panel includes testing for Eastern Equine Encephalitis (EEE), LaCrosse Encephalitis (LAC), and West Nile Virus (WNV). Classical WNV fever is often associated with headache, lymphadenopathy, nausea, vomiting, and fatigue. WNV Central Nervous System (CNS) infection is associated with meningitis, encephalitis, meningoencephalitis, and/or acute flaccid paralysis resembling Guillian-Barre syndrome. All specimens received will be tested for IgM antibodies to EEE, WNV and LAC by enzyme immunoassay (EIA).

Molecular testing for chikungunya, Zika, and dengue viruses is available at the NCSLPH, with IgM serology available for chikungunya and dengue. All clinical and travel information, including date of onset, **must** be included on the test request form; the provider must complete the form and sign the Physician Attestation statement. Specimens from symptomatic patients with travel history collected <14 days post-illness onset will be tested by RT-PCR. Urine, CSF, whole blood, and amniotic fluid may also be submitted for Zika molecular testing, but these specimen types must be submitted along with a paired serum specimen. Special requests for molecular testing on specimen types such as cord blood, placental tissue, or umbilical tissue can be arranged at CDC.

For more information about these viruses, go to http://www.cdc.gov/

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Specimen Collection and Identification

Only serum and CSF may be submitted for arboviral serologic testing. Clearly label each specimen vial with the patient's name (first and last) and either the date of birth, Social Security number, or other unique identifier. Be sure to label vials with date collected for paired serum specimens. Complete a DHHS Form #3445 submission form specifying all required patient information and which infectious agents are suspected. Failure to supply the requested patient information may result in significantly delayed specimen testing. Assure an onset date, collection date(s), submitter name and address, signs/symptoms, travel history, and vaccination history are given. This information is crucial for accurate interpretation of results. Tests must be requested by name. Nonspecific requests for "viral studies" or "viral serologies" will not be accepted. Consult with the laboratory if there is a question as to which test is appropriate.

The serodiagnosis of a current or recent infection generally requires the simultaneous testing of paired serum specimens, principally acute and convalescent serum specimens. The acute serum should be collected no later than 3-5 days after the onset of illness. The convalescent serum should be collected 2-3 weeks after onset, or at the time of hospital discharge, for confirmation of probable cases. Since paired sera are advised for all arboviral studies (except for chikungunya, Zika and dengue viruses), it is to the advantage of both the submitter and this laboratory if the acute serum is stored frozen by the submitter until the convalescent serum is collected. Both serum specimens may be submitted with one submission form. Antibody determinations on

cerebrospinal fluid may be of value in diagnosing viral encephalitis and other central nervous system diseases. **CSF for serologies should always be accompanied by a serum collected the same day.**

Equine specimens for Arborviral testing should be submitted through the Rollins Animal Diagnostic Laboratory.

Shipment

For detailed specimen and submission requirements, refer to the **Virology/Serology section in Appendix A** and contact SLPH if further guidance is needed. See appendix C for local health department specimen transport guidance.

Reporting Procedure and Interpretation

Failure to detect a significant antibody response may be the result of a number of factors including improperly collected specimens, specimens collected too early or too late during the immune response, selection of the incorrect infectious agent for testing, or lack of sensitivity in the serological system being used.

The following chart lists the arboviral assays performed by this lab. A brief statement of the "normal" values for each assay is given under the heading "Negative Reference Range". The test method, specimen requirements, and turn-around times are also listed for each assay performed.

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ARBOVIRAL ASSAYS

Test	Test Method	Negative Reference Range	Specimen Requirement	Turn-Around Time
LAC, IgM	EIA Qual	Negative	2 mL serum/CSF PSA	6 working days
EEE, IgM	EIA Qual	Negative	2 mL serum/CSF PSA	Send to referral lab
SLE, IgM	EIA Qual	Negative	2 mL serum/CSF PSA	Send to referral lab
WEE, IgM	EIA Qual	Negative	2mL serum/CSF PSA	Send to referral lab
WNV, IgM	EIA Qual	Negative	2mL serum/CSF PSA	6 working days
Chikungunya Virus, IgM	EIA Qual	Negative	2mL serum	6 working days
Chikungunya Virus	RT-PCR	Negative	2mL serum/CSF/ whole blood (EDTA)	6 working days
Zika Virus	RT-PCR	Negative	2 mL serum /CSF /urine/amniotic fluid/whole blood (EDTA)	6 working days
Dengue Virus, IgM	EIA-Qual	Negative	2 mL serum	6 working days
Dengue Virus	RT-PCR	Negative	2 mL serum /CSF/whole blood (EDTA)	6 working days

Abbreviations:

EIA Enzyme Immunoassay IgM Immunoglobulin M QUAL Qualitative
PSA Paired Sera Advised

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Hepatitis B and Hepatitis A Serology

(919) 733-3937

Introduction

Hepatitis B serologies are available on a limited basis for diagnosis of acute and chronic disease, for monitoring the course of disease and the effectiveness of therapy, and for screening select patient populations. Hepatitis A IgM testing is available on a limited basis for the diagnosis of acute disease.

Three testing panels are available: screen, symptomatic, and HAV outbreak. The available panels, the markers used with specific patient populations, and the rationale for testing are detailed in the chart at the end. Serologic testing for hepatitis infection is available only to patients who are seen in local health departments and state-operated healthcare facilities. Additionally, testing is only approved for patients ≥28 days old.

Hepatitis B virus testing is available to the following patient populations:

1. Symptomatic patients (abnormal liver functions)
2. Prenatal patients
3. Refugees
4. Past or present drug users
5. Sexual partners of drug users
6. Patients who are household contacts of hepatitis B carriers or acute cases and are candidates for vaccine
7. Infants born to infected mothers
8. Known previous HbsAg positives
9. Previously vaccinated health department employees with percutaneous exposure to hepatitis B virus
10. Source patient of percutaneous exposure
11. Men who have sex with men

Hepatitis A virus serology is available to patients who are:

1. Symptomatic without an epidemiological link to another case of known hepatitis A infection
2. Suspected cases, whether or not epidemiologically-linked, who are:
    - food handlers
    - health care workers
    - day care attendees
    - day care workers
    - at risk of liver disease through IV drug use, alcohol abuse, etc.
2. Associated with an outbreak situation (prior approval required)

Routine testing for either hepatitis A or B is limited to those groups listed above; however, if you have special needs that are not addressed in the acceptance criteria, please call (919) 733-3937. Special arrangements for testing can be made on an individual basis.

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Note: Hepatitis B immune status testing will not be performed to determine immune status of health care workers, dental workers, etc. who are candidates for routine vaccination or to establish routine post-vaccination immunity.

Specimen Collection and Identification (for Hepatitis A or B)

A full 3 mL of serum should be submitted for hepatitis testing. Serum transport tubes should not be overfilled past the 3.0 mL line on the tubes. Submit the serum in a well-constructed plastic screw-capped vial with threads on the outside. Excessively hemolyzed, grossly contaminated, or extremely lipemic sera are unacceptable for hepatitis assays.

Clearly label each vial of serum with the patient's first and last name and either the date of birth, Social Security number or other unique identifier. Complete a submission form DHHS Form #3722. All items on this form must be completed before the specimen can be processed.

Only serum may be submitted for serologic testing. Specimens submitted to the Virology/Serology Unit must be accompanied by a fully completed submission form DHHS Form #3722. Failure to supply the requested patient information may result in significantly delayed specimen testing.

Specimens submitted for testing that are not labeled with two identifiers, received more than 4 days from collection, or not received cold (2-8°C) or frozen (≤-20°C) will not be tested. Specimens which, for any reason, are deemed unsuitable or inappropriate for serologic testing will not be tested. Rejected specimens will be properly stored for 3 business days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

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Shipment

Please refer to the **Virology/Serology section of Appendix A** for Hepatitis specimen and shipment requirements and contact the lab if further guidance is needed. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

The following chart provides information regarding turn-around times, test methods, and negative reference ranges.

Description	Test Method	Negative Reference Range	Turn-Around Time
Hepatitis B virus surface antigen	IA-Qualitative Screen	Antigen not detected	2 working days
Hepatitis B virus surface antigen	IA-Confirmatory	Interpreted by report	3 working days
Hepatitis B virus core-IgM antibody	IA-Qualitative	No antibody detected	3 working days
Hepatitis B virus core-total antibody	IA-Qualitative	No antibody detected	3 working days
Hepatitis B virus surface antibody	IA-Qualitative	No antibody detected	3 working days
Hepatitis A IgM antibody	IA-Qualitative	No antibody detected	1 working days

Abbreviations:
IA Immunoassay
IgM Immunoglobulin M

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Hepatitis Testing Panels and Corresponding Markers

Population	Panel Markers	Purpose for testing
HBV Screen	HbsAg anti-HBs anti-HBc*	CDC recommended screening
Hepatitis Symptomatic	HbsAg anti-HBc-IgM (if HbsAg is reactive) anit-HBs anti-HBc-Total anti-HAV-IgM	To determine the course of the disease, i.e., has infection been resolved or progressed to chronic carrier state, and determine whether immune either by previous vaccination or natural infection.
HAV Outbreak or Confirmation	anti-HAV-IgM	To identify HAV exposed individuals

*Babies aged <24 months will not be tested for anti-HBc as part of screening, due to longevity of maternal antibodies.

Abbreviations

HBV	Hepatitis B virus
HAV	Hepatitis A virus
anti-HBs	Antibody to hepatitis B surface antigen
anti-HBc-IgM	IgM Antibody to hepatitis B core antigen
anti-HAV-IgM	IgM antibody to hepatitis A virus
HbsAg	Hepatitis B surface antigen
anti-HBc-total	Total antibody to hepatitis B core antigen

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Hepatitis C

(919) 733-3937

Introduction

Serologic testing for Hepatitis C (HCV) infection is available only to patients with specific risk factors. The HCV testing algorithm includes initial screening for antibodies to HCV using an immunoassay (IA). Patients who test nonreactive for HCV antibodies by the IA screening assay can be considered negative for both acute and past HCV infection. All reactive Ias are then tested for the presence and quantity of HCV RNA by nucleic acid amplification (NAAT). Patients with detectable HCV RNA should be considered as having active HCV infections. Patients with a reactive antibody test but undetectable HCV RNA may be considered to have had a resolved past infection.

At least 1.5 mL of serum is required for the complete HCV testing protocol. NOTE: If also requesting HIV testing on the specimen, a second tube of serum is required.

Hepatitis C virus testing at NCSLPH is available to patients ≥2 years old. Patients <2 years old are not acceptable for testing.

Sample Collection and Identification

Submit at least 1.5 mL of serum in a well-constructed plastic screw-capped vial with threads on the outside. Serum transport tubes should not be overfilled past the fill line on the tubes. Excessively hemolyzed or extremely lipemic sera are unacceptable for HCV assays. Refer to **Appendix C** for requirements regarding specimen storage after collection and prior to shipment.

Label each vial of serum with the patient's first and last name and either the date of birth, Social Security number, or other unique identifier. A pre-printed HSIS or LWP label may be used. Complete the HIV/HCV submission form (DHHS Form #1111) or LWP test request form in its entirety. All items on this form must be completed before the specimen can be processed.

Only serum samples are acceptable for HCV testing. Specimens must be received cold (2-8°C) on frozen ice packs ≤ 5 days from the collection or frozen (≤-20°C) on dry ice or will be rejected. Specimens submitted to the Virology/Serology Unit must be accompanied by a fully completed HIV/HCV OCR scannable submission form (DHHS Form #1111). If two identifiers (the patient's first and last name and either date of birth, Social Security number, or other unique identifier) are not present on the HIV/HCV scannable form, the specimen is deemed "Unsatisfactory" for HCV testing and the specimen is discarded. A minimum of two identifiers on the patient specimen must match the identifiers on the form exactly or the specimen will be discarded and reported as "Unsatisfactory" for HCV testing. HIV/HCV forms submitted without a specimen will be held for three business days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of the missing specimen, the paperwork will be deemed "Unsatisfactory" at the end of the holding period.

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Shipment

Refer to the **Virology/Serology section of Appendix A** for HCV specimen and shipment requirements and contact the lab if additional shipping guidance is needed. See appendix C for local health department specimen transport guidance.

The DHHS Form #1111 scannable HIV/HCV form, along with instructions for completing the form, is available on this website. Forms should be printed directly from the website on white paper only; photocopies of the form are not acceptable.

Reporting Procedures

The following chart provides information regarding test methods and turn-around times. The linear range of the HCV Quant Dx NAAT test is 10-100,000,000 IU/mL (1.0-8.0 log IU/mL).

Description	Test Procedure	Negative Reference Range	Turn-Around Time
HCV antibodies	IA-Qualitative	No antibody detected	3 working days
HCV RNA	Nucleic Acid Amplification Test (NAAT)- Detection and Quantitation	No HCV RNA deteced	5 working days

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Human Immunodeficiency Virus (HIV) Serology

(919) 733-3937

Introduction

Serologic screening for HIV infection is available only through designated counseling and testing sites. NCSLPH can only perform testing on patients ≥2 years old (see send-out section for patient testing 0-2 years old).. Two HIV serologic assays are utilized as part of an HIV testing algorithm. Initial screening for HIV-1 p24 antigen and antibodies to HIV-1 (including Group O and subtypes) and HIV-2 is performed using an immunoassay (IA). All reactive IAs are repeated in duplicate to verify the initially reactive test result. All repeatedly reactive IA tests (two or more reactive) are tested by the Geenius HIV-1/HIV-2 discriminatory assay that differentiates HIV-1 and HIV-2**.** Patients who test HIV-1 positive on the Geenius assay should be considered HIV infected. If the test result indicates HIV-2 reactivity, the sample is referred to CDC for HIV-2 confirmation.

Patients who test nonreactive for HIV p24 antigen and HIV-1/HIV-2 antibodies by the IA screening assay can be considered negative for both acute and established HIV infection. Samples that test repeatedly reactive on the screening assay but test as either HIV negative, HIV positive-untypable (undifferentiated), HIV-2 positive with HIV-1 cross-reactivity, HIV indeterminate, HIV-1 indeterminate, HIV-2 indeterminate, or invalid by Geenius are further tested for HIV-1 RNA by nucleic acid amplification (NAAT). Prenatal samples being tested for HIV-1 RNA will be sent to the Wadsworth Center in New York for testing. Patients with detectable HIV-1 RNA should be considered as likely acute HIV infections.

At least 3 mL of serum is required for the complete HIV testing protocol. NOTE: If also requesting HCV testing on the specimen, a second tube of serum is required.

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Sample Collection and Identification

Submit a full 3 mL of serum in a well-constructed plastic screw-capped vial with threads on the outside. Serum transport tubes should not be overfilled past the fill line on the tubes. Excessively hemolyzed or extremely lipemic sera are unacceptable for HIV assays.

Label each vial of serum with the patient's first and last name and either the date of birth, Social Security number, or other unique identifier. A pre-printed HSIS or LWP label may be used. Complete the HIV/HCV submission form (DHHS Form #1111) or LWP test request form in its entirety. All items on this form must be completed before the specimen can be processed.

Only serum samples are acceptable for HIV testing. Specimens submitted to the Virology/Serology Unit must be accompanied by a fully completed HIV/HCV OCR scannable submission form (DHHS Form #1111). If two identifiers (the patient's first and last name and either date of birth, Social Security number, or other unique identifier) are not present on the HIV/HCV scannable form, the specimen is deemed "Unsatisfactory" for HIV testing and the specimen is discarded. A minimum of two identifiers on the patient specimen must match the identifiers on the form exactly or the specimen will be discarded and reported as "Unsatisfactory"

for HIV testing. HIV/HCV OCR forms submitted without a specimen will be held for ten days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of the missing specimen, the paperwork will be deemed "Unsatisfactory" at the end of the holding period.

Shipment

Refer to the **Virology/Serology section of Appendix A** for HIV specimen and shipment requirements and contact the laboratory if additional shipping guidance is needed. See appendix C for local health department specimen transport guidance.

The DHHS Form #1111 scannable HIV/HCV form, along with instructions for completing the form, is available on this website. Forms should be printed directly from the website on white paper only; photocopies of the form are not acceptable.

Reporting Procedures and Interpretation

The following chart provides information regarding test methods and turn-around times. A brief statement of the "normal" values for each assay is given under the heading "Negative Reference Range":

Description	Test Procedure	Negative Reference Range	Turn-Around Time
Human Immunodeficiency Virus type 1 (Groups M & O) and type 2 antibodies; HIV p24 antigen	IA-Qualitative	No antibody or p24 antigen detected	3 working days
Human Immunodeficiency Virus type 1 (Groups M&O) and type 2 antibodies	Rapid EIA-Qualitative	No antibody detected	3 working days
Human Immunodeficiency Virus type 1 RNA	Nucleic Acid Amplification Test (NAAT)- Qualitative	No HIV-1 RNA detected	5 working days

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Send-Outs

NCSLPH can only perform testing on patients ≥2 years old. However, patients 0-2 years old will be received and submitted to a reference laboratory. Prenatal patients will also be sent out for reference testing for HIV NAAT only.

Rabies Virus

(919) 733-3937

Introduction

The North Carolina State Laboratory of Public Health (NCSLPH) is the sole source for rabies diagnostic testing in North Carolina. This service is available to all health care providers within the state. Submission of specimens for rabies testing must meet the established testing criteria. Specimens submitted for testing that fail to meet the testing policy will be rejected and destroyed.

Testing resources are reserved for situations where the testing outcome will influence patient management decisions. Terrestrial animal submissions are limited to significant rabies vector species that expose humans, livestock, or unvaccinated pets. Exposure is defined as a bite that breaks the skin or contact of mucous membranes or broken skin with either animal saliva or nervous tissue. Significant rabies vector terrestrial species include raccoons, skunks, foxes, most other carnivores, and woodchucks. **Domestic animals exhibiting signs of rabies and wild animals that have potentially exposed a person, unvaccinated pet, or livestock to rabies should be submitted for testing without delay.**

Dogs, cats, and ferrets that do not exhibit signs of rabies and which bite people, pets or livestock should not be euthanized, but rather should be confined and observed for 10 days, unless circumstances demand otherwise. A healthy domestic dog, cat, or ferret that bites a person should be confined and observed for 10 days. Those that remain alive and healthy 10 days after a bite would not have been shedding rabies virus in their saliva and would not have been infectious at the time of the bite. Dogs, cats, and ferrets that survive the 10-day quarantine period should not be submitted to the rabies laboratory for testing. Conversely, if the dog, cat, or ferret does not survive the 10-day quarantine period, the specimen should be submitted to the rabies laboratory for testing.

Wild animals (unlike dogs, cats, and ferrets) do not have a predictable time for shedding of rabies virus prior to presentation of symptoms. Therefore, animals in this group should not be held for observation following an exposure. These animals should be caught, euthanized immediately, and the head submitted for rabies virus detection.

Bats that have interaction with humans should be submitted for testing only if the contact involves: 1) a bite; 2) handling where a bite cannot be ruled out; or 3) are found in a domicile with access to humans while they were asleep, unconscious, or incapacitated. If one or more bats escape capture, do not submit the remaining bats since recommendations regarding post-exposure prophylaxis will not be altered by testing only some of the bats. The State Public Health Veterinarian or epidemiologist on-call should be consulted regarding multiple bat submissions (defined as more than 1 bat) or bat infestations and will make any decisions to treat potentially exposed individuals.

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Surveillance animals will be tested only with prior approval. Low risk animals (i.e., rabbits, squirrels, opossums, and small rodents) rarely require testing and should not be submitted without prior approval from either our laboratory or the State Public Health Veterinarian at (919) 733-3419.

Routine testing is available Monday through Friday (7:30 am to 4:00 pm).

Weekend/Holiday Testing

Weekend/holiday testing will be handled via a "duty cell phone on-call system" and restricted to emergency situations only. An emergency situation for human exposure to suspected rabies must satisfy one of the following criteria:

1. Unprovoked bite from a wild animal, such as a raccoon, fox, skunk, bobcat, etc.
2. Unprovoked bite from an unvaccinated dog or cat.
3. Bite (provoked or not) resulting in skin breakage on either the head or neck.
4. Bites from bats.
5. Bat(s) found in a domicile where people were asleep, unconscious, or incapacitated.

The laboratory on-call person can be reached at (919) 733-3937 during regular hours of operation or by telephoning the duty cell phone at (919) 280-8915 between 4:30 pm Friday and noon on Saturday. Weekend/holiday specimens **should not be submitted without prior approval** from either our laboratory or the Communicable Disease Branch at (919) 733-3419. Specimens received after noon on Saturday (without prior approval) will be tested on the following routine workday, i.e. usually Monday.

NOTE: In addition to the instructions below, an instructional PowerPoint presentation "Guide to Rabies – Packaging and Shipping" can be accessed and viewed at the NC State Laboratory website https://slph.dph.ncdhhs.gov/virology-serology/rabies.asp. The purpose of the presentation is to assist in training people who collect and submit rabies samples to the NCSLPH for testing. Following the instructions should result in optimal quality of test samples and the expeditious reporting of test results. The presentation may be reviewed for guidance or continuing education.

Specimen Collection and Identification

Animals should be euthanized in a manner that will not destroy the brain tissue which is examined in the diagnosis of rabies. Thus, only the animal's head should be submitted for diagnostic purposes. The animal's neck should be severed at the midpoint between the base of the skull and the shoulders. Small animals no larger than a squirrel may be submitted whole. **Treat any specimens for fleas, ticks, maggots, ants, etc. prior to packing.**

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For bats, the whole dead animal must be submitted and should be secured in a clear container such as a zip-lock bag or equivalent. **DO NOT SUBMIT LIVE BATS – PLEASE ENSURE THAT THE BAT HAS BEEN EFFECTIVELY EUTHANIZED BEFORE PLACING IN THE BAG.**

Submitters need to fully complete the submission form (DHHS Form # 1614) indicating the species of animal, vaccination history, date and type ofexposure, and county (including zip code and GPS location, if known) where the animal was located. Also list the name of the individual who will be responsible for contacting this patient, if necessary. Include telephone numbers with area code where the responsible individual can be reached during working hours and nights, weekends, or holidays. Include the Submitter's facility name and address as well as the Federal Tax Number (EIN) as this is where the final report will be sent. If a specimen is received on the weekend or holiday without this information, the specimen will be held and tested on the next routine workday. Seal the rabies submission form in a separate plastic bag and enclose within the specimen container. Complete one form for each specimen submitted.

Shipment

Specimens being shipped for rabies testing must meet standards set forth as detailed in 49 CFR 173.199 including:

1. Clear watertight primary, i.e. inner, container. (A clear plastic bag that can be sealed to be leak-proof should suffice.)
2. Absorbent material between the specimen and primary container must be sufficient to absorb all liquids in the primary container. (A butchers meat packaging absorbent pad or equivalent should suffice.)
3. Watertight secondary container. (Another plastic bag that can be sealed to be leak-proof should suffice.)
4. An insulated tertiary container with lid should be utilized, since refrigeration is needed.
5. The last inner container must be marked with the International Biohazard symbol (39 CFR part 111 8.6).
6. Sturdy outer packaging tested to meet the standards must secure the above items. (An ordinary cardboard box does not meet the requirements set forth in 49 CFR.)
7. The outer shipping container must be clearly and durably marked "Biological Substance, category B UN3373".
8. A label must be securely affixed to the outer shipping container that lists complete information about both the shipper and consignee.

Enclose sufficient refrigerants to keep the specimen cold and tightly seal. Specimens should be kept cold but NOT FROZEN. **DO NOT USE LOOSE WET ICE**. Specimens inadvertently frozen are still suitable for testing; however, testing may be delayed due to thawing. Submit specimens to the rabies laboratory at the N. C. State Laboratory of Public Health as soon as possible. If shipment will be delayed, refrigerate specimens prior to shipment.

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Large animal heads such as cows, horses, and other large livestock should be submitted to our rabies laboratory via the Dept. of Agriculture's Rollins Animal Disease Diagnostics Laboratory in Raleigh (919) 733-3986 or one of their satellite laboratories throughout the state:

Rollins Animal Disease Diagnostic Lab (Raleigh)	(919) 733-3986
Hoyle C. Griffin Animal Diagnostic Lab (Monroe)	(704) 289-6448
Northwestern Animal Disease Diagnostic Lab (Elkin)	(336) 526-2499
Western Animal Disease Diagnostic Lab (Arden)	(828) 684-8188

These laboratories will remove the brain tissue and forward the tissue to the NCSLPH rabies laboratory for testing. Contact the agriculture labs directly for specimen submission information. The anatomical tissues that the NCSLPH requires for a satisfactory rabies test include either hippocampus or cerebellum and a complete cross section of the brain stem. Specimens fixed in formalin cannot be tested at the NCSLPH and will be reported as "test not performed." (These specimens may be tested at the CDC; the submitter must contact the CDC regarding testing.)

Shipment via State Courier Service is usually the most rapid mode of transit. Personal conveyance or FedEx shipment for overnight delivery may be used when courier service is unsuitable. The laboratory should be informed in advance of the manner of shipment to be used for samples that have been approved for weekend testing. In addition, the outside of the box should be clearly labeled **"Approved for Weekend (or Holiday) Testing"** if the sample is to be tested on Saturday or a holiday. Address all shipping containers using the special label (white with red lettering) available from the NCSLPH mail room or online at https://slph.dph.ncdhhs.gov/Forms/Rabies-Printable-Shipping-Label.pdf. This label instructs the transporting service to call the NCSLPH upon arrival and will assure proper handling of the specimen. If you do not have a specific mailing label, the following information should be clearly visible on the exterior of the mailing container containing the animal head:

TO: NC State Laboratory of Public Health
4312 District Drive
Raleigh NC 27607
MSC 1918

"This package contains an animal head suspected of having rabies."

Delivery in Person: From 8:00 a.m. to 5:00 p.m., Monday-Friday
Specimens/samples are delivered to the "Specimen Receiving and Drop Off" area adjacent to the facility loading dock (please follow signs).

AFTER HOURS: Specimens/Samples are delivered to the same location, but delivery personnel must notify on-site Capital Police for access to the building via intercom. DO NOT leave unattended packages on the loading dock, even if arrangements have been made for after-hours testing.

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Reporting Procedures and Interpretation

Test results for any animal that are not negative for rabieswill be telephoned automatically by laboratory staff to the appropriate parties (Public Health veterinarians, submitter, and county animal control) at the numbers provided. **IT IS THE RESPONSIBILITY OF THE SUBMITTER, NOT THE LABORATORY, TO NOTIFY THE PERSON EXPOSED.** All test results will be sent via US Mail or the State Courier System to the submitter and county health department director in the county where the animal specimen was obtained. It should be noted that although the fluorescent antibody test is very reliable, a negative test does not completely exclude the possibility of the animal being rabid.

All Rabies results are also available on-line to the submitter (https://celr.dph.ncdhhs.gov/). Go to "login" on the home page. If you are a new user, follow the link at the bottom of the page to request a new account.

Note: Human Rabies Testing:

All suspected cases of rabies in humans are handled on a case-by-case basis. Contact the laboratory at (919) 733-3937 for special instructions on specimen collection criteria and shipping directions. Hospital infection control consultation should be obtained Monday-Friday, 8:00 a.m. to 5:00 p.m., from the rabies public health veterinarians at (919) 733-3419. Consultation services are available after working hours and during weekends or holidays. Leaving a message in the voice mailbox at (919) 733-3419 will automatically activate a beeper for the on-call individual.

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Rabies Virus Serology

Rabies virus antibody testing is available through commercial laboratories. Testing of specimens should be arranged directly with those laboratories. The following laboratory is known to offer the Rapid Fluorescent Focus Inhibition Test for rabies virus antibody:

Rapid Fluorescent Focus Inhibition Test
Department of Veterinary Diagnosis
Veterinary Medical Center
Kansas State University
Manhattan, Kansas 66506
(785) 532-4483
http://www.ksvdl.org/rabies-laboratory/rffit-test/

Post-Exposure Prophylaxis*:*

Consultation prior to post-exposure prophylaxis should be obtained Monday-Friday, 8:00 a.m. to 5:00 p.m., from one of the Public Health Veterinarians or the epidemiologist on-call at (919) 733-3419.

Consultation services are available after work hours and during weekends or holidays. Leaving a message in the voice mailbox at (919) 733-3419 will automatically activate a beeper for the on-call individual.

Rubella Serology

(919) 733-3937

Introduction

Immune status testing for rubella antibody is available only to local health departments for prenatal patients with no documentation of vaccination or previous immune status testing. Immune status testing for rubella is also available for both clients and health department employees when vaccination is contraindicated (e.g., pregnancy, immunosuppression, or allergy to vaccine components). Reason for contraindication must be noted on the test request.

Sample Collection and Identification

Submit 2 mL of serum in a plastic screw-capped vial. Serum transport tubes should not be overfilled past the 3.0 mL line on the tubes. Hemolyzed, icteric, or lipemic serum may be unacceptable for certain serologic assays. Refer to **Appendix C** for requirements regarding specimen storage after collection and prior to shipment.

Clearly label each vial of serum with the patient's name (first and last) and either the date of birth, Social Security number, or other unique identifier. Complete DHHS Form #1188 (immune status testing) or DHHS Form #3445 (serodiagnosis of current or recent infection). Please note that all suspect or probable rubella cases must be reported to the Communicable Disease Branch at (919)733-3419 for prior approval of Rubella IgM laboratory testing. Failure to supply the requested patient information may result in significantly delayed specimen testing. Specimens approved for Rubella diagnosis will be forwarded to a reference laboratory for Rubella IgM or PCR testing.

Specimens submitted for testing that are not labeled with two identifiers will not be tested. Specimens which, for any reason, are deemed unsuitable or inappropriate for serologic testing will not be tested. Specimen will be rejected if received greater than 5 days from collection or the specimen is not received cold on ice packs (2-8°C) or frozen on dry ice (≤-20°C). Rejected specimens will be properly stored for 3 business days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

Although the serodiagnosis of many current or recent viral infections requires the simultaneous testing of paired sera, rubella IgM assays on a single acute serum specimen may provide evidence of a recent rubella infection. Immune status determinations for rubella also require only a single serum sample.

Shipment

Refer to the **Virology/Serology section of Appendix A** for Rubella specimen and shipment requirements, and contact the laboratory if additional guidance is needed. See appendix C for local health department specimen transport guidance.

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Reporting Procedures and Interpretation

The following chart provides information regarding test methods, serum requirements, turn-around times, and negative reference ranges.

Description of Antibody Test	Test Method	Negative Reference Range	Specimen Requirements	Turn-Around Time
Rubella, Immune Status, IgG	EIA-Qual	Negative specimen is not immune by either vaccination or resolved infection	2mL serum	2 working days
Rubella, IgM (reference lab)	EIA-Qual	No antibody detected	2 mL serum	2 weeks

Abbreviations:

EIA Enzyme Immunoassay
IgG Immunoglobulin G
IgM Immunoglobulin M
Qual Qualitative

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Serological Tests Referred to the Centers for Disease Control and Prevention (CDC) through the NC State Laboratory of Public Health

(919) 733-3937

Introduction

Serologic tests for antibodies to some bacterial, fungal, parasitic, chlamydial, rickettsial, and viral agents not performed at this laboratory are available from the Centers for Disease Control and Prevention (CDC), Atlanta, Georgia.

Sample Collection and Identification

Submit 2mL of serum in a plastic screw-capped vial. Hemolyzed, icteric, or lipemic serum may be unacceptable for certain serologic assays. Clearly label each vial of serum with the patient's name (first and last), date collected, and either the date of birth, Social Security number, or other unique identifier. Complete a DHHS Form #3445 specifying all required patient information and which infectious agents are suspected. Specimens sent to the CDC for testing also require a fully completed CDC 50.34 (DASH form). The CDC 50.34 form and instructions are available from the State Lab website https://slph.dph.ncdhhs.gov/forms.asp. CDC's specific test requirements can be found in their directory of services http://www.cdc.gov/laboratory/specimen-submission/list.html.

Services are available to all health care providers. Only serum may be submitted for serologic testing. Specimens must be submitted through the State Laboratory of Public Health, Virology/Serology Unit in the same manner as those for special serology specimens. Specific requirements for specimen submission vary depending upon the nature of the infectious agent involved and the assay requested. In general, all specimens submitted to the State Laboratory to be forwarded to the CDC must include the patient's age, sex, the date of the onset of illness, collection date, pertinent history, and clinical information.

Specimens submitted for diagnostic testing labeled with incorrect patient identification information will not be tested. Patient identification includes full first and last name and either date of birth, Social Security number, or other unique identifier. Specimens that, for any reason, are deemed unsuitable or inappropriate for diagnostic testing will not be tested. Rejected specimens will be properly stored for ten days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

Shipment

Refer to the **Virology/Serology section of Appendix A** for Special Serology specimen and shipment requirements and contact the laboratory if additional guidance is needed. See appendix C for local health department specimen transport guidance.

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Reporting Procedures and Interpretation

The average turn-around-time in which results can be expected back from the CDC is about three weeks. Interpretation of test results is included in the report, if sufficient clinical information was included on the submission form.

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Special Serology Testing: Measles, Mumps, Varicella Zoster, Rickettsia (Rocky Mountain Spotted Fever-RMSF)

(919) 733-3937

Introduction

Diagnostic and immune status serologic assays are performed for various rickettsial and viral agents. Assay methods vary depending upon the specific test requested. For hepatitis, syphilis, rubella, and HIV serologies, see separate sections.

Screening for immunity to measles, mumps, and varicella zoster is not available on a routine basis. Exceptions to this policy apply to local health departments only and include the following:

1. All suspect or probable cases of vaccine preventable diseases (measles, mumps, varicella zoster) must be reported to the Communicable Disease Branch at (919)733-3419 for prior approval of laboratory testing.

2. Immune status testing for measles is available for clients when vaccination is contraindicated (e.g., pregnancy, immunosuppression, or allergy to vaccine components). Reason for contraindication must be noted on the test request. Use DHHS Form #3445.

3. Serologic testing for Rickettsia (RMSF), VZV and mumps will be sent out for testing, if approved. Approved cases include prenatal patients without a clear history of VZV infection or whose immune status is unknown and have been exposed to a known case of VZV. Mumps and VZV testing is available for acute cases through our Virology laboratory (see below).

4. PCR testing for Rickettsia (RMSF) will be sent out for testing at CDC if approved for patients with clinically compatible illness. Please see additional information in appendix A.

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Sample Collection and Identification

Submit 2-3 mL of serum in a plastic screw-capped vial. Hemolyzed, icteric, or lipemic serum may be unacceptable for certain serologic assays. For Rickettsia (RMSF) testing, venous whole blood preserved with EDTA or ACD-A are acceptable, if drawn during the week of acute illness and before or within 48 hours of antibiotic therapy.

Clearly label each vial of serum with the patient's name (first and last), date collected, and either the date of birth, Social Security number, or other unique identifier. Complete a DHHS Form #3445 submission form specifying all required patient information and which infectious agents are suspected.

Specimens submitted to the Virology/Serology Unit must be accompanied by a fully completed submission DHHS form #3445. Failure to supply the requested patient information may result in significantly delayed specimen testing. Tests must be requested by name. Nonspecific requests for "viral studies" or "viral serologies" will not be accepted. Consult with the laboratory if there is a question as to which test is appropriate.

Specimens submitted for testing that are not labeled with correct patient identification information will not be tested. Patient identification includes two identifiers. Specimens more than 3 days from collection, not received cold (2-8°C) or frozen (≤-20°C) or for any reason deemed unsuitable or inappropriate for serologic testing will not be tested. Rejected specimens will be properly stored for three business days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

Note: The serodiagnosis of a current or recent infection generally requires the simultaneous testing of paired serum samples, acute and convalescent serum samples. The acute serum should be collected no later than 3-5 days after the onset of illness. The convalescent serum should be collected 2-3 weeks after onset. Where paired sera are advised or required, it is to the advantage of both the submitter and this Laboratory if the acute serum is stored frozen by the submitter until the convalescent serum is collected. Both serum samples may be submitted with one submission form.

Serologic diagnosis of mumps between acute and convalescent sera can be made by demonstrating a four-fold or greater rise in titer. For certain agents, such as measles, specific IgM assays on a single acute serum specimen may provide evidence of a recent infection. Additionally, single "high" antibody titers to viral and rickettsial agents may be considered presumptive evidence of recent infection. Immune status determinations require a single serum sample only and should be clearly designated on the request form.

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Shipment

Refer to the **Virology/Serology section Appendix A** for Special Serology specimen and shipment requirements and contact the laboratory for further guidance as needed. See appendix C for local health department specimen transport guidance.

Reporting Procedures and Interpretation

Failure to detect a significant antibody response may be the result of a number of factors including improperly collected specimens, specimens collected too early or too late during the immune response, selection of the incorrect infectious agent for testing, or lack of sensitivity in the serological system being used.

The following chart lists the special serologic assays performed by this laboratory. A brief statement of the "normal" values for each assay is given under the heading "Negative Reference

Range." The test method, specimen requirements, and turn-around times are also listed for each assay performed.

Special Serology Assays

Description of Antibody Test	Test Method	Negative Reference Range	Specimen Requirements	Turn-Around Time
Ehrlichia chaffeensis, IgG	CDC send out	<1:64	1 mL serum, PSA	Reference lab send out
Measles, IgM	EIA Qualitative	Normal is negative	0.5 mL serum	48 Hours
Measles, IgG	CDC Send out	Negative specimen is not immune by either vaccination or resolved infection	0.5 mL serum	Reference lab send out
Mumps, Diagnostic IgG	CDC Send out	Negative specimen is not immune by either vaccination or resolved infection	0.5 mL serum; PSA	Reference lab send out
Rickettsia (RMSF), IgG	CDC Send out	<1:64	1 mL serum, PSA	Reference lab send out
Rickettsia typhi (Typhus), IgG	CDC Send out	<1:64	1 mL serum, PSA	Reference lab send out
Rickettsia (RMSF) detection	CDC Send out	Normal is negative	1 mL Acute serum, whole blood	Reference lab send out
Varicella zoster, IgG	Reference lab send out	Negative specimen is not immune by either vaccination or	0.5 ml serum	Reference lab send out

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		resolved infection		

Abbreviations:

IgG Immunoglobulin G
IgM Immunoglobulin M
CSF Cerebrospinal fluid
PSA Paired Sera Advised

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Virus Culture

(919) 733-3937

Introduction

Successful performance of virologic studies is in part dependent upon the cooperation of informed clinicians who will obtain proper specimens taken at the correct time during the patient's illness and provide sufficient clinical information for the laboratory to select the appropriate test or tests. Virus culture employing assorted cell culture systems and molecular assays provide a mechanism for the detection and identification of many human viruses which cause a wide variety of common illnesses. The Viral Culture lab is capable of isolating and identifying most Biological Safety Level I through III viruses that can be propagated in conventional cell culture. Molecular testing by RT-PCR is also routinely available for some viral agents, such as influenza, measles, SARS-CoV-2, herpes, and VZV. If Highly Pathogenic Avian Influenza (HPAI) is suspected, pre-approval from the Communicable Disease Branch is required (919)-733-3419.

Sample Collection and Identification

Routine Viral Cultures:

All appropriate diagnostic specimens for culture of human viruses will be accepted from both public and private providers of health care. Routine culturing of viruses are currently being sent-out for testing.

Viruses are obligate intracellular parasites. Consequently, diagnostic specimens for viral culture must be vigorously collected to ensure the presence of infected cells for optimal results. Specimens for viral culture should be collected as soon as possible after the onset of clinical illness (i.e., 24-72 hours). Specimens collected more than one week after onset usually do not yield live viruses. Clearly label each specimen with the patient's full name (first and last) and either the date of birth, Social Security number, or unique identifier (such as internal record number). Complete DHHS Form #3431, supplying all required patient information and specifying the virus agent suspected. Please provide a complete submitter's mailing address, EIN#, physician name, and telephone number. Minimal essential patient information that must be provided includes: the patient's first and last name, date of birth, either Social Security Number or unique identifier (such as internal medical record number), Medicaid number (if applicable), sex, onset date, **plus** specimen source and collection date. Also provide information on the suspected infectious agent(s) and/or provide the patient's signs and symptoms, including vaccination and/or travel history, if applicable. Failure to supply the requested patient information may result in significantly delayed specimen testing.

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Specimens that, for any reason, are deemed unsuitable or inappropriate for diagnostic testing will not be tested. Rejected specimens will be properly stored for ten days pending verbal and/or written notification of the submitter. Unless alternate arrangements are initiated by the submitter upon notification of specimen rejection, the specimen will be discarded at the end of the holding period.

The source of the specimen(s) collected must be carefully matched with the virus suspected. A chart is included which describes the virus isolation service available at the State Laboratory, the turn-around time for virus cultures, and the specimens of choice for each virus listed. Dacron-tipped, rayon-tipped, or flocked swabs with plastic or aluminum shafts are acceptable. Cotton-tipped swabs with wooden shafts are not recommended; calcium alginate swabs are not acceptable. Refer to the **Virology/Serology section in Appendix A** for specimen and shipment requirements, and contact SLPH if additional guidance is needed.

The following general guidelines may be used when properly collecting specimens for virus culture:

A. Autopsy or Biopsy

Collect fresh, unfixed tissue from the probable sites involved using a separate sterile instrument for each sample. Place each specimen into a separate small, sterile vial of virus transport medium. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

B. Cerebrospinal Fluid

Discard the virus transport medium from a small specimen vial. Aseptically collect about 3 ml of CSF and transfer to the empty vial. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

C. Feces

Discard transport medium from small specimen vials. Place a piece of feces about 2-5 grams (approximately the size of the end of an adult thumb) into a vial. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

D. Nasal/Nasopharyngeal Swab

Pass a flexible, fine-shafted swab into the nostril/nasopharynx. Rotate slowly for 5 seconds to absorb secretions. Remove swab and place into a vial of viral transport medium. Repeat for the other nostril using a fresh swab. Place both swabs in the same transport tube.

E. Nasopharyngeal Aspirate or Wash

Pass appropriately sized tubing or catheter into the nasopharynx. Aspirate material with a small syringe. If material cannot be aspirated, tilt patient's head back about 70º and instill 3 to 7 mL of sterile saline or viral transport medium until it occludes the nostril. Re-

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aspirate. If < 2 mL is recovered, deposit directly into viral transport medium. If > 2 mL is recovered, no additional viral transport medium is required.

F. Rectal Swabs

Generally, rectal swabs are less satisfactory than feces for the isolation of viruses. If used, rectal swabs are obtained by inserting a dry swab at least 5 cm into the anal orifice, rotating the stick and then withdrawing it. Some fecal material must be obtained on the swab tip. The swab tip is then broken off into a vial of viral transport medium. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

G. Throat Swabs

Vigorously rub the tonsils and posterior wall of the pharynx with a dry, sterile swab. The swab should not touch the tongue or buccal mucosa. Break off the swab tip into a vial of virus transport medium. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

H. Urine

Discard the virus transport medium from the small specimen vials. Collect clean voided urine, preferably first voided morning urine. Transfer to the small specimen vials. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

I. Vesicle

Using a sterile instrument, open the fluid filled vesicle. Using firm pressure, absorb the fluid with a sterile swab and scrape the perimeter of the lesion obtaining cellular material on the swab tip. Avoid causing excessive bleeding. Break off the swab tip into a vial of virus transport medium. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks.

J. Tissue Culture Isolates

The Virus Culture Lab provides referral identification services for laboratories throughout North Carolina which perform viral isolation. Referral specimens should be observed microscopically at the initial laboratory until 50% or more of the available cell sheet is exhibiting viral cytopathogenic effect (CPE). These specimens may be shipped as a Biological Substance Category “B”. If the virus is suspected to be a Category “A” infectious substance, as defined by the Federal Register, then ship as “dangerous goods”. Samples should be frozen on dry ice and be accompanied by a completed DHHS #3431 indicating the original anatomical site and the type of cell culture which grew the viral-like agent. Please indicate the suspected virus when completing the test request form.

K. Buccal Swabs

The parotid gland is located below the zygomatic arch (triangular bone of the cheek), below and in front of the ear. The parotid (Stenson’s) duct drains this gland and empties into the buccal cavity opposite the second upper molar. Massage the parotid gland for 30 seconds,

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and then use a swab to sweep the parotid duct area of the buccal surface from the upper to the lower molars.

Herpes Simplex Virus/Varicella Zoster Virus (HSV/VZV) Molecular Testing:

HSV/VZV molecular testing of cutaneous and mucocutaneous lesions is available only to local health departments and other state operated health care facilities. Specimens acceptable for HSV/VZV molecular testing are limited to the following:

1. Specimens from prenatal patients who have a suspicious lesion not previously confirmed as herpes. Routine testing in the absence of lesions will not be accepted.
2. Specimens from patients presenting with an atypical lesion where a clinical distinction cannot be made between herpes, chancroid, and syphilis. Testing done simply to confirm a clinical diagnosis of herpes is not available on a routine basis.

Swabs should be rayon or synthetic polyester fiber-tipped with a plastic shaft. Calcium alginate, cotton tipped swabs or wooden-shafts will be rejected. Using a sterile instrument, open the fluid filled vesicle. Using firm pressure, absorb the fluid with a sterile swab and scrape the perimeter of the lesion obtaining cellular material on the swab tip. Avoid causing excessive bleeding. Break off the swab tip into a vial Remel M4RT transport medium. Screw the cap on tightly. Keep cold (~ 4°C) pending prompt shipment on icepacks. Clearly label the specimen with the patient's full name (first and last) and either the date of birth, Social Security number, or unique identifier (such as internal medical record number).

Specimens submitted for herpes/VZV testing must be accompanied by a DHHS Form #3431 that includes the clinic in which the patient was seen and the specific reason for testing, i.e., differential diagnosis of an atypical lesion, lesions in pregnant women, etc. Submitters need to fully complete the submission form indicating patient's first and last name, date of birth, either Social Security Number or unique identifier (such as internal medical record number), Medicaid number (if applicable), sex, race, specimen source, collection date, onset date, submitter information (including clinic and contact information), pregnancy status and due date (if applicable), date specimen submitted, and patient signs and symptoms. Select HSV/VZV as the agent requested. Failure to supply the requested clinical patient information may result in significantly delayed specimen testing or rejected specimens.

HSV/VZV testing from urogenital sites is limited to one specimen per patient. If more than one urogenital site is sampled, both swabs should be submitted in the same transport tube. Specimens from multiple sites submitted individually will be pooled in the laboratory at the risk of diluting out the virus. Please DO NOT place more than two swabs in a single viral transport medium vial.

Shipment

Seal the form in a separate plastic bag and enclose with the specimen between the secondary and tertiary container. Submit no more than three specimens per patient with each form. One form can be used for up to three different specimens from the same patient.

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Although the virus transport mailer was designed for several specimens, the cost of the transport medium is negligible and unused medium can simply be discarded. Do not delay the shipment of specimens until all the vials of transport medium are used. Refer to the **Virology/Serology section Appendix A** for HSV/VZV specimen and shipment requirements and contact SLPH if additional shipping guidance is needed. See appendix C for local health department specimen transport guidance.

Specimens submitted for viral isolation should be packaged according to 49 CFR and Department of Transportation Regulations.

1. Wrap absorbent material around the primary container containing the specimen, which is properly labeled with the patient's name and either the date of birth, Social Security number, or unique identifier (such as internal medical record number).

2. Place the properly identified inoculated vials of transport medium into the large conical plastic shipping tubes. If all of the transport medium is not used, return the unused large conical plastic shipping tubes to maintain a tight pack and prevent breakage. Place the two frozen ice packs into the shipping container.

3. Place the large conical plastic tubes containing specimen(s) or tubes without specimens (for a total of three tubes) between the ice packs. Place the completed forms into the plastic bag and slide into the space at the narrow end of the ice packs. Replace the Styrofoam lid on the box, seal the cardboard box, and attach the return pre-addressed shipping label on top of the label used to ship the kit to you. Ship the specimen to the State Laboratory by the fastest means possible.

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Report Procedures and Interpretation

Turn-around time for negative cultures varies from one to six weeks. Cultures yielding virus isolates may require more time for identification of the virus, depending upon the isolate involved. Failure to isolate a virus may be the result of a number of factors, including improperly collected specimens, specimens collected at a period in the disease when the patient is not shedding virus, improperly transported specimens, or a lack of sensitivity in the system being used for isolation. Failure to isolate a virus should not rule out the virus as a cause of the clinical illness. Conversely, since people may asymptomatically carry a variety of viruses, viruses may be isolated which are unrelated to the current illness. The clinician should interpret the laboratory report in conjunction with patient history and clinical findings.

Virus Culture Service

Virus Description	Test Method	Negative Reference Range	Specimen Requirements	Turn-Around Time (if Negative)
Adenovirus (Reference Lab)	Cell culture	Normal is negative	Throat washing or swab, nasal swab, nasopharyngeal washing or swab, conjunctival swab, feces, pericardial fluid	3 weeks
Cytomegalovirus (Reference Lab)	Cell culture	Normal is negative	Urine, throat swab, lung tissue, lung aspirate	6 weeks
Enterovirus (including Coxsackie, Echo, and polioviruses) (Reference Lab)	Cell culture	Normal is negative	Throat swab, feces, CSF, pericardial fluid, vesicle scraping (Enterovirus) Throat swab, feces, CSF, pericardial fluid, skin tissue (Coxsackie and Echo) Throat swab, feces, CSF (poliovirus)	3 weeks
Herpes simplex (Reference Lab)	Cell culture	Normal is negative	Brain biopsy, CSF, conjunctival swab	1 week
Herpes simplex	PCR	Normal is negative	Vesicle scraping	2 days
High Pathogenic Avian Influenza	PCR	Normal is negative	If respiratory symptoms (2 tubes): 1(nasopharyngeal swab 2) oropharyngeal and nasal swab If conjunctival symptoms (3 tubes): 1) conjunctival swab 2) conjunctival swab 3) nasopharyngeal swab	1 day
Influenza	Cell culture PCR	Normal is negative	Throat washing or swab, nasal swab, nasopharyngeal washing or swab, lower respiratory specimens	3 weeks PCR: 3 days

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Measles	PCR	Normal is negative	Nasopharyngeal swab in VTM, urine , throat swab (reference lab)	3 weeks PCR: 2 days
Mumps (Reference Lab)	Cell culture PCR (Reference Laboratory)	Normal is negative	Throat swab, CSF, buccal swab	PCR: 2-3 days
Parainfluenza virus (Reference Lab)	Cell culture	Normal is negative	Throat washing or swab, nasal swab, nasopharyngeal washing or swab	3 weeks
Respiratory syncytial (Reference Lab)	Cell culture	Normal is negative	Nasopharyngeal washing or swab	3 weeks
Rubella (Reference Lab)	PCR	Normal is negative	Nasopharyngeal swab	2 to 3 days
SARS-CoV-2	PCR	Normal is negative	Nasopharyngeal swab or oropharyngeal swab	2 days
Varicella-zoster	PCR	Normal is negative	Vesicle scraping swab in VTM	2 days
Virus isolate identification (Reference Lab)	Cell culture	Normal is negative	Frozen isolate	Varies

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APPENDIX A

CLINICAL SPECIMEN AND SHIPMENT REQUIREMENTS

See appendix C for local health department specimen transport guidance.

MICROBIOLOGY

Bacteriology	• ***Bordetella pertussis* clinical** ○ Nasopharyngeal (NP) swab collected in Copan ESwab Liquid Amies transport medium is the preferred specimen. Swabs in Copan ESwan Liquid Amies transport medium must be received cold on frozen ice packs (2-8°C) at SLPH within ≤ 96 hours of collection. Specimens will be rejected if not received cold (2-8°C) or if received at SLPH > 96 hours from date of collection. • ***Bordetella pertussis* PCR** ○ NP ESwab Liquid Amies transport medium is provided in *B. pertussis* collection kits ordered from NCSLPH. Specimens must be received cold on frozen ice packs (2-8°C) at SLPH ≤ 7 days from date of collection. Specimen will be rejected if not received cold (2-8°C), collected in improper transport medium, or if received at SLPH > 7 days from date of collection. • ***Legionella* clinical samples** ○ Appropriate specimens for culture of legionellae are those from the lower respiratory tract including sputum, pleural fluid, lung biopsy tissue, bronchial washings and lavages, and tracheal aspirates. Although blood and tissue from liver or other organs occasionally have yielded legionellae, respiratory tract specimens are preferred. Nasopharyngeal and oropharyngeal swab specimens are not acceptable. Specimens for culture should be shipped in leak-proof containers refrigerated with frozen ice packs (1-8°C) in an insulated container. Specimens must be received cold on frozen ice packs (1-8°C) at SLPH ≤ 3 days from date of collection. If there is a delay in shipping (>3 days) specimens to SLPH, specimens

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	must be frozen and then shipped at ≤-20°C and shipped in an insulated container on dry ice overnight via commercial courier. Specimens rejected if not received cold on frozen ice packs(1-8°C) or received at SLPH > 3 days from date of collection unless sample is frozen. Specimens of NP or oropharyngeal swabs will be rejected. Specimens will be rejected if not received frozen ≤-20°C after three days from collection. • ***Legionella* reference isolate for culture** ○ Reference isolates of suspected Legionella should be submitted on BCYE agar slants or plates. Isolates must be shipped cold on frozen ice packs (1-8°C) to SLPH. Specimen rejected if SLPH cannot subculture and obtain a viable isolate. Excessively mixed cultures may be deemed unsatisfactory, and resubmission requested from the submitter. • **Diagnostic Enteric clinical culture** ○ Acceptable diagnostic clinical specimens for enteric pathogens include those collected within a maximum of 72 hours (preferably 1-2 days) of receipt and have been securely packaged and shipped with a completed Enteric Bacteriology Form 3390. Specimens should be shipped to SLPH in enteric transport media either ambient or cold on frozen ice packs (1-8°C). (Refrigerated transport is recommended for specimens cultured for E. coli). Diagnostic specimens for enteric pathogens will be rejected if not received preserved in enteric transport media. Diagnostic specimens will be rejected if received > 72 hours from date and time of collection. Specimen will be rejected if transport media with indicator exhibits a yellow-colored solution. Specimen will be rejected if stool plus preservative exceeds fill-line on the collection container. • **CIDT (Culture Independent diagnostic testing)** ○ SLPH also accepts clinical fecal samples in enteric transport media from positive culture independent tests (CIDT) reflexed for specific pathogen confirmation/ surveillance. These stool samples must be received within 7 days of collection.

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	○ Acceptable CIDT clinical surveillance specimens for enteric pathogens include those collected within a maximum of 7 days of receipt and have been securely packaged and shipped with a completed Enteric Bacteriology Form 3390. Specimens should be shipped to SLPH in enteric transport media either ambient or cold on frozen ice packs (1-8oC). (Refrigerated transport is recommended for specimens cultured for E. coli). CIDT specimens for enteric pathogens will be rejected if not received preserved in enteric transport media. CIDT specimens will be rejected if received > 7 days from date of collection. Specimen will be rejected if transport media with indicator exhibits a yellow-colored solution. Specimen will be rejected if stool plus preservative exceeds fill-line on the collection container. • **Enteric reference culture** ○ Acceptable reference cultures include isolates grown on agar slants (preferred), plated media, or enteric growth/transport systems which have been appropriately packaged for shipment and which are accompanied by a completed Enteric Bacteriology Form 3390. Pure isolates may be shipped ambient to SLPH. Specimen rejected if SLPH cannot subculture and obtain a viable isolate. Excessively mixed cultures may be deemed unsatisfactory, and resubmission requested from the submitter. • ***Neisseria gonorrhoeae* culture and/or Neisseria gonorrhoeae antimicrobial susceptibility** ○ Clinical samples from Local Health Departments (LHD) are directly inoculated on Thayer Martin Modified agar (or similar selective media), enclosed with a CO2-generating ampule in a BD Bio-Bag type C, and incubated at 35°C. All specimens are to be shipped to SLPH at ambient temperature. Plated specimens should be shipped in a BD Bio-Bag Type C as soon as possible after growth is present on the plate. Do not refrigerate during storage or transport. If shipment is delayed (e.g., over a weekend), growth on these cultures must be subcultured by the submitter at least every 2-3

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	days to maintain viability. Submitter should maintain a viable isolate in case organism does not survive shipment. ○ Isolates from cultures positive for N. gonorrhieae are retained frozen at SLPH in case a provider desires to order N. gonorrhoeae susceptibility testing for cases of suspect treatment failure. ● ***Neisseria species*** ○ Reference cultures of N. meningitidis from invasive sites are submitted for confirmation and serotyping (as required by law) on chocolate or blood agar slants. This organism also grows on the selective media listed above. Pure isolates must be shipped ambient to SLPH. Specimen rejected if SLPH cannot subculture and obtain a viable isolate. ○ Reference cultures of saprophytic Neisseria spp. or M. catarrhalis may be submitted for identification on blood, chocolate, or infusion agar slants. Pure isolates must be shipped ambient to SLPH. Specimen rejected if SLPH cannot subculture and obtain a viable isolate. ● **Other Reference Cultures** ○ Acceptable reference cultures for **Gram positive cocci, Haemophilus** and **Gram positive and gram-negative bacilli** include isolates grown on agar slants (preferred) or plated media, which have been appropriately packaged for shipment. Pure isolates must be shipped ambient to SLPH. Specimens will be rejected if SLPH cannot subculture and obtain a viable isolate. Excessively mixed cultures may be deemed unsatisfactory, and resubmission requested from the submitter.
Mycology	● **Clinical specimens** ○ Clinical specimens should be shipped as soon as possible after collection. Clinical specimens should be received at SLPH within ≤ 3 days from date of collection. Ship urine, cerebral spinal fluid (CSF), and respiratory tract samples cold on frozen ice packs (1-8ºC). All other clinical specimens should be shipped at ambient temperature. Frozen samples are unacceptable. Specimen rejected if received > 3 days from date of collection. Urine, CSF, or respiratory tract samples rejected if shipped at

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	ambient temperature. Any specimen received frozen will be rejected. • **Reference specimens** ○ Submitter to send pure isolate on solid medium (slants). Pure isolates may be shipped ambient or cold on frozen ice packs (1-8°C)as soon as possible to SLPH. Isolate rejected if SLPH cannot subculture and obtain a viable isolate. Excessively mixed cultures may be deemed unsatisfactory, and resubmission requested from the submitter.
Parasitology	• **Stool specimens** can be shipped ambient or cold on frozen ice packs (1-8°C) to SLPH. Stool collected in 10% formalin must not exceed "fill line" of collection vial. Specimen will be rejected if not received in 10% formalin, or if the sample plus preservative exceeds fill – line of the collection vial. • **Sputum -** unpreserved sputum for Paragonimus must be shipped cold on frozen ice packs (1-8°C) if it will be received by SLPH at <= 2 days from date of collection. These specimens will be rejected if received >2 days post collection or received ambient. If there will be a delay in transport to SLPH > 2 days, sputum should be preserved in 10% formalin and shipped ambient or cold on frozen ice packs (1-8°C) to SLPH. • **Cryptosporidium Giardia** - Stool collected in 10% formalin must not exceed "fill line" of collection tube. Specimens will be rejected if the sample plus preservative exceeds the “fill line”. Formalin or SAF preserved specimens can be stored frozen (≤-20), refrigerated (1-8°C), or at ambient temperature. Cary Blair can be stored refrigerated (1-8°C). MIF preserved specimens can be stored frozen (≤-20), refrigerated (1-8°C), or at ambient temperature. Ship specimens at ambient or cold on frozen ice packs (1-8°C). Samples in formalin, SAF or MIF must be received, and testing completed within 2 months of date of collection and will be rejected if they exceed 2 months post collection. Samples in Cary Blair must be received, and testing completed within 2 weeks of date of collection if stored refrigerated (1-8°C) or within 2 months of date of collection if stored frozen (≤-20). Samples in Cary Blair will be rejected if received >2-week post collection, refrigerated (1-8°C) or >2 months post collection if stored

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	frozen (≤-20). All specimens will be rejected if not received in an appropriate preservative. • **Whole Worms or Proglottids**: Whole worms should be preserved in 70% alcohol, if possible. Place in plastic or glass container; label with two patient identifiers. Proglottids may be preserved in 10% formalin or placed in saline or 70% alcohol. Parasitology mailer may be used if it is large enough, as it contains 10% formalin. Specimens should be shipped ambient (recommended) or cold on frozen ice packs (1-8°C). Specimen rejected if received frozen (≤-20). • **Arthropods**: Arthropods are referred to the Entomology Department at NC State University through the Insect and Plant Disease Clinic (919-515-9530) for identification for a fee of $30. Submitter should contact the clinic directly to arrange testing.
Mycobacteriology	• **Sputum and Other Respiratory Specimens-** Must be shipped 2-8°C and received at SLPH ≤ 7 days from the date of collection. A minimum volume of 0.5ml will be accepted. Specimen will be rejected if received >7 days from date of collection, if volume is <0.5ml, contains obvious food particles or if shipped >8°C. SLPH does not perform NAAT on sputa specimens for pediatric patients (<18). • **Resuspended Sediments-** Decontaminated resuspended sediments must be shipped 2-8°C and received at SLPH ≤ 7 days after processing. Resuspended sediments will be rejected if received > 7 days after processing or if shipped >8°C. • **Other Clinical Specimens-** Must be shipped 2-8°C and received at SLPH ≤ 7 days from the date of collection. A minimum volume of 0.5ml will be accepted for urine, blood, stool, and sterile body fluids other than CSF. Specimens will be rejected if <0.5ml is received for testing. • **Blood, CSF, Bone Marrow Specimens –** Blood, CSF, or bone marrow aspirates should be shipped 15-25°C and received at SLPH ≤3 days from date of collection. Specimens will be rejected if received >3 days post collection. Sufficient volume (>50 uL) for subculturing is required. Blood specimens must be received in green top (heparin) or yellow top (SPS) tubes and will be rejected if not received in heparin or SPS tubes.

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	• **Mycobacterium Reference Cultures** - Pure isolates in liquid or on solid media must be shipped 2-30°C as soon as possible to SLPH. The recommendation for liquid cultures is 3ml. Specimens will be rejected if a viable isolate cannot be obtained at SLPH. Liquid media samples must be shipped with minimum volume of 1.5 mL and will be rejected if <1.5 mL of liquid sample is received.
Bacterial STD	**NOTE**: The performance of the Aptima Combo 2 assay for Chlamydia/Gonorrhea detection has not been evaluated in adolescents less than 14 years of age. Samples received by NCSLPH for patients aged 10-14 years of age will be forwarded to LabCorp for testing. Testing for CT/GC on patients <10 years of age and medicolegal testing for CT/GC are not available through NCSLPH. • **Chlamydia/GC Aptima Multitest Swabs** ○ Only the swabs and the specimen transport tubes contained in the APTIMA Combo 2 Assay Multitest Swab Specimen Collection kit may be used to collect swab specimens (vaginal, rectal, and oropharyngeal) ○ Swabs should be transported and received 2-30°C ≤28 days post collection. If longer storage is needed, freeze specimens in the Aptima specimen transport tube within 7 days of collection at -20°C to -70°C to allow testing up to 60 days after collection for extragenital swab samples and up to 12 months after collection for vaginal swab and urine samples. ○ Specimens received that are not APTIMA MTS collection devices will be rejected, as they are not acceptable for testing. Specimens received for CTGC testing that are punctured or broken will be rejected. Specimens not received 2-30°C or frozen (-20°C to -70°C) will be rejected. Specimen received >28 days of collection will be rejected. • **Chlamydia/GC Aptima Urine** ○ The APTIMA Combo 2 Assay Urine Specimen Collection Kit for Male and Female urine specimens is used for the collection of urine specimens. Urine is not the preferred specimen type for females. ○ Specimens not received 2-30°C or frozen (-20°C to -70°C) will be rejected. Specimen received >28 days of collection will be rejected. Specimens received that are not APTIMA urine collection devices will be rejected, as they are not acceptable for testing. Specimens

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	received for CTGC testing that are punctured or broken will be rejected. • **Syphilis Serum (RPR, TP)** ○ **RPR testing -** Blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for RPR testing without a minimum of 300ul will be rejected. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤5 days of collection or frozen (≤-20°C) on dry ice at ≤ 28 days will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen (≤-20°C). Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. ○ **TP -** Blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Cadaveric specimens have not been validated. Specimens received for TP testing without a minimum of 300ul will be rejected. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤5 days of collection or frozen (≤-20°C) on dry ice at ≤28 days will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen (≤-20°C). Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Serum specimens that are heat-inactivated, grossly hemolyzed or have obvious microbial contamination are unsatisfactory for testing and will be rejected.

NC Antimicrobial Resistance Laboratory Network (ARLN) Laboratory

Carbapenemase Producing Organisms (CPO): • Carbapenem-resistant Enterobacterales (CRE), • Carbapenem-resistant *Pseudomonas*	• Acceptable CRE, CRPA, and CRAB isolates include pure colony growth on agar slant (preferred) or agar plates (sealed with tape or parafilm, enclosed in a leak-proof bag, and securely packaged in a crush-proof container) which have been appropriately packaged for shipment, and which are accompanied by a completed Enteric Bacteriology Form DHHS 3390. Pure isolates must be shipped ambient to NCSLPH. Specimens will be rejected if NCSLPH cannot subculture and obtain a viable isolate. Mixed cultures are deemed

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aeruginosa (CRPA) • Carbapenem-resistant *Acinetobacter baumannii* (CRAB)	unsatisfactory and a resubmission of the isolate will be requested from the submitter.
***Candida auris* (ARLN)**	• Submitter to send pure isolate on solid medium (slants). Pure isolates may be shipped ambient or cold on frozen-ice packs (1-8°C)as soon as possible to SLPH. Isolate rejected if SLPH cannot subculture and obtain a viable isolate. Excessively mixed cultures may be deemed unsatisfactory, and resubmission requested from the submitter.
Norovirus Outbreaks	• Prior approval by the NC Communicable Disease Branch (CDB) epidemiologists (919-733-3419) is required. Stools submitted without approval by the CDB epidemiologists will be rejected. • A minimum of five (5) stools are required to be submitted per suspected outbreak accompanied by a completed Enteric Bacteriology Form 3390. Specimens will be rejected if less than five (5) stools submitted. • Stool specimens must be submitted in commercially available enteric transport medium such as Cary-Blair Transport Medium, ETM™, or Para-Pak® Enteric Plus Transport System. Formed stool or vomitus will be rejected. • Stool specimens must be kept refrigerated until shipped. • Stools must be shipped with pre-frozen freezer packs in an insulated container. Stools received without pre-frozen freezer packs will be rejected

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VIROLOGY/SEROLOGY

All specimens must be shipped as soon as possible after collection, to ensure specimen integrity, timely results, and turnaround for any public health actions.

HIV, HCV, HAV Serum	• **HIV only** - Blood specimens are collected aseptically by venipuncture, centrifuged, and at least 2 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens that are received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for testing without a minimum of 250uL will be rejected. Specimens must be received cold (2-8°C) on frozen

	ice packs at SLPH ≤5 days of collection or will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens (≤-20°C)must be shipped to SLPH overnight via commercial courier on dry ice. • **HCV only -** Blood specimens are collected aseptically by venipuncture, centrifuged, and at least 2 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for testing without a minimum of 250uL will be rejected. Specimens must be received cold (2-8°C) on frozen ice packs at SLPH ≤5 days of collection or frozen (≤-20°C) on dry ice or will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen (≤-20°C). Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Contact SLPH for further guidance. Frozen specimens should not exceed three freeze-thaw cycles. Serum specimens that are heat-inactivated, grossly hemolyzed or have obvious microbial contamination are unsatisfactory for testing and will be rejected. • **HIV/HCV combination -** Blood specimens are collected aseptically by venipuncture, centrifuged, and 3 ml of serum is transferred to 2 appropriately labeled, plastic screw-capped vials. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for HIV/HCV combination testing without a minimum of 250 uL in each tube will be rejected. Specimens must be received cold (2-8°C) on frozen ice packs at SLPH ≤5 days of collection or frozen or will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens (≤-20°C) must be shipped to SLPH overnight via commercial courier on dry ice. Contact SLPH for further guidance. Frozen specimens should not exceed three freeze-thaw cycles. Serum specimens that are heat-inactivated, grossly hemolyzed or have obvious microbial contamination are unsatisfactory for testing and will be rejected. • **HAV -** Blood specimens are collected aseptically by venipuncture, centrifuged, and at least 2 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for HAVAB-M testing without a minimum of 300uL will be rejected. Specimens not received cold (2-8°C) on frozen ice

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	packs at SLPH ≤5 days of collection or frozen (≤-20°C) will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice.
HBV Serum	• Blood specimens are collected aseptically by venipuncture, centrifuged, and 2 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens received for anti-HBs, HBc IgM, HBsAg, or anti-HBc testing without a minimum of 300 uL will be rejected. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤4 days of collection or frozen (≤-20°C) will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Specimens for patients <28 days old will be rejected.
Rubella IgG Serum	• Blood should be collected aseptically by venipuncture, allowed to clot as soon as possible, and 2-3 ml of serum transferred to an appropriately labeled, plastic screw capped vial. Grossly hemolyzed, icteric, or lipemic specimens as wells as specimens containing particulate matter or exhibiting obvious microbial contamination are not recommended, should not be tested, and will be rejected. Specimens that are not serum will be rejected, as they are not acceptable for testing. Specimens received for Rubella IgG testing without a minimum of 250uL will be rejected. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤5 days of collection or frozen (≤-20°C) on dry ice will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen (≤-20°C). Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice.
Arbovirus Serology (WNV, EEE, LACV, DENV, CHIKV)	• **Chikungunya -** Blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Serum specimens must be received refrigerated at 2-8°C or frozen at ≤-20 °C not more than 12 days after collection. Specimens not received cold (2-8°C)or frozen ≤-20°C at NCSLPH ≤12 days after collection will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Specimens received that are not serum will be rejected, as they are not acceptable for

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	testing. Contaminated sera will be rejected. Specimens received for CHIKV IgM ELISA testing without a minimum of 200 ul will be rejected. • **Dengue -** Acute and/or convalescent blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Serum specimens must be received refrigerated at 2-8°C or frozen at ≤-20 °C up to 12 days after collection. Specimens not received cold (2-8°C) or frozen at ≤-20 °C at NCSLPH ≤12 days of collection will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Specimens received that are not serum or sera that has been heat-inactivated will be rejected, as they are not acceptable for testing. Specimens received for Dengue IgM ELISA testing without a minimum of 200 ul will be rejected. • **EEE/ LAC/WNV -** Acute and convalescent blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3 ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Serum specimens must be received refrigerated at 2-8°C or frozen at ≤-20 °C up to 12 days after collection. Specimens not received cold at 2-8°C or frozen at ≤-20 °C at NCSLPH ≤12 days of collection will be rejected. Specimens received that are not serum or CSF will be rejected, as they are not acceptable for testing. Specimens received without a minimum of 200 ul will be rejected.
Arbovirus molecular detection (CHIKV, DENV, and ZIKV)	• Serum is the preferred diagnostic specimen. Whole blood, CSF, urine and amniotic fluid may only be tested alongside a patient-matched serum sample. Serum, urine, and CSF should be stored refrigerated 2-8°C not more than 3 days after collection. If specimen shipment is delayed, the specimen should be frozen at ≤-20 °C and shipped on dry ice. At NCSLPH, serum, urine, and CSF specimens that are stored refrigerated and received at 2-8°C on ice packs up to 3 days after collection can be tested. Serum, urine, and CSF samples that are stored frozen and received on dry ice at ≤-20 °C can be tested up to 12 days after collection. Specimens not received cold on frozen ice packs at NCSLPH ≤3 days or frozen at ≤-20 °C on dry ice ≤12 days after collection will be rejected. Specimens received for CDC Trioplex Real-time RT-PCR testing without a minimum of 250 µl will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen, though whole blood specimens may only be stored

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	cold. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice.
Rickettsia and Ehrlichia chaffeenis Serology	• Submit serum samples only; the use of whole blood, plasma or other specimen matrices have not been established. Acute and convalescent blood specimens are collected aseptically by venipuncture, centrifuged, and 2-3ml of serum is transferred to an appropriately labeled, plastic screw-capped vial. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤3 days of collection or frozen (≤-20°C) will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Sera that is hyper-lipemic, heat-inactivated, hemolyzed, icteric, or contaminated will be rejected. Specimens received for Rickettsia/Ehrlichia IgG IFA panel testing without a minimum of 200 ul will be rejected.
Rickettsia Molecular Detection	• Submit acute serum from serum separator tube or cryotubes, or acute whole blood samples only from EDTA treated or ACD-A treated whole blood samples, or tissue biopsies including skin biopsy specimens from site of rash or eschar. Molecular detection is most sensitive during the first week of acute illness or when symptomatic and before or within 48 hours of appropriate antibiotic therapy. Specimens not received cold (2-8°C) on frozen ice packs at NCSLPH ≤7 days of collection or frozen (≤-20°C) on dry ice ≤60 days after collection will be rejected. Specimens that are not serum, whole blood, or tissue biopsies will not be accepted. A minimum of 1 ml is needed for testing.
Vaccine Preventable Disease (MMR/VZV IgM) Serology – REQUIRES APPROVAL FROM COMMUNICABLE DISEASE BRANCH	• **MMR/VZV IgM –** Submit serum samples only. The use of whole blood, plasma or other specimen matrices has not been established. Specimens received that are not serum will be rejected, as they are not acceptable for testing. Specimens not received cold (2-8°C) on frozen ice packs at SLPH ≤2 days of collection or frozen (≤-20°C) will be rejected. If there is a delay in shipping specimens to SLPH, specimens should be frozen. Frozen specimens must be shipped to SLPH overnight via commercial courier on dry ice. Serum samples that are hemolyzed, contaminated or hyper-lipemic will be rejected. Specimens received for testing without a minimum of 2mL will be rejected.

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HSV/VZV Nucleic Acid Amplification Technique (NAAT)	• Using a sterile instrument, open the fluid filled vesicle. Using firm pressure, absorb the fluid with a sterile swab and scrape the perimeter of the lesion obtaining cellular material on the swab tip. Avoid causing excessive bleeding. Break off the swab tip into a vial of Remel M4RT viral transport medium. Screw the cap on tightly. Keep cold pending prompt shipment on frozen icepacks. Specimen will be rejected if received >5 days from collection OR specimen is not received cold (2-8°C). Non-vesicle specimens, such as ocular, that are received will be rejected for this method but may be cultured.
Flu and SARS-CoV-2 PCR	• **Flu –** Acceptable specimens from human patients with signs and symptoms of respiratory infection: Upper respiratory tract clinical specimens [including nasopharyngeal swabs (NPS), nasal swabs (NS), throat swabs (TS), nasal aspirates (NA), nasal washes (NW), and dual nasopharyngeal/throat swabs (NPS/TS)]; Lower respiratory tract specimens [including bronchoalveolar lavage (BAL), bronchial wash (BW), tracheal aspirate (TA), sputum and lung tissue; positive viral culture isolates of the these listed specimen. Swab specimens should be collected using only swabs with a synthetic tip such as nylon or Dacron® and an aluminum or plastic shaft. Calcium alginate swabs are not acceptable and cotton swabs with wooden shafts are not recommended and will be rejected. Specimen types outside of those listed will be rejected. Human respiratory specimens, to be tested within 72 hours post-collection, should be placed into viral transport media (VTM) and transported on cold packs. Alternatively, specimens may be frozen and transported for testing. Specimens that are not received cold (2-8°C) on frozen ice packs ≤3 days from collection or received >3 days after collection without being frozen at ≤-70°C on dry ice will be rejected. **Note: HPAI testing requires Communicable Disease Branch approval.** • **SARS-CoV-2** – Nasopharyngeal (NP), Oropharyngeal (OP), Nasal Mid-Turbinate (NMT), and Nasal Swabs that have been collected according to standard technique and immediately placed in 1-3mL of SLPH VTM or commercial transport media kept cold are acceptable. A minimum of 300 µL is required for testing. Other specimen types will be rejected. Specimens that are not received cold (2-8°C) on frozen ice packs ≤3 days from collection or received >3 days after collection without being frozen on dry ice (≤-70°C) will be rejected.

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Measles/Mumps PCR – REQUIRES APPROVAL FROM COMMUNICABLE DISEASE BRANCH	• **Measles** - Acceptable primary specimens for measles nucleic acid extraction in-house include nasopharyngeal swabs in VTM, UTM, or UVT or urine (must be paired with swab specimen), Throat swabs may be tested at a reference lab. Swab specimens should be collected using swabs with a Dacron® tip and aluminum or plastic shaft. Swabs with calcium alginate will not be accepted and will be considered unsatisfactory. Cotton tips and wooden shafts are not recommended for sample collection and will be rejected. Swab specimens should be submitted in viral transport medium and stored and shipped on cold packs. Specimens that are not received cold (2-8°C) on frozen ice packs ≤3 days from collection or received >3 days after collection without being frozen on dry ice (≤-70°C) will be rejected. Specimens for the detection of measles should be collected within the first 72 hours after onset of symptoms. Swab specimens without a minimum of 200ul will be rejected. Urine specimens should be clean catch in a sterile container. Specimens that are not received cold (2-8°C) on frozen ice packs ≤3 days will be rejected. Urine specimens should not be frozen prior to shipping. Urine specimens with hematuria or with volumes <10ml will be rejected. • **Mumps** - Acceptable primary specimens for Mumps nucleic acid extraction include throat or buccal swabs; preferred specimen is an oral/buccal swab. Swab specimens should be collected using swabs with a synthetic tip such as Dacron® with aluminum or plastic shafts. Cotton tips and wooden shafts are not recommended for sample collection and will be rejected. Swabs with calcium alginate will not be accepted and will be considered unsatisfactory. Swab specimens should be submitted in viral transport medium and stored and shipped cold. Specimens for the detection of Mumps should be collected within the first 72 hours after onset of symptoms. Specimens that are not received cold (2-8°C) on frozen ice packs ≤3 days from collection or received >3 days after collection without being frozen on dry ice (≤-70°C) will be rejected. Specimens received with less than 200ul will be rejected.

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Viral Culture	• Specimens for viral culture should be collected as soon as possible after the onset of clinical illness (i.e., 24-72 hours). Dacron tipped, rayon-tipped, or flocked swabs with plastic or aluminum shafts are acceptable. Cotton-tipped swabs with wooden shafts are not recommended; calcium alginate swabs are not acceptable and will be rejected. Specimens will be rejected if received >2 days from collection OR specimen is not received cold (2-8°C). Frozen specimens not received on dry ice will be rejected. However, specimens to be tested by viral culture for respiratory syncytial virus (RSV), varicella zoster virus (VZV), or cytomegalovirus (CMV) should NOT be frozen since these viruses are easily inactivated. **Refer to the Virus Culture Service chart on page 147 for acceptable specimen type for viral culture testing.**
Rabies Specimens	• See SLPH Rabies Virus webpage and Rabies Packing and Shipping Handout for further guidance. Freezing is NOT recommended, as this may lead to increased turnaround times.

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NEWBORN SCREENING/CLINICAL CHEMISTRY

NBS Blood Spot Filter Specimen	• For routine testing services, dried blood spot specimens can be held at room temperature away from sunlight, moisture, and heat. All specimens should be shipped as soon as possible, ideally within 24 hours of collection to NCSLPH, and should not be batched for shipment. Do not mail in plastic bags. Specimens received 14 or more days from the date of collection cannot be tested due to the age of the specimen.
Sickle Cell	• Dried blood spot specimens collected on the Hemoglobin Screen Form, DHHS 1859, can be held at room temperature away from sunlight, moisture, and heat. All specimens should be shipped as soon as possible. Do not ship in plastic bags, use only paper or cardboard mailers. Specimens received > 14 days post collection will be rejected. • EDTA whole blood specimens must be refrigerated after collection and received cold on frozen ice packs ≤6 days post collection.

HEMACHEMISTRY

<table>
<tr>
<td>Blood lead (including prenatal)</td>
<td>
The specimen type is EDTA anti-coagulated whole blood collected into pre-screened polyethylene vials and capillary tubes containing EDTA.

Optimal specimen volume is 1-2 mL; minimum acceptable volume is 0.15 mL.
Specimen stability for capillary and venous specimens has been demonstrated for 14 days at ambient temperature (15 to 38 ºC).
Note: The preferred shipping temperature for blood lead specimens is ambient (15 to 38 ºC). The table below shows alternative shipping temperatures and stability. Any specimen received at temperatures outside of the specimen stability shown below will be rejected.

<table>
<tr><th>Specimen Type</th><th>Storage Conditions</th><th>Specimen Stability</th></tr>
<tr><td>Capillary (EDTA whole blood)</td><td>Cold (2 – 8 ºC)
Frozen (-15 to -25 ºC)</td><td>14 days</td></tr>
<tr><td>Venous (EDTA whole blood)</td><td>Cold (2 – 8 ºC)
Frozen (-15 to -25 ºC)</td><td>14 days</td></tr>
</table>
The criteria for specimen rejection include:

Specimen volume ≤ 0.15 mL
Specimen is older than the established stability from time of collection to time of testing.
Specimen received is outside of stated temperature acceptability ranges
Specimen contains suspected contamination due to improper collection procedures or collection devices
Specimens that are clotted upon receipt

</td>
</tr>
</table>

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BIOTERRORISM/EMERGING PATHOGENS

For collection of all samples, see PHP&R Powder Protocol guidelines at https://epi.dph.ncdhhs.gov/phpr/docs/NCSSRG-Final- 120219.pdf. Environmental samples include powder, swabs, wipes, envelopes suspected of or containing threats of bio- threat agents, various environmental samples including water, animal tissues, etc.

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TABLE 1. SUSPICIOUS SUBSTANCE: ENVIRONMENTAL

ORGANISM / TOXIN	TESTING PERFORMED	REQUIREMENTS (All items)
Bacillus anthracis	Culture, phage, capsule, PCR, other conventional microbiology tests	·**Accepted from law enforcement or PHP&R representatives only** ·Prescreen for radioactivity, VOCs and explosives ·Securely bag and label each item separately ·Triple package and transport using **ambient** conditions unless food ·Complete BT environmental submission form, see: https://slph.dph.ncdhhs.gov/forms.asp#bioterrorism ·Describe incident and all items to be tested ·Be prepared to prioritize samples should multiple samples require testing. ·Be prepared to provide all known information and guidance in regard to possible agents involved; ·**NOTIFY lab prior to arrival** (discussion should include possible agents, types, and number of samples to be submitted) ·**NOTIFY lab of approximate arrival time**
Brucella species	Culture, PCR, other conventional microbiology tests	
Burkholderia mallei / Burkholderia pseudomallei	Culture, PCR, other conventional microbiology tests	
Francisella tularensis	Culture, DFA, PCR, slide agglutination, other conventional microbiology tests	
Yersinia pestis	Culture, phage, PCR, other conventional microbiology tests	
Ricin toxin	Time Resolved Fluorescence	
Botulinum toxin Call NCSLPH CDB	**Call NCSLPH CDB for assistance (919-733-3419)**	

Note: As each incident is unique, call the BTEP Duty Phone (919-807-8600) for specific details.

TABLE 2. CLINICAL SUBMISSIONS (culture isolates from clinical specimens and/or clinical specimens)

ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
Bacillus anthracis	Culture isolate, Clinical specimens include swab of lesions; tissue; sputum, whole blood (EDTA or sodium citrate), serum, plasma, pleural fluid, respiratory specimens, CSF	Culture, gamma phage, antimicrobial susceptibility testing (Etest), capsule production, PCR, other conventional microbiology tests	**Culture isolate:** 18-24 hr. culture of unknown gram-positive *Bacillus* bacteria, where submitter is unable to rule-out *Bacillus* bacteria when using ASM Sentinel Level Clinical Laboratory Guidelines. **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. •**Culture isolate:** Submit pure isolate on a slant; ship at 15 – 25° C (with room temperature ice packs). • **Clinical specimens**: must be received at 2-8°C, within 14 days of collection. **OR** frozen (≤ -20°C). Frozen specimens are good for up to 28 days post collection.
Brucella species	Culture isolate, Clinical specimens (whole blood [EDTA or sodium citrate] or serum)	Culture, PCR, other conventional microbiology tests	**Culture isolate:** 24-72 hr. culture of unknown gram-negative bacteria, where submitter is unable to rule-out *Brucella* when using ASM Sentinel Level Clinical Laboratory Guidelines. **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. • **Culture isolate:** Submit pure isolate on a slant; ship at 15 – 25° C (with room temperature ice packs). • **Clinical specimens**: must be received at 2-8°C, up to 14 days of collection, **OR** frozen (≤ -20°C). Frozen specimens are good for up to 28 days post collection.

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ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
***Botulinum* toxin**	Contact the NCSLPH at (919) 807-8600 and the CDB at (919) 733-3419	Not performed at the NCSLPH	Contact the NCSLPH BTEP Duty Phone at (919) 807-8600 and CDB at (919) 733-3419	Contact the NCSLPH and the CDB (919) 733-3419. Testing performed at CDC or the Virginia LRN Laboratory
Burkholderia mallei* and/or *Burkholderia pseudomallei	Culture isolate, Clinical specimens (whole blood [EDTA or sodium citrate], bone marrow, serum, sputum, bronchoscopically collected specimens, tissue specimens, wound swabs, and urine)	Culture, PCR, other conventional microbiology tests	**Culture isolate:** 24-72 hr. culture of unknown gram-negative bacteria, where submitter is unable to rule-out *Burkholeria* when using ASM Sentinel Level Clinical Laboratory Guidelines. **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. •**Culture isolate:** Submit pure isolate on a slant; ship at 15 – 25° C (with room temperature ice packs). • **Clinical specimens**: •For culture inoculation: specimens must be received within 24 hours of collection to inoculate cultures. If specimens received within 2 hours of collection, specimens can be received at 15 – 25° C. If received 2-24 hours post collection, specimens must be received at 2-8°C. •For PCR: specimens must be received at 2-8°C, up to 14 days of collection, **OR** frozen (≤ -20°C). Frozen specimens are good for up to 28 days post collection.

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TABLE 2. CLINICAL SUBMISSIONS (culture isolates from clinical specimens and/or clinical specimens)

ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
Coxiella burnetii	Clinical specimens only (whole blood [EDTA or sodium citrate], tissues, body fluids, cell cultures, cell culture supernatants, serum). Specimens must be collected within 72 hours of initiation of antibiotic therapy, or, if occurring outside of this established time frame, patients must be symptomatic.	PCR	**Clinical specimens** – Refer to ASM Sentinel Level Clinical Laboratory Guidelines, CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. • **Clinical specimens**: must be received at 2-8°C, within 7 days of collection, **OR** frozen (≤-20°C). Frozen specimens are good for up to 60 days post collection.
Francisella tularensis	Culture isolate, Clinical specimens (whole blood [EDTA or sodium citrate], swab of lesion, aspirate, bronchial/tracheal wash, pleural fluid or sputum)	Culture, DFA, PCR, other conventional microbiology tests	**Culture isolate:** 24-72 hr. culture of unknown gram-negative bacteria, where submitter is unable to rule-out *Francisella* when using ASM Sentinel Level Clinical Laboratory Guidelines. **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. •**Culture isolate:** Submit pure isolate on a slant; ship at 15 – 25° C (with room temperature ice packs). • **Clinical specimens**: must be received at 2-8°C, within 14 days of collection, **OR** frozen (≤ -20°C). Frozen specimens are good for up to 60 days post collection.

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TABLE 2. CLINICAL SUBMISSIONS (culture isolates from clinical specimens and/or clinical specimens)

ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
Yersinia pestis	Culture isolate, Clinical specimens (whole blood; tissue; lymph node aspirate; bronchial wash, transtracheal aspirate, sputum, nasopharyngeal swabs)	Culture, phage, PCR, other conventional microbiology tests	**Culture isolate:** 24-72 hr. culture of unknown gram-negative bacteria, where submitter is unable to rule-out *Yersinia* when using ASM Sentinel Level Clinical Laboratory Guidelines. **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. •**Culture isolate:** Submit pure isolate on a slant; ship at 15 – 25° C (with room temperature ice packs). • **Clinical specimens**: must be received at 2-8°C, within 7 days of collection, **OR** frozen (≤ -20°C). Frozen specimens are good for up to 60 days post collection.
Avian influenza	Contact the NCSLPH and the CDB at (919) 733-3419	Not performed at NCSLPH. The NCSLPH will contact the CDC	Contact the NCSLPH and the CDB (919) 733-3419	

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TABLE 2. CLINICAL SUBMISSIONS (culture isolates from clinical specimens and/or clinical specimens)

ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
Variola virus (smallpox), *Orthopox* virus, Non-Variola *Orthopox,* and Varicella-Zoster Virus (VZV)	Clinical specimens - Vesicle fluid, skin, crust, "roof", dry or wet swab of lesion, touch prep (slide), biopsy (no formalin), formalin-fixed tissue, EM grids	PCR; Electron Microscopy if needed (for Variola virus)	Contact the NCSLPH (BTEP 24/7 Duty Phone 919-807- 8600) and the CDB (919)733-3419 **Clinical specimens** – Refer to CDC website / LRN procedure.	•Contact BTEP Duty phone for submission approval •Package as Category A •All specimens shipped via contract or commercial courier. • **Clinical specimens**: must be refrigerated or frozen within one hour of collection. Specimens must be received at 2-8°C, within 7 days of collection, **OR** frozen (≤ -20°C). Frozen specimens are good for up to 60 days post collection.
Ebolavirus Disease (EVD) CDC approval for testing is required. Contact the NCSLPH BTEP 24/7 Duty Phone (919) 807-8600 and the CDB (919) 733-3419	Clinical Specimens - Whole blood in EDTA, serum, plasma, urine	PCR	**Clinical specimens** – Refer to CDC website / LRN procedure.	•Upon testing approval from CDC, contact BTEP Duty Phone for submission guidelines. •Package as Category A •All specimens shipped via contract or commercial courier. •**Clinical Specimens** must be received at 2-8°C.

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TABLE 2. CLINICAL SUBMISSIONS (culture isolates from clinical specimens and/or clinical specimens)

ORGANISM/ AGENT/TOXIN	SAMPLE	TESTING PERFORMED	COLLECTION	SHIPPING REQUIREMENTS Do NOT use State Courier
Marburgvirus Disease **CDC approval for testing is required.** Contact the NCSLPH BTEP 24/7 Duty Phone (919) 807-8600 and the CDB (919) 733-3419	Clinical Specimens - Whole blood in EDTA, serum, plasma, urine	PCR	**Clinical specimens** – Refer to CDC website / LRN procedure.	•Upon testing approval from CDC, contact BTEP Duty Phone for submission guidelines. •Package as Category A •All specimens shipped via contract or commercial courier. •**Clinical Specimens** must be received at 2-8°C.
***MERS-CoV (Middle Eastern Respiratory Syndrome Coronavirus*)** **Epi CDB approval for testing is required.**	Clinical specimens - Lower respiratory specimen (bronchial lavage or sputum), NP and/or OP swab, serum	PCR	**Clinical specimens** – Refer to CDC website / LRN procedure for multiple specimen types	•Upon testing approval from CDB, DPH Epidemiology, contact BTEP Duty Phone for submission guidelines. •Package as Category B •All specimens shipped via contract or commercial courier. •**Clinical Specimens** must be received at 2-8°C.
Ricin	Performed on environmental samples	Time Resolved Immunofluorescence (TRF)	Contact the NCSLPH (BTEP 24/7 Duty Phone 919-807- 8600)	See **Table 1**, environmental submissions.

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Ricinine (biomarker associated with ricin poisoning)	Urine (collect within 48 hours of exposure).	Performed by Chemical Terrorism and Testing Unit (CTAT) - LC-MS/MS	Freeze (≤ -20°C) as soon as possible.	Urine must be transported frozen (-20 ± 5°C).

All BTEP clinical specimens and samples	• Specimens and samples should be packaged Category A and either driven to the lab by contract courier, Law Enforcement, or shipped via UPS / FEDEX Overnight Priority, following DOT/IATA regulations. All specimens and samples sent to BTEP for rule out testing must be coordinated through the BTEP Unit. Call 24/7 BTEP Duty Phone at 919-807- 8600. • Unlabeled specimens or specimens received outside of stated parameters (temperature, time, etc.) with be rejected.

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Table 3. **FOOD SUBMISSIONS FOR BTEP**

SAMPLE TYPE		COLLECTION & PRESERVATION	PACKAGING & SHIPPING
Solid food >50 grams	Contact NCSLPH at 919-807-8600 first	Cut or separate portions of food with sterile knife or other implement. Aseptically collect a representative sample; transfer to sealable plastic bag or other leak-proof sterile container and refrigerate until transport.	Label each food item; pack in an insulated container with cold packs and take to the NCSLPH as soon as possible.
Liquid food >50 mls	Contact NCSLPH at 919-807-8600 first	Stir or shake liquid to mix contents. Aseptically collect sample in a leak-proof sterile container and refrigerate until transport.	Label each food item; pack in an insulated container with cold packs and take to the NCSLPH as soon as possible.

Dehydrated food >50 grams	Contact NCSLPH at 919-807-8600 first	Aseptically collect a representative sample using a sterile implement. Transfer to a sealable plastic bag or other leak-proof sterile container and refrigerate until transport.	Label each food item; pack in an insulated container with cold packs and take to the NCSLPH as soon as possible.
Frozen food >50 grams	Contact NCSLPH at 919-807-8600 first	Chip food with a sterile implement. Aseptically collect a representative sample; transfer to sealable plastic bag or other leak-proof sterile container and refrigerate until transport.	Label each food item; pack in an insulated container with cold packs or dry ice and take to the NCSLPH as soon as possible.

All BTEP clinical samples	• All samples should be either driven to the lab by contract courier or Law Enforcement or shipped via FEDEX Overnight Priority following DOT/IATA regulations. All samples sent to BTEP for rule out testing must be coordinated through the BTEP Unit. Call 24/7 BTEP Duty Phone at 919-807-8600. • Unlabeled specimens with be rejected.

CHEMICAL TERRORISM AND THREAT

All samples	• All samples should be either driven to the lab by contract courier or Law Enforcement or shipped via FEDEX Overnight Priority following DOT/IATA regulations.
Toxic Metals in Urine	**SPECIMEN REQUIREMENTS** **Procedures for collecting, storing, and handling specimens** 1. This method does not require any special instructions such as fasting or a special diet before collection of urine.

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	2. The specimen type is urine. 3. Acceptable containers are sterile, screw-capped, plastic containers for specimen collection. 4. Collect at least 40-60 mL of urine for each patient. Do not overfill. Freeze as soon as possible (-20°C (±5°C) or dry ice preferred). 5. In general, urine specimens should be transported frozen, preferably packed in dry ice. However, if dry ice is not available specimens may be shipped frozen with freezer packs. 6. Once received, store at 1-10°C until time for analysis (if storing long term prior to analysis, store at ≤-20°C). Refreeze unused portions of the sample that remain after analytical aliquots are withdrawn at ≤-20°C. Thawing and refreezing samples has not been found to compromise results. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (<2.0 mL), specimen not cold or frozen, or suspected contamination due to improper collection procedures or collection devices. In these cases, a second urine specimen should be requested.
Toxic Metals in Whole Blood	**SPECIMEN REQUIREMENTS** **Procedures for Collecting, Storing and Handling Specimens** 1. This method does not require any special instructions such as fasting or a special diet. 2. The specimen type is anticoagulated whole blood. 3. Acceptable containers include pre-screened polyethylene vials and pre-screened vacutainers containing EDTA. 4. Optimal amount of specimen required is 1+ mL, minimum is 0.25 mL. 5. Draw the blood through a stainless-steel needle into a pre-screened vacutainer. 6. Specimens should be transported at 1-10°C. Once received, the specimens are stored at ≤5°C until time for analysis. Specimen stability has been demonstrated for several months at -20°C or at -70°C for several years. Refreeze unused portions of the sample that remain after analytical aliquots are withdrawn at ≤-20°C. Samples frozen and thawed several times are not compromised.

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	Criteria for Specimen Rejection The criteria for an unacceptable specimen are low volume (<0.25mL), out of range temperature (> 10°C), significant clotting, or suspected contamination due to improper collection procedures or collection devices. In all cases, a second blood specimen should be requested.
Cyanide in Whole Blood	**SPECIMEN REQUIREMENTS** **Procedure for collecting, storing and handling specimens** 1. This method does not require any special instructions, such as fasting or special diets. However, a small amount of cyanide is present in all blood samples. Due to the fact that cyanide is present at higher levels in the blood of cigarette smokers, the smoking status the individual providing the specimen should be known but is not required. 2. The specimen type is whole blood. Whole blood specimens should be collected from subjects as quickly as possible after exposure since blood cyanide is rapidly converted in the body to thiocyanate or lost through respiration. 3. Specimens are collected in 5- or 7-mL Vacutainers™ containing K3-EDTA as the anticoagulant. Heparin-anticoagulated Vacutainers™ may also be used. Headspace in the vacutainers should be minimized, if possible. Specimens should be refrigerated at 1- 10°C as soon as possible. 4. In general, whole blood specimens should be transported on cold packs or with enough wet ice to ensure that the samples will remain cool throughout the shipment process. Specimens should not be frozen or stored at freezer temperatures at any time during sample collection and shipment. Special care must be taken in packing to protect tubes from breaking during shipment. a. Specimen stability has been demonstrated for measurement of CN by this method to be at least 4 weeks at 5°C. 5. Once received, specimens should be refrigerated at 1-10°C until time for analysis. Refrigerate (at 1-10°C) portions of the sample that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (<0.75 mL), out of range temperature (>10°C), significant clotting, frozen specimen, suspected contamination, damaged tube and clotting of the specimen. In all cases, a second blood specimen should be requested.

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Tetramine in Urine	**SPECIMEN REQUIREMENTS** **Procedure for collecting, storing and handling specimens** 1. This method does not require any special instructions, such as fasting or special diets. 2. The specimen type is urine. In the case of suspected tetramine exposure, collect urine as soon as possible after the incident. 3. Acceptable containers are sterile, screw-capped, plastic containers for specimen collection. Collect at least 40-60 mL of urine for each patient. Do not overfill. Freeze as soon as possible. 4. In general, urine specimens should be transported frozen, preferably packed in dry ice. If dry ice is not available specimens may be shipped frozen with freezer packs. 5. Once received, store samples in a freezer of at least -20±5°C until time for analysis. Refreeze portions of the sample (at least -20±5°C) that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (<1.2 mL), specimen not cold or frozen, visible blood in the sample and suspected contamination due to improper collection procedures or collection devices. In these cases, a second urine specimen should be requested.
Volatile Organic Compounds in Whole Blood	**SPECIMEN REQUIREMENTS** **Procedure for collecting, storing and handling specimens** 1. This method does not require any special instructions, such as fasting or special diets. 2. The specimen type is anticoagulated whole blood. Specimens are collected in 3, 5 or 7-mL grey-top vacutainers containing potassium oxalate and sodium fluoride, or green-top vacutainers containing heparin. Headspace in the vacutainers should be minimized, if possible. The optimal amount of specimen to collect is 10 mL. The minimum amount is 3 mL. a. Once samples have been collected, they are mixed thoroughly to completely dissolve and distribute the anticoagulant. b. Specimens should be refrigerated at 1-10°C as soon as possible, preferably within 30 mins. 3. In general, whole blood specimens should be transported on cold packs or with enough wet ice to ensure that they remain cool throughout the shipment process. Specimens should not be frozen or

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	stored at freezer temperatures at any time during sample collection and shipment. Special care must be taken in packing to protect tubes from breaking during shipment. a. Specimen stability has been demonstrated for analytes measured by this method to be 16 weeks at refrigerated temperatures (~5°C). 4. Once received, specimens should be refrigerated at 1-10°C until time for analysis. Refrigerate (at 1-10°C) portions of the sample that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criteria for an unacceptable specimen are low volume (< 3 mL), out of range temperature (>10°C), frozen specimen, suspected contamination due to improper collection procedures or collection devices, or significant clotting of the specimen. In all cases, a second blood specimen should be requested.
Ricinine/Abrine in Urine	**SPECIMEN REQUIREMENTS** **Procedures for collecting, storing, and handling specimens** 1. Condition for patient preparation: This method does not require any special instructions, such as fasting or special diets. 2. The specimen type is urine. The specimen should be collected within 48 hours of exposure. 3. Acceptable containers are sterile, screw-capped, plastic containers for specimen collection. Collect at least 40-60 mL of urine for each patient. Do not overfill. Freeze as soon as possible. 4. In general, urine specimens should be transported frozen, preferably packed in dry ice. If dry ice is not available, specimens may be shipped frozen with freezer packs. 5. Once received, store at -20 ±5°C until time for analysis. Refreeze (at -20 ±5°C) portions of the sample that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (<1.0 mL), specimen not cold or frozen, or suspected contamination due to improper collection procedures or collection devices. In all cases, a second urine specimen should be requested.

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HNPAA in Urine	**SPECIMEN REQUIREMENTS** **Procedure for collecting, storing and handling specimens** 1. This method does not require and special instructions such as fasting or special diets. 2. The specimen type is urine. In case of suspected TNM exposure, collect urine as soon as possible after the incident. 3. Acceptable containers are sterile, screw-capped, plastic containers for specimen collection. Collect at least 40-60 mL of urine for each patient. Do not overfill. Freeze as soon as possible (-20°C (±5°C) or dry ice preferred). 4. In general, urine specimens should be transported frozen, preferably packed in dry ice. If dry ice is not available specimens may be shipped frozen with freezer packs. Take special care in packing to protect the urine cups from breakage during shipment. 5. Once received, store samples in a freezer at -20±5°C until time for analysis. Refreeze portions of the sample (at -20±5°C) that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (< 500µL), specimen not cold or frozen, and suspected sample contamination, such as a leaking or a damaged specimen container. In these cases, a second urine specimen should be requested.
Nerve Agents in Urine and Serum	**SPECIMEN REQUIREMENTS** **Procedure for collecting, storing and handling specimens** 1. Condition for patient preparation: This method does not require any special instructions, such as fasting or special diets. 2. The specimen type can be urine or serum. 3. If the specimen type is urine, it should be collected as soon as possible after the incident, preferably within 48 hours of exposure. a. Acceptable containers for urine are sterile, screw-capped, plastic containers for urine specimen collection. Collect at least 40-60 mL of urine for each patient. Do not overfill. Freeze as soon as possible. b. In general, urine specimens should be transported frozen, preferably packed in dry ice. If dry ice is not available, specimens may be shipped with freezer packs.

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	c. Once received, store at -20±5°C until time for analysis. Refreeze (at -20±5°C) portions of the sample that remain after analytical aliquots are withdrawn. 4. If the specimen type is serum, it should be collected as soon as possible after the incident, preferably within 48 hours of exposure. a. In general, serum specimens should be transported frozen, preferably packed in dry ice. If dry ice is not available, specimens may be shipped with freezer packs. b. Once received, store serum specimens at -20±5°C or lower until time for analysis. Refreeze (at -20±5°C) portions of the sample that remain after analytical aliquots are withdrawn. **Criteria for Specimen Rejection** The criterion for an unacceptable specimen is low volume (<1.5ml), specimen not cold or frozen, and suspected sample contamination, such as a leaking or a damaged specimen container. In all cases, a second specimen should be requested.

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APPENDIX B

ENVIRONMENTAL HOLDING TIMES AND SHIPMENT CONDITIONS

Reference *EPA Manual for the Certification of Drinking Water Laboratories*. Not all the environmental tests listed below are performed by the SLPH.

CHEMISTRY

Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time & Storage Conditions	Suggested Sample Size	Type of Container
Metals (except Hg)	HNO_3 pH<2	6 months		1 L	Plastic or Glass
Mercury	HNO_3 pH<2	28 days		100 mL	Plastic or Glass
Alkalinity	Cool, 4C	14 days		100 mL	Plastic or Glass
Asbestos	Cool, 4C	48 hours		1 L	Plastic or Glass
Chloride	none	28 days		100 mL	Plastic or Glass
Residual Disinfectant	none	immediately		200 mL	Plastic or Glass
Color	Cool, 4C	48 hours		100 mL	Plastic or Glass
Conductivity	Cool, 4C	28 days		100 mL	Plastic or Glass
Cyanide	Cool, 4C, Ascorbic acid (if chlorinated), NaOH pH>12	14 days		1 L	Plastic or Glass
Fluoride	none	1 month		100 mL	Plastic or Glass
Foaming Agents	Cool, 4C	48 hours			
Nitrate (chlorinated)	Cool, 4C non-acidified	14 days		100 mL	Plastic or Glass
Nitrate (non-chlorinated)	Cool, 4C, non-acidified	48 hours		100 mL	Plastic or Glass
Nitrite	Cool, 4C	48 hours		100 mL	Plastic or Glass
Nitrate+ Nitrite	H2SO4 pH<2	28 days		100 mL	Plastic or Glass

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Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time & Storage Conditions	Suggested Sample Size	Type of Container
Odor	Cool, 4C	24 hours		200 mL	Glass
pH	none	immediately		25 mL	Plastic or Glass
o-Phosphate	Cool, 4C	48 hours		100 mL	Plastic or Glass
Silica	Cool, 4C	28 days		100 mL	Plastic
Solids (TDS)	Cool, 4C	7 days		100 mL	Plastic or Glass
Sulfate	Cool, 4C	28 days		100 mL	Plastic or Glass
Temperature	none	immediately		1 L	Plastic or Glass
Turbidity	Cool, 4C	48 hours		100 mL	Plastic or Glass
502.2	Sodium Thiosulfate or Ascorbic Acid, 4C, HCl pH<2	14 days		40-120 mL	Glass with PTFE Lined Septum
504.1	Sodium Thiosulfate Cool, 4C	14 days	4C, 24 hours	40 mL	Glass with PTFE Lined Septum
505	Sodium Thiosulfate Cool, 4C	14 days (7 days for Heptachlor)	4C, 24 hours	40 mL	Glass with PTFE Lined Septum
506	Sodium Thiosulfate Cool, 4C, Dark	14 days	4C, dark 14 days	1 L	Amber Glass with PTFE Lined Cap
507	Sodium Thiosulfate Cool, 4C, Dark	14 days (see method for exceptions)	4C, dark 14 days	1 L	Amber Glass with PTFE Lined Cap

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Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time & Storage Conditions	Suggested Sample Size	Type of Container
508A	Cool, 4C	14 days	30 days	1 L	Amber Glass with PTFE Lined Cap
508.1	Sodium Sulfite HCl pH<2 Cool, 4C	14 days (see method for exceptions)	30 days	1 L	Glass with PTFE Lined Cap
515.1	Sodium Thiosulfate Cool, 4C, Dark	14 days	4C, dark 28 days	1 L	Amber Glass with PTFE Lined Cap
515.2	Sodium Thiosulfate or Sodium Sulfite HCl pH<2 Cool, 4C, Dark	14 days	£4C, dark 14 days	1 L	Amber Glass with PTFE Lined Cap
515.3	Sodium Thiosulfate Cool, 4C, Dark	14 days	£4C, dark 14 days	50 mL	Amber Glass with PTFE Lined Cap
515.4	Sodium Sulfite, dark, cool £10C for first 48 hr. £6C thereafter	14 days	21 days at £0C	40 mL	Amber glass with PTFE lined septum
524.2	Ascorbic Acid or Sodium Thiosulfate HCl pH<2, Cool 4C	14 days		40-120 mL	Glass with PTFE Lined Septum
525.2	Sodium Sulfite, Dark, Cool, 4C, HCl pH<2	14 days (see method for exceptions)	30 days from collection	1 L	Amber Glass with PTFE Lined Cap
531.1, 6610	Sodium Thiosulfate, Monochloroacetic acid, pH<3, Cool, 4C	Cool 4C 28 days		60 mL	Glass with PTFE Lined Septum
531.2	Sodium Thiosulfate, Potassium Dihydrogen Citrate buffer to pH 4, dark, £10C for first 48 hr, <6C after that	28 days		40 mL	

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Parameter/ Method	Preservative	Sample Holding Time	Extract Holding Time & Storage Conditions	Suggested Sample Size	Type of Container
547	Sodium Thiosulfate Cool, 4C	14 days (18 months frozen)		60 mL	Glass with PTFE Lined Septum
548.1	Sodium Thiosulfate (HCl pH 1.5-2 if high biological activity) Cool, 4C, Dark	7 days	14 days £4C	[3] 250 mL	Amber Glass with PTFE Lined Septum
549.2	Sodium Thiosulfate, (H_2SO_4 pH<2 if biologically active) Cool, 4C, Dark	7 days	21 days	[3] 250mL	High Density Amber Plastic or Silanized Amber Glass
550, 550.1	Sodium Thiosulfate Cool, 4C, HCl pH<2	7 days	550, 30 days 550.1, 40 days Dark, 4C	1 L	Amber Glass with PTFE Lined Cap
551.1	Sodium Sulfite, Ammonium Chloride, pH 4.5-5.0 with phosphate buffer Cool, 4C	14 days		[3] 40 mL	Glass with PTFE Lined Septum
552.1	Ammonium chloride Cool, 4C, Dark	28 days	£4C, dark 48 hours	250 mL	Amber Glass with PTFE Lined Cap
552.2	Ammonium chloride Cool, 4C, Dark	14 days	7 days £4C, dark 14 days £-10C	50mL	Amber Glass with PTFE Lined Cap
555	Sodium Sulfite HCl, pH£2 Dark, Cool 4C	14 days		[3] 100 mL	Glass with PTFE Lined cap
1613	Sodium Thiosulfate Cool, 0-4C, Dark		Recommend 40 days	1 L	Amber Glass with PTFE Lined Cap

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RADIOCHEMISTRY

Parameter	Preservative	Container	Maximum* Holding Time
Gross Alpha	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Gross beta	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Strontium-89	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Strontium-90	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Radium-226	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Radium-228	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Cesium-134	Conc. HCl to pH <2	P or G	6 mo
Iodine-131	None	P or G	8 days
Tritium	None	G	6 mo
Uranium	Conc. HCl or HNO_3 to pH <2	P or G	6 mo
Photon emitters	Conc. HCl or HNO_3 to pH <2	P or G	6 mo

*The holding time varies for non-EPA public water supply samples.

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ENVIRONMENTAL MICROBIOLOGY

Total Coliforms	• The time between sample collection and the placement of sample in the incubator must not exceed 30 hours (per regulation at 40 CFR 141.21(f)(3)). All samples received in the laboratory should be analyzed on the day of receipt. If the laboratory receives the sample late in the day, the sample may be refrigerated overnight as long as analysis begins within 30 hours of sample collection.
Total coliforms and fecal coliforms in surface water sources	• Preferably should not exceed eight hours. The maximum time the sample should be held in the refrigerator is 24 hours at 4˚C.
Heterotrophic bacteria in drinking water	• Preferably should not exceed eight hours. The maximum time the sample should be held in the refrigerator is 24 hours at 4˚C.

Pseudomonas, *Enterococcus*, Iron Bacteria and Sulfate Reducing/Sulfur Bacteria are not EPA regulated and therefore do not appear in the above table from the Certification Manual. For *Pseudomonas* and *Enterococcus*, a standard 150-mL bottle will be provided containing a dechlorinating agent. Do not exceed 30 hours between collection and analysis in the laboratory. Sulfate Reducing/Sulfur bacteria are collected in a 1-Liter cubitainer. Iron bacteria are typically submitted in a cubitainer but a 50-mL tube may also be used.

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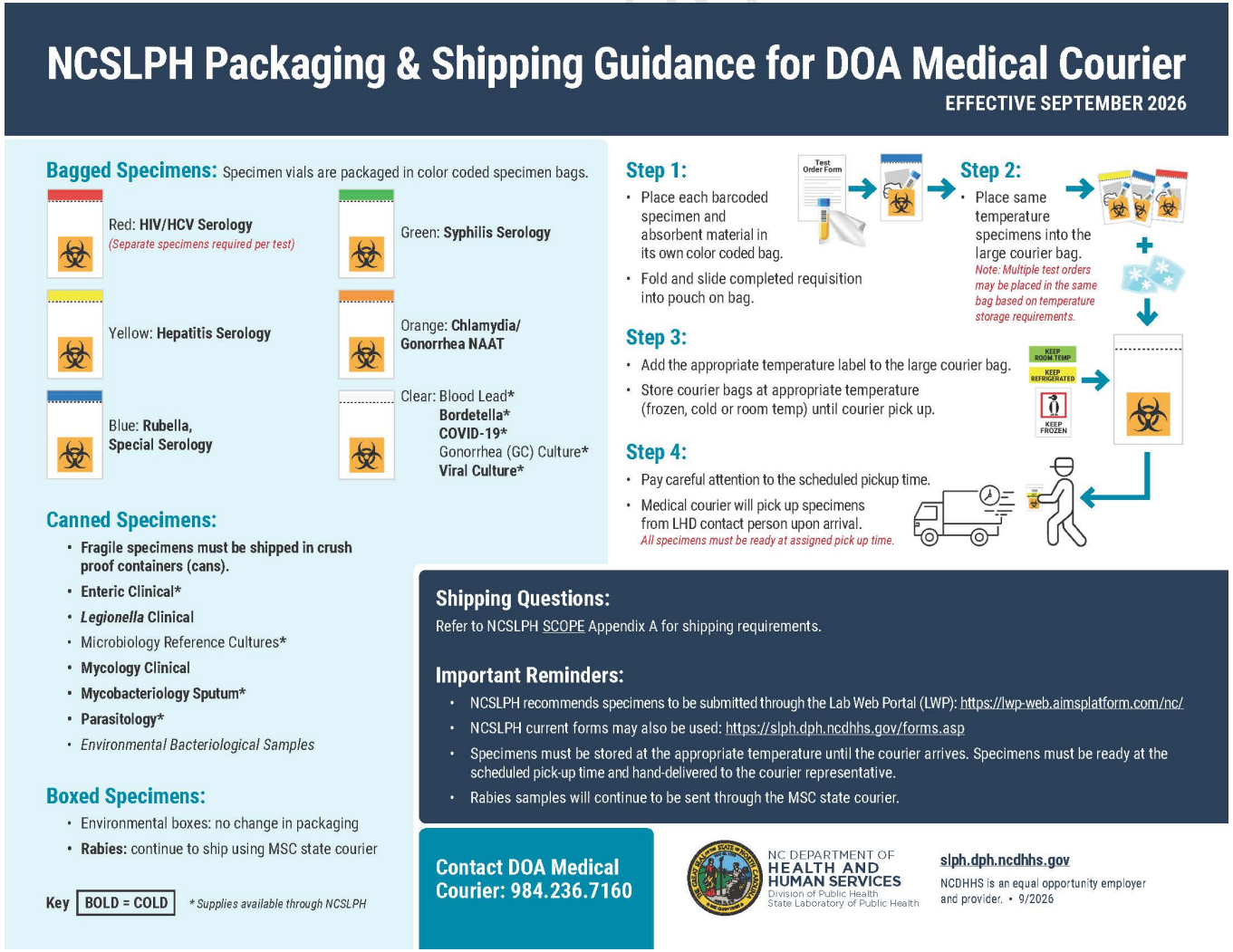
APPENDIX C: NCSLPH CLINICAL SPECIMEN STORAGE, SHIPPING, AND TRANSPORT

Local Health Department specimen/sample transport guidance



NCSLPH Clinical Specimen Storage and Shipping

Clinical specimens for testing at the NCSLPH should be shipped within 24 hours of collection.
When shipping must be delayed (e.g., inclement weather, courier closures), guidelines are given below on proper storage and shipping of common specimen types. Please see our SCOPE for detailed guidance.

	If shipping immediately	*If shipping is delayed*
COVID-19 + Flu PCR	≤ 72 hours	DRY ICE REQUIRED
Legionella Clinical**	≤ 3 days	DRY ICE REQUIRED
CHIKV, EEE, LACV, SLE, WEE, WNV	≤ 2 days	DRY ICE REQUIRED
Dengue (DENV)	≤ 5 days	DRY ICE REQUIRED
Hepatitis A (HAV)	≤ 5 days	DRY ICE REQUIRED
Hepatitis B (HBV)	≤ 4 days	DRY ICE REQUIRED
Hepatitis C (HCV)	≤ 5 days	DRY ICE REQUIRED
HIV	≤ 5 days	DRY ICE REQUIRED
HIV/HCV	≤ 5 days	DRY ICE REQUIRED
Measles/Mumps PCR*	≤ 3 days	DRY ICE REQUIRED
Measles Serology*	≤ 3 days	DRY ICE REQUIRED
Rickettsia + Ehrlichia	≤ 3 days	DRY ICE REQUIRED
Rubella IgG	≤ 5 days	DRY ICE REQUIRED
Syphilis RPR	≤ 5 days	DRY ICE REQUIRED
Syphilis TP	≤ 5 days	DRY ICE REQUIRED
Bordetella Culture**	≤ 3 days	
Bordetella PCR**	≤ 7 days	
HSV/VZV NAAT	≤ 5 days	
Hemoglobinopathy Whole Blood	≤ 6 days	
Legionella Culture**	Ship as soon as possible	
Micro Reference Cultures	Ship ambient as soon as possible	
NBS Dried Blood Spots (DBS)	≤ 14 days, avoid excessive heat and/or humidity	
Hemoglobinopathy Screening DBS	≤ 14 days	
Neisseria Culture	Must be shipped ambient as soon as possible, see SCOPE for N. gonorrhoeae subculture details	
Blood Lead	≤ 14 days for capillary and venous specimens at ambient (15-38 °C) temperature. See SCOPE for details on submitting cold or frozen specimen.	
BTEP* and CTAT*	Call 919-807-8600 (BTEP) or 919-602-2481 (CTAT) prior to any submission for guidance on collection, labeling, packaging, and shipment	
Chlamydia/Gonorrhea TMA	May be received cold or ambient, ≤ 28 days	
Enteric Bacteriology	Varies by specimen type, see SCOPE for details	
Mycobacteriology (TB)	Varies by specimen type, see SCOPE for details	
Mycology	Varies by specimen type, see SCOPE for details	
Parasitology	Varies by specimen type, see SCOPE for details	
Rabies	Ship cold ASAP, freezing not recommended	
Viral Culture	Varies by specimen type, see SCOPE for details	

LHDs follow NCSLPH DOA Medical Courier Packaging & Shipping Guidance.

Refrigerate specimens 2-8°C post collection. Specimens must be received cold (2-8°C) on frozen ice packs within the number of hours/days as indicated in the chart from time of collection.

Freeze specimens at ≤ -70°C post collection. Ship overnight via commercial courier on dry ice.

Freeze specimens at ≤ -20°C post collection. Ship overnight via commercial courier on dry ice.

** Specimens must be received cold (1-8°C) on frozen ice packs.
* Submission requires prior approval.

Store and ship at ambient temperature. Specimens must be received within the number of hours/days as indicated in the chart from time of collection.

Unique requirements, refer to SCOPE.

NCSLPH DOA Medical Courier Packing and Shipping Guidance

NC Department of Health and Human Services
Division of Public Health North Carolina State Laboratory of Public Health
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