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July, 2013

Dear Georgia Public Health Laboratory Customer:

We are pleased to provide you with the latest revision of the “Laboratory Service Manual” (LSM) for the Georgia Public Health Laboratory (GPHL). We have included material about changes to our service menu and in the way we provide services. For those of you who have Internet access, the LSM is available on the Department of Public Health Web Site at www.health.state.ga.us/programs/lab/index.asp. At this website you will also find the new consolidated GPHL Submission Form (#3583) for submitting all specimens other than Newborn Screening, as well as Fee and FAQ lists.

If you have any questions or concerns regarding the services provided by the Georgia Public Health Laboratory, please do not hesitate to contact me at 404/327-7900 or to call one of the Service Directors, Unit Supervisors or Managers listed in the following pages. As always, we solicit your comments and suggestions. Thank you for your continued enthusiastic support of the Georgia Public Health Laboratory and our work on behalf of the citizens of Georgia.

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DIAGNOSTICS LABORATORY SERVICES

MICROBIOLOGY SERVICES
INTRODUCTION

The Bacteriology Unit accepts cultures for the isolation of Bordetella pertussis and Bordetella parapertussis, nasopharyngeal swabs in charcoal-blood transport medium for both agents, and slides for direct fluorescent antibody (DFA) testing. Specimens may be sent from public and private health care providers.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Nasopharyngeal secretions are the optimal specimens for isolating pertussis bacterium and obtaining a lab confirmed diagnosis. A specimen should be collected as soon as possible after onset of illness, preferably before antibiotic treatment. Polyester (Dacron), rayon, or nylon-flocked swabs are superior to other types of swabs and are recommended for use in collecting nasopharyngeal specimens. Cotton-tipped or calcium alginate swabs are not suitable. Regan Lowe semisolid transport medium tube is recommended for transport to the laboratory. The medium should be stored in a refrigerator at 2-8 degrees Celsius. Note: Regan-Lowe medium should be removed from the refrigerator and warmed to room temperature before use.

A. Specimen for Nasopharyngeal Swab Culture:
   1. Immobilize and tilt the patient’s head.
   2. Pass nasopharyngeal swab very gently into a nostril until the posterior nares is reached.
   3. Leave the swab in place for up to 10 seconds (this may induce a cough and in practice only a few seconds may be possible.) If resistance is encountered during insertion of the swab, remove it and attempt insertion on the opposite nostril.
   4. Remove the swab slowly.
   5. Streak slides (frosted side up) then insert and immerse swab into the tube of Regan-Lowe transport medium, available commercially. Cut the handle end of the swab extending above the transport tube if necessary and cap the container tightly. Note: If Regan-Lowe plate is used, streak the plate and then discard the swab.
   6. Label slide holder with the patient’s name and date of specimen collection (avoid using wax pencil or gummed labels on slides).
   7. Label Regan-Lowe transport tube with the patient’s name and date of specimen collection.
B. Specimen for Slides:
Prepare 2 dime-sized smears on each of 2 microscope slides (one slide per nostril). Use frosted-end slides with prestamped circles if possible (frosted side up). Label slide holder with the patient’s name or other unique identifier and date of specimen collection (avoid using wax pencil or gummed labels on slides).

C. Culture (B. pertussis isolated at submitting laboratory):
1. Inoculate a pure culture onto a plate of charcoal agar with horse blood, such as Regan-Lowe medium, and send to GPHL within 24 hours or incubate at 35° C under high humidity. Schedule sub-culture so that time between optimal growth and transport of culture is < 24 hours.
2. Examine medium beginning after 3 days incubation until confluent growth appears in the first quadrant of the plate.
3. Using a polyester (Dacron), rayon, or nylon-flocked swab; aseptically harvest all growth from the first quadrant of the plate by sweeping the swab head through the area of confluent growth while rotating the swab shaft. Immerse swab containing harvested growth 2mm deep into the agar of a charcoal-blood transport tube, warmed to room temperature.
4. Aseptically cut the swab shaft flush with the top of the transport tube and replace cap.
5. Label transport tube with patient identifier information.
6. Maintain additional subculture(s) on plates at submitting laboratory until viability of referred culture is confirmed by the Bacteriology Unit.

Requisition Form:
Use form #3583 for specimen submission. It is extremely important that the form is entirely completed. Please include the following information:
1. Unique patient identifier (name or number).
2. Date of specimen collection.
3. Test requested, such as culture for B. pertussis and B. parapertussis or DFA.
4. Submitter’s name and address.
5. Name and telephone number of clinician to contact.
6. Source of specimen, such as nasopharyngeal.
7. Patient’s race, sex, age, and address, if available.
8. Brief clinical history, if available.

The patient identifier (name, number, or both) indicated on the requisition form should match that written on the slide holder, transport tube, or culture. Unlabeled specimens will not be tested.

SHIPMENT OF SPECIMENS AND CULTURES

Note: Always submit the specimen/culture according to current DOT and IATA guidelines.
A. Slides: Place slides securely in the plastic slide holders provided (outfit #0525, available from Laboratory Services and Supply, 404-327-7920). Place plastic holder in a plastic biohazard bag. Insert requisition form in the pouch in the front of the bag. Place the bag with form affixed in the orange-labeled cardboard mailing container (Decatur address). Seal the lid of the outside container with tape. The specimens should be transported (room temperature) to the Bacteriology Unit immediately by a courier or a shipping vendor with a traceable system. If the shipment is delayed, the specimens should be refrigerated at 2-8 degrees Celsius and then sent the next day on ice packs by a courier or a shipping vendor with a traceable system.

B. Nasopharyngeal Specimens for Culture: The method of shipment is dependent upon the selection of transport media used and the length of time required to arrive at the Bacteriology Unit. Inoculated plates must be incubated at 35° C with increased humidity or transported (room temperature) to the Bacteriology Unit immediately by courier. Specimens in tubes of charcoal-blood transport media should be transported (room temperature) to the Bacteriology Unit immediately by courier, or if there is any delay in shipment, they should be stored and sent refrigerated (with ice packs) by a courier or a shipping vendor with a traceable system.

C. Isolates inoculated into charcoal-blood transport media may be shipped at room temperature within 24 hours by a courier or a shipping vendor with a traceable system.

REPORTING AND INTERPRETATION OF RESULTS

Results of DFA testing are completed the day of receipt or next day. Results of positive reports are telephoned to the submitter the day of testing. Nasopharyngeal smears are reported positive for *Bordetella pertussis* if there are ≥ 5 organisms present with typical cellular morphology and intense fluorescence. Due to shortage of quality reagent, *Bordetella parapertussis* DFA testing is confined to confirmation of positive cultures for this organism.

Cultures are held for 7-10 days from the date of inoculation and read daily. Nasopharyngeal swabs received in transport medium tubes are inoculated immediately onto Regan-Lowe plates when received and then incubated. After the final day of incubation, if there are no colonies typical of *B. pertussis* or *B parapertussis* present, the culture is reported negative for these organisms. A positive culture report is based upon typical cellular and colonial morphology and is confirmed by fluorescent antibody testing. Positive cultures or cultures overgrown with mold or normal flora are reported immediately upon detection, and results are telephoned to the submitter.

Both culture and DFA procedures are recommended for diagnosis of *B. pertussis* whenever possible. “False negative” DFA results may occur from low numbers of
organisms present in nasopharyngeal secretions. The DFA test is most valuable during the early phase of illness and before antibiotic treatment when the largest numbers of organisms are being shed. Positive FA results should be considered presumptive. As with any subjective test, “false positive” DFA results are possible. Only highly experienced staff in the Bacteriology Unit read slides and report results to minimize false positives. “False negative” culture results may follow from any procedures that render the organisms nonviable, such as improper handling of plates and transport medium after collection or prolonged antibiotic treatment. The DFA test will detect nonviable organisms. A positive culture result is the most reliable.

**UNACCEPTABLE SLIDES AND CULTURES**

1. Smears that are too thick or too thin for accurate interpretation
2. Slides broken in transit.
3. Cultures overgrown with mold or normal flora.
4. Cultures or transport medium improperly submitted (see above for the recommended procedure).
5. No patient identifier on specimen or culture.
INTRODUCTION

The Bacteriology Unit uses Target-amplified direct nucleic acid amplification test for chlamydia and gonorrhea. *Chlamydia trachomatis* is the most commonly reported bacterial sexually transmitted disease in the US. Complications of untreated chlamydial infection in females include acute pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, and infertility. *Neisseria gonorrhoeae* often pass unnoticed and asymptomatic carriers contribute significantly to the public health concern of gonorrhea. In women, gonorrhea is a common cause of pelvic inflammatory disease.

The screening criteria for chlamydia and gonorrhea have been revised based on risk criteria and national recommendations. The screening criteria for Georgia are:

**Family Planning:**
- Screen at the routine initial/annual exam:
  - all clients less than age 26;
- For clients ages 26 and over only screen the following:
  - a client being prepared for IUD insertion;
  - a client with documented NEW signs or symptoms;
  - a client named as a contact;
  - a client using drugs;
  - a client exchanging sex for money or drugs;
  - a client who have multiple partners or a new partner in the past 60 days.
- Regardless of age, a client who has been treated for a positive chlamydia or gonorrhea test should be retested 3 months after treatment or whenever the client next seeks medical care within the following 3-12 months regardless of whether the client believes partner was treated. After 12 months from treatment or if they come in and are symptomatic their visit will be considered a new visit.

**STD:**
- Test STD clients:
  - Of women less than age 26
  - if contact to any STD;
  - if symptomatic for any STD;
  - a client who request an examination for any STD.
- Regardless of age, a client who has been treated for a positive chlamydia or gonorrhea test should be retested 3 months after treatment or whenever the
client next seeks medical care within the following 3-12 months regardless of whether the client believes partner was treated. After 12 months from treatment or if they come in and are symptomatic their visit will be considered a new visit

- **Notable exception:** CT/GC should be offered to clients requesting only an HIV test and who are asymptomatic for any other STD.

**EPSDT:**
- All sexually active minors should be screened for sexually transmitted diseases (STDs) during routine EPSDT visits.
- All sexually active minors should be tested for STDs during annually EPSDT visits.

**Adult Health/Other:**
- Offer testing to any sexually active client less than age 26.
- Test clients with signs or symptoms suggestive of gonorrhea or chlamydia.

**SPECIMEN COLLECTION/LABELING/REQUISITION FORM**

The APTIMA Combo 2 Assay is designed to detect the presence of *C. trachomatis* and *N. gonorrhoeae* in urine, endocervical and urethral specimens. The Georgia Public Health Laboratory has validated testing for rectal and pharyngeal specimens. Specimens can be submitted for these collection sites per instructions provided below. **Please note that the existing Gen Probe unisex collection kit will be used for these specimens.** Specimen collection kits are supplied to the health districts for clients seen at the Public Health STD and Family Planning Clinics.

**Endocervical swab**
1. Remove excess mucus from the cervical opening and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab. **Note:** To remove excess mucus from the cervical opening, a large tipped cleaning swab (not provided) may be used. Discard the swab after use.
2. Insert the specimen collection swab (blue shaft) into the endocervical canal.
3. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft at the score line; avoid splashing the contents.
7. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.
**Male urethral swab**

1. The patient should not have urinated for at least one hour prior to specimen collection.
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
3. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
4. Withdraw the swab carefully.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
6. Carefully break the swab shaft at the score line; avoid splashing the contents.
7. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Urine**

**Note:** The patient should not have urinated for at least one hour prior to specimen collection.

1. Direct the patient to provide first catch urine (approximately 20 to 30 ml of the initial urine stream) into a urine collection cup which is free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
2. Remove the cap and transfer 2 ml of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube label.
3. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Rectal Specimens for Males**

**Note:** Rectal testing of asymptomatic females is not recommended for routine screening since there is no data on the sequel of rectal infection and females who are engaged in rectal sex only, are not necessarily positive for vaginal sex.

1. Insert the unisex (blue shaft) swab 3-5 cm in the rectum and rotate 3-4 times.
2. Withdraw the swab carefully.
3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
4. Carefully break the swab shaft at the score line; avoid splashing the contents.
5. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Pharyngeal Specimens**

1. Press the tongue with a tongue depressor and insert the unisex (blue shaft) specimen swab and firmly rub the tonsils and the posterior of pharynx.
2. Withdraw the swab carefully.
3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
4. Carefully break the swab shaft at the score line; avoid splashing the contents.
5. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Requisition Form:**

Use form #3583 for specimen submission. Fill out the form completely by printing or typing legibly. Only legible information can be entered correctly into the laboratory database. Incomplete or illegible information may delay your results. Information required is as follows:

1. **Submitter information** (submitter code, submitter address, and phone number).
2. **Patient information** (name, patient ID number, county of residence, zip code, State, race, ethnicity, gender, date of birth).
3. **Specimen information** (test requested, reason for test, date collected, source of specimen, specimen status).

The patient identifier (name, number, or both) indicated on the requisition form should match that written on transport tube. **Unlabeled specimens will not be tested.**

**SHIPMENT OF SPECIMENS**

For best results, specimens should be transported to the laboratory on the date of collection; however, if this is impossible, specimens may be kept at room temperature and shipped as soon as possible by a courier or a shipping vendor with a traceable system. **Urine specimens over 30 days old and/ or swab specimens over 60 days old at the time of arrival in the laboratory will be reported unsatisfactory.**

1. Chlamydia/Gonorrhea APTIMA Combo 2 specimens may be transported at room temperature. Use the specimen transport cans and Decatur address labels (available from the laboratory).
2. Be sure the caps on the transport tubes are secure, and wrap each specimen in absorbent packing material. Place the wrapped specimen inside the aluminum can, and close the can securely.
3. Wrap the completed requisition form around the aluminum can and secure it with a rubber band.
4. Place the aluminum can inside the labeled (Decatur address) fiberboard can, close, and secure the lid with tape.
5. An alternate shipping method may be utilized by substituting the biohazard bag for the inner aluminum container. If this method is chosen, the matching requisition forms should be placed in the pouch located in the front of each bag.
6. Specimens may be sent by a courier or a shipping vendor with a traceable system.

REPORTING AND INTERPRETATION OF RESULTS

An electronic copy of all positive Chlamydia and Gonorrhea reports is transmitted to the State Sexually Transmitted Disease (STD) Program. A hard copy of all positives is also mailed to the State STD Surveillance Office.

Results are reported as follows:
1. Positive for *C. trachomatis* and/or *N. gonorrhoeae* by Amplified Aptima Combo 2 Assay.
2. Negative for *C. trachomatis* and/or *N. gonorrhoeae* by Amplified Aptima Combo 2 Assay.
3. Indeterminate, a new specimen should be collected.
4. Unsatisfactory, specimen compromised in some manner making it unsatisfactory for testing. The reason for each unsatisfactory result will be listed on the report form.

UNACCEPTABLE SPECIMENS

1. No patient identifier on the specimen, or discrepancy between identifier on the specimen and requisition form.
2. Cleaning swab is used for specimen collection and placed in the specimen collection tube.
3. Two swabs received in the specimen collection tube.
4. No solution in the specimen collection tube.
5. No swab or improper swab (not from Gen-Probe kit) in the collection outfit.
6. Urine specimens over 30 days old and/or swab specimens over 60 days old from date of collection when received.
7. Collection kit expired.
8. No specimen received.
10. Overfilled. Liquid level in the urine transport tube must fall between the two black indicators lines.
**ENTERIC BACTERIOLOGY**  
404-327-7997

**INTRODUCTION**

The **Bacteriology Unit** examines feces and other specimens for the presence of enteric pathogens, namely *Salmonella* serotypes, *Shigella sp, Campylobacter sp., Aeromonas sp., Yersinia enterocolitica*, and Shiga-like toxin producing *E. coli* (STEC), on a routine basis. Testing for Shiga-like toxin (SLT) will be done on all diarrheal stools and on all stools when STEC is requested. Stool specimens for other foodborne etiologic agents, such as *Bacillus cereus, Staphylococcus aureus, Vibrio sp.* and *Clostridium perfringens*, will be tested if the patient’s clinical history and the epidemiological data warrant testing (see section on Foodborne Illness). Environmental samples may be accepted for enteric culture, testing only when implicated in cases of human illness or by prior consultation.

**All isolates** of *Salmonella, Shigella, Campylobacter, STEC, Yersinia enterocolitica*, and *Vibrio* recovered from specimens by other clinical laboratories in Georgia should be referred to the Bacteriology Unit, either directly or through the Emerging Infections Program (EIP) site. Referred isolates will be further characterized by various methods, such as biochemical reactions, serogrouping and serotyping, Polymerase Chain Reaction (PCR) and by Cell Wall Fatty Acid Analysis when necessary. **Pulsed-Field Gel Electrophoresis (PFGE)** will be performed on selected serotypes of *Salmonella* and STEC to determine if strains are related.

**SPECIMEN COLLECTION/LABELING/REQUISITION FORM**

A. Feces Specimens for *Salmonella, Shigella, Campylobacter, Aeromonas, Yersinia, STEC, Listeria, Staphylococcus aureus, and Vibrio*

1. Feces specimens for the above agents should be collected in the ParaPak C&S outfit, orange-colored top (do not use the Parasitology O&P kit, blue and white-colored top, because it contains formalin that kills bacteria). Collect freshly passed feces as soon as possible after onset of illness and before antimicrobial therapy has been initiated (stools for *S. aureus* must be collected within 24 hours after onset). The patient should be cautioned against the use of antacid, barium, bismuth, anti-diarrheal medication or oily laxatives prior to specimen collection. An appropriate (i.e. bloody, slimy, watery) area of stool should be selected and sampled with the collection spoon provided on the cap of the container. Add specimen only to the red line on the vial, tighten the cap securely, and invert several times. The solution in the vial should be salmon colored before the specimen is added. Three consecutive specimens collected on different days during the acute stage of diarrheal disease are suggested (first three days). Ship at **room temperature**.
2. Rectal swabs containing detectable feces may be collected and placed in a Culturette with Stuarts, Cary-Blair, or other commercially available transport medium, if a feces specimen cannot be obtained. Ship under appropriate conditions for the transport medium and test to be performed. **Note:** Pathogens are less likely to be recovered from rectal swabs than from feces.

3. Shiga toxin positive broths (GN or MC) are acceptable and should be sent to GPHL as soon as possible if culture is not performed onsite. Ship refrigerated and in compliance with current DOT and IATA guidelines.

B. **Feces specimens for Clostridium perfringens, C. botulinum, and Bacillus cereus**
   1. Collect fresh stool specimens and place in a leak-proof, non-crushable, clean container (not provided by GPHL). Do not use the enteric ParaPak C&S stool culture outfit.
   2. For *C. perfringens* and *B. cereus*, stool specimens must be collected **within 48 hours** from the time symptoms begin.
   3. Store and ship refrigerated.

**Requisition Form:**
Use form #3583 for specimen submission. It is extremely important that the form is entirely completed. Please include the following information:
   1. Unique patient identifier (name or number).
   2. Date of specimen collection.
   3. Test requested, such as Stool culture for STEC.
   4. Submitter’s name and address.
   5. Name and telephone number of clinician to contact.
   6. Source of specimen, such as nasopharyngeal.
   7. Patient’s race, sex, age, and address, if available.
   8. Brief clinical history, if available.

The patient identifier (name, number, or both) indicated on the requisition form should match that written on the slide holder, transport tube, or culture. **Unlabeled specimens will not be tested.**

A. **Referred Cultures (for identification)**
Submit an overnight, pure culture of the isolated bacteria on carbohydrate-free media available commercially (TSA, TSI and LIA are acceptable). Label tube with the patient’s name and complete form #3583 for specimen submission. Please include any clinical data, cultural characteristics, biochemical reactions, or serology. The form must include the following information:
   1. Patient identifier (name or number).
   2. Date of collection.
   4. Agent suspected.
5. Submitter’s name and address.

B. Each stool specimen must be clearly labeled with the patient’s name and accompanied by a properly completed form #3583. The form must include the following information:

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

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

SHIPMENT OF SPECIMENS AND REFERRED CULTURES

**Note:** Always submit the specimen/culture according to current DOT and IATA guidelines.

Mailing containers for submitting fecal specimens and referred enteric cultures are available from Laboratory Services and Supply (404) 327-7920. For stool culture specimens, order outfit #0555, and for culture referral for identification, order outfit #0505.

To facilitate handling, the following should be observed:

1. Wrap kyfax absorbent around the specimen/culture and place in the biohazard bag provided. Put form # 3583 in the pouch located in front of the bag.
2. Place the biohazard bag in the cardboard mailing container with the Decatur address label (orange). Seal the lid of the outside can with tape.
3. Ship specimens as soon as possible after collection. If there is a delay in transport, keep the specimen at room temperature; do not refrigerate (except as noted above for stool specimens for C. perfringens, C. botulinum, and B. cereus).
4. Specimens and referred cultures should be sent by a courier or a shipping vendor with a traceable system.
5. When large numbers of specimens are expected (such as in an outbreak), please alert the Bacteriology Unit by telephone (404) 327-7990 before mailing so adequate amounts of media will be available for processing.

REPORTING AND INTERPRETATION OF RESULTS

Serotyping and confirmation or identification results are usually reported within 3 to 5 working days for *Salmonella, Shigella, Aeromonas, Vibrio,* and *Yersinia;* within 4 to 6 working days for STEC, and up to 10 working days for *Campylobacter.*
Stool specimen results are reported within 3 to 6 working days. A negative stool culture report reflects the organisms for which the stool specimen was routinely examined: No Salmonella, Shigella, Campylobacter, Aeromonas, Yersinia, or STEC found. Other organisms will be reported, as appropriate, per request. The results of SLT testing will be reported when performed.

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

- Salmonella sp. or serotype
- Aeromonas sp.
- Shigella sp. and serotype
- Vibrio sp.
- Campylobacter sp.
- Yersinia sp. and serotype
- STEC

UNACCEPTABLE SPECIMENS

1. Specimens submitted in wrong preservative, e.g., PVA or 10% formalin.
2. Refrigerated specimen for Shigella.
3. Multiple specimens collected on the same day (only one specimen will be tested).
4. No patient identifier on specimen or culture.
5. Name or patient identifier mismatch.
6. Specimens received more than 7 days after collection.
7. Swab submitted in Para-Pak C&S outfit.
FOODBORNE OUTBREAKS
404-327-7997

INTRODUCTION

The Bacteriology Unit assists physicians and county health department officials in the diagnosis and epidemiological investigation of outbreaks of suspected foodborne illness. The laboratory examines food, feces, and other epidemiologically implicated specimens for the presence of disease-producing bacteria or toxins. Food samples from single cases of suspected foodborne illness will not be examined with the exception of suspected botulism cases. The Georgia Environmental Health and Injury Control Branch (404-657-6534) must be notified by the County Health Department in which the suspected outbreak has occurred, unless botulism is suspected, in which case the Georgia Epidemiology and Prevention Branch (404-657-2588) should be notified. The Bacteriology Laboratory must be advised by either the Environmental Health and Injury Control Branch or the County Health Department of the forthcoming samples, the method of shipment, and the expected time of arrival. This will facilitate the necessary preparations that must be made for processing and examining the samples. Suspect food samples from commercial or retail stores should be referred to the Georgia Department of Agriculture http://www.agr.georgia.gov/.

Pulse-field gel electrophoresis will be done on STEC, Listeria monocytogenes, Salmonella, and Shigella isolates, as part of the foodborne illness investigation.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

All food items must be clearly labeled as to contents and type of food. Fecal or other specimens should be clearly labeled with the patient's name or other unique identifier and indicated as being associated with the outbreak under investigation. When submitting food samples, clinical signs and symptoms, incubation periods, duration of illness, the type of food being submitted, and other pertinent clinical or epidemiological data, must be indicated. This information should also be appropriate for the suspected organism before testing will be initiated. Unlabeled specimens will not be tested.

A. Food
All food specimens (25 grams minimal, preferably 100 grams) should be collected under sterile conditions, placed in sterile plastic bags (whirl packs) or other suitable leak proof containers, and refrigerated. It is the responsibility of the environmental health specialist who collects the specimens to ensure that each food item is accompanied by a completed form #3583. The following minimum information must be included: source of sample; type of sample; date collected; incubation period; clinical symptoms; organism suspected; and submitter's name and address.
Botulism (testing performed at CDC)

a. Contact the Bacteriology Unit (404-327-7990) for the initial coordination of specimen collection.

b. The submitter must also contact the GA Epidemiology and Prevention Branch, (404-657-2593), to assess through epidemiological and patient clinical history and determine if testing is warranted.

c. If approval is given, Epidemiology will notify both the Bacteriology Unit and CDC that specimens will be coming.

d. Feces, food, and bowel contents (at autopsy) may be examined directly for C. botulinum specific neurotoxins A through G. These specimens may also be cultured for C. botulinum, and if an isolate is recovered, it may subsequently be tested for the presence of the specific neurotoxins.

e. Collect feces and food samples in leak-proof, non-crushable containers, refrigerate immediately, and keep refrigerated after collection.

f. Complete a CDC form #50.34 (available from the Bacteriology Unit) and a form #3583 (Environmental/ Food section) for each specimen or food sample submitted.

B. Fecal Specimen

1. Enteric Pathogens and Staphylococcus aureus: Refer to the Enteric Bacteriology section of this manual for instructions pertaining to collecting and shipping specimens in the ParaPak™ stool culture outfit. Do not refrigerate these stool specimens. Ensure that each specimen is properly collected and labeled and submitted with form #3583 (Environmental/ Food section). Indicate the enteric pathogens suspected on this form.

2. Clostridium perfringens and Bacillus cereus: Collect a stool specimen within 48 hours from the time symptoms begin, place in a leak-proof, non-crushable container and refrigerate immediately. Label the specimen with the patient’s name or other unique identifier. Do not use the enteric ParaPak™ stool culture outfit, as this will result in erroneous quantitative count results. Form #3583 (Environmental/ Food section) must be filled out and C. perfringens or B. cereus, depending upon the request, checked mark as the agent suspected.

C. Food Handlers

1. S. aureus: Swab the infected area and/or anterior nasal membranes. Place the swab in a culturette with Stuarts, Cary-Blair, or other commercially available transport medium. Label specimen with the patient’s name or other unique identifier and complete form #3583 (Environmental/ Food section).

2. Enteric Pathogens: Follow procedure in section B.1, above.
D. Environmental
Swab the suspected area(s) and submit as in C. above.

SHIPMENT OF SPECIMENS

A. **Food**: Keep food samples refrigerated. Do not freeze or use dry ice. However, if a food is received frozen, keep it frozen and ship on dry ice. Place samples and refrigerant in the shipper, using a sturdy and waterproof shipping container. Complete and insert form # 3583 and other epidemiological and clinical information in an envelope attached to the outside of the shipper, or put the form(s) in a separate waterproof plastic bag inside the shipper with the food. Deliver sample(s) to the Georgia Public Health Laboratory by courier or a shipping vendor with a traceable system. Always notify the Bacteriology Unit of the expected time of arrival.
   1. Botulism
      a. Specimens may be sent to the Bacteriology Unit for referral to CDC and Epidemiology should be notified. Prior approval is required.
      b. All specimens for botulism must be shipped **refrigerated**.

B. **Feces and Other Types of Clinical Specimens** (except those for botulism):
   Feces for enteric pathogens and *Staphylococcus aureus* should be shipped according to the instructions in the Enteric Bacteriology section of this manual, they should not be sent refrigerated. **Specimens for *Clostridium perfringens* and *Bacillus cereus* should be sent refrigerated** and may be delivered to the Bacteriology Unit by a courier or a shipping vendor with a traceable system.

REPORTING AND INTERPRETATION OF RESULTS

Examination of food samples and fecal specimens may require up to seven working days depending upon the suspected etiologic agent. Positive reports will reflect the etiological agent(s) which have been detected and/or enumerated and may include one or more of the following: *Salmonella* sp. or serotype, *Shigella* sp., *Campylobacter* sp., STEC, *Clostridium perfringens*, *Staphylococcus aureus*, *Bacillus cereus*, *Vibrio* sp., or other possible pathogens. Negative reports will be issued in those cases where the suspected organism is not detected. "Test Not Performed" will be indicated when the organism does not fit the epidemiological and clinical data indicated. Testing for Toxin may be performed in appropriate cases: enterotoxin for *S. aureus* and SLT for *E. coli*, and may take an additional two to three working days. Swab results from food handlers are usually reported within three days.

Confirmation that a certain food sample is involved in an outbreak is made by detecting the same pathogen (or toxin) in patient specimens and also in suspect food(s). See Table, Guidelines for Confirmation of Foodborne-Disease Outbreaks of Bacterial Origin.
UNACCEPTABLE SPECIMENS

1. No identifier on the specimen, or discrepancy between identifier on the specimen and requisition form.
2. Specimen or transport medium improperly submitted (see above for the recommended procedure).
3. Less than 25 grams of food (preferably 100 grams).
4. Other unacceptable food specimens will be assessed on an individual basis.
## Guidelines for Confirmation of Foodborne-Disease Outbreaks of Bacterial Origin

<table>
<thead>
<tr>
<th>Etiological Agent</th>
<th>Incubation Period</th>
<th>Clinical Syndrome</th>
<th>Required Specimen</th>
<th>Collection Vial</th>
<th>Submission Form</th>
<th>Shipping</th>
<th>Criteria for Outbreak Association</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus cereus</em></td>
<td>1 – 6 h</td>
<td>Nausea &amp; vomiting, sometimes diarrhea. Fever rare. Duration of ≤ 1 day.</td>
<td>Stool w/in 48 h</td>
<td>Sterile container</td>
<td>#3583</td>
<td>Refrigerated</td>
<td>Isolation of organism from ≥ 2 people.</td>
</tr>
<tr>
<td></td>
<td>6 – 24h</td>
<td></td>
<td>after onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Emetic toxin</em> (heat stable)</td>
<td></td>
<td>Food</td>
<td>Zip-lock bags; clean container</td>
<td>#3583</td>
<td>Refrigerated</td>
<td>Isolation of ≥ $10^5$ organisms/g from implicated food, provided specimen properly handled.</td>
</tr>
<tr>
<td></td>
<td>6 – 24h</td>
<td>Diarrheal toxin (heat labile)</td>
<td></td>
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<tr>
<td><em>Campylobacter sp.</em></td>
<td>2 – 10d; usually 2 – 5d</td>
<td>Diarrhea (often bloody), fever, abdominal pain. Duration 1 - 5 days.</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>#3583</td>
<td>Ambient Temp.</td>
<td>Isolation of organism from ≥ 2 people.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Food</td>
<td>Zip-lock bags; clean container</td>
<td>#3583</td>
<td>Refrigerated</td>
<td>Isolation of organism from implicated food.</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>6 – 24h, median 12h</td>
<td>Diarrhea, abdominal cramps; vomiting, fever, &amp; chills rare. Short duration of ≤ 1 day.</td>
<td>Stool w/in 48h</td>
<td>Sterile container</td>
<td>#3583</td>
<td>Refrigerated</td>
<td>Isolation of ≥ $10^5$ organisms/g from ≥ 2 people; Demonstration of enterotoxin from ≥ 2 people.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Food</td>
<td>Zip-lock bags; clean container</td>
<td>#3583</td>
<td>Refrigerated</td>
<td>Isolation of ≥ $10^5$ organisms/g from implicated food; isolation of enterotoxin-producing strain of C. <em>perfringens</em>.</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em></td>
<td>2h - 8d; usually 12 - 48h</td>
<td>Illness of variable severity; nausea, vomiting, abdominal pain, diarrhea may appear early. Headache, diplopia, blurred</td>
<td>Serum <em>Stool</em> Gastric Contents Food <em>Best for</em></td>
<td>Clean vials and/or container</td>
<td>#3583 and CDC Form #50.34 - one per specimen</td>
<td>Refrigerated</td>
<td>Detection of botulinal toxin in serum, stool, gastric contents, or implicated food; Isolation of organism from stool or intestine. Isolation of <em>C. botulinum</em>, but not the toxin, in a food consumed by a patient with suspected botulism is</td>
</tr>
</tbody>
</table>

*Note: *parasites are not included in the table.
<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Disease</th>
<th>Incubation Period</th>
<th>Symptoms</th>
<th>Sample Type</th>
<th>Sample Collection</th>
<th>Reference</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shiga-like toxin producing <em>E. coli</em> (STEC)</td>
<td>Diarrhea (often bloody), abdominal cramps (often severe), little or no fever.</td>
<td>1 – 10d; usually 3 – 4d</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of STEC from ≥ 2 people, same subtype (PFGE).</td>
<td></td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>Meningitis, neonatal sepsis, fever</td>
<td>Invasive disease - 2-6 wks</td>
<td>Pure Isolate</td>
<td>Culture Referral Outfit #0505</td>
<td>Ambient Temp.</td>
<td>Confirmation of identification of organism &amp; of same serotype/subtype as implicated food.</td>
<td></td>
</tr>
<tr>
<td>Salmonella sp.</td>
<td>Diarrhea, abdominal cramps, fever</td>
<td>6h - 10d, usually 6 - 48h</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of organism, same serotype/subtype: (a) from ≥ 2 people exposed to implicated food, or (b) as isolate recovered from implicated food.</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Vomiting, diarrhea. Short duration of not</td>
<td>30 min - 8h, usually</td>
<td>Stool within 24h after</td>
<td>Para-Pak #0555</td>
<td>Refrigerated</td>
<td>Isolation of organism from stool.</td>
<td></td>
</tr>
<tr>
<td>Pathogen</td>
<td>Incubation Period</td>
<td>Onset Duration</td>
<td>Sample Type</td>
<td>Sample Code</td>
<td>Temperature</td>
<td>Diagnosis</td>
<td></td>
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<tr>
<td>Shigella sp.</td>
<td>12h - 6d; usually 2-4d</td>
<td>Diarrhea (often bloody), fever, abdominal cramps. Duration of several days.</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of organism, same serotype/subtype, from ≥ 2 people.</td>
<td></td>
</tr>
<tr>
<td><strong>Vibrio cholerae O:1 and O:139</strong></td>
<td>1 – 5d</td>
<td>Sudden onset, profuse watery diarrhea, often w/ mucus, abdominal pain, rapid dehydration.</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of toxigenic organism from ≥ 2 people.</td>
<td></td>
</tr>
<tr>
<td><strong>Vibrio parahaemolyticus</strong></td>
<td>4 – 30 h</td>
<td>Diarrhea</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of Kanagawa-positive organism from ≥ 2 people.</td>
<td></td>
</tr>
<tr>
<td><strong>Yersinia enterocolitica</strong></td>
<td>1 – 10d, usually 4 – 6d</td>
<td>Diarrhea, abdominal pain (often severe) - may mimic appendicitis</td>
<td>Stool</td>
<td>Para-Pak #0555</td>
<td>Ambient Temp.</td>
<td>Isolation of pathogenic strain or serotype from ≥ 2 people.</td>
<td></td>
</tr>
</tbody>
</table>

INTRODUCTION

The Bacteriology Unit accepts cultures for the isolation of Neisseria gonorrhoeae from endocervical, rectal, oropharyngeal, and urethral sources. Neisseria gonorrhoeae remains one of the most frequently reported causes of sexually-transmitted diseases including urethritis, cervicitis, pharyngitis, and proctitis. This organism may also cause neonatal infections, pelvic inflammatory disease, bacteremia, and joint infections. N. gonorrhoeae is the most fastidious of the Neisseria species and dies rapidly outside of the body. The identification of Neisseria gonorrhoeae is performed by determining the phenotypic characteristics of the culture, biochemicals and rapid DNA probe. Specimens may be sent from STD approved health care providers.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

The enriched selective medium Thayer-Martin improved agar is used for culture and is designed for the isolation of pathogenic Neisseria species and the suppression of normal flora. Label each plate carefully using waterproof marker such as “Sharpie” with the patient name, culture, and collection date.

Endocervical: Moisten the speculum with water only (do not use any other lubricant). Insert the speculum, and visualize the cervix. Then, insert a sterile dacron or rayon swab 2-3 cm into endocervical canal, rotate gently for 10-15 seconds to allow absorption of the secretions, and remove.

Rectal: Insert a sterile dacron or rayon swab approximately 2-3 cm into the anal canal, rotate gently for 10-15 seconds to allow absorption of the secretions, and remove.

Oropharyngeal: Swab the posterior pharynx and tonsilar crypts with a dacron or rayon applicator.

Urethral: Collect at least one hour after patient has urinated. Exudates expressed into the urethral meatus can be transferred to the selective culture medium with a dacron or rayon swab.

Prepubertal children: A vaginal specimen is collected by swabbing the vaginal wall for 10-15 seconds to absorb any secretions, or, if the hymen is intact, the specimen is collected from the vaginal orifice using a dacron or rayon swab. Rectal, urethral, and oropharyngeal specimens may be taken according to the procedures described for adults.
Storage and inoculation of selective medium culture plates:

**Storage:** Store plates sealed in plastic sleeves at 2 to 8°C; place the plates in an inverted position (bottom, or medium side up). Medium should be used before the expiration date and be at room temperature before inoculation. The medium surface should be smooth, glistening, and free of excessive moisture. Dried medium that has pulled away from the sides, has cracked, has fallen into plate lid, or has a wrinkled surface should not be used.

**Inoculation:** Roll dacron swab over a 20-25% segment of the medium surface. Streak the media using the standard microbiologic procedure for colony separation.

Handling of inoculated selective culture medium plates:

1. Place the culture plate in a CO₂-enriched atmosphere (e.g., candle jar or CO₂ tablet/plastic bag system) within 15 minutes of inoculation.
2. Put the jar or bag in the incubator as soon as possible, certainly within 1-2 hours after inoculation, and incubate at 37°C.
3. For optimal results, inoculated plates should be transported directly to the laboratory the same day or pre-incubated within 1 to 2 hours after inoculation for minimum of 18 hours and a maximum of 24 hours at 37°C in an incubator which is monitored daily. If incubation is not possible or incubation criteria cannot be met, ship immediately to the laboratory by a courier or a shipping vendor with a traceable system.

**Note:** At all times, protect from extreme temperatures.

**Test requisition instructions:**
Requisition Form: Use form #3583 for specimen submission. It is extremely important that the form is entirely completed. Please include the following information:

1. Unique patient identifier (name or number).
2. Date of specimen collection.
3. Test requested (Neisseria gonorrhoeae culture).
4. Submitter’s name and address.
5. Name and telephone number of clinician to contact.
7. Patient’s race, sex, age, and address, if available.
8. Brief clinical history, if available.
9. It is very important to include incubation status of specimen in the form and the culture plate.

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

SHIPMENT OF SPECIMENS AND CULTURES

After packing carefully in a sturdy box or padded envelope, the specimen may be dispatched to the laboratory by a courier or a shipping vendor with a traceable system after 18-24 hours of incubation. Note: Always submit the specimen/culture according to current DOT and IATA guidelines.

REPORTING AND INTERPRETATION OF RESULTS

Cultures are held for 2 days from the date of inoculation and read daily. After the final day of incubation, if there are no colonies typical of Neisseria gonorrhoeae present, the culture is reported negative for this organism. A positive culture report is based upon typical phenotypic characteristics of the culture, biochemicals, and it is confirmed by rapid DNA probe.

UNACCEPTABLE SLIDES AND CULTURES
1. Specimen leaked, damaged, or crushed in transit.
2. Specimen received > 6 days from collection.
3. Specimen received in incorrect media.
4. Wrong specimen submitted.
5. Overgrown with contaminants.
7. Dried media (media in lid).
8. Media not inoculated - No streak.
9. Media compromised (appears to be frozen).
10. Media compromised (appears to be overheated).
11. No specimen received.
12. Laboratory accident.
13. Name discrepancy.
INTRODUCTION

The Bacteriology Unit accepts specimens from public health care providers for the detection of Group A \emph{Streptococcus} and other beta-hemolytic streptococci from throat. Reference cultures will be accepted from public and private health care providers for identification and/or serogrouping of beta-hemolytic streptococci. Culture is the method used for isolation of the organism, and latex agglutination is used for serogrouping isolates.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

The sterile swab supplied in outfit #0560 should be used for throats. Outfits are available from Laboratory Services and Supply, 404-327-7920. The Group A \emph{Streptococcus} outfit may be used for the isolation of any beta-hemolytic \emph{Streptococcus} from throat.

**Specimen collection**

1. After adequately exposing and illuminating the pharynx, rub tonsils and pharynx with the swab provided. Be careful to obtain any exudate present and avoid the tongue and uvula tissues.
2. Place swab in the silica gel envelope, according to instructions supplied with the outfit by placing the silica gel package in the polyfoil kraft envelope.
3. Clearly write the patient’s name or other unique identifier in the space provided.

**Requisition Form:**

Use form #3583 for specimen submission. Please supply the following information:

1. Patient identifier (name or number).
2. Date of specimen collection. website
3. Name and telephone number of clinician to contact.
4. Submitter’s name and address.
5. Patient’s race, sex, age, and address, if available.

The patient identifier on the form should match that on the specimen. **Unlabeled specimens will not be tested.**
SHIPMENT OF SPECIMENS

Place the polyfoil envelope and requisition form in the brown mailing envelope provided. Specimens may be sent to the Laboratory by a courier or a shipping vendor with a traceable system. If there is any delay in shipment, hold specimens at room temperature.

REPORTING AND INTERPRETATION OF RESULTS

Culture results of beta-hemolytic *Streptococcus* will be completed within 2 days after receipt of the specimen. Any Group A *Streptococcus* detected will be reported. Other groups of beta-hemolytic *Streptococci* will be reported if they are the predominate organism present. The report will read "No Group A *Streptococcus* Found by Culture" for negatives; if no growth is detected this also will be noted. For positives, the report will read, "Group A *Streptococcus* Found by Culture," or Group B, C, F, G *Streptococcus* Found by Culture, Predominate Organism Present."

UNACCEPTABLE SPECIMENS

1. Specimens not submitted in the silica gel outfit (or other suitable transport outfit approved by the Bacteriology Unit).
2. Silica gel envelope not sealed.
3. Specimens received >4 weeks after collection.
4. No patient identifier on specimen.
INTRODUCTION

The Bacteriology Unit accepts reference cultures from public and private health care providers for the identification, confirmation, and/or serotyping of bacterial isolates. This includes a wide variety of aerobic, and facultative organisms isolated from clinical sources. Isolates should be submitted as pure cultures. Techniques used in the identification process include a combination of some or all of the following: cellular and colonial morphology, conventional biochemical tests, Cell Wall Fatty Acid Analysis (CWFAA), and DNA probes.

All isolates of Neisseria meningitidis, Haemophilus influenzae and Listeria monocytogenes, recovered from sterile sources should be forwarded to the Bacteriology Unit, either directly or through the Emerging Infections Program (EIP) site for grouping and typing.

Submission of Group A Streptococcus, Group B Streptococcus and S. pneumoniae isolates to GPHL is no longer required. Nevertheless, these organisms remain reportable to the Notifiable Diseases Unit. In addition, CDC no longer provides typing and/or molecular characterization for them, unless by prior arrangement.

Antimicrobial susceptibilities are not performed except as an aid to identification. Such requests can be forwarded to the CDC through the Bacteriology Unit by special arrangement. Any unidentified organisms isolated from sterile sources will also be sent to the CDC for further studies, upon request.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

A. Pure cultures for anaerobic identification from sterile sites only are referred to CDC. Chopped meat glucose broth is the recommended transport media. Clearly label referred cultures with the patient's name or other unique identifier.

B. Pure culture for aerobic identification from autopsy material, tissues, urine, respiratory and urogenital tract secretions, wounds, abscesses, spinal fluid, and blood are acceptable. Clearly label referred cultures with the patient's name or other unique identifier.

See Table 1 for organisms requiring special handling. In all of the cases noted in Table 1, notify the Bacteriology Unit prior to shipping.
Requisition Form:
Use form #3583 for specimen submission. Please include the following information:

1. Unique patient identifier (name or number).
2. Agent suspected or test requested.
3. Submitter's name and address.
4. Name and telephone number of contact person.
5. Date of specimen collection.
7. Date of transplant (if applicable).
8. Brief clinical history.
9. Patient's race, sex, age, and occupation, if available.

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

SHIPMENT OF SPECIMENS AND REFERRED CULTURES

Note: Always submit the specimen/culture according to current DOT and IATA guidelines

Submit referred cultures as pure cultures in the appropriate medium. For anaerobic identification, chopped meat glucose broth is recommended and commercially available (test performed at CDC). For aerobic identification, slants of solid medium appropriate for growth of the organism in question are recommended and are commercially available.

Use screw-capped tubes and tighten securely. Place a strip of parafilm around the cap of the tube to help prevent loosening of the cap in transit. In all cases, submit young, actively growing subcultures to ensure viability. Wrap the sides and bottom of culture tubes in kyfax packing material or paper towels to prevent breakage. Use outfit #0505, "Culture Referral Isolation for Identification," available from Laboratory Services and Supply, 404-327-7920, and follow these instructions:

1. Place culture wrapped in packing material in the biohazard bag provided.
2. Put the requisition form in the pouch in the front of the bag.
3. Place the biohazard bag in the orange-labeled cardboard mailing container (Decatur address) and secure the lid with tape.
4. Place the return address on the outside of the container.
5. Send by a courier or a shipping vendor with a traceable system.
6. Avoid submitting cultures in petri dishes, but if necessary, cushion them with absorbent material and securely package in leak-proof containers. Seal culture plates for anaerobic identification in an anaerobic "bag" system before packaging.

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REPORTING AND INTERPRETATION OF RESULTS

Organisms are identified to the genus and species level when there is agreement with all appropriate data, such as cultural, morphologic, biochemical, and cell wall fatty acid analysis. Genus and species designations are current with new bacterial nomenclature. The identification of the organism will be reported. When serotyping is requested and available, the appropriate serotype or serogroup will be reported. Unidentified organisms isolated from sterile sources may be forwarded to CDC upon request, but those isolated from nonsterile sites must be accompanied by a detailed clinical history to justify sending to CDC and requires prior approval from CDC.

Culture results for the identification of aerobic, facultative, and anaerobic bacteria are usually completed within seven working days, but may require up to fifteen working days, depending upon the organism. Mixed cultures, fastidious, slow-growing, or nutritionally-deficient bacteria may occasionally require additional time beyond the fifteen working days for a complete identification. Results of serotyping are usually completed as follows: Neisseria meningitidis (1-3 working days) and Haemophilus influenzae (2-3 working days). Cultures referred to the CDC may require up to six months for a final identification.

UNACCEPTABLE SPECIMENS

1. Cultures broken in transit.
2. Non-viable cultures: all cultures received will be subcultured upon receipt. Every attempt will be made to obtain viable growth. If no growth occurs, a report will be issued and another subculture will be requested, if available.
3. Cultures overgrown with contaminants.
4. No patient identifier on the specimen or culture.
5. Specimens improperly collected or submitted (see section on specimen collection and shipment).
### Table 1. Organisms Requiring Special Handling

<table>
<thead>
<tr>
<th>Organism</th>
<th>Handling and Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clostridium botulinum</strong></td>
<td>See section on Foodborne Illness for further details. For wound infections, submit material from wound, refrigerated with cold pack, in anaerobic environment system. Send suspected isolate in chopped meat broth or motility test medium (inoculate near bottom of tube) in culture referral outfit (#0505) at ambient temperature. Specimens and isolates will be forwarded to CDC for isolation, confirmation, and/or toxin testing.</td>
</tr>
<tr>
<td><strong>Clostridium perfringens</strong></td>
<td>See Foodborne Outbreaks Section for further details. Submit material from site of infection, refrigerated with cold pack, in anaerobic environment system; or send suspected isolate in chopped meat broth or motility test medium (inoculate near bottom of tube) in culture referral outfit (#0505) at ambient temperature.</td>
</tr>
<tr>
<td><strong>Corynebacterium diphtheriae</strong></td>
<td>Collect throat or skin lesion swabs (use Strep outfit #0560 or place on Loeffler's agar slant, available commercially). Subculture suspected isolates to Loeffler or cysteine tellurite blood agar slants. Toxigenicity testing will be performed at CDC. Send suspected isolates in culture referral outfit (#0505). Contact the Bacteriology Lab prior submission as special media is required for testing.</td>
</tr>
<tr>
<td><strong>Haemophilus ducreyi</strong></td>
<td>Collect specimens from lesions or inguinal bubo. Inoculate onto enriched chocolate agar with vancomycin. Incubate 33-35°C in 5-10% CO2 in water-saturated atmosphere. Referred cultures only will be accepted.</td>
</tr>
<tr>
<td><strong>Haemophilus influenzae</strong></td>
<td>For serotyping and/or culture confirmation, submit 18-24 hr. subculture on chocolate slant, available commercially. Submit through the EIP site, by a courier or a shipping vendor with a traceable system.</td>
</tr>
<tr>
<td><strong>Leptospira</strong></td>
<td>Collect blood during first 10 days of illness, and urine (3 consecutive samples) from second to fourth week of illness. Obtain instructions for inoculation from the Bacteriology Unit prior to specimen collection. Ellinhausen's medium is available commercially. Immediately inoculate tubes and submit at room temperature to the Bacteriology Unit. Specimens and isolates will be forwarded to CDC for isolation and confirmation.</td>
</tr>
<tr>
<td><strong>Neisseria gonorrhoeae</strong></td>
<td>For culture confirmation, submit 18-24 hr. subculture on chocolate slant or emulsify fresh growth in trypticase soy broth with 20% glycerol and freeze. Submit preferably by overnight mail (slant) or frozen on dry ice (broth). See separate section for GC culture screening.</td>
</tr>
<tr>
<td><strong>Neisseria meningitidis</strong></td>
<td>For serogrouping and/or culture confirmation, submit 18-24 hr. subculture on chocolate slant, available commercially. Submit through the EIP site, by a courier or a shipping vendor with a traceable system.</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td>Submit coagulase positive isolates from outbreaks or multiple isolates from different sources in same patient. Submit on nutrient or heart infusion agar slants.</td>
</tr>
</tbody>
</table>
IMMUNOLOGY

INFECTIONOUS DISEASE SEROLOGY
404-327-7970

INTRODUCTION

The Microbial Immunology Unit performs infectious disease serology. Various serologic procedures are performed for a variety of bacterial, parasitic, and viral agents except for HIV. HIV (Human Immunodeficiency Virus) is performed in the Virology Unit. Hepatitis serology is only performed for county health departments and Georgia Department of Public Health agencies. Tests not performed in the Public Health Laboratory can be forwarded to CDC, if the submitter requests the testing.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Collection Using Universal Precautions, and standard venipuncture technique, collect approximately six milliliters of whole blood (for serum) in a red top tube (no additive), labeled with patient’s identifier (name, first and last, or number), data, and name of the submitter. Use a marker that will not fade, smear, or run during transportation. Use proper size needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient. Allow blood specimen to clot, at least 30 minutes undisturbed, at room temperature, and transport, or place in the refrigerator for transporting. Collect blood specimens in, or transfer them to, non-breakable, leak resistant tubes. Specimens should be transported as soon as possible, do not hold over 7 days. Specimens over 14 days old are unacceptable. Many of the procedures we perform are not approved for use with plasma. Therefore, please submit only serum or whole blood without anticoagulants, not plasma.

Collect cerebrospinal fluids (CSF) according to proper hospital procedure. CSF contaminated with blood or grossly contaminated with bacteria is unacceptable.

Labeling All specimens must be labeled with patient identification (name or number), in acceptable testing condition, and accompanied by a completed requisition form. If the form is not specific for one test or a set of tests, the specific testing requested must be hand-written in the proper area, e.g., “viral serology” is not acceptable, the specific agent, e.g., “CMV”, must be clearly requested. Failure to provide proper patient information may result in testing delays.

Requisition Form: Use Form #3583 for all tests performed by the Microbial Immunology Unit. There is a single requisition form for all tests performed in the Georgia Public Health Laboratory. Hepatitis B
testing is performed for the (Department of Public Health facilities and county health
departments only). Completely fill out the form and include the following information:

1. Unique patient identifier (name or number).
2. **TEST(S) REQUESTED** (Please check only the corresponding box for
test(s) requested).
3. Date specimen collected.
4. Submitter’s name, address and code number, where applicable.
5. For hepatitis the reason for testing, e.g., routine, or prenatal.
6. Any information the submitter needs for patient identification, e.g., chart number,
   address.
7. The date of onset of illness, if applicable.
8. Race, sex, and age, where applicable, e.g., hepatitis testing.

**SHIPMENT OF SPECIMENS**

Use outfit #0500, available from Laboratory Services and Supply, 404-327-7920, and follow
the specific instructions below. For HCV Viral Load testing please use outfit 502.
Routine specimens may be mailed at room temperatures overnight or delivered cold to the
laboratory by courier. HCV Viral Load should be sent frozen by overnight courier.

**Shipping Instructions for USPS and Couriers:**
Place the tubes of blood in protective, leak resistant, doubled-walled containers, e.g.,
aluminum and cardboard box, for transport. Wrap the requisition form around the inner
(aluminum) can, secure with a rubber band and place in the outer container. If a screw-cap
outer container is used, the screw-cap must be secured with tape or the Postal Service will
return it for taping. Up to 50 milliliters of blood may be transported in one package (U.S.
postal regulations). Therefore, an individual tube of blood may be placed in the metal can,
with the requisition form secured to the outside by a rubber band, and several aluminum
cans placed in one cardboard box for transporting.

**Shipping Instructions for Courier Services Only:**
Tubes of blood may be placed in leak proof biohazard bags. Wrap brown absorbent
material around the tube, then secure with a rubber band. Place the requisition form in the
sleeve located on the outside of the bag.

**REPORTING AND INTERPRETATION OF RESULTS**

**Table 1** summarizes the interpretation of results for all serological tests performed in the
Microbial Immunology Unit. The turnaround time after receipt of the specimen depends on
the testing methodology and the frequency of testing. The frequency of testing depends on
the demand for a specific test. Several tests are performed daily, while others are
performed weekly. The turn-around time for specimens referred to CDC depends on CDC’s
schedule, which varies from laboratory to laboratory.
UNACCEPTABLE SPECIMENS

1. Spinal fluid obviously contaminated with bacteria or blood;
2. All specimens:
   Not approved for testing by the indicated method, e.g., plasma for RPR.
   Grossly hemolyzed, lipemic, turbid, or contaminated.
   Over 14 days old.
   Broken in transit.
   Insufficient quantity for testing.
   No identification on specimen.
   Name on the tube and form does not match.

The submitter will be notified of all rejected specimens. Most serologic services are available to both the public and private sectors. However, hepatitis B testing is limited to the public health care providers, and not available to the private providers.
INTRODUCTION

The Abbott Real-Time HCV assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantification of Hepatitis C Virus (HCV) in human serum/plasma from HCV infected individuals. The detection system is on an automated m20000 platform and the range of detection is 12 to 100,000,000 copies of target/ml. Specimens containing HCV genotypes 1-6 have been validated for quantitation in the assay. The assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiviral treatment as measured by changes in plasma HCV RNA levels. This assay is not attended to be used as a donor screening test for HCV or as a diagnostic test to confirm the presence of HCV infection.

The HCV Viral Load assay is offered to patients in the Ryan White Program or the management of individuals infected with HCV, and as a supplemental test to routine submitters. The results are reported as HCV RNA copies/ml.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

1. Follow all safety precautions when drawing blood from patients.
2. No special patient preparation is necessary before collection. Use proper size needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient.
3. Please collect all specimens in a sterile collection tube EDTA as the anticoagulant or in the Prepared Serum Separator Tube (SST) provided by the Georgia Public Health Lab (GPHL).
4. Collect one SST tube using standard venipuncture techniques. Immediately after collection, gently invert the SST tube 8-10 times. Whole blood may be held at (2-30°C) for up to 6 hours.
5. Label the specimen with the patient’s identification number, submitter code and the date.
6. Centrifuge at 1000 x g (2400RPM) for 10-15 minutes or 2500 x g (3600RPM) for 5 minutes. If the red cells have settled prior to centrifugation, mix contents by gently inverting the collection tube 10-15 times.
7. Aliquot plasma/serum into the appropriately labeled vial. The minimum volume is 2.5ml for the HCV Viral Load. Please use the supplied screw cap aliquot tube supplied with HCV Viral Load collection kit.
   **NOTE:** Use sterile pipettes and tubes to reduce possible bacterial contamination that may destroy some or all of the HCV nucleic acid (RNA).
8. Place the properly labeled vial with plasma in a biohazard bag.
9. Plasma/Serum may be stored at 2-8°C for up to 3 days. Freeze in an upright position -20°C for up to 60 days or ≤ -70°C for extended storage. Do not use frost-free freezers for storing samples. Do not exceed more than 3 freeze/thaw cycles.

Requisition Form

Use form #3583 for specimen submission. The following information will be required for both manual and electronic data entry:

1. Unique patient identifier number.
2. Data specimen collected.
3. Submitter’s name, address and code, if applicable.
4. Check the “HCV Viral Load” box.
5. Any information submitter needs for patient identification, e.g., chart number or address.
6. The date of onset of illness, if applicable.
7. Race, ethnicity, sex and age
8. Legibly label the aliquot tubes with patient name, patient I.D. no. and date of collection, or use electronic labels if submitting specimen through remote data entry. Unlabelled specimens will not be tested.

Place the HCV form in the pouch of the biohazard bag along with the specimen so that it is ready for courier pick up.

SHIPMENTS OF SPECIMENS

Specimens will be delivered frozen on dry ice to the laboratory by courier according to a schedule provided for your facility.

REPORTING AND INTERPRETATION OF RESULTS

The sensitivity of the Abbot Real Time RT-PCR Assay is 12 copies/ml with a linearity range of 12-100,000,000 copies/ml. Turnaround time is 7-14 days. The test results are reported as:

1. A sample with result of “Not Detected” signifies that no target was detected.
2. A sample with result less than 12 copies/ml (<1.80 log copies/ml) indicates that target was detected but is less than the lower limit of quantitation (LLQ).
3. A sample with result equal to or greater than 12 copies/ml (<1.80 log copies/ml) contain HCV-RNA in the quantity identified in the report. A result of “12 copies/ml to 100,000,000 copies/ml (1.80 to 8.00 log copies/ml)” indicates that the target was detected and the concentration falls between 1.8 log copies per ml (LLQ) and 8.0 log copies for the upper limit of quantitation (ULQ).
4. A sample with result greater than the 100,000,000 copies/ml (>8.00 log copies/ml) are above the upper quantitative level of the assay and are reported > 100,000,000 copies/ml (>8.00 log copies/ml).
UNACCEPTABLE SPECIMENS

1. No ID on form.
2. No name on form or tube.
3. No ID on specimen.
4. ID on specimen and form do not match.
5. Not approved for testing by the indicated method, e.g., blood for VDRL.
6. Grossly hemolyzed, lipemic, turbid, or contaminated
8. With an insufficient quantity for testing (QNS)
9. Specimen received unspun.
10. Specimens left at ambient temperature for more than 24 hours.
11. Specimens not frozen within 3 days.
12. Specimens not collected in SST tubes for viral load testing.
<table>
<thead>
<tr>
<th>Agent</th>
<th>Test</th>
<th>Method</th>
<th>Negative</th>
<th>Positive</th>
<th>Diagnostic</th>
<th>Presumptive</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Encephalitis</td>
<td>IgG&lt;sup&gt;1&lt;/sup&gt; IgM&lt;sup&gt;1&lt;/sup&gt;</td>
<td>IFA&lt;sup&gt;1&lt;/sup&gt;</td>
<td>IgG &lt;1:16 IgM &lt;1:16</td>
<td>IgG ≥1:16 IgM ≥ 1:16</td>
<td>Four-fold rise in titer between paired sera&lt;sup&gt;4&lt;/sup&gt;</td>
<td>≥ 1:16</td>
</tr>
<tr>
<td>Cytomegalovirus (CMV)</td>
<td>IgG IgM</td>
<td>EIA&lt;sup&gt;1&lt;/sup&gt;</td>
<td>No IgG Detected No IgM Detected</td>
<td>IgG Detected IgM Detected</td>
<td>IgM detected and/or significant rise in titer between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>IgM Equivocal</td>
</tr>
<tr>
<td>Eastern Equine Encephalitis</td>
<td>IgG IgM</td>
<td>IFA</td>
<td>IgG &lt;1:16 IgM &lt;1:16</td>
<td>IgG ≥1:16 IgM ≥ 1:16</td>
<td>Four-fold rise in titer between paired sera&lt;sup&gt;4&lt;/sup&gt;</td>
<td>≥ 1:16</td>
</tr>
<tr>
<td>Hepatitis A Total</td>
<td>IgG</td>
<td>EIA</td>
<td>Negative</td>
<td>Positive</td>
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<td></td>
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<tr>
<td></td>
<td>IgM</td>
<td>EIA</td>
<td>Negative</td>
<td>Positive</td>
<td>Presumptive evidence of IgM antibodies to HAV</td>
<td></td>
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<tr>
<td>Hepatitis C</td>
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<td>Negative</td>
<td>Positive</td>
<td>Positive confirmed by HCV RNA</td>
<td></td>
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<td>HCV Viral Load</td>
<td>AG</td>
<td>PCR</td>
<td>Not detected</td>
<td>Detected</td>
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<td></td>
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<td>Hepatitis B Virus (HBV)&lt;sup&gt;6&lt;/sup&gt;</td>
<td>HSbs&lt;sup&gt;1&lt;/sup&gt;</td>
<td>EIA</td>
<td>Negative</td>
<td>Positive</td>
<td>Positive HBs</td>
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<tr>
<td></td>
<td>Hbe&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>Negative</td>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anti-HBs&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
<td>Negative</td>
<td>Positive</td>
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<td></td>
<td>Anti-HBc&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>Negative</td>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herpes Simplex Virus (HSV)</td>
<td>Type 1</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>Significant difference between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Type 2</td>
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<td>Agent</td>
<td>Test</td>
<td>Method</td>
<td>Negative</td>
<td>Positive</td>
<td>Diagnostic</td>
<td>Presumptive</td>
</tr>
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<td>--------------------------------------------------------</td>
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</tr>
<tr>
<td>Mumps</td>
<td>IgG</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>Significant difference between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>None</td>
</tr>
<tr>
<td>Murine typhus</td>
<td>IgG</td>
<td>IFA</td>
<td>&lt;1:16</td>
<td>≥ 1:16</td>
<td>Four-fold rise in titer between paired sera&lt;sup&gt;4&lt;/sup&gt;</td>
<td>≥ 1:128</td>
</tr>
<tr>
<td>Rocky Mountain Spotted Fever</td>
<td>IgG</td>
<td>IFA</td>
<td>&lt; 1:16</td>
<td>≥ 1:16</td>
<td>Four-fold rise in titer between paired sera&lt;sup&gt;4&lt;/sup&gt;</td>
<td>≥ 1:128</td>
</tr>
<tr>
<td>Rubeola (Measles)</td>
<td>IgG</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>IgM detected and/or significant increase between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>IgM Equivocal</td>
</tr>
<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>No IgM Detected</td>
<td>IgM Detected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rubella (German Measles)</td>
<td>IgG</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>IgM detected and/or significant increase between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>Not Applicable</td>
</tr>
<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>No IgM Detected</td>
<td>IgM Detected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>St. Louis Encephalitis</td>
<td>IgG</td>
<td>IFA</td>
<td>IgG &lt;1:16</td>
<td>IgG ≥1:16</td>
<td>Four-fold rise in titer between paired sera&lt;sup&gt;4&lt;/sup&gt;</td>
<td>≥ 1:16</td>
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<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>IgM &lt;1:16</td>
<td>IgM ≥1:16</td>
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<tr>
<td>Syphilis</td>
<td>RPR</td>
<td>Agg</td>
<td>Non-Reactive</td>
<td>Reactive ≥ 1:1</td>
<td>RPR and EIA Reactive</td>
<td>Reactive RPR and Equivocal EIA</td>
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<tr>
<td></td>
<td></td>
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<td>Reactive</td>
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<td>FTA</td>
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<td>Reactive</td>
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<td>Equivocal EIA</td>
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<tr>
<td>Syphilis</td>
<td>VDRL</td>
<td>Agg</td>
<td>Non-Reactive</td>
<td>Reactive</td>
<td>VDRL Reactive</td>
<td>Reactive VDRL</td>
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<td></td>
<td>(CSF)</td>
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<tr>
<td>Toxoplasmosis</td>
<td>IgG</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>IgM detected and/or significant increase between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>IgM Equivocal</td>
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<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>No IgM Detected</td>
<td>IgM Detected</td>
<td></td>
<td></td>
</tr>
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<td>Varicella Zoster</td>
<td>EIA</td>
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<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>Significant increase between paired sera&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>None</td>
</tr>
<tr>
<td>Agent</td>
<td>Test</td>
<td>Method</td>
<td>Negative</td>
<td>Positive²</td>
<td>Diagnostic</td>
<td>Presumptive³</td>
</tr>
<tr>
<td>----------------------------</td>
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<td>-----------------------------------------------</td>
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</tr>
<tr>
<td>West Nile Virus</td>
<td>IgG</td>
<td>EIA</td>
<td>No IgG Detected</td>
<td>IgG Detected</td>
<td>IgM detected and/or significant increase between paired sera⁴,⁵</td>
<td>IgM Equivocal</td>
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<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>No IgM Detected</td>
<td>IgM Detected</td>
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<tr>
<td>Western Equine Encephalitis</td>
<td>IgG</td>
<td>IFA</td>
<td>IgG &lt;1:16</td>
<td>IgG ≥1:16 IgM &lt;1:16</td>
<td>Four-fold rise in titer between paired sera⁴</td>
<td>≥ 1:16</td>
</tr>
<tr>
<td></td>
<td>IgM</td>
<td></td>
<td>IgM &lt;1:16</td>
<td>IgM ≥ 1:16</td>
<td></td>
<td></td>
</tr>
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</table>

Abbreviations (in alphabetical order)¹

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agg.</td>
<td>Agglutination</td>
</tr>
<tr>
<td>Anti-HBs</td>
<td>Hepatitis B surface antibody</td>
</tr>
<tr>
<td>CSF</td>
<td>Cerebrospinal Fluid</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Hepatitis B core antibody</td>
</tr>
<tr>
<td>EIA</td>
<td>Enzyme Immunoassay</td>
</tr>
<tr>
<td>IgM</td>
<td>Immunoglobulin M</td>
</tr>
<tr>
<td>IgG</td>
<td>Immunoglobulin G</td>
</tr>
<tr>
<td>TPPA</td>
<td>Treponema pallidium antibody</td>
</tr>
<tr>
<td>RPR</td>
<td>Rapid Plasma Reagin</td>
</tr>
<tr>
<td>HBs</td>
<td>Hepatitis B surface antigen</td>
</tr>
<tr>
<td>VDRL</td>
<td>Venereal Disease Research Laboratory</td>
</tr>
<tr>
<td>HBe</td>
<td>Hepatitis B e antigen</td>
</tr>
</tbody>
</table>

²A positive result indicates natural or acquired immunity, especially for vaccine-preventable diseases.
³Presumptive results identify a significant result for a single (not paired) serum, and need confirmation by clinical symptoms, recollection of specimen for retesting, or if applicable, submission of a convalescent specimen.
⁴Paired sera (acute and convalescent) dates of collection and date of onset of illness are needed for proper interpretation of results.
⁵A significant difference is determined by instructions given in individual enzyme immunoassay procedures, and may differ manufacturers.
⁶Performed for county health departments and DPH facilities only.

FOR ADDITIONAL INFORMATION REGARDING TEST INTERPRETATION CALL THE MICROBIAL IMMUNOLOGY LABORATORY AT (404)327-7970
INTRODUCTION

The Mycobacteriology Unit accepts specimens for the isolation and identification of Mycobacterium tuberculosis complex and other mycobacteria which may cause disease under certain circumstances. Susceptibility testing is performed on isolates of the Mycobacterium tuberculosis complex only. The services of this laboratory are available to both public and private health care providers.

SPECIMEN COLLECTION/LABELLING/REQUISITION FORM

A. Clinical Specimens

Although the most common specimen received in the TB Unit is sputum, the GPHL accepts specimens of various other types: bronchial washings, gastric lavage, urine (voided early morning or catheterized), pus (aspirated or on swab), tissue (biopsied lymph node or biopsied portions of lung or other organs), bone, stool, and body fluids (cerebrospinal, pleural, pericardial, or joint).

If a case has not been diagnosed as tuberculosis, a series of three early morning sputum specimens should be collected on successive days and transported to the laboratory as soon as possible. Specimen collection outfits (Item #0550) are available at no charge from the Laboratory Supply Office (404-327-7928). The patient’s name must be clearly printed on the 50 ml specimen collection tube.

Laboratory Submission Form #3583 should be filled out completely, giving the following information: patient’s name (please print and be sure it is evident which is the patient’s first and last name), address including county of residence, race, sex, date of birth, type of specimen, date collected, and name and address of submitter. All information requested on the form should be provided on all request forms, since the laboratory information system creates a unique tracking number for each patient based on these demographics.

B. Isolates for Identification and/or Susceptibility Testing

Isolates/cultures for identification and/or drug susceptibility testing should be submitted on solid media or in liquid media after good growth has occurred. The patient’s name must be clearly printed on the media. Laboratory Submission Form #3583, appropriately marked for either “Culture for identification” or “Culture for susceptibility testing,” should be filled out completely and legibly and submitted with each isolate. If an isolate submitted for
identification is identified as *M. tuberculosis complex*, susceptibilities will automatically be performed.

**SHIPMENT**

**A. Clinical Specimens**

GPHL specimen collection/shipping outfits (Category B) consist of a rigid mailing container that holds a specimen collection tube (50 ml plastic screw-cap tube), a biohazard bag, a square of absorbent material, and a white Tyvek envelope. The specimen collection tube is placed in the biohazard bag along with the square of absorbent material. The bag is sealed and placed inside the white Tyvek envelope. The white envelope is sealed and placed inside the outer rigid container. A Laboratory Submission Form #3583, marked for “Clinical Specimen for smear, culture & susceptibility,” is also placed in the rigid container. The lid of the rigid container is screwed on tightly and secured with tape. The specimen should be mailed or delivered to the laboratory as soon as possible after collection to avoid overgrowth of unwanted bacteria. If mailing is delayed overnight, the specimen should be refrigerated.

**B. Isolates or Cultures for Identification and/or Susceptibility Testing**

If isolates or cultures are submitted in glass tubes or bottles, they must be wrapped with absorbent cushioning material before being placed inside any shipper component.

MGIT tubes showing growth of acid-fast bacilli may be submitted for identification and drug susceptibility testing. The MGIT tube must be placed inside a plastic 50 ml conical tube, capped securely and then packaged according to federal shipping regulations. In case of breakage of the MGIT tube, the broth will still be contained inside the 50 ml conical tube, provided all caps have been securely tightened.

Category B Shippers are available from the Laboratory Supply Office (404-327-7928). Isolates which have been identified as *Mycobacterium tuberculosis complex* must be shipped as Category A. GPHL does not supply Category A shippers.

**REPORTING/INTERPRETATION OF TEST RESULTS**

**PCR Test for *M. tuberculosis complex* (Cepheid GeneXpert)**

The Cepheid GeneXpert MTB/RIF Assay is a diagnostic test that can identify *Mycobacterium tuberculosis* (MTB) in clinical specimens from respiratory sources. The GeneXpert purifies, concentrates, amplifies (by real-time PCR), and identifies targeted nucleic acid sequences in the TB genome.

The GeneXpert MTB/RIF Assay does not take the place of culture. A negative MTB/RIF Assay does not exclude the possibility of isolating *M. tuberculosis* from culture.

The test should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but
has not yet been established, and for whom the test result would alter case management or TB control activities. Results are reported as “M. tuberculosis detected” or “M. tuberculosis not detected.” In addition, if M. tuberculosis is detected the assay will look for Rifampin resistance, reported as “Rifampin resistance not detected” or “Rifampin Resistance Detected”.

**Microscopic Examination**

Fluorochrome stained slides are prepared from all clinical specimens and are examined using a fluorescent microscope for the presence of bacilli showing a yellow-green fluorescence. Results are reported as “No AFB found”; “+/−” (1-3 AFB/slide); “1+” (4-36 AFB/100 fields); “2+” (4-36 AFB/10 fields); “3+” (4-36 AFB/field); or “4+” (>36 AFB/field). Submitters are notified by telephone of a positive smear on a new patient.

**Culture**

A tube of solid medium (Lowenstein-Jensen agar) and a tube of liquid medium (BACTEC MGIT broth) are inoculated from each clinical specimen. These cultures are incubated for six weeks before a report of “No Mycobacteria Isolated” is issued. If growth in either medium occurs at any time during the six weeks, identification procedures begin. Lowenstein-Jensen agar slants are examined weekly for signs of growth and morphology.

**Identification**

As soon as growth has been detected, the culture is stained to determine if acid-fast organisms are present. Sometimes the growth is made up of other bacteria which are not acid-fast, and the specimen is then reported as “Contaminated.” Cultures showing acid-fast organisms are tested by High Performance Liquid Chromatography (HPLC) to determine the identification of the organism.

**Drug Susceptibility Testing**

Drug susceptibility testing is performed only on *M. tuberculosis* complex organisms. Each new isolate is automatically tested at the time of identification, and testing is repeated every three months if the organism is still being isolated from culture. Results are usually available within 10-14 days after identification of the organism. Susceptibility testing is performed using the BACTEC 960 MGIT procedure with a panel of three drugs (isoniazid, rifampin, and ethambutol) initially. If any of the drugs show resistance, the test is repeated, and streptomycin is added to the panel. Isolates which are resistant to one or more drugs are sent to the Centers for Disease Control and Prevention for testing with an expanded drug panel. The CDC drug testing usually requires approximately 4-6 weeks. Reports on isolates showing drug resistance for the first time are called to submitters as soon as results are available.
Reporting

Results for all mycobacterial testing are reported electronically to the submittter as soon as they are available. In addition, copies of reports for positive specimens (i.e. positive AFB smears, positive TB identification, and susceptibilities) are sent to the Georgia TB Control Program. Test results will only be released to the submittter of the specimen.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen or culture.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
INTRODUCTION

The Parasitology Unit accepts fecal specimens to be examined for human parasites from all county health departments. Reference specimens for confirmation of parasite identity or further identification are accepted from all laboratories and health care providers. Diagnosis of most intestinal parasitic infections is dependent upon finding the eggs or larvae of helminths and trophozoites or cysts of protozoa in feces by microscopic examination. If particular infections are suspected, please alert our laboratory to your suspicions. Molecular methods are more sensitive than microscopy and may be required for the differentiation of morphologically identical species such as *Entamoeba histolytica* and the non-pathogenic *Entamoeba dispar* and species of Cyclospora and Cryptosporidium. In such instances, a fresh sample of stool preserved in potassium dichromate or unpreserved frozen specimen is preferred.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Intestinal worms shed eggs in varying numbers intermittently, and certain protozoan cysts are shed in "showers". Due to this cyclic shedding, samples from the same patient may be positive one day and negative the next. Therefore, it is ideal to submit three sets of samples collected on consecutive days of bowel movement for each patient. Submitting only one set of samples 1 pink vial (10% Formalin) and 1 blue vial (LV-PVA) provides only a 30% chance of recovering the organism. All sample containers should be properly labeled with the patient's name and collection date. Samples without patient's name and/or collection date will be marked unsatisfactory and discarded. Multiple specimens collected on the same date will be treated as a single specimen and only one will be tested. The rest will be discarded. The submission form should be filled out completely.

A. Formalin/LV-PVA outfit: Only specimens preserved in 10% formalin (pink vial) and LV-PVA (blue vial) should be submitted. Follow the instructions provided in the kit for collecting the stool sample. The kit systems are packaged in ziplock bags with illustrated, multilingual patient instructions to assist in safe and sanitary specimen collection by personnel and/or patients. Remove vials from ziplock bags and discard the bag. Do not contaminate specimen with dirt, urine, or paper. The ingestion of antidiarrheal compounds, antacids, bismuth, and mineral oils may interfere with the diagnosis of parasites. Three collection outfits (i.e. three pairs of pink and blue vials per patient), collected on consecutive days of bowel movement, should be submitted for testing (for instance, one pair of vials (pink and blue) collected on Monday, another one on Tuesday, and a third one on Thursday). It is important that a pair of vials (1 pink and 1 blue) be collected each time to enable the diagnosis of the full range of parasitic
infections. Write the collection date on each vial immediately after collection. This is very important as multiple samples with no collection dates will not be tested and those with the same collection date will be regarded as one collection. Complete one Form 3583 per pair of samples, making sure the collection date on the form and samples are matched. Under “Test Requested” in Form 3583, check both “Formalin-Feces and PVA-Feces”. In the new form the selection would be under “Parasitology”. Fold completed forms in half and place in outside pouch of the biohazard bag. Please make sure the patient’s race/nationality and foreign travel, if applicable, is marked on the submission form. Please write the patient’s last name first separated by a comma from the first name on the submission form to avoid confusing the two names for data entry and reports and records.

B. **Potassium dichromate outfit for PCR:** Feces can be tested by molecular diagnostic procedures. Follow steps as in section “A” above for collection of fecal specimen. Do not contaminate specimen with dirt, urine, or paper. Place enough feces in container to bring the liquid up to the red line; mix thoroughly. Place in the biohazard transport bag; seal and complete appropriate form. Fold completed form in half and place in outside pouch of the biohazard bag. Place biohazard transport bag in the fiberboard mailing container, secure lid and mail. Please make sure the patient’s race/nationality and foreign travel is marked on the submission form. Please write the patient’s last name then the first name on the submission form to avoid confusing the two names for data entry and reports and records.

C. **Pinworm Outfits:** Because the female *Enterobius vermicularis* (Pinworm) leaves the intestinal tract to lay her eggs around the anal opening, we have a special collection outfit to collect these eggs. The specimen needs to be immediately collected upon the patient’s awakening in the morning since the eggs may be lost later during the day as a result of scratching, bowel movement or bathing. Collect the specimen following the printed instructions for Pinworm Slide Outfit. Do not let feces get on the tape or slide. Place slide inside the cardboard mailing container and close the top. Make sure patient’s name is written on the cardboard mailing container label. Place container with slide inside the mailing envelope. Use form #3583 for specimen submission.

D. **Whole Worms or Proglottids:** At times individuals will pass whole worms or small white segments (Proglottids) with feces; these should be separated from the feces and preserved in 70% alcohol. If the worm/Proglottids cannot be separated, please note on the submission form that worms or white segments were seen upon collection. If worms/Proglottids were passed without feces, they should also be preserved in 70% alcohol. Place in a plastic or glass container to mail. Make sure the patient’s name is on the container. Complete Form 3583.
SHIPMENT OF SPECIMENS

Specimens may be delivered to the laboratory by a courier or a shipping vendor with a traceable system. Be sure specimens are placed in the correct mailing container; otherwise they may get lost in shipment or be delayed in delivery. The double-walled mailing containers for submitting fecal specimens are available from Laboratory Services and Supply (404-327-7920). The round fiberboard-mailing container is not necessary for specimens delivered by courier. Place several biohazard transport bags containing specimens in a box or a large envelope for courier delivery. Parasitology specimens sent through the mail have to conform to postal regulations. If a screw-cap outer container is used to mail the specimen, the screw cap must be secured with tape or the Postal Service will return it for taping. It is the responsibility of the sender to make sure any viable or preserved biological material conforms to the most recent postal regulations. When unusually large numbers of specimens are anticipated (such as outbreak situations), the Parasitology Unit should be alerted so that preparations may be made (404-327-7961/7963).

REPORTING AND INTERPRETATION OF RESULTS

The turnaround time for the diagnosis of intestinal parasitic infections is 24-72 hrs on weekdays depending on the volume of specimens received. For all other specimens the turnaround time is 12-24 hrs. The turnaround times may however be longer for all specimens received on Fridays and prior to holiday weekends. The turnaround time for specimens sent to CDC for identification or confirmation may be up to two weeks. If there is an emergency situation, the specimen will be considered stat and processed immediately. The lab should be notified when emergency samples are sent.

When testing is completed the results are entered into MLAB and verified by the testing personnel and become immediately viewable and printable by clients with online privileges. Others will receive a hard copy of their results in the mail. The MLAB-EE laboratory data management system allows submitters with Internet and MLAB access to view and print results online. Laboratory results become available to the submitters immediately upon verification by the testing personnel.

If the report indicates the presence of pathogenic parasites, the patient needs to be treated. Non-pathogenic parasites are also reported, but their presence indicates hand to mouth fecal contamination. Unsatisfactory results indicate the specimen was compromised in a way that might render the test results invalid. Below is the list of unsatisfactory specimen submissions.
UNACCEPTABLE SPECIMENS

**Formalin and LV/PVA Specimens**
1. No patient identifier on specimen container.
2. No specimen (submission form only) received.
3. No feces (container only) received.
4. No preservative in container.
5. Severely leaked in transit and are considered a hazard to open.
7. Multiple specimens collected on the same day (one specimen will be tested).
8. Insufficient material to examine.
10. Inappropriate specimen/collection outfit for test requested.
11. Refractile material interfering with diagnosis.
12. PVA solution jelled.
13. Frosted tape used for pinworm collection.
14. Pinworm tape stuck to applicator paddle.
15. Feces or powder on pinworm slide or tape.
INTRODUCTION

The Parasitology Unit examines specimens for blood and tissue parasites. Due to the ease of foreign travel and the influx of immigrants and refugees, it is very important to fill out patient history on the form. Some “exotic” parasites enter this country by travelers who visit or those who come from a foreign country. We need to know any recent health problems, symptoms, travel history, place of residence, typical and unusual food preferences and environmental exposure. Many parasites have well-defined geographical ranges and unless an individual has traveled or resided within an endemic or enzootic zone, infection with the parasite is unlikely. There are other situations in which individuals may become infected with blood parasites. Ones to consider are - blood transfusions, use of hypodermic needles contaminated by prior use, possibly congenital infection and transmission in the United States by indigenous mosquitoes that acquired the parasites from imported infections. Food fads have introduced new parasites into the human population. Some of the blood and tissue parasites that we examine are malaria, microfilaria, Trypanosoma, Isospora, and Babesia, Leishmania. Molecular methods are used to confirm a diagnosis. The advantages of this method over the traditional blood film examination include (1) ability to detect lower parasitemia (2) confirmation of false-negative microscopy results as true positive and (3) identification of organisms to the species level even in mixed infections. Parasites in human tissue are also examined in our lab, but are often sent to a reference lab for confirmation.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

At present, the microscopic examination of blood parasites in stained blood smears is the standard method employed in this laboratory for the diagnosis of malaria and other blood parasites. For malaria parasites the most favorable time for collecting blood for examination is halfway between the chill/fever. For other blood parasites such as trypanosomes and microfilaria, blood samples should be collected in early morning and/or late evening to coincide with the feeding habit of the insect vector and the period when parasite is most abundant in the peripheral blood. Prepare three thick and three thin smears immediately from capillary blood (fingerstick) or within one hour from venous blood in EDTA anticoagulant to minimize morphological changes in stored samples that make species differentiation difficult. If possible one each of the thick and thin smear should be stained with Giemsa stain. Send the following to the lab:

1. The stained thick and thin smears
2. The unstained thick and thin smears
3. 1-2 ml of blood in EDTA to be used for PCR confirmation if necessary.
Blood Parasites

A. Thick smear preparation

1. Cleanse the finger-tip with alcohol and allow to dry thoroughly.
2. Puncture the skin deeply enough to allow the blood to well up in a large drop. Do not squeeze the finger; this will dilute the blood with tissue fluid.
3. Touch the clean slide to the crest of the drop of blood, or place a drop of venous blood using a Pasteur pipette, in the center of the slide.
4. With a wooden applicator stick, using a circular motion spread the blood to the size of a dime. The thick smear should just be thick enough so that newspaper print can barely be read through it. Do not place too large a drop of blood on the slide. Too much blood will cause it to flake off the slide after drying.
5. Allow the smear to air dry in a flat, horizontal position so that the blood will be evenly distributed. Protect from dust and insects (roaches enjoy eating the blood on the slide). Do not fix with alcohol.
6. Write patient identifier number or name, and the date the smear was made on the frosted-end portion of the slide. Place in the cardboard mailing container with completed Form 3583.

B. Thin Smear Preparation

1. Cleanse the fingertip with alcohol and allow to dry thoroughly.
2. Puncture the skin deeply enough to allow the blood to well up in a large drop. Do not squeeze the finger; this will dilute the blood with tissue fluid.
3. Touch the clean slide to the crest of the drop of blood, or place a drop of venous blood using a Pasteur pipette, at the frosted end of the slide.
4. Hold a second spreader slide at a 40-45-degree angle and touch edge of blood, allow blood to spread by capillary action along the edge of the slide.
5. Rapidly and smoothly push the spreader slide to the opposite end of the slide while pulling the blood behind it. The smear should have a feathered edge.
6. Air dries at room temperature. Protect from dust and insects. Remember that roaches will eat the blood on the slides.
7. Write patient identifier number or name, and the date the smear was made on the frosted end portion of the slide. Place in the cardboard mailing container with completed Form 3583.

Tissue Parasites

Histology preparations from biopsy material are prepared in the hospital or private laboratories and mailed to our lab for review, consultation, or confirmation. Most of these smears are H&E or Giemsa stained. Place patient identifier number or name, and the date the smear was made on the frosted end portion of the slide. Place in a cardboard mailing container with completed Form 3583.
SHIPMENT OF SPECIMENS

Specimens may be delivered to the laboratory by a courier or a shipping vendor with a traceable system. Be sure specimens are placed in the correct mailing container; otherwise they may get lost in shipment or be delayed in delivery. The mailing containers for submitting blood and tissue specimens are available from Laboratory Services and Supply (404-327-7920). The round fiberboard-mailing container is not necessary for specimens delivered by courier. Place several biohazard transport bags containing specimens in a box or large envelope for courier delivery. Prepared slides can be packed in boxes, cardboard slide holders, or any other suitable container that will prevent damage or breakage. Specimens for Parasitology sent through the mail have to conform to postal regulations. If a screw-cap outer container is used to mail the specimen, the screw cap must be secured with tape or the Postal Service will return it. It is the responsibility of the sender to make sure any biological material preserved, or viable, conforms to the most recent postal regulations.

REPORTING AND INTERPRETATION OF RESULTS

Specimens are reported as quickly as possible. The specimen results may be reported the same day that they are received. We strive for a 12-24 hour turnaround time. If there is an emergency situation, the specimen will be considered stat and immediately processed, and reported. Please notify the lab of any emergency. Malaria parasites are identified to the species when possible. The four species reported are *Plasmodium malariae*, *Plasmodium ovale*, *Plasmodium vivax* and *Plasmodium falciparum*. At times when species diagnosis cannot be made from the smears a PCR test is performed if blood is available to determine the species. This may delay the reporting in some cases. PCR results in some areas of parasitology are considered experimental and are provided for information only.

At times, we report a specimen unsatisfactory. Unsatisfactory results indicate the specimen was compromised in a way that might render the test results invalid. Below is the list of unsatisfactory specimen submissions.

UNACCEPTABLE SPECIMENS

**Blood and Tissue Parasites**
1. No patient identifier on specimen container.
2. No specimen received.
3. Smear is too thin or too small.
4. Smear damaged by flies or roaches.
5. Smear is improperly dried.
6. Thick smear is too thick (portion flaked off).
7. Thin smear not feathered at the end.
8. Grease on slide.
9. Smear improperly fixed.
10. Blood coagulated or dried up.
INTRODUCTION

The Parasitology Unit examines specimens collected from the environment as well as from humans for identification. There are many arthropods of medical importance that transmit diseases to man and other animals. Transmission may be mechanical or biological. Some of the common vectors that are sent in are flies, midges, lice, bedbugs, ticks, mites, chiggers, spiders and many more. Some specimens sent in for identification are pseudoparasites and artifacts. These need to be distinguished from the true parasite because of the physical and mental relief it has upon individuals. Parasites such as Entamoeba histolytica, Giardia lamblia, Cryptosporidium parvum, Cyclospora cayetanensis and Microsporidia spp. can cause waterborne and foodborne illness.

SPECIMEN COLLECTION/LABELING/SUBMISSION FORM

All specimen containers/slides should be properly labeled with the patient's name, and date and time collected. It will be marked unsatisfactory and discarded if the patient's name is not on the container/slide. Use form #3583 for specimen submission.

A. Skin scrapings: Gently scrape the skin with a scalpel. Collect the scrapping on a piece of paper and transfer into a bottle containing 70% alcohol.

B. Impression Smears: Smears from the aspirated material/tissue can be made and examined for parasites. To prepare the smear, press the material/tissue to the slide, air dry, and fix if needed.

C. Arthropods: Place in 70% alcohol or on a pad of tissue or loose cotton to avoid damaging fragile body structures. Do not place on cellophane tape. Place in plastic or glass container and mail.

D. Water Samples for Giardia/Cryptosporidium: Water samples thought to be the source of human giardiasis or cryptosporidiosis will be accepted by special arrangement. Please contact your local County Health Department’s environmental specialist to collect the water and notify the laboratory before submitting the water sample. Three gallons of water (as specified below) should be collected in sterile containers and sent to the lab. One gallon should be from the well-head; one from an inside faucet and one from an outdoor faucet. Before the water is accepted for testing, a positive test for Giardia/Cryptosporidium infection must be confirmed in stool specimens of people who have used the water. Complete Form 3583, one for each location that water was collected.
E. Worms for Identification: When worms are found in diapers, on bed linens, in the toilet bowel, etc., they should be retrieved as carefully as possible and placed in a vial containing 70% alcohol. Some of the worms have delicate structures used for identification and should be collected carefully. Make sure the patient’s name is on the container.

SHIPMENT OF SPECIMENS

Specimens may be delivered to the laboratory by a courier or a shipping vendor with a traceable system. To avoid delay, loss or damage during shipment specimens must be sent in appropriate container. It is the responsibility of the sender to ensure that any specimen sent through regular mail conforms to most recent postal regulations.

A. Stool: Double-walled mailing containers are available from Lab Services and Supply (404-327-7920). The round fiberboard-mailing container is not necessary for specimens delivered by courier. Several specimens in separate biohazard transport bags may be placed in a box or a large envelope for courier delivery.

B. Blood: The mailing containers for submitting blood and tissue specimens are available from Laboratory Services and Supply (404-327-7920). Prepared slides can be packed in boxes, cardboard slide holders, or any other suitable container that will prevent damage or breakage.

C. Miscellaneous samples: If a screw-cap outer container is used to mail the specimen, the screw cap must be secured tightly with cellophane tape so as to avoid leakage. The Postal Service will not deliver leaky biological materials. Specimens are to be packaged in suitable boxes and sent to the lab by the sender’s preferred method of shipment.

REPORTING AND INTERPRETATION OF RESULTS

Specimens are reported as quickly as possible. The specimen results may be reported the same day that they are received. We strive for a 12-24 hour turnaround time. If there is an emergency situation, the specimen will be considered stat and immediately processed, and reported. Please notify the lab or any emergency. If we have to send it to a reference lab, it may take up to two weeks to get the results back. PCR results in some areas of parasitology are considered experimental and are provided for information only.

At times, we report a specimen as unsatisfactory. Unsatisfactory results indicate the specimen was compromised in a way that might render the test results invalid. Below is a list why the report may have been marked unsatisfactory.
UNACCEPTABLE SPECIMENS

Arthropods and Misc. Specimens
1. No patient identifier on specimen container/slide.
2. No specimen received.
3. Smear is too thin or too small.
4. Smear damaged by flies or roaches.
5. Smear is improperly dried.
6. Sample amount is insufficient for accurate diagnosis.
7. Identifying structure is missing.
8. No preservative in container.
9. Severely leaked in transit and considered a hazard to open.
10. Slide or container broken in transit.
**TELE-DIAGNOSIS**

**404-327-7961/7963**

**The DPDx program**

DPDx is a Web site developed and maintained by CDC's Division of Parasitic Diseases (DPD) to train and also to assist laboratories and pathologists in parasite identification within and outside the United States. Under the program laboratories may submit digital images of parasites through the internet to the Georgia Public Health Laboratory for identification and or confirmation. It requires that prospective submitters be equipped with microscopes mounted with a digital camera and a computer with internet access. The Georgia Public Health Laboratory was one of the first to receive all the necessary equipment and training from CDC to implement the program. The following are some of the advantages of the program:

1. Eliminates the necessity to send specimen to CDC
2. Results are available within minutes to hours of submission
3. Available expertise in different areas are utilized
4. Strengthens the diagnosis of parasitic diseases
5. There is no charge for the service

In addition to the diagnostic assistance, the DPDx also offers a Reference and Training function which enables you to browse through concise reviews of parasites and parasitic diseases, an image library and a review of recommended procedures for collecting, shipping, processing and examining biologic samples are available at [http://www.dpd.cdc.gov/dpdx](http://www.dpd.cdc.gov/dpdx)

**Submission of Images to GPHL:**

1. With a digital camera capture several images (at different magnifications) of the organism you need assistance with
2. Save as a TIFF or GIF file
3. Email as an attachment to the following email address:
   a. mindubuisi@dhr.state.ga.us or cdaniell@dhr.state.ga.us
4. In your email provide the following information:
   a. Full name of patient
   b. DOB or age of patient
   c. Sex of patient
   d. Source of specimen
   e. Stain used if applicable
   f. Travel history of patient if known
   g. Magnification of image
   h. Symptoms of illness
   i. Telephone # of contact
   j. Any relevant information that will aid in the identification of the object
5. In most instances, results are available within hours of submission.
INTRODUCTION

The 4th generation antigen/antibody immunoassay is the current test used for the detection of antigen and antibodies to the human immunodeficiency virus (BioRad HIV Ag/Ab Combo EIA). This enzyme immunoassay (EIA) is used as a screening test for the detection of HIV-1 (M and O groups), HIV-2 antibodies and HIV-1 p24 antigen. Reactive EIAs are repeated in duplicate to verify the initially reactive test result. Repeatedly-reactive EIA tests (two or more reactive EIAs) are differentiated by the supplemental HIV-1/HIV-2 Multispot Assay. If the HIV-1/HIV-2 Multispot is negative or undifferentiated, an additional test or a follow up specimen is recommended.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Using Universal Precautions, and standard venipuncture technique collect approximately five milliliters of whole blood (or serum) in a gold serum separator tube (BD Vacutainer® tube with BD Hemagard™ closure), labeled with patient's identifier, date, and name of the submitter, use a marker that will not fade, smear, or run during transportation. Use proper size syringe needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient. Invert tube 5 times to mix clot activator with blood. Allow blood to clot for a minimum of 30 minutes in a vertical position. Centrifuge for 10 minutes at 1100g to 1300g (approx. 1800 – 2200 rpm) for a swing-head unit, or 15 minutes fixed angle units. http://www.hettweb.com/mobile-app

Wrap the specimen in the absorbent packing paper provided to absorb any fluid from leaking or broken specimens (do not use rubber bands or tape). Place the wrapped specimen inside a biohazard bag. Place the completed GPHL Laboratory submission form in the pouch of the biohazard bag. Allow blood specimen to clot and transport, or place in the refrigerator if not transporting at that time. Do not hold over seven days before transporting.

Handling Conditions

Samples may be stored for no longer than 2 days at room temperature, 7 days at 2°C - 8°C, including the time that samples are in transit. Minimize room temperature storage of samples to the shortest time possible in order to preserve maximum HIV-1 p24 antigen reactivity. For long-term storage, the serum should be removed from the clot, red blood cells, or separator gel and should be frozen at -20°C or colder. Avoid freezing and thawing.

Requisition form: The Routine HIV Combo Ag/Ab EIA screen test request is included in the GPHL Laboratory submission form #3583. Order the test by checking the box of 13500 Routine HIV Combo Ag/Ab EIA Screen.
SHIPMENT OF SPECIMENS

Specimens are recommended to be sent by a courier or a shipping vendor with a traceable system. Place the biohazard bag with gold serum separator tubes, absorbent paper, cold pack, etc. inside the fiberboard shipper. Place one to ten specimens in the fiberboard shipper so that they can be removed without mishap. The shipper can be shipped by UPS or the United States Postal Service. The shipper must be secured by tape, or will be returned for taping. Be sure to use the proper mailing label for the final specimen destination. Virology HIV outfits can be obtained from Laboratory Services and Supply, telephone number is (404) 327-7920.

REPORTING AND INTERPRETATION OF RESULTS

GPHL has used the American Public Health Association/Centers for Disease Control recommendation of the new 4th Generation Algorithm from the December 2012 HIV Diagnostic Conference as a reference for the new HIV algorithm.

The following recommendations are made regarding additional tests or follow-up specimens:
1. If the result of the HIV-1/HIV-2 Multispot is undifferentiated, perform additional tests such as HIV-1 WB or submit another specimen for testing within a month.
2. If the result of the HIV-1/HIV-2 Multispot is negative, perform additional test such as the HIV-1 RNA Qualitative for high risk population or submit another specimen for testing within a month.
3. When a patient receives his/her first positive test result and has not identified a high risk behavior, collect a verification specimen at the time the patient is given the results of the first test.

Interpreting Routine HIV EIA Screening and Supplemental/Confirmation Test Results

1. Specimens that are Initially Non Reactive by HIV Ag/Ab Combo EIA will be reported as negative for HIV-1 (M and O Groups), HIV-2 antibodies and HIV-1 p24 Ag.
2. Specimens that are Initially Reactive by HIV Ag/Ab Combo EIA are retested in duplicate to validate the initial test results. If, after repeat testing, both duplicate specimens are Non Reactive results will be reported as negative for HIV-1 (M and O Groups) and HIV-2 antibodies and p24 Ag.
3. If, after repeat testing, either of the duplicates are Reactive the result is considered Repeatedly Reactive. Repeatedly Reactive specimens will be tested by HIV-1/HIV-2 Multispot to differentiate HIV-1 and HIV-2 antibodies.
4. If HIV Ag/Ab Combo screen and HIV-1 Multispot results are positive, the results will be reported as positive for HIV-1 antibody and patient clinical follow up is recommended. If HIV Ag/Ab Combo screen and HIV-2 Multispot results are positive, the results will be reported as positive for HIV-2 antibody and patient clinical follow up is recommended.
5. If the HIV-1/HIV-2 Multispot is undifferentiated or negative, additional tests such as the HIV-1 WB or the HIV-1 RNA Qualitative PCR assays are performed or a second specimen for testing will be requested. The final results will depend on the test outcome and will be reported as negative, indeterminate or positive for HIV-1 WB or as reactive, invalid or non-reactive for HIV-1 RNA Qualitative PCR.

The Georgia Public Health Laboratory uses the APHL/CDC criteria shown below for the interpretation of the supplemental Multispot HIV-1/HIV-2 tests to differentiate HIV-1 and HIV-2 antibodies.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td>The absence of both HIV-1 and HIV-2 antibodies</td>
</tr>
<tr>
<td>Undifferentiated</td>
<td>The presence of both HIV-1 and HIV-2 antibodies</td>
</tr>
<tr>
<td>Positive</td>
<td>The presence of either HIV-1 or HIV-2 antibodies</td>
</tr>
</tbody>
</table>

The Georgia Public Health Laboratory uses the APHL/CDC criteria shown below for the interpretation of the confirmatory HIV-1 Western Blot.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td>The absence of any and all bands-not just viral bands.</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>The presence of any viral or non-viral band or bands that fail to meet the positive criteria.</td>
</tr>
<tr>
<td>Positive</td>
<td>The presence of any two of the following bands:</td>
</tr>
<tr>
<td></td>
<td>• P24</td>
</tr>
<tr>
<td></td>
<td>• Gp41</td>
</tr>
<tr>
<td></td>
<td>• Gp120/gp160</td>
</tr>
</tbody>
</table>

The Georgia Public Health Laboratory uses the APHL/CDC criteria shown below for the interpretation of the confirmatory HIV-1 RNA Qualitative RT-PCR.

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Reactive</td>
<td>Analyte S/CO $^1$&lt;1 and IC$^2$ $\geq$ IC Cutoff and IC &lt; 475,000 RLU$^3$</td>
</tr>
<tr>
<td>Reactive</td>
<td>Analyte S/CO &gt; 1 and IC &lt; 475,000 RLU</td>
</tr>
<tr>
<td>Invalid</td>
<td>IC &gt; 475,000 RLU or Analyte S/CO &lt; 1 and IC &lt; IC Cutoff</td>
</tr>
</tbody>
</table>

Note:  
S/CO$^1$=Signal to Cutoff ratio  
IC$^2$=Internal Control  
RLU$^3$=Relative Light Units
UNACCEPTABLE SPECIMENS

1. ID on form and specimen do not match (ID mismatch).
2. No ID on form.
3. No name on form or tube.
4. No ID on specimen.
5. Over 14 days old.
7. Insufficient quantity for testing (QNS).
8. No sample received with form.
INTRODUCTION

The Abbott Real-Time HIV-1 assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantification of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma from HIV-1 infected individuals. The detection system is on an automated m2000 platform and the range of detection is 40 to 10,000,000 copies of target/ml. The Abbott Real-Time HIV-1 assay amplifies pol integrase region of the HIV-1 RNA genome. The assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels. This assay is not intended to be used as a donor screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection.

The HIV-1 Viral Load assay is offered to patients in the Ryan White Program for the management of individuals infected with HIV-1. The results are reported as HIV-1 RNA copies/ml as well as log copies/ml.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

1. Follow all safety precautions when drawing blood from patients.
2. No special patient preparation is necessary before collection. Use proper size needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient.
3. Please collect all specimens in a sterile collection tube with EDTA as the anticoagulant or in the Prepared Plasma Tube (PPT) provided by the Georgia Public Health Lab (GPHL).
4. Collect one PPT tube using standard venipuncture techniques. Immediately after collection, gently invert the PPT tube 8-10 times. Whole blood may be held at room temperature (15-30 °C) for up to 6 hours or refrigerated (2-8 °C) for up to 24 hours, prior to centrifugation.
5. Label the specimen with the patient’s identification number, submitter code and the date.
6. Centrifuge at 1000 x g (2400 RPM) for 10-15 minutes or 2500xg (3600 RPM) for 5 minutes. If the red cells have settled prior to centrifugation, Mix contents by gently inverting the collection tube 10-15 times.
7. Aliquot plasma into the appropriately labeled vial. The minimum volume is 2.5ml for the HIV Viral Load. Please use the supplied screw cap aliquot tube supplied with the HIV-1 Viral Load collection kit.
   **Note:** Use sterile pipettes and tubes to reduce possible bacterial contamination that may destroy some or all of the HIV nucleic acid (RNA).
8. Place the properly labeled vial with plasma in a biohazard bag.
9. Plasma may be stored at 2-8°C for up to 5 days. Freeze in an upright position at -20°C for up to 60 days or ≤ -70°C for extended storage. Do not use frost-free freezers for storing samples. Do not exceed more than 3 freeze/thaw cycles.

Requisition Form:
Please use Laboratory Submission Form #3583 and include the following information:

1. Unique patient identifier number.
2. Date specimen collected.
3. Submitter’s name, address, and code, if applicable.
4. Check the “HIV-1 Viral Load” box.
5. Any information submitter needs for patient identification, e.g., chart number, or address.
6. The date of onset of illness, if applicable.
7. Race, ethnicity, sex and age.
8. Legibly label the aliquot tubes with patient name, patient I.D. no. and date of collection, or use electronic labels if submitting specimen through remote data entry. Unlabelled specimens will not be tested.
Place the HIV form in the pouch of the biohazard bag along with the specimen so that it is ready for courier pickup.

SHIPMENT OF SPECIMENS

Specimens will be delivered frozen on dry ice to the laboratory by courier according to a schedule provided for your facility.

REPORTING AND INTERPRETATION OF RESULTS

The sensitivity of the Abbott RealTime RT-PCR Assay is 40 copies/ml with a linearity range of 40-10,000,000 copies/ml. Turnaround time is 5-7 days. The test results are reported as:

1. A sample with result of “Not Detected” signifies that no target was detected.
2. A sample with result less than 40 copies/ml (<1.60 log copies/ml) indicates that target was detected but is less than the lower limit of quantitation (LLQ).
3. A sample with result equal to or greater than 40 copies/ml (≥1.60 log copies/ml) contain HIV-1 RNA in the quantity identified in the report. A result of “40 copies/ml to 10,000,000 copies/ml (1.60 to 7.00 log copies/ml)” indicates that the target was detected and the concentration falls between 1.6 log copies per ml (LLQ) and 7.0 log copies for the upper limit of quantitation (ULQ).
4. A sample with result greater than the 10,000,000 copies/ml (>7.00 log copies/ml) are above the upper quantitative level of the assay and are reported >10,000,000 copies/ml (>7.00 log copies/ml).
The goal of antiretroviral therapy (ARV) is to reduce the concentration of HIV in the plasma to below the detectable levels of ($\leq 40$ C/ml, $1.6$ LC/ml). During therapy, as drug-resistant strains replace sensitive strains, the plasma viral load rises. An increase in the viral load of less than 3-fold (0.5-log) may be due to assay variability. From the “Guidelines for the Use of Antiretroviral Agents in HIV-1 infected Adults and Adolescents” virologic treatment failure is defined by current Department of Health and Human Services as “Two consecutively confirmed plasma HIV RNA levels $>200$ copies/ml after 24 weeks”. For more information, The Guidelines for the Use of Antiretroviral Agents can be found at the following web site: [http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf](http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf)

**UNACCEPTABLE SPECIMENS**

1. No ID on form.
2. No name on form or tube.
3. No ID on specimen.
4. ID on specimen and form do not match.
5. Not approved for testing by the indicated method, e.g., blood for VDRL.
6. Serum instead of plasma.
7. Grossly hemolyzed, lipemic, turbid, or contaminated.
9. With an insufficient quantity for testing (QNS).
10. Specimen received unspun.
INTRODUCTION

The Virology Unit accepts animal heads submitted for testing rabies in accordance with the Georgia Rabies Animal Control Manual for testing at the Central Laboratory in Decatur. The goal is to report an accurate and reliable diagnosis so that rabies treatment can be initiated or terminated as necessary. The current methodology for rabies detection is the direct fluorescent antibody (DFA) test, which is the most accurate microscopic test available for the diagnosis of rabies. The key factor in obtaining quality results is the condition of the specimen received. Due to the importance of rabies diagnosis, the specimen must not be compromised.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

1. Only specimens received in good condition with at least two identifiable principal brain parts are approved for reporting test results. Brain parts must include the cerebellum and the brain stem.
2. In all cases, there must have been exposure of human or domestic animals to the suspected rabid animal.
3. The Virology Unit is not equipped to handle whole carcasses; therefore, only the head is accepted as a specimen, except bats and animals of similar size, which should be submitted whole. Whole carcasses of any larger animal will be returned to the sender for resubmission.
4. The following guidelines are recommended for the removal of animal heads: (Whenever possible, this procedure should be performed by a person who has received pre-exposure rabies vaccine).
   a. Protective gloves and clothing as well as face and eye protection should be worn while the head is being removed and packaged.
   b. Sever the head between the foramen magnum and the atlas so as not to damage the skull. Local veterinarians or trained animal control personnel can assist in this removal. Never advise clients to remove animal heads!
   c. Allow fluids and blood to drain from the head. Keep the head as clean as possible and place the head in a double plastic bag for transport to the laboratory.
   d. If fleas or ticks are present, spray insecticide into the plastic bag containing the head before closing. Do not send maggots.
   e. Gloves should be cleaned and disinfected or discarded following use, and cutting surfaces and instruments should be thoroughly cleaned and disinfected.
5. Only brain material (not the entire head) of very large animals (e.g. cows/horses) will be accepted, as the laboratory is not equipped to handle these large heads due to limited hood and sterilizer space. Removal of the brain should only be attempted by a veterinarian. Whole heads of large animals received by the laboratory will be returned to the sender for resubmission of the brain only.
6. Rodents (rats, rabbits, mice, gerbils, hamsters, guinea pigs, chipmunks, squirrels, moles, etc.) are not usually involved in the rabies cycle and will not be accepted for testing without prior arrangements with the Epidemiology Branch (404-657-2588) or the Georgia Public Health Lab in Decatur (404-327-7980).

7. If specimens cannot be delivered to the laboratory immediately, refrigerate, but do not freeze. Frozen specimens cannot be tested until they thaw, which may cause a delay in reporting.

8. Do not send tissue in a preservative such as formalin, as rabies testing cannot be performed on such specimens.

Requisition Form:

1. A Laboratory Submission Form #3583 should accompany each specimen submitted for rabies examination. This form should be filled out completely and legibly, making sure to include accurate addresses and phone numbers for use in reporting results. If you do not have a GPHL submitter code, please call GPHL at 404-321-2240 to have one assigned to you prior to submission.

2. Fill out the form completely and legibly. Include accurate addresses and phone numbers for reporting.

3. A copy of the rabies report is forwarded to the Georgia Department of Public Health Health Office of Epidemiology for data collection and review. Rabies reports are kept for a period of three years.

SHIPMENT OF SPECIMENS

Containers for rabies shipment are available from the Decatur Central Lab Virology Unit (404-327-7980).

1. Properly package the specimen by placing the animal head in a double plastic bag and secure the bag by twisting and knotting. For bats or similar size animals, do not remove heads, but submit the whole animal. For large animals (e.g. cows, horses, bears, goats, etc.) submit the brain only.

2. Place the sealed bag containing the specimen on top of the cold packs in the shipper container. Seal the Styrofoam shipper. Place the completed submission form in the brown envelope, and tape to the lid of the sealed shipper. Place the shipper in a cardboard box and tape the address for shipment. Do not seal the box until shipment, so the animal control officer can inspect the container.

3. The package should be shipped prepaid to the Virology Unit by a courier or a shipping vendor with a traceable system.

4. Any bite case in which the case history reveals a strong probability of rabies, particularly in a case of human exposure, should be handled with utmost speed. Call the Virology Unit ahead of time and advise the laboratory of expected time of arrival if rabies detection test need to be done same day. Hand deliver such specimens to the laboratory.

5. Avoid shipping specimens on weekends or holidays without prior approval. A better alternative is to refrigerate and ship on Monday, unless the test result is urgent.

6. Rabies outfits can be obtained from the GPHL Virology Unit; the telephone number is (404) 327-7980. The Virology Unit does not furnish cold packs.
REPORTING AND INTERPRETATION OF RESULTS/CONSULTATION

Rabies testing is available Monday through Friday. All results are called to the submitters and reports will be issued the next business day following the receipt of the specimen, provided the specimen is received by 10:00 a.m. Reporting will be delayed on specimens that are received frozen.

1. Specimens received on Friday or those involved in emergency situations such as severe human head or neck exposures or human exposure for which emergency testing has been approved by Epidemiology Branch at 404-657-2588 will be tested and reported the same day received.

2. If the brain is damaged or decomposed to the point that the laboratory is uncertain as to whether the specimen is, in fact, the appropriate brain tissue, testing will not be done. Report will read “Unsatisfactory” with the comment: “brain tissue is damaged or decomposed beyond recognition of at least two identifiable brain parts.” Only in case of human or animal exposure will the specimen be tested. If the test is positive, we will report as such. If the test is negative, a report of “Unsatisfactory” will be made with the comment: “brain tissue is damaged or decomposed beyond recognition of at least two identifiable brain parts.” In this situation, an unsatisfactory test result should be managed as if positive.

3. All positive, negative, and unsatisfactory rabies results are telephoned to the contact submitter listed on the Rabies Submission form with follow-up electronic reporting (if available) or hard copy of the report sent by mail. For human exposures, the Virology lab contacts the health district office as well. Copies of each rabies submission form and results are mailed to the Georgia Public Health Epidemiology Office. All specimens should be submitted through animal control/environmental/health department only (not from victims, veterinarians office, etc).

4. If you have any more specific questions, please refer to the Georgia Rabies Animal Control Manual at the following website: http://health.state.ga.us/pdfs/epi/zvbd/Rabies%20Manual%202007%20Final%20with%20Cover.pdf.

If you need consultation for rabies exposure call Poison Control statewide 1-800-282-5846, Atlanta (404) 589-4400, or if you have difficult or emergency cases, contact the Epidemiologist-On-Call, (404) 657-2588.

UNACCEPTABLE SPECIMENS

The Central Laboratory specimen acceptance policy requires that all specimens be received in good condition with at least two (2) identifiable brain parts and there must have been exposure of humans or domestic animals to the suspected rabid animal. Specimens will be reported “Unsatisfactory” with comments for the following reasons:

1. No known exposure of humans or domestic animals.
2. Brain tissue is damaged or decomposed beyond recognition of at least two (2) identifiable brain parts.
3. Tissue in preservative such as formalin.
**Virus Isolation and Identification**

**Introduction**

Virus culture provides a mechanism for the detection and identification of many human viruses which cause a wide variety of common illnesses. Viruses are isolated in cell culture and confirmed by enzyme immunoassay tests, and indirect fluorescence antibody tests. Respiratory viruses and herpes zoster virus can be detected by a direct fluorescent antibody test. Respiratory virus panel can be detected by PCR. Norovirus from gastrointestinal viral outbreaks can be detected by electron microscopy and PCR.

**Specimen Collection/Labeling/Requisition Form**

Refrigerate specimens promptly after collection at 2-6°C for no more than 3 days prior to transporting. Specimens that must be held for longer intervals before transporting should be promptly frozen to −70°C or below. Avoid freezing specimens to −20°C because infectivity of viruses is rapidly lost at this temperature and they cannot be recovered by culture. Any container used for viral culture specimens should be sterile.

**Swab Collection Procedures:**

1. Do not use calcium alginate swabs to collect specimen as it inactivates some viruses.
2. Use only transport media supplied with outfit or approved by the Virology Laboratory.
3. After collection, place swab in tube of transport medium, break off stem where handled and discard, and cap tube.

**Nasal/Pharyngeal:** Swab each nostril leaving the swab in nose for a few seconds to absorb secretions. Rub the walls of the posterior pharynx with either dry swab or swab wetted with transport media.

**Oral:** Swab oral lesions.

**Eye:** Use sterile swab to remove any exudate or pus present in eye and discard. Moisten second swab with transport medium/saline rubbing affected conjunctiva. An Ophthalmologist or trained physician should collect corneal specimens using a spatula.

**Cervical:** Use sterile swab to remove mucus from cervix and discard. Inserts second swab about 1 cm into cervical canal, rotate, swabbing lesions and remove.

**Rectal:** Swab rectum in a manner to collect feces.

**Vesicle Fluids/Skin Scrapings:** Do not prepare site with disinfectants such as alcohol or betadine as these may inactivate virus; use only after specimen collection. In the case of primary infections with herpes simplex, virus may be recovered up to 7-10 days.
after onset. Collect specimen from base of lesions. Aspirate vesicle fluid with 26/27-gauge tuberculin syringe or capillary pipette. Promptly rinse fluids collected into small volume of transport medium to prevent clotting. Swab open lesions to obtain both fluid and cells from the lesion base.

**Other Collection Procedures:**

**Throat Washings:** Adults-Gargle with smallest convenient volume (10 to 20 ml) of cell culture medium or general-purpose bacteriological broth expectorates into paper cup. Pour contents of the cup into screw-cap vial. Pediatrics to be collected in similar manner, however, throat swabs is sufficient.

**Stools:** Collect stool in a sterile container, transfer small portion (1 to 4 grams) into empty screw cap vial.

**Urine:** Collect urine in a sterile container; refrigerate immediately at 2 to 6 degrees Celsius.

**CSF:** Adults-obtain at least 2 ml, infants-1 ml, place in sterile screw cap vial. Do not dilute, refrigerate immediately.

**Serum/Blood:** Although serum is rarely used to recover viruses it is a suitable specimen for isolation of enterovirus from infected infants.

**Autopsy/Biopsy:** Aseptically collect specimens as soon as possible after death. Use separate sterile instrument for each collection site. Collect fresh tissue (1-2 grams) from affected site/lesion. Place each specimen in separate sterile container containing small amount of transport medium or saline, clearly label, and refrigerate. Specimen should not be fixed or placed in any sort of preservative solution.

**Requisition Form:**
Please use Laboratory Submission Form #3583 and include the following information:

1. Physician or contact person's name and phone number.
2. Patient's name, age and sex.
3. Date of illness onset, symptoms.
4. Submitter name/address ("send report to") box.
5. Type of specimen collected, date collected.
6. Test requested.

**SHIPMENT OF SPECIMENS**

For shipping instructions, refer to the transportation section of this manual. Wrap packing material around specimen container, secure cap to prevent leakage; place the wrapped specimen inside a biohazard bag and seal tightly. Place the completed Virology requisition form #3595 rev. 1/2010 in the pouch of the biohazard bag. Place the biohazard bag with specimen in a Styrofoam shipper with adequate ice/cold packs to keep
cold until the specimen is received. Dry ice is not recommended. Send specimens to GPHL by a courier or a shipping vendor with a traceable system, Attn: Virology Unit, 1749 Clairmont Road, Decatur, GA 30033 with deliveries made between 8:00am-4:30pm Monday-Friday. Viral culture outfits are available from the Laboratory Services and Supply, 1749 Clairmont Road; Decatur, GA 30033-4050, telephone number is 404-327-7920.

REPORTING AND INTERPRETATION OF RESULTS

Turn-around time (time specimen is received to the time the test is completed) for cultures varies from two to five weeks. See Table 1, for summary. Cultures yielding virus isolates may require more or less 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 test sensitivity. Failure to isolate a virus should not rule out the virus as a cause of the illness. Conversely, since people may asymptptomatically carry a variety of viruses, viruses may be isolated which are unrelated to the current clinical illness.

UNACCEPTABLE SPECIMENS

1. Improperly identified specimens (name on tube/form do not match).
2. No identification on form or tube.
3. Specimens with insufficient quantity for testing (QNS).
4. Improper specimen type sent.
EMERGENCY PREPAREDNESS

The Georgia Public Health Laboratory (GPHL) Emergency Preparedness (EP) unit functions as the State of Georgia Laboratory Response Network (LRN) reference laboratory. The LRN was established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation (FBI) in accordance with Presidential decision directive # 39. The LRN, operational since August 1999, has the objective to ensure an effective laboratory response to bioterrorism and chemical terrorism by helping to improve the nation's public health laboratory infrastructure. The overall concept of the LRN is based upon strengthening existing state, local and federal public health laboratories and improving linkage with the network of private and hospital laboratories that submit specimens for routine and referral testing to the public health system. The LRN is a unique asset in the nation's growing preparedness for biological and chemical terrorism. In the years since its creation, the LRN has played an instrumental role in improving the public health infrastructure by helping to boost laboratory capacity and by ensuring a structured response to potential bioterrorism and chemical threat events.

The Georgia Public Health Laboratory (GPHL) is a member of LRN for biological and chemical testing support and can respond to bioterrorism, chemical terrorism and other public health emergencies. The laboratory is better equipped, and employs advanced technology, standardized and validated methods. The membership to the LRN provides access to a national network of laboratories for surge capacity and utilization of same reagents and kits like all other LRN labs for consistent and comparable testing results. The GPHL also participate in development of consensus protocols for testing BT and CT agents, training, and infrastructure improvement.


Molecular Biology/Biological Threat (MB/BT). The MB/BT laboratory has the capability of performing suspicious substance analysis to rule out agents of bioterrorism on environmental specimens that meet the credible threat criteria e.g. letter with/without unknown powder, unknown powder that cannot be explained, obvious/direct threat samples, samples with implied threat (based on circumstances) and samples with political considerations. The laboratory also provides testing support for outbreaks and surveillance e.g. influenza, norovirus, mumps, measles, pertussis, rash illnesses like varicella zoster virus (VZV), orthopox, and vaccinia.

Chemical Terrorism. GPHL is Level 2 and 3 CT laboratory. Our chemical testing capabilities include trace elements in urine and blood, volatile organic compounds (VOC), cyanide (CN), tetramine (TET), organophosphate nerve agents (OPNA), metabolic toxins panel (MTP), abrine and ricinine (ABRC). In addition GPHL provides packaging and shipping guidance during a chemical exposure event. As a Level 3 laboratory, we maintain the capability to
store and refer specimens to CDC for Rapid toxic screen (RTS) that includes 150 analytes. The results for RTS are reported within 36 hours and coordinated through the GPHL.

**BioWatch Laboratory.** The BioWatch is the early warning bio-surveillance system implemented in 2003. This program is designed to detect the intentional release of select aerosolized biological agents. The laboratory is federally managed and funded by the Department of Homeland Security (DHS) and housed within the Georgia Public Health Laboratory.

**Training.** The training unit provides guidance and training for emergency preparedness component for Georgia’s sentinel clinical laboratory network. This unit offers packaging and shipping division 6.2 materials, agents of bioterrorism wet workshops, biosafety, and biosecurity courses as well as biological and chemical threat exercises to hospital laboratories and first responders.

The manual provides detail information on testing and specimen submission requirements for each type of test offered. The GPHL advises hospital sentinel laboratories of evolving testing guidance or language for rule out and refer procedures provided by the LRN, the College of American Pathologists and the American Society of Microbiologists. If you see or suspect a select agent and you cannot rule out using the protocol flow chart. Then contact your GPHL LRN reference laboratory.

Georgia Public Health Laboratory (GPHL)
Suresh Pai, Ph.D., M (ASCP)
Laboratory Emergency Preparedness Coordinator
srpai@dhr.state.ga.us
404-327-7906 Ofc.
866 PUBHLTH (782-4584), select laboratory option; After hours contact phone

GPHL Front Desk
404-327-7900
8:00 am – 5:00 pm
CHEMICAL THREAT

INTRODUCTION

Georgia Public Health Laboratory is an active member of the Laboratory Response Network (LRN). The LRN was established by the Centers for Disease Control (CDC) and the Association of Public Health Laboratories (APHL) to address the need for analysis of clinical specimens for exposure to chemicals in a Chemical Terrorism (CT) event. The LRN response to chemical terrorism consists of a network of laboratories throughout the country that have trained personnel to handle sample collection, proper storage, handling and shipping of specimens. These laboratories also have the requisite expertise for chemical agent testing in clinical specimens using special methodologies already developed and put in place nationwide by CDC. The LRN chemical laboratories operate in concert and collaboration with each other in a three-tiered system consisting of:

Level 3: Sample collection, storage, and shipment.
Level 2: Analysis of specimens for specific agents in addition to having level 3 expertise.
Level 1: Serve as the CDC’s surge capacity for the analysis of specific agents using elaborate and higher level methodologies besides having the established capability to work as Level 2 laboratories.

Submission of Specimens: In the event of a possible act of terrorism where Chemical agents may be suspected, The GPHL will accept specimens through either the FBI or district health departments and/or other submitting clinical laboratories. Proper forensic specimen collection requirements and protocol can be obtained by referring to the CDC website or by contacting the GPHL or local health department.

For all necessary information relating to a CT event, the GPHL can be contacted at 404-327-7900 (GPHL main) 1-866-PUB-HLTH (24/7).

GPHL Capacity: The GPHL laboratory in Decatur has the expertise to serve both at Level 3 and level 2. The laboratory currently offers testing for the following level 2 agents and will also function as a source reference for specimen collection, shipping, and storage. Testing offered is updated continuously. GPHL may be contacted for its' updated testing capabilities.
RAPID TOXIC SCREEN (RTS)

Rapid Toxic Screen (RTS) is a series of tests performed by the CDC. The purpose of RTS is to determine levels of 150 chemicals likely used as agents of chemical threat. These include biomarkers of nerve agents, blistering agents, cyanide-based compounds, pesticides, metals, incapacitating agents and other chemicals that can cause significant disease or death. At the onset of an event, GPHL may request assistance from CDC for performing RTS on the first 40 samples from people with symptoms. Data produced from RTS is communicated back to GPHL using secure electronic data transfer technique.

For further information on Rapid Toxic Screen, please refer to the CDC website at http://www.cdc.gov/biomonitoring/rapid_tox_screen.html

CYANIDE IN WHOLE BLOOD

INTRODUCTION

This method is a quantitative procedure for measurement of Hydrogen Cyanide (HCN) in whole blood using static headspace sampling and gas chromatography with mass selective detection. The method uses automated sample preparation and isotopically labeled internal standard for cyanide analysis. In situations of exposure, the method would be used to identify the toxic agent and to assist in assessing the degree of exposure.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Whole blood specimens should be collected soon after exposure, as possible, since blood cyanide is converted in the body to thiocyanate or lost through respiration. Specimens should be collected in 5 or 7 mL vacutainers containing EDTA (K2). Headspace in the vacutainers should be minimized if possible. An absolute minimum of 0.75 mL of sample is needed for this analysis. Samples should be properly labeled and refrigerated at 5 ± 3°C within 30 minutes of sample collection.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.
SHIPMENT OF SPECIMENS

Samples should be shipped cold with enough coolant to remain cold (5 ± 3°C) throughout the shipment process. Care should be taken to avoid freezing of the sample as hemolyzed samples will be rejected.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

REPORTING/INTERPRETATION OF TEST RESULTS

Cyanide is present in all blood however, because cyanide is present in higher amounts in the blood of cigarette smokers, the smoking status of the individual providing the sample should be known but is not required. The fatal threshold for CN exposure is difficult to assess due to factors such as route of exposure, variability of elimination half-lives, storage conditions prior to analysis, and effects of antidotes. As per CDC guidelines a level of <100 µg/L is generally accepted as normal. Levels >1000 µg/L are considered toxic and even potentially lethal.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 0.75 mL)
7. Failure to maintain temperature at 5 ± 3°C,
8. Freezing/specimen hemolyzed
9. Suspected contamination
10. Clotting of the specimen.
11. Expired sample collection container
12. No GPHL Specimen Submission Form # 3583.
INTRODUCTION

This LRN-C developed method is used to quantitatively measure volatile organic compounds (VOCs) such as Benzene, 1, 2 Dichloroethane, Carbon tetrachloride, Chloroform Benzene, 1, 2 Dichloroethane, Ethylbenzene, Styrene, Toluene, Tetrachloroethene, m/p-Xylene, and o-Xylene, in whole blood samples by solid phase micro extraction (SPME) gas chromatography with mass selective detection (3,4). The method uses an isotopically labeled internal standard to quantitate the amount of each analyte. In situations of exposure, the method would be used to identify the toxic agent and to assist in assessing the degree of exposure.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Specimens should be collected in Green (Lithium Heparin) or Gray (Sodium Fluoride) tubes. An absolute minimum of 1 mL of sample is needed for this analysis. Samples should be properly labeled and refrigerated at 5 ± 3°C within 30 minutes of sample collection.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped cold (5 ± 3°C) with enough coolant to remain cold throughout the shipment process. Care should be taken to avoid freezing of the sample as hemolyzed samples will be rejected.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Lower reportable limit (µg/L)</th>
<th>Reference range* (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloroform</td>
<td>50</td>
<td>0.8</td>
</tr>
<tr>
<td>1,2 Dichloroethane</td>
<td>50</td>
<td>9.2</td>
</tr>
<tr>
<td>Carbon Tetrachloride</td>
<td>50</td>
<td>0.03</td>
</tr>
<tr>
<td>Benzene</td>
<td>50</td>
<td>0.48</td>
</tr>
<tr>
<td>Toluene</td>
<td>50</td>
<td>1.5</td>
</tr>
<tr>
<td>Tetrachloroethene</td>
<td>50</td>
<td>0.62</td>
</tr>
<tr>
<td>Ethylbenzene</td>
<td>50</td>
<td>0.25</td>
</tr>
<tr>
<td>m/p-Xylene</td>
<td>100</td>
<td>0.78</td>
</tr>
<tr>
<td>o-Xylene</td>
<td>50</td>
<td>0.3</td>
</tr>
<tr>
<td>Styrene</td>
<td>50</td>
<td>0.18</td>
</tr>
</tbody>
</table>

* Blood levels of VOCs in non-occupationally exposed U.S. population at 95th percentile

Due to environmental exposure, detection of these compounds does not necessarily indicate an adverse health effect.

Benzene is listed as a potential human carcinogen. Chronic Benzene exposure may cause hematopoietic injury. Tetrachloroethene (Tetrachloroethylene), and Chloroform have demonstrated carcinogenic potential in laboratory animals and are suspect human carcinogens. ¹

The acute toxic effects of these chemicals are related to central nervous system depression. Nephro and hepatotoxic effects have been associated with exposure to certain volatile organic compounds including Carbon Tetrachloride, Chloroform, Tetrachloroethene, and Toluene. The hepatotoxic effects associated with Carbon Tetrachloride may be potentiated by alcohol.²

UNACCEPTABLE SPECIMENS
1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 1 mL)
7. Failure to maintain temperature at 5 ± 3°C,
8. Freezing/specimen hemolyzed
9. Suspected contamination
10. Clotting of the specimen.
11. Expired sample collection container
12. No GPHL Specimen Submission Form # 3583.
TETRAMINE IN URINE

INTRODUCTION

Tetramethylene-disulfotetramine (tetramine) is a banned rodenticide in the United States. Symptoms associated with tetramine exposure can include headache, dizziness, fatigue, numbness of lips, nausea, seizures, coma and death. This LRN-C developed method is for the quantitative determination of Tetramine in urine samples using gas chromatography with mass selective detection. The method uses Solid Phase Extraction (SPE) sample preparation and isotopically labeled internal standard for detection and quantification of Tetramine.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for this assay is 5.0 µg/L -500 µg/L. The reference range for Tetramine is not detected.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 1.5 mL)
7. Failure to keep specimen frozen
8. No GPHL Specimen Submission Form # 3583.
ORGANOPHOSPHATE NERVE AGENT METABOLITES (OPNA) IN URINE

INTRODUCTION

This LC-MS-MS method is for the detection of metabolites excreted in urine after exposure to organophosphate nerve agents sarin (GB), soman (GD), cyclohexylsarin (GF), Russian VX (rVX) and VX. The method utilizes isotopically labeled standards to detect and quantify metabolites GB acid (methylphosphonic acid, isopropyl ester), GD acid (methylphosphonic acid, 1, 2, 2-trimethylpropyl ester), GF acid (methyl phosphonic acid, monocyclohexyl ester), rVX acid (methyl phosphonic acid, 2-methylpropyl ester) and VX acid (methylphosphonic acid, monoethyl ester).

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form s# 3583 hould be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Lower Reportable Limit (µg/L)</th>
<th>Reference range (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GB</td>
<td>1</td>
<td>Not Detected</td>
</tr>
<tr>
<td>GD</td>
<td>1</td>
<td>Not Detected</td>
</tr>
<tr>
<td>GF</td>
<td>1</td>
<td>Not Detected</td>
</tr>
<tr>
<td>VX</td>
<td>1</td>
<td>Not Detected</td>
</tr>
<tr>
<td>rVX</td>
<td>1</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 1.5 mL)
7. Failure to keep specimen frozen
8. No GPHL Specimen Submission Form # 3583.
METABOLIC TOXINS IN URINE

INTRODUCTION

This method is a quantitative procedure for the measurement of Monochloroacetate (MCA) and Monofluoroacetate (MFA) in urine samples. The method uses Solid Phase Extraction (SPE) sample preparation and isotopically labeled internal standards for each analyte. In situations of exposure, the method would be used to identify the toxic agent and to assist in assessing the degree of exposure.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Lower reportable limit (µg/L)</th>
<th>Reference range (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCA</td>
<td>50</td>
<td>Not Detected</td>
</tr>
<tr>
<td>MFA</td>
<td>50</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 1.5 mL)
7. Failure to keep specimen frozen
8. No GPHL Specimen Submission Form # 3583.
ABRINE AND RICININE (ABRC) IN URINE

INTRODUCTION

This method is a quantitative procedure for the measurement of Ricinine and L-Abrine in urine samples. Ricinine is a biomarker of ricin while L-Abrine, is a biomarker for Abrin. The method uses Solid Phase Extraction (SPE) sample preparation and isotopically labeled internal standards for each analyte. In situations of exposure the method would be used to identify the toxic agent and to assist in assessing the degree of exposure.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Lower reportable limit (µg/L)</th>
<th>Reference range (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Abrine</td>
<td>3.5</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Ricinine</td>
<td>0.3</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

This test may be affected by the ricin extraction process. Negative results do not necessarily preclude exposure to Abrin or Ricin.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 1.5 mL)
7. Failure to keep specimen frozen
8. No GPHL Specimen Submission Form # 3583.
MERCURY, LEAD, AND CADMIUM IN WHOLE BLOOD

INTRODUCTION

This inductively coupled plasma mass spectrometer method uses an internal standard dilution technique for the determination of Mercury (Hg), Lead (Pb), and Cadmium (Cd) in whole blood. The method is used to screen whole blood specimens from patients to evaluate environmental and other non-occupational exposure to these elements.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Whole blood collected in 5 or 7 mL vacutainers containing EDTA (k2).

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Chemical Threat sample submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped cold (5 ± 3°C) with enough coolant to remain cold throughout the shipment process.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows:

<table>
<thead>
<tr>
<th>Element</th>
<th>Lower reportable limit</th>
<th>Reference range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadmium (Cd)</td>
<td>1 µg/L</td>
<td>5 µg/L</td>
</tr>
<tr>
<td>Mercury (Hg)</td>
<td>2 µg/L</td>
<td>10 µg/L</td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>2 µg/dL</td>
<td>10 µg/dL</td>
</tr>
</tbody>
</table>

The critical call level for Hg, Pb, and Cd are shown below. Any patient sample that has concentration greater than these levels will be reported by phone to the supervising physician.

<table>
<thead>
<tr>
<th>Element</th>
<th>Children (6yrs and younger)</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cd</td>
<td>&gt;5 µg/L</td>
<td>&gt;5 µg/L</td>
</tr>
<tr>
<td>Hg</td>
<td>&gt;100 µg/L</td>
<td>&gt;200 µg/L</td>
</tr>
<tr>
<td>Pb</td>
<td>&gt;25 µg/dL</td>
<td>&gt;40 µg/dL</td>
</tr>
</tbody>
</table>

Blood lead levels 10 µg/dL and above will be reported per the State reportable disease.

Finding measurable amounts of these elements in urine does not necessarily mean they will cause an adverse health effect.


UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< .25 mL)
7. No GPHL Specimen Submission Form # 3583.
**TOXIC ELEMENTS SCREEN (TES) IN URINE**

**INTRODUCTION**

This inductively coupled plasma mass spectrometer method uses a multi-internal standard dilution technique to provide rapid and accurate quantification of multiple elements; Arsenic (As), Beryllium (Be), Cadmium (Cd), Barium (Ba), Thallium (Th), Lead (Pb), and Uranium (Ur) in spot urine. This procedure can be used for all 7 elements or subset of the 7 elements. The method may be used to evaluate environmental and other non-occupational exposure to these elements.

**SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM**

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

**SHIPMENT OF SPECIMENS**

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for each analyte in the assay is as follows:

<table>
<thead>
<tr>
<th>Element</th>
<th>Lower reportable limit (µg/L)</th>
<th>Reference Range 95th percentile (µg/L)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic (As)</td>
<td>16.25</td>
<td>30</td>
</tr>
<tr>
<td>Beryllium (Be)</td>
<td>0.5</td>
<td>&lt;0.13</td>
</tr>
<tr>
<td>Cadmium (Cd)</td>
<td>0.25</td>
<td>1.36</td>
</tr>
<tr>
<td>Barium (Ba)</td>
<td>1.0</td>
<td>7.48</td>
</tr>
<tr>
<td>Thallium (Tl)</td>
<td>0.1</td>
<td>0.440</td>
</tr>
<tr>
<td>Lead (Pb)</td>
<td>0.75</td>
<td>2.60</td>
</tr>
<tr>
<td>Uranium (U)</td>
<td>0.025</td>
<td>0.046</td>
</tr>
</tbody>
</table>

Finding measurable amounts of these elements in urine does not necessarily mean they will cause an adverse health effect.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 2 mL)
7. No GPHL Specimen Submission Form # 3583.
MERCURY IN URINE

INTRODUCTION

The inductively coupled plasma mass spectrometer method uses an internal standard dilution technique to provide rapid and accurate quantification of Mercury in urine. The method may be used to evaluate environmental and other non-occupational exposure to Mercury.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Spot Urine should be collected in a clean sterile urine container. The minimum volume for collection is 1.5 mL of urine. Urine should be frozen, preferably at -70° C.

Two empty containers of the same lot number should be submitted with the specimen. These will be used as blanks to quantify contributions associated with the container or the environment.

The Georgia Public Health Laboratory submission form # 3583 should be filled out as completely as possible. Required information includes patient and submitter information and date and time of collection of the sample. A separate form should be submitted for each specimen.

SHIPMENT OF SPECIMENS

Samples should be shipped frozen on dry ice.

If samples are being submitted from a known or suspected intentional chemical release, forensic integrity should be maintained. Two layers of forensic evidence tape should be applied. Initials of the person sealing the containers should appear half on and half off the tape. Contact GPHL for additional information related to Chain of Custody and packaging guidelines.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

REPORTING/INTERPRETATION OF TEST RESULTS

The reportable range for Mercury in the assay is as follows:

<table>
<thead>
<tr>
<th>Element</th>
<th>Lower reportable limit (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercury (HG)</td>
<td>0.1</td>
</tr>
</tbody>
</table>
Finding measurable amounts of Mercury in urine does not necessarily mean it will cause an adverse health effect.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 2 mL)
7. No GPHL Specimen Submission Form # 3583.

REFERENCES

1. Disposition of Toxic Drugs and Chemicals in Man, Seventh Edition, Baselt, Randall C. 2004, Biomedical Publications, P.O. Box 8299, Foster City, CA.


INTRODUCTION

In an effort to address the threat of chemical and bioterrorism, the Centers of Disease Control (CDC) and the Association of Public Health Laboratories (APHL) have established the Laboratory Response Network (LRN). The LRN response to biological terrorism consists of a tiered network of laboratories throughout the country that have trained personnel to handle sample collection, proper storage, handling, shipping, and testing of specimens. These laboratories also have the expertise for biological agent testing in clinical specimens using special methodologies already developed and put in place nationwide by CDC. The LRN biological laboratories operate in concert and collaboration with each other in a three-tiered system consisting of:

- **Sentinel Laboratories**: Performs rule out of suspected biological threat agents and refer procedures according to the American Society of Microbiology (ASM) guidelines. Organisms that cannot be ruled out are sent to reference laboratories.
- **Reference Laboratories**: The Georgia Public Health Laboratory (GPHL) serves as a reference laboratory within the LRN-B system. Performs reference level testing for confirmation of biological threat agents.
- **National Laboratories**: Includes the CDC and United States Army Medical Research Institute of Infectious Diseases (USAMRIID) for characterization and archiving of isolates and specimens. Provides guidance on the safe handling and testing of specimens.

**Submission of Specimens**: In the event of a possible act of terrorism where biological agents may be suspected, the GPHL will accept specimens through either the Federal Bureau of Investigation (FBI) or through district health departments and/or other submitting clinical laboratories. Proper forensic specimen collection requirements and protocol can be obtained by referring to the CDC website, by contacting the GPHL or local health department.

For all necessary information relating to a BT event, the GPHL can be contacted at 404-327-7900 (main) and 1-866-PUB-HLTH (24/7).

**GPHL Capacity**: The GPHL in Decatur in addition to serving as the LRN-B reference lab. has capabilities and capacities for the identification and characterization of specific infectious agents.
INTRODUCTION

This real time Polymerase Chain Reaction (RT-PCR) molecular assay is intended for the qualitative detection of *Bacillus anthracis*, *Brucella spp.*, *Francisella tularensis*, *Yersinia pestis*, and *Burkholderia mallei/pseudomallei* DNA from culture isolates exhibiting colony morphology and bio-chemical testing consistent with an agent of bioterrorism. Additional reflex testing at the GPHL may be used to confirm specific agents.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

The culture isolates exhibiting colony morphology and bio-chemical testing consistent with an agent of bioterrorism should be referred to Georgia Public Health Molecular unit. Specimens should be labeled according to facility procedures including patient name, identification number and facility. GPHL Specimen Submission Form # 3583 should be filled out as completely as possible including patient and submitter information. A separate form must be submitted for each specimen.

SHIPMENT OF SPECIMENS

The GPHL should be contacted prior to submitting a culture isolate for testing.

Samples should be shipped ambient according to DOT/IATA guidelines for Category A Division 6.2 infectious substances.

At the direction of law enforcement, Chain of Custody documentation may be necessary.

REPORTING/INTERPRETATION OF TEST RESULTS

These assays are used to detect DNA of specific biothreat agents (BT) from suspect isolates. Additional confirmatory testing may be required to confirm the presence of a particular BT agent. Test results will be immediately called to the submitter.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (isolate not growing).
3. Specimen damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. No GPHL Specimen Submission Form # 3583.
**INTRODUCTION**

This RT-PCR multiplex assay is intended for the qualitative detection of *Bordetella pertussis*, *B. parapertussis*, and *B. holmesii* in DNA extracted from clinical specimens or culture isolates. This assay may be used along with culture, other diagnostic assays, and clinical observations of signs or symptoms to determine infection in clinical specimens.

**SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM**

Acceptable specimens include nasopharyngeal (NP) Dacron swabs with aluminum shafts in a dry sterile container, nasopharyngeal aspirates (minimum volume of collection is 500µl) in a sterile container and culture isolates (plate or slant) exhibiting colony morphology and biochemical testing consistent with *Bordetella spp.*

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583. A separate submission form is required for each specimen submitted for testing.

**SHIPMENT OF SPECIMENS**

Nasopharyngeal aspirates should be shipped cold with enough coolant to remain cold throughout the shipment process. Culture isolates may be shipped cold or at ambient temperatures.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

**REPORTING/INTERPRETATION OF TEST RESULTS**

This assay may be used in conjunction with clinical observations and other diagnostic assays to determine infection with *Bordetella pertussis*, *B. parapertussis*, and *B. holmesii* from patients presenting with signs and symptoms that lead to suspicion of pertussis and to confirm the identification from culture isolates.

Clinical specimens collected subsequent to initiation of antimicrobial treatment may not be positive for *Bordetella spp.* due to reduction of organisms. Whenever possible, specimens collected prior to administration of antimicrobial agents should be used to determine infection with *Bordetella spp.*
UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube) or no growth on media plates or slants submitted for isolate testing.
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Low volume (< 500 µL)
7. Failure to maintain temperature at 5 ± 3°C
8. Cotton swabs
9. No GPHL Specimen Submission Form # 3583.
INFLUENZA A AND B SCREENING PANEL BY rRT-PCR

INTRODUCTION

The Influenza A and B screening molecular assay is used for the qualitative detection of both Influenza A and B viral ribonucleic acid (RNA) by rRT-PCR. This test will reflex to the Influenza characterization panel if Influenza A RNA is detected.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Nasal swab, nasopharyngeal swab and/or nasal wash in Viral Transport Media (VTM). Swabs should be made of either Nylon or Dacron with aluminum or plastic shafts. Sterile screw cap containers for bronchoalveolar lavages (BAL), tracheal aspirate (TA), and bronchial wash (BW) are acceptable. All specimens should be submitted in viral transport media (VTM).

Specimens can be stored at 4 °C for up to 3 days. Specimens held longer than 3 days should be frozen. A false negative result may occur if a specimen is improperly collected, transported and handled. Testing specimens from adults will have a lower sensitivity since children tend to shed virus more abundantly.

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583. In addition to including completing patient and submitter information, patient travel history outside of the United States and treatment with anti-viral should be documented on the form.

SHIPMENT OF SPECIMENS

Refrigerated specimens should be shipped cold with enough coolant to remain cold throughout the shipment process. Frozen samples should be shipped frozen on dry ice.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

REPORTING/INTERPRETATION OF TEST RESULTS

This procedure is designed to universally detect Influenza A and B virus RNA. If Influenza A virus RNA is detected this test will automatically reflex to Influenza A characterization panel to determine the sub-type.

Test Limitations include the following:
A false negative result may occur if a specimen is improperly collected, transported and handled. False negative may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

Analyze targets (viral sequences) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus is infectious, or is the causative agents for clinical symptoms.

Testing specimens from adults will have a lower sensitivity since children tend to shed virus more abundantly

Individuals who received nasal vaccine may have positive test results for up to three days after vaccination.

A negative test result for the bronchoalveolar lavages (BAL), tracheal aspirate (TA), and bronchial wash (BW) is presumptive and it is recommended these results be confirmed by viral culture or by collecting additional specimens.

**UNACCEPTABLE SPECIMENS**

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Specimen shipped at ambient temperature
7. Cotton swabs/wooden shafts
8. Swab not submitted in viral transport media (VTM)
9. No GPHL Specimen Submission Form # 3583.
INTRODUCTION

The rRT-PCR assay is used for the qualitative detection and sub-typing of influenza virus. The test detects Type A viral ribonucleic acid (RNA) as seasonal A/H1, A/H3, A/H5, 2009 A (H1N1) and A/H7 in clinical specimens on patients presenting symptoms such as an abrupt onset of fever, sore throat, cough, headache, myalgia, and malaise. This test is run as a reflex test to the Influenza A/B by rRT-PCR.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Acceptable specimens include nasal swabs (NS), nasopharyngeal swabs (NPS), nasals aspirates (NA), nasal washes (NW), dual nasopharyngeal/throat swabs (NPS/TS), bronchoalveolar lavages (BAL), tracheal aspirates (TA), and bronchial washes (BW).

Swabs should be made of either Nylon or Dacron with aluminum or plastic shafts. Sterile screw cap containers for bronchoalveolar lavages (BAL), tracheal aspirate (TA), and bronchial wash (BW) are acceptable. All specimens should be submitted in viral transport media (VTM).

Specimens can be stored at 4°C for up to 3 days. Specimens held longer than 3 days should be frozen. A false negative result may occur if a specimen is improperly collected, transported and handled. Testing specimens from adults will have a lower sensitivity since children tend to shed virus more abundantly.

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583. In addition to including completing patient and submitter information, patient travel history outside of the United States and treatment with anti-viral should be documented on the form.

SHIPMENT OF SPECIMENS

Refrigerated specimens should be shipped cold with enough coolant to remain cold throughout the shipment process. Frozen samples should be shipped frozen on dry ice.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

The Influenza A subtyping primer and probe sets are designed to specifically detect human A/H1, A/H3, A/H5, 2009 A (H1N1) and A/H7 (Asian lineage) influenza viruses.

Test Limitations include the following:

A false negative result may occur if a specimen is improperly collected, transported and handled. False negative may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

Analyte targets (viral sequences) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus is infectious, or is the causative agents for clinical symptoms.

Testing specimens from adults will have a lower sensitivity since children tend to shed virus more abundantly

Individuals who received nasal vaccine may have positive test results for up to three days after vaccination.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Specimen shipped at ambient temperature
7. Cotton swabs/wooden shafts
8. Swab not submitted in VTM
9. No GPHL Specimen Submission Form # 3583.
**MUMPS VIRUS BY rRT-PCR**

### INTRODUCTION

The patients with mumps may exhibit an acute viral illness with symptoms including fever, headache, muscle aches, tiredness, and loss of appetite, followed by swelling of salivary glands. The Mumps virus real time reverse transcription Polymerase Chain Reaction (rRT-PCR) qualitative assay detects viral RNA in clinical specimens.

### SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Acceptable specimens include Oral/Buccal swab, oropharyngeal swab and CSF. Only Dacron swabs with aluminum or plastic shafts are acceptable. All swabs should be submitted in viral transport media. Swabs with calcium alginate or cotton tips and wooden shafts are unacceptable. A minimum of 200µL of CSF can be submitted in a sterile, screw capped container.

Specimens should be stored at 4°C until ready for testing.

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583.

### SHIPMENT OF SPECIMENS

Refrigerated specimens should be shipped cold with enough coolant to remain cold throughout the shipment process. Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

### REPORTING/INTERPRETATION OF TEST RESULTS

Test will be reported as either mumps virus RNA detected or not detected. A false negative result may occur if a specimen is improperly collected, transported and handled. Negative test results do not preclude infection. This is a research use only procedure and requires epidemiology consultation.

### UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked or was damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Specimen shipped at ambient temperature
7. Cotton swabs/wooden shafts
8. Swab not submitted in VTM
9. No GPHL Specimen Submission Form # 3583.
**NOROVIRUS GI AND GII BY rRT-PCR**

**INTRODUCTION**

This is a qualitative reverse transcriptase real time polymerase chain reaction (rRT-PCR) duplex assay that detects both GI and GII Norovirus (NoV) RNA in clinical samples from patients exhibiting symptoms of gastrointestinal illness.

**SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM**

0.5 grams or 0.5 mL of fresh stool submitted in a sterile collection container is the preferred specimen. Whole Stool submitted in Carrie Blair media (Para-pak) is acceptable. Swabs should not be submitted. The greatest likelihood of detecting the virus is within 48-72 hours from onset of illness.

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583.

**SHIPMENT OF SPECIMENS**

Specimens for testing can be submitted at ambient temperature.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

**REPORTING/INTERPRETATION OF TEST RESULTS**

Results for GI and GII Norovirus will be reported as detected or not detected.

The presence of inhibitors in the specimen may sometimes result in false-negative results.

**UNACCEPTABLE SPECIMENS**

1. No patient identifier on specimen.
2. No specimen received (empty collection container).
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Less than 0.5 grams or 0.5 mL of specimen received.
7. No GPHL Specimen Submission Form # 3583.
POX VIRUSES BY REALTIME-PCR

INTRODUCTION

The Pox virus RT-PCR molecular assay is intended for the qualitative detection of Orthopoxvirus DNA in clinical specimens from patients presenting with pustular or vesicular rash illness. The assay detects orthopoxvirus DNA, including variola, vaccinia, cowpox, monkeypox, camelpox, ectromelia, and gerbilpox viruses at varying concentrations. This assay should be utilized for situations where there is a low to medium risk of Variola according to the CDC risk assessment algorithm. It is important that these testing procedures should not be carried out on patient samples with a high suspicion of variola orthopox virus. All high risk specimens are to be forwarded directly to the CDC with coordination with the GPHL. No attempt to culture this virus should be made for these specimens. GPHL epidemiology should be contacted before referral of high risk specimens.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

The following guidance is provided by the CDC for collection of specimens from Patients meeting the moderate and high risk criteria.

Only personnel successfully vaccinated recently (within 3 years) wearing appropriate barrier protection (gloves, gown, and shoe covers) should be involved in specimen collection for suspected cases of smallpox. Respiratory protection is not needed for personnel with recent, successful vaccination. Masks and eyewear or face shields should be used if splashing is anticipated.

If unvaccinated personnel must be utilized to collect specimens, only those without contraindications to vaccination should be utilized as they would require immediate vaccination if the diagnosis of smallpox is confirmed. Fit-tested N95 masks should be worn by unvaccinated individuals caring for suspect cases.

All procedures for obtaining, processing, packing and shipping potentially infectious materials should be performed using BSL-2 or, if available, BSL-3 practices.

While working with specimens, personnel should avoid any activity that brings hands or fingers in contact with mucosal surfaces, such as eating, drinking, smoking, or applying make-up.

Upon removal of gloves, personnel should thoroughly wash their hands with soap containing Lysol or soaps such as Hibiclens before leaving the laboratory. Areas of the skin known or suspected to have come in contact with virus/specimen should be washed with soap. If possible, skin should be decontaminated with a 0.5% sodium hypochlorite solution with at least a 1-min contact time.
Low risk: Low risk specimens, including those specimens associated with a known vaccination or associated with a known poxvirus (non-smallpox) outbreak should be handled with the following precautions:

All procedures for obtaining, processing, packing and shipping potentially infectious materials should be performed using BSL-2 or, if available, BSL-3 practices.

While working with specimens, personnel should avoid any activity that brings hands or fingers in contact with mucosal surfaces, such as eating, drinking, smoking, or applying make-up.

Upon removal of gloves, personnel should thoroughly wash their hands with soap containing Lysol or soaps such as Hibiclens before leaving the laboratory. Areas of the skin known or suspected to have come in contact with virus should be washed with soap. If possible, skin should be decontaminated with a 0.5% sodium hypochlorite solution with at least a 1-min contact time.

After specimen collection is completed, all non-reusable protective materials worn by the specimen collector (e.g., gloves, mask, gown, shoe covers) and sample collection materials and equipment (e.g., tubes, swabs) must be placed in biohazard bags for disposal with other medical waste. Reusable equipment (e.g., goggles, face shield) should be decontaminated and set aside for reprocessing. Needles and other sharp instruments should be placed in the appropriate sharps container.

Unknown risk: If sufficient information is not available to make a determination of the risk associated with the specimen, the specimen should be treated as high risk.

The following procedures should be utilized for collection of specimens.

1. After specimen collection is completed, all protective materials worn by the specimen collector (e.g., gloves, mask, gown, shoe covers) and all non-reusable sample collection materials and equipment (e.g., needles, tubes, swabs) must be double bagged in biohazard bags and autoclaved or incinerated before disposal.

Put on protective equipment (e.g., protective eyewear, gown and gloves)

2. Label all vials and microscope slide holders with the following:
   - Patient’s name and social security number or date of birth
   - Unique identifier (e.g., lab number, hospital number)
   - Date and time of collection
   - Source of specimen (vesicle, pustule, scab, or fluid)
   - Name or initials of person collecting the specimen

3. Avoid cross-contamination of samples (e.g., use one sample per primary container) and collect a sufficient amount of material to permit multiple diagnostic tests and confirmations.
4. Vesicular material – If VZV is suspected, please include a swab from an unroofed vesicle or scab from a crusted vesicle among the specimens collected.

   a. Sanitize skin with alcohol wipe and allow to completely dry.
   b. Open and remove the top of the lesion using a sterile scalpel or 26-gauge needle.
   c. Place the vesicle skin “roof” in a dry, sterile 1.5-2 ml screw-capped plastic vial with O-ring. Cap vial to maintain relative sterility, and keep vial in as cool an environment as reasonably possible to preserve virus viability.

   For EM slide collection.
   a. Scrape the base of the blister with the blunt edge of the scalpel or a wooden applicator and smear the scrapings onto a microscope slide.
   b. Touch a microscopic slide multiple times to the open lesion.
   c. If available, lightly touch the plastic-coated side of an electron microscope (EM) grid to the base of the open lesion. Multiple EM grids should be prepared with varying amounts of pressure applied.
   d. Allow slides and grids to air dry for approximately 10 min.
   e. If a slide is not available, swab the base of the lesion with a Dacron swab, place in a screw-capped plastic vial, break off swab handle and screw on cap. DO NOT add transport medium to the vial (see Section 8 below).
   f. Verify all items are properly labeled.
   g. Place electron microscope grids in grid box and record which slot was used for each specimen.
   h. Place slides in appropriate, labeled containers. Wrap slide holder with Parafilm to prevent accidental opening.
   i. Repeat these procedures for 2 or more lesions. Sampling multiple lesions significantly increases the chances for successful poxvirus detection.

5. Scabs
   a. Remove scab from 2-4 lesions using a sterile scalpel or 26-gauge needle.
   b. Place scab in a sterile (1.5-2 ml) screw-capped plastic vial with O-ring (see 4. b-c above).

6. Swabs
   CDC and collaborating laboratories are in the process of evaluating the use of Dacron swabs to collect material from lesions or ocular sites. Preliminary experience suggests that swabs taken from either lesions or ocular sites are adequate sources of
DNA for detection by real-time PCR assays, based on the detection of human β-actin gene in extracted swab samples.

a. Swab the base of the lesion or ocular site and place swab in a sterile screw-capped plastic vial with O-ring.
b. Break off swab handle and screw on cap.
c. DO NOT add transport medium to the vial.

7. Ocular impression smears
   a. Ocular impressions should only be collected by an ophthalmologist.
   b. Touch a microscope slide to the ocular site. Prepare 2 to 3 slides.
   c. Allow slides to air dry for approximately 10 min.
   d. Place slides in appropriate, labeled containers. Wrap slide holder with parafilm to prevent accidental opening.

8. Biopsy specimens of individual lesions (if possible, obtain at least 2 separate lesions)
   a. Use a 3.5- or 4-mm punch biopsy device to sample an entire lesion.
   b. Bisect the biopsied material, using sterile scissors or scalpel.
   c. Place half the biopsied material in formalin for histopathologic and immunohistochemical evaluation and keep at room temperature or above freezing (e.g., 2-8°C).
   d. Place the other half of the biopsied material dry (do not add transport medium) in a sterile (1.5-2 ml) screw-capped plastic vial with O-ring. Refrigerate if shipment occurs within 24 hours; otherwise, freeze specimen.
   e. Repeat procedure with at least one more lesion.

9. Serum
   Draw blood specimens using the marble-topped or yellow-topped serum separator tube for serologic testing. If possible, centrifuge specimen to separate serum from blood clot and send only serum (significant hemolysis typically occurs if serum is not separated from red cells on-site, prior to shipment). Testing requires at least 1 ml of serum.

   With the exception of EM slides, serum, and formalin fixed tissue, specimens not shipped within 24 hours of collection should be frozen at -20 to -70 ° C.

   Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583.

   **Testing for Poxviruses must be coordinated through Epidemiology.**
SHIPMENT OF SPECIMENS

Refrigerated specimens should be shipped cold with enough coolant to remain cold throughout the shipment process. Frozen samples should be shipped frozen on dry ice.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

REPORTING/INTERPRETATION OF TEST RESULTS

Results are reported to the submitter of record as Non-Variola Orthopox DNA detected or not detected.

Negative results do not preclude infection with pox virus.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Specimen shipped at ambient temperature
7. No GPHL Specimen Submission Form # 3583.
VARICELLA-ZOSTER VIRUS BY REAL TIME-PCR

INTRODUCTION

This research use only assay is intended for the qualitative detection of varicella-zoster virus (VZV) DNA by RT-PCR from clinical specimens. This assay may be used in conjunction with clinical observations and other diagnostic assays to determine infection with varicella-zoster virus (VZV) in specimens collected from patients presenting with pustular or vesicular rash illness.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

Appropriate specimens include vesicular tissue and fluid, scabs from a crusted vesicle and Dacron swabs from unroofed vesicle. Specimens should be placed in a sterile, screw-capped cup or vial. Specimens should be stored refrigerated.

Specimens must be labeled with patient information and submitted with a completed GPHL Specimen Submission Form # 3583.

Testing for VZV must be coordinated through Epidemiology.

SHIPMENT OF SPECIMENS

Samples should be shipped cold (2-8 °C) with enough coolant to remain cold throughout the shipment process. Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.

REPORTING/INTERPRETATION OF TEST RESULTS

Results are reported as qualitatively VZV DNA detected or not detected

Negative results do not preclude infection with VZV.

A false negative result may occur if a specimen is improperly collected, transported and handled. False negative may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. No GPHL Specimen Submission Form # 3583.
MEASLES VIRUS BY REAL TIME-PCR

INTRODUCTION

Measles is a respiratory disease caused by the measles virus. The disease is also called Rubella. The virus normally grows in the cells that line the back of the throat and lungs. It is extremely contagious and causes fever, runny nose, cough and a rash all over the body. The disease can also cause a miscarriage or premature birth in pregnant women. This assay is for diagnostic purpose and used to detect measles virus (MeV) RNA by RT-PCR in patients presenting signs and symptoms of measles disease.

SPECIMEN COLLECTION/ LABELING/ REQUISITION FORM

1. Throat or nasopharyngeal swab in 3-4 ml of viral transport medium (VTM). Cotton and Dacron swabs are acceptable.
2. Nasopharyngeal aspirate in a sterile container.
3. Urine, cataracts, lens aspirate, oral fluid, cerebrospinal fluid (CSF), dry blood spots, and tissue specimens will be referred to CDC
4. Virus can usually be detected 2-3 days before rash and up to about 14 days post rash. The optimal timing for virus isolation is day of rash through day 5 post rash.
5. Place swab in 3-4 ml Viral Transport Media (VTM). Any sterile isotonic fluid, like phosphate buffered saline (PBS) or common tissue culture medium like Eagle’s MEM can be used. Swabs may be broken off and shipped with media. Alternatively, swirl/agitate the swab in the media for several minutes before removal.
6. Commercially available kits containing swabs and viral transport media are acceptable.
7. Use a cotton/Dacron swabs to collect the specimen. Swab the posterior pharynx and tonsillar areas, avoiding the tongue (tongue depressor may be helpful). The mucosa behind the uvula and between the tonsils should be gently swabbed with a back-and-forth motion. Keeping swabs moist after collection is most important (see transportation below).
8. Specimens should be received at the lab within 48 hours of collection cold and with ice packs. If shipment is delayed and facilities are available, the specimens should be frozen at –70°C and shipped on dry ice. Otherwise, store specimens in refrigerator (freezing at -20°C reduces viability of virus).
9. Care must be taken to ensure that clinical samples are kept cold during storage and shipment.

SHIPMENT OF SPECIMENS

Specimens should be shipped cold (2- 8°C) with enough coolant to remain cold throughout the shipment process.

Samples should be shipped according to DOT/IATA/USPS service guidelines for Category B infectious substances.
REPORTING/INTERPRETATION OF TEST RESULTS

Results are reported as qualitatively Measles virus RNA detected or not detected

Negative results do not preclude infection with the Measles virus.

A false negative result may occur if a specimen is improperly collected, transported and handled. False negative may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

UNACCEPTABLE SPECIMENS

1. No patient identifier on specimen.
2. No specimen received (empty collection tube).
3. Specimen leaked, damaged or crushed in transit.
4. Wrong type of specimen submitted.
5. Patient identifier on specimen does not match that on form.
6. Specimen shipped at room temperature
7. No Specimen Submission Form # 3583.
INTRODUCTION

Newborn screening is performed as mandated by Georgia Law. Effective January 1, 2007, Georgia law (OCGA 31-12-6 & 31-12-7) and Rules and Regulations (Chapter 290-5-24) require that every live born infant have an adequate blood test for 28 disorders. These disorders include: Phenylketonuria (PKU), Congenital Hypothyroidism, Maple Syrup Urine Disease (MSUD), Galactosemia, Tyrosinemia, Homocystinuria, Congenital Adrenal Hyperplasia (CAH), Biotinidase Deficiency, Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCAD), Sickle Cell Disorders (SS, SC, S-beta thalassemia), Isovaleric acidemia (IVA), Glutaric acidemia type I, 3-hydroxy 3-methyl glutaric aciduria (HMG), Multiple carboxylase deficiency, Methylmalonic acidemia, 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC), Propionic acidemia, Beta-ketothiolase deficiency, Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD), Long-chain 3-hydroxy acyl CoA dehydrogenase deficiency (LCHAD), Trifunctional protein deficiency, Carnitine uptake defect, Citrullinemia, Argininosuccinic acidemia, and Cystic Fibrosis.

Newborn screening analyses are only performed on dried blood spot (DBS) specimens. Specific instructions for specimen collection, preparation of the requisition form, and guidelines for proper packaging and transport of specimens are described below. Details regarding procurement of collection kits, specimen acceptance policies, turn-around time, result reporting, and result interpretation are also given.

Reports are printed and mailed the day following completion of all testing. Critical results are faxed and called to the follow-up centers. Non-critical presumptive positive results are sent nightly via HL7 messages. For Sickle Cell Disorders, follow-up is performed by the Georgia Reagents University, Augusta and the Newborn Screening Program in the Department of Public Health. For all other disorders, follow-up is performed by the Department of Human Genetics at the Emory University School of Medicine.

Questions concerning the collection and submission of newborn screening specimens or the reporting of test results should be directed to:

Ginger Stevens, Manager  
Newborn Screening  
Phone: 404/327-7951  
Email: gestevens@dhr.state.ga.us

Arthur Hagar, Ph.D., Director  
Chemistry & Hematology  
Phone: 404/327-6800  
email: afhagar@dhr.state.ga.us
SPECIMEN COLLECTION/LABELLING/REQUISITION FORM

See "Blood Collection on Filter Paper for Newborn Screening Programs", CLSI Document LA4-A5, Vol. 27 No. 21

Materials Needed

1. Form 3491 is a FDA-licensed medical collection device. It consists of a form and an attached filter paper strip for collection of the specimen. A pre-addressed UPS envelope is available for hospitals. Form 3491 and the pre-addressed envelope can be ordered from: Laboratory Services and Supply, 1749 Clairmont Road, Decatur, GA 30033, (phone: 404-327-7921). Clients should order amounts that can be used within six months. Store forms upright in a cool dry area. When submitting metabolic screens to the GPHL, use only the material supplied. The filter paper collection devices must be used prior to the expiration date, which is two years from the printing date. The expiration date is printed on the filter paper portion of the form. Destroy all forms after the expiration date. The forms currently in use include a protective wrap-around cover for the filter paper, and do not require an individual envelope for each specimen card.

2. 75% isopropanol

3. Sterile lancets with a point of 2.5 mm in length. A longer point should not be used, because it may pierce the heel bone. Sterile prepackaged lancets designed for pediatric use are available through private vendors.

4. Sterile gauze

5. Gloves

Recommendations for Blood Collection

Infants - The infants should preferably be on a protein diet 24 hours prior to collecting the blood sample. The sample should be collected between 24 hours and 72 hours of age.

Early Discharge of an Infant - If the infant is discharged earlier than 24 hours after birth or before a 24 hour period of protein feeding, a specimen should still be collected. The parents should be informed in writing that the child should be retested by one week of age.

Preterm, Low Birth Weight, and/or Sick Infants – Infants who weigh less than 5 1/2 pounds (2500 grams) should be retested when the child is four weeks of age. Collect the first specimen 24 hours after protein feeding or 48 hours after birth. If the infant is transferred to a Special Care Baby Unit (i.e., NICU) prior to collection of a newborn screening specimen, a specimen should be collected upon admission and prior to initiation of any treatment (e.g., transfusion, parenteral nutrition, or antibiotics). A second specimen should be collected 48 – 72 hours after birth, and ideally at least 24 hours after any transfusion. A third specimen should be collected 28 days after birth or at discharge, whichever occurs first. For more information, see “Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns”, CLSI Document I/LA31-A, Vol. 28, No. 34.
**Blood Collection Procedure**

In order to provide sufficient blood, if retesting is required, five (5) spots of blood should be submitted. If the infant is not bleeding freely, three spots completely filled are better than five partially filled spots.

If the infant is to be transfused, collect a specimen before the transfusion regardless of the age. If the child is less than 24 hours old, collect a second sample 24 hours after the last transfusion and a third sample 4-6 months after the last transfusion.

The blood collector should wear gloves and take universal precautions for handling blood.

Collect the blood from the infant's heel, using the most medial or lateral portion of the plantar surface of the heel, where "medial" is defined as that closest to the midline of the body, and "plantar surface" as the walking surface of the foot. Do not use previous puncture sites or the curvature of the heel. Do not perform skin punctures on the central area of a newborn's or infant's foot (area of the arch) as this may result in injury to the nerves, tendons or cartilage. Do not perform skin punctures on the fingers of newborns or infants.

Warming the skin-puncture site can increase blood flow to the site. A warm, moist towel or diaper at a temperature no higher than 42° C may be used to cover the site for three minutes.

Clean the skin with an alcohol swab (75% isopropanol). Wipe off the excess alcohol with dry sterile gauze, and allow the skin to air-dry. Alcohol residue remaining on the skin may dilute the specimen and adversely affect test results.

To obtain sufficient flow of blood, forcefully puncture the infant's heel with a sterile lancet with a tip no longer than 2.5 mm, or with an automated lancet device. Wipe away the first drop of blood with sterile gauze.

Hold the infant's heel loosely so as not to impede the flow of blood. If bleeding does not immediately occur, massage the lower portion of the leg in a downward direction. Avoid milking or squeezing the puncture site, because this may cause hemolysis of the specimen and/or dilute the blood with tissue fluid. If this occurs, the specimen will be rejected as “unsatisfactory, contaminated”.

When a large drop of blood appears, fold back the protective wrap-around cover and gently touch the filter paper to the drop of blood. Allow a sufficient quantity of blood to soak through to completely fill a printed circle on the filter paper. Only apply blood to one side of the filter paper. Do not layer successive drops of blood in the printed circle. If blood flow diminishes so that the circles are not completely filled, repeat the sampling in a new circle. Examine the opposite side to be sure that blood has penetrated through to make a circle which is approximately the same size as the printed circle. Success lies in allowing the
blood drop to grow to its full size, and touching with the filter paper when it is about to fall. Repeat this process until all circles are filled. Keep the cover folded away from the wet blood while it is being air-dried. Each circle should be filled with only one application of free-flowing blood. If not, the specimen will be rejected as "unsatisfactory, unevenly saturated".

After blood has been collected from the heel of the newborn, the foot should be elevated above the body, and a sterile gauze, pad or cotton swab pressed against the puncture site until the bleeding stops.

After the blood has been collected, keep the cover folded away from the wet blood. Allow the blood to dry at room temperature for a minimum of three hours by placing the form horizontally on a table top or rack with the wet blood spots extending over the edge to allow air drying from both sides. Do not place the form inside an envelope until completely dry. Do not put near a heat source, in direct sunlight, or on an absorbent surface. Do not touch the filter paper with your hand at any time.

Requisition Form:

The test requisition (form 3491) is combined with the collection device (i.e., filter paper). All of the information requested on the form is important for test result interpretation or physician/parent notification. The infant's name, date and time of birth, hospital of birth, gender, date and time of specimen collection, the physician of record, and the telephone number to report abnormal test results are mandatory. The birth weight, protein feeding source, and transfusion status are needed to interpret the results. Complete all fields with block print letters. To aid in researching missing reports, keep the submitter's copy of the requisition. This can be useful in tracking and identifying missing reports.

SHIPMENT

Due to the life threatening nature of several of the disorders, the law requires that the specimen collection, testing, follow-up of suspected cases, and specific diagnosis be performed before the infant is three weeks old. For this reason the blood specimen must be collected when the infant is no less than 24 hours old, but not later than one week of age. In order to expedite testing and to insure the integrity of the sample, all specimens should be shipped to the laboratory within one day of collection. Specimens must be completely dry before covering and inserting in the mailing envelope. The dried blood spot specimens must not be packaged in airtight, leak-proof bags. The lack of air exchange in the inner environment of a sealed plastic bag may cause heat buildup, moisture accumulation and/or chemical leaks from the plastic that can damage the specimen integrity. Once collected, specimens can either be mailed to the testing laboratory using the pre-addressed envelope that is part of the collection device, or they may be sent by courier. Precautions should be taken that mailed specimens are not put in mail boxes. The specimen must reach the laboratory within seven days of the collection date or it will be rejected as "unsatisfactory, delayed".
REPORTING/INTERPRETATION OF TEST RESULTS
Normal results for all tests other than hemoglobins are reported as **Within Normal Limits**.

Abnormal results for Galactosemia are reported as **Positive**. For all other diseases, abnormal results are reported as **Above Normal Limits** or **Below Normal Limits**, and the value for the ‘outside normal limit’ analyte is given.

Normal hemoglobin results are reported as FA or AF. Heterozygote results (abnormal hemoglobin plus A) are reported as traits. Homozygote abnormal results (absence of hemoglobin A) are reported as a disease. Traits that cannot be identified by the methods used by the GPHL are reported as “FA-Variant”; confirmation is recommended.

Initial tests for all diseases are performed (or, in the case of overnight assays, started) the day of receipt in the lab or the next working day. Reports are mailed to the hospital of birth and the physician of record on the day after completion of all testing. This is generally 2-3 working days after specimen receipt. All critical abnormal results are also reported by telephone and fax to the appropriate follow-up center (see above) for diagnosis, treatment, and counseling of presumptive positive results. Non-critical abnormal results are sent to the appropriate follow-up center nightly via HL7 messages.

UNACCEPTABLE SPECIMENS
Specimens will be deemed unsatisfactory to test for the following reasons:

1. **Inadequate blood collection/Quantity not sufficient (QNS)** - A specimen will be considered QNS if at least three filled and evenly soaked circles are not submitted, if the blood spot has an inadequate quantity of blood, or if the spots are not soaked completely through the filter paper.
2. **Oversaturated** – A specimen will be considered to be oversaturated if too much blood is allowed to soak into the filter paper, causing the paper to bend, fold or crumple. Oversaturation may also result in clots on the surface of the paper.
3. **Delayed** – A specimen will be considered to be delayed if it is received in the lab more than seven days after the date of collection.
4. **Contaminated** – A specimen will be considered to be contaminated if there is visible evidence of dilution of the specimen with a disinfectant, alcohol, water, tissue fluid, or other foreign substance.
5. **Unevenly Saturated** – A specimen will be considered to be Unevenly Saturated if there is visible evidence of multiple applications of blood causing a layering effect of blood on the filter paper.
6. **Scratched/Abraded** - Recognizable as unevenly soaked blood in a circular pattern with roughed up filter paper tracks caused by dragging the tip of the capillary across the surface of the filter paper.
7. **Obsolete Form** – The use of an expired or recalled filter paper device.
8. Roughed Up - Collection of specimen on damaged filter paper so that fibers from paper are standing on end.

9. No Blood – Collection device submitted with no blood applied.

10. Insufficient Information - Specimens without a name (infant or mother) or other critical demographic information (e.g., date of birth, date of collection).

11. Specimen Damaged in Transit – Specimens that get wet or are somehow else damaged during shipment to the laboratory.

12. Invalid/Illegible Demographics – Specimens that have critical demographic information that is illegible or invalid (e.g., date of birth is after date of collection, future date is entered).

**A training videotape titled "How to Collect Acceptable Filter Paper Specimens" is available from the Genetics Program upon request. Call (404) 657-4143 for details.**
SCIENTIFIC SERVICES

The Scientific Services Unit prepares microbiological culture media for the Central Laboratory in Decatur and the Waycross Regional Laboratory.

On April 1, 2013 Scientific Services Unit started to perform the quality control on microbiological culture media prepared in house.

Sterilization and biohazardous waste disposal for the entire Decatur facility are handled by the Scientific Services area. Glassware is also cleaned, sterilized and delivered to the Decatur laboratory sections.

On January 1, 2000, the Scientific Services Unit began fluoride split sample testing for the DHR, Office of Oral Health. Each water system in Georgia that adjusts the fluoride level in drinking water is asked to participate in this testing, which consists of sending monthly split samples to the Decatur Laboratory. This work had previously been handled by the Environmental Protection Division of the Georgia Department of Natural Resources.
INTRODUCTION

The Waycross Public Health Laboratory is a Clinical Laboratory Improvement Act (CLIA) of 1988 approved multi-functional clinical public health laboratory which operates under the Public Health Division of the Georgia Department of Public Health. The laboratory is located at 1751 Gus Karle Parkway in Waycross, Georgia with Dr. E. A. Franko serving as the Laboratory Director. The facility is licensed by the State of Georgia.

The laboratory performs tests mandated by state laws as well as those examinations required to support the State of Georgia’s public health programs. These services are available to county health departments and units of the Department of Public Health. Services are also available to private sector customers. The GPHL fee schedule, as well as Submission Form #3583 and FAQ list, is available at www.health.state.ga.us/programs/lab/index.asp. The following pages describe the examinations available at the Waycross Public Health Laboratory with specific requirements for specimen collection and handling for each test category. Included also, are expected turn-around times for reports, specimen acceptance policies, and guidelines for interpretation of reported results.

Specimen collection outfits are provided free of charge for those services performed in the Waycross Public Health Laboratory and may be ordered using the Specimen Collection Outfit order form.

For additional information contact:
Waycross Public Health Laboratory
1751 Gus Karle Parkway
Waycross, Georgia 31503
Telephone: 912-338-7050
INTRODUCTION

The Waycross Regional Laboratory uses Target-amplified direct nucleic acid amplification test for chlamydia and gonorrhea. *Chlamydia trachomatis* is the most commonly reported bacterial sexually transmitted disease in the US. Complications of untreated chlamydia infection in females include acute pelvic inflammatory disease, ectopic pregnancy, chronic pelvic pain, and infertility. *Neisseria gonorrhoeae* often pass unnoticed and asymptomatic carriers contribute significantly to the public health concern of gonorrhea. In women, gonorrhea is a common cause of pelvic inflammatory disease.

Family Planning:

- Screen at the routine initial/annual exam:
  - all clients less than age 26;
- For clients ages 26 and over only screen the following:
  - a client being prepared for IUD insertion;
  - a client with documented NEW signs or symptoms;
  - a client named as a contact;
  - a client using drugs;
  - a client exchanging sex for money or drugs;
  - a client who have multiple partners or a new partner in the past 60 days.
- Regardless of age, a client who has been treated for a positive chlamydia or gonorrhea test should be retested 3 months after treatment or whenever the client next seeks medical care within the following 3-12 months regardless of whether the client believes partner was treated. After 12 months from treatment or if they come in and are symptomatic their visit will be considered a new visit.

STD:

- Test STD clients:
  - Of women less than age 26
  - if contact to any STD;
  - if symptomatic for any STD;
  - a client who request an examination for any STD.

- Regardless of age, a client who has been treated for a positive chlamydia or gonorrhea test should be retested 3 months after treatment or whenever the client next seeks medical care within the following 3-12 months regardless of whether the client believes partner was treated. After 12 months from treatment or if they come in and are symptomatic their visit will be considered a new visit.

  **Notable exception:** CT/GC should be offered to clients requesting only an HIV test and who are asymptomatic for any other STD.
EPSDT:
- All sexually active minors should be screened for sexually transmitted diseases (STDs) during routine EPSDT visits.
- All sexually active minors should be tested for STDs during annually EPSDT visits.

Adult Health/Other:
- Offer testing to any sexually active client less than age 26.
- Test clients with signs or symptoms suggestive of gonorrhea or chlamydia.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM
The APTIMA Combo 2 Assay is designed to detect the presence of *C. trachomatis* and *N. gonorrhoeae* in urine, endocervical and urethral specimens. The Georgia Public Health Laboratory has validated testing for rectal and pharyngeal specimens. Specimens can be submitted for these collection sites per instructions provided below. Please note that the existing Gen Probe unisex collection kit will be used for these specimens. Specimen collection kits are supplied to the health districts for clients seen at the Public Health STD and Family Planning Clinics.

**Endocervical swab**
1. Remove excess mucus from the cervical opening and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). Discard this swab. **Note:** To remove excess mucus from the cervical opening, a large tipped cleaning swab (not provided) may be used. Discard the swab after use.
2. Insert the specimen collection swab (blue shaft) into the endocervical canal.
3. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
4. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the swab shaft at the score line; avoid splashing the contents.
7. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Male urethral swab**
1. The patient should not have urinated for at least one hour prior to specimen collection.
2. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.
3. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
4. Withdraw the swab carefully.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
6. Carefully break the swab shaft at the score line; avoid splashing the contents.
7. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

Urine

**Note:** The patient should not have urinated for at least one hour prior to specimen collection.
1. Direct the patient to provide first catch urine (approximately 20 to 30 ml of the initial urine stream) into a urine collection cup which is free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
2. Remove the cap and transfer 2 ml of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube label.
3. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

Rectal Specimens for Males

**Note:** Rectal testing of asymptomatic females is not recommended for routine screening since there is no data on the sequel of rectal infection and females who are engaged in rectal sex only, are not necessarily positive for vaginal sex.
1. Insert the unisex (blue shaft) swab 3-5 cm in the rectum and rotate 3-4 times.
2. Withdraw the swab carefully.
3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
4. Carefully break the swab shaft at the score line; avoid splashing the contents.
5. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

Pharyngeal Specimens

1. Press the tongue with a tongue depressor and insert the unisex (blue shaft) specimen swab and firmly rub the tonsils and the posterior of pharynx.
2. Withdraw the swab carefully.
3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the specimen transport tube.
4. Carefully break the swab shaft at the score line; avoid splashing the contents.
5. Recap the swab specimen transport tube tightly. Legibly label tube with patient name, patient ID# and date of collection or use electronic labels if are submitting specimens through remote data entry. Unlabeled specimens will not be tested.

**Requisition Form:**

Use Submission Form #3583 for specimen submission. Fill out the form completely by printing or typing legibly. Only legible information can be entered correctly into the laboratory database. Incomplete or illegible information may delay your results. Information required is as follows:

1. **Submitter information** (submitter code, submitter address, and phone number).
2. **Patient information** (name, patient ID number, county of residence, zip code, State, race, ethnicity, gender, date of birth).
3. **Specimen information** (test requested, reason for test, date collected, source of specimen, specimen status).

The patient identifier (name, number, or both) indicated on the requisition form should match that written on transport tube. **Unlabeled specimens will not be tested.**

**SHIPMENT OF SPECIMENS**

For best results, specimens should be transported to the laboratory on the date of collection; however, if this is impossible, specimens may be kept at room temperature and shipped as soon as possible by a courier or a shipping vendor with a traceable system.

**Urine specimens over 30 days old and/ or swab specimens over 60 days old at the time of arrival in the laboratory will be reported unsatisfactory.**

1. Chlamydia/Gonorrhea APTIMA Combo 2 specimens may be transported at room temperature. Use the specimen transport cans and Waycross address labels (available from the laboratory).
2. Be sure the caps on the transport tubes are secure, and wrap each specimen in absorbent packing material. Place the wrapped specimen inside the aluminum can, and close the can securely.
3. Wrap the completed requisition form around the aluminum can and secure it with a rubber band.
4. Place the aluminum can inside the labeled (Waycross address) fiberboard can, close, and secure the lid with tape.
5. An alternate shipping method may be utilized by substituting the biohazard bag for the inner aluminum container. If this method is chosen, the matching requisition forms should be placed in the pouch located in the front of each bag.
6. Specimens may be sent by a courier or a shipping vendor with a traceable system.
REPORTING AND INTERPRETATION OF RESULTS

An electronic copy of all positive Chlamydia and Gonorrhea reports is transmitted to the State Sexually Transmitted Disease (STD) Program. A hard copy of all positives is also mailed to the State STD Surveillance Office.

Results are reported as follows:

Positive for *C. trachomatis* and/or *N. gonorrhoeae* by Amplified Aptima Combo 2 Assay.

Negative for *C. trachomatis* and/or *N. gonorrhoeae* by Amplified Aptima Combo 2 Assay.

Indeterminate, a new specimen should be collected.

Unsatisfactory, specimen compromised in some manner making it unsatisfactory for testing. The reason for each unsatisfactory result will be listed on the report form.

UNACCEPTABLE SPECIMENS

1. No patient identifier on the specimen, or discrepancy between identifier on the specimen and requisition form.
2. Cleaning swab is used for specimen collection and placed in the specimen collection tube.
3. Two swabs received in the specimen collection tube.
4. No solution in the specimen collection tube.
5. No swab or improper swab (not from Gen-Probe kit) in the collection outfit.
6. Urine specimens over 30 days old and/or swab specimens over 60 days old from date of collection when received.
7. Collection kit expired.
8. No specimen received.
10. Overfilled. Liquid level in the urine transport tube must fall between the two black indicators lines.
INTRODUCTION

The Waycross Public Health Laboratory performs blood lead testing on children from birth to six years of age for the Georgia Childhood Lead Poisoning Prevention Program (GCLPPP). The laboratory uses graphite-furnace atomic absorption spectrometry to analyze capillary and venous specimens. Blood lead concentrations $\geq 10$ micrograms/deciliter (µg/dl) are reported to the GCLPPP for follow-up.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Finger-stick specimens
A. Preparation of Finger
   1. Powder-free examination gloves should be used to avoid contaminating the specimen.
   2. Thoroughly wash the patient’s hands with soap and water, and dry using a clean, low-lint towel. A foam-type soap can be used if water is not available.
   3. Do not let the finger to be punctured come into contact with any surface; including the patient’s other fingers.
   4. The finger to be punctured (usually the middle finger) must be free of any visible infection or wound.
   5. Grasp the finger to be punctured between your thumb and index finger with the palm of the patient’s hand facing up.
   6. If not done during the washing step, gently massage the fleshy portion of the patient’s finger.
   7. Clean the ball or pad of the finger with an alcohol swab.
   8. Dry the finger with a sterile gauze.
   9. It is not recommended to puncture the fingers of infants less than one year of age. Puncturing the heel is more suitable for these children (see GDHR Child Health Manual, Section B10, #1).

B. Puncturing of Finger
   1. Grasp the finger and quickly puncture it with a sterile lancet in a position slightly lateral to the center of the fingertip.
   2. Wipe away the first drop of blood with a sterile gauze. (This drop contains tissue fluids that will produce inaccurate results.)
   3. If blood flow is inadequate, gently massage the proximal portion of the finger and then press firmly on the digital joint of the finger. A well-beaded drop of blood should form at the puncture site.
4. Do not let the blood run down the finger or onto the fingernail. (This blood is unsuitable for analysis and will give inaccurate results.)

C. Filling the Collection Container
1. The collection container must contain EDTA as the anticoagulant. No other anticoagulant is acceptable. These tubes have purple or lavender tops.
2. Touch the tip of the collection container to the beaded drop of blood.
3. Draw the blood into the container while maintaining a continuous flow of blood.
4. Fill the microcontainer at least have full, or to the middle line. Cap the microcontainer.
5. Holding the microcontainer between your thumb and forefinger, immediately invert the tubes several times to mix the blood and anticoagulant thoroughly. If this is not done the blood may clot. The specimen will be reported as unsatisfactory if any clots are observed, or if the quantity of blood is insufficient.
6. After filling and mixing the container, put a sterile gauze on the puncture site and have the patient or patient’s mother apply pressure until bleeding stops. If bleeding continues for more than 5 minutes, consult a physician.
7. Label the container with the patient’s first and last names. The specimen will be rejected if the name is missing or illegible.

Venous specimens
1. Use powder-free gloves to avoid contamination of the specimen.
2. Clean the puncture site with an alcohol swab, and dry with a sterile gauze.
3. Apply a tourniquet, and perform venipuncture using a butterfly needle of the appropriate size.
4. The vacutainer tube must contain EDTA as the anticoagulant (purple or lavender top). Allow the tube to fill to the appropriate mark.
5. Immediately invert the tube several times to thoroughly mix the blood and the anticoagulant. Specimens exhibiting clotting will be reported as unsatisfactory.
6. Label the tube with the patient’s first and last names. The specimen will be rejected if the name is missing or illegible.

Requisition Form:
1. Use the Submission Form #3583 found on the Georgia Public Health website.

2. Fill out the form completely and legibly. Required fields include:
   a. Submitter name, address, and phone number
   b. Patient name
   c. County of residence
   d. Patient date of birth
e. Patient race, ethnicity, & gender
f. Date of collection
g. Collection method (capillary, venous)
h. Reason for test (routine screen, confirmation, follow-up, other)

3. Make sure that the patient name on the sample matches the patient name of the form.

SHIPMENT OF SPECIMENS

For best results specimens should be shipped to the Waycross Public Health Laboratory on the day of collection. If this is not possible, specimens may be refrigerated at 2-8°C and mailed by a courier or a shipping vendor with a traceable system. The specimens may be shipped at ambient temperature.

1. Make sure the caps are on securely.
2. Wrap each specimen in absorbent packing material, place specimens inside the aluminum can provided; and close the can securely. Alternatively, the specimens can be placed in a biohazard bag. If a biohazard bag is used, place the requisition in the outer pocket of the bag.
3. Place the specimen or multiple specimens inside the labeled (Waycross Public Health Laboratory address) fiberboard container. Place the lid on the container, and secure with tape.
4. Specimens must be received by the laboratory within 14 days of collection or they will be reported as unsatisfactory.

REPORTING AND INTERPERATION OF RESULTS

The laboratory strives to test all blood lead specimens on the day of arrival. Result reports are printed and mailed the day after the analysis is completed. Specimens with blood lead concentrations $\geq 10 \, \mu g/dl$ are considered elevated. All elevated results are called to the submitter and faxed to the GCLPPP coordinator for immediate action.

UNACCEPTABLE SPECIMENS
Specimens will be reported “No test – Unsatisfactory” for the following reasons:
1. No patient identification on the specimen (first and last names much be legible);
2. Discrepancy between the patient identification on the specimen and the requisition form;
3. Insufficient quantity for testing;
4. Specimen broken or leaked in transit;
5. More than 14 days elapsed from specimen collection to receipt in Waycross Public Health Laboratory;
6. Specimen clotted; and
7. Wrong anticoagulant used (only EDTA is acceptable). Purple top tubes contain EDTA and these are typically used.
INTRODUCTION

Stool specimens may be submitted for examination for intestinal parasites by county health departments and for confirmation purposes by the private sector. There is only a minimal charge for this service and for the collection outfit. The current tests performed at the Waycross Public Health Laboratory to detect intestinal parasites include a Formalin ethyl acetate concentration, a Kinyoun acid-fast stain and a Trichrome stained PVA permanent slide on each specimen.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Each collection outfit kit contains two unbreakable plastic vials, each having a color-coded cap and label, a clearly marked “fill to here” line, and a built-in collection spoon in the screw cap top. The kit systems are packaged in ziplock bags with illustrated, multilingual patient instructions to assist in safe and sanitary specimen collection by personnel and/or patients. A biohazard bag for secure transportation to the laboratory completes the outfit.

Health Department Instructions
1. Collection instructions should be reviewed with the patient.
2. It should be stressed to the patient that each specimen must be properly identified with the patient’s name. Unidentified or misidentified specimens will not be tested.
3. It should be made clear to the patient that multiple specimens collected on the same day will be considered unsatisfactory. Collect one pink and one blue specimen each day and date of collection must be written on pink and blue specimen.
4. Patient should bring the specimen back to the Health Department upon completion.

Patient Instructions
1. Remove IP/PVA vials from ziplock bags and collect fecal specimens as directed by instructions included in outfit.
2. Carefully label each vial with the patient’s name.
3. Replace only the vials in original ziplock bag.
4. Place ziplock bag inside biohazard bag and seal.

Requisition Form:

Use Submission Form #3583.

Health Department Instructions
1. Fill in submitter return address in proper area on form.
2. Instruct patient in the correct manner to complete remainder of form.
Patient Instructions
1. Complete form as directed.
2. Fold form in half and place in outside pouch of biohazard bag.
3. Return the outfit to the Health Department for transportation to the Waycross Public Health Laboratory.

SHIPMENT OF SPECIMENS
The specimen vials correctly placed and sealed within the provided ziplock bag within the biohazard bag may be carried by a courier or a shipping vendor with a traceable system in a sturdy fiber board box which meets U.S. postal regulations to:

Waycross Public Health Laboratory
1751 Gus Karle Parkway
Waycross, Georgia 31503

REPORTING AND INTERPRETATION OF RESULTS
Submitters may expect to have test results reported within two to three working days after receipt in the laboratory.

The following results are reported:
1. No parasites found.
2. A specific parasite found. **Note:** Reported parasites are classed as pathogenic or nonpathogenic.
3. Unsatisfactory results indicate that the specimen was compromised in a way that might render the test results invalid. The reason for the unsatisfactory report is indicated on each form.

UNACCEPTABLE SPECIMENS
Specimens will be reported unsatisfactory for the following reasons.
1. Overfilled;
2. Quantity not sufficient;
3. No preservative in bottle;
4. Leaked or broken in transit;
5. Expired outfit;
6. More than one specimen collected on same day;
7. No specimen received;
8. Non-fecal material received;
9. No specimen in bottle;
10. Specimen unidentified.
INTRODUCTION

The female Enterobius (Pinworm) leaves the intestinal tract to lay her eggs in the area surrounding the anus. For this reason, Enterobius (Pinworm) ova are not often present in detectable numbers within fecal specimens. The outfit best suited for the detection of pinworm infections consists of a clear, plastic tape and glass slide outfit. This outfit is designed for the direct collection of the eggs from around the anal area upon the awakening of the patient and the transportation of the specimen to the laboratory for examination. Please note that this examination is satisfactory only for detection of Enterobius (Pinworms) and no other intestinal parasites.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

Each collection outfit kit contains collection instructions, a glass slide with clear plastic tape, a tongue blade, a labeled cardboard slide holder, and requisition form.

Health Department Instructions:
1. Collection instructions should be carefully reviewed with the collector.
2. It should be stressed to the collector that each specimen must be properly identified with the patient's name. Unidentified or misidentified specimens will not be tested.
3. It should be made clear to the collector that multiple specimens collected on the same day will be considered unsatisfactory.

Collection Instructions:
1. Collect the specimen immediately upon patient's awakening in the morning since the eggs may be lost later during the day as a result of scratching, bowel movements or bathing.
2. Place the round end of tongue blade at middle of the slide. Hold the slide near center with one hand; grasp the blade and white tab on end of tape with the other hand.
3. Rotate slide while lifting up on blade and tape.
4. Continue to rotate slide until one half of tape is stripped from it.
5. Turn the slide back over tongue blade and grasp other tab with thumb.
6. Strip tape completely off slide.
7. Spread the buttocks apart to expose the anus and press the tape firmly against side at the level of the zone between the moist anal canal and dry skin surrounding it.
8. Replace tape and tongue blade on slide.
9. Smooth tape down with tongue blade.
10. Place slide in holder and discard tongue blade.
11. Label cardboard slide holder with patient's name.
Requisition Form:

Use Submission Form #3583.

Health Department Instructions
1. Fill in submitter return address in proper area on the form.
2. Instruct patient in the correct manner to complete remainder of form.
3. Indicate type of specimen submitted (for example, Pinworm slide)

Patient Instructions
1. Complete Form as directed.
2. Fold form in half and wrap around the slide holder securing with rubber band before placing in mailing envelope.

SHIPMENT OF SPECIMEN

The specimen may be returned to the health department after attaching proper amount of postage:

Waycross Public Health Laboratory
1751 Gus Karle Parkway
Waycross, Georgia 31503

REPORTING AND INTERPRETATION OF RESULTS

Submitters may expect to have test results reported within 1 to 2 working days after receipt in the laboratory. The following results are reported:
1. No parasites found;
2. Enterobius (Pinworm);
3. Unsatisfactory results indicate that the specimen was compromised in a way that might render the test results invalid. The reason for the unsatisfactory report is indicated on each form.

UNACCEPTABLE SPECIMENS

Specimens will be reported unsatisfactory for the following reasons:
1. No specimen on tape;
2. Slide broken or crushed in transit;
3. More than one specimen collected on the same day;
4. No specimen received;
5. Excess Feces on tape;
6. Specimen unidentified or misidentified;
7. Frosted tape used instead of clear plastic tape.
INTRODUCTION

The goal of the Waycross Public Health Laboratory is to confidently report an accurate and reliable diagnosis so that rabies treatment can be initiated if necessary. The Laboratory currently uses Fluorescent Antibody (FA) methodology, the most accurate microscopic test available for the diagnosis of rabies. One vitally important factor in obtaining accurate results is the quality of the specimen received. Due to the importance of rabies diagnosis it is imperative that neither the condition nor the identity of the specimen be compromised.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

1. Only specimens received in good condition with at least two identifiable principal brain parts are approved for reporting.
2. In all cases, there must have been exposure of human or domestic animals to the suspected rabid animal.
3. The Waycross Public Health Laboratory is not equipped to handle whole carcasses; therefore, only the heads of animals are accepted except for bats or small rodents. Bats or small rodents should be submitted whole.

   Environmentalists should follow these instructions for the removal of animal heads:
   a. Rubber gloves, face and eye protection and protective clothing should be worn while the head is being removed and packaged.
   b. Sever neck so as not to damage the skull. Local veterinarians can assist in this removal. Never advise clients to remove animal heads!
   c. Allow fluids and blood to drain from the head, and keep head as clean as possible. Place head in a double plastic bag for transportation to the laboratory. Leak proof.
   d. If fleas or ticks are in evidence, spray insecticide into the plastic bag containing the head before closing.
   e. Gloves should be cleaned and disinfected or discarded following use and cutting surfaces should be carefully cleaned and disinfected.

4. Only brain material (not the entire head) of very large animals (cows or horses) will be accepted, as the laboratory is not equipped to handle these large heads due to limited hood and sterilizer space. Veterinarians should be requested to perform this necropsy procedure.
5. Rodents or rabbits are not accepted for laboratory examination-unless the animal attacks a person unprovoked. Bites from animals that constitute no risk from rabies are hamster, guinea pigs, gerbils and white mice that are obtained directly from pet shops and have never been exposed to carnivorous animals or bats.
6. Reporting will be delayed on specimens that are received frozen or if no human exposure is documented. If specimens cannot be delivered to the laboratory immediately, refrigerate, but do not freeze.

**Requisition Form:**

One Rabies History Report Form from Sendss should accompany each specimen for rabies examination. The Bite Identity (BI) number must be obtained from the environmentalist prior to sending specimens. The BI number is to be written or typed onto the form. This form provides the laboratory with the needed information for accurate results and for reporting results. Include Submission Form #3583.

Fill out the form completely and legibly, being careful to include accurate names, addresses and telephone numbers for reporting. A copy of each Rabies report is forwarded to the State Office of Epidemiology for review and date of collection.

**SHIPMENT OF SPECIMENS**

Notify the Waycross Public Health Laboratory of the shipment or expected arrival of all rabies specimens so that tracking can be initiated immediately on those which become misdirected.

1. Properly package the specimen by placing the severed animal head in a double plastic bag and secure the bag by twisting and knotting. For bats and rodents, do not remove heads, but submit the whole animal.

2. Place the bag containing the specimen into a shipper with wet ice. Ice and fluids should not be allowed to leak. Triple bagging may be required. DO NOT USE DRY ICE! Seal the shipper. Place the completed history form in a separate plastic bag, and tape to the lid of the sealed shipper. Place the shipper in a cardboard box, tape, and address for shipment.

3. The package should be shipped prepaid to the laboratory. Use the method of shipment (such as FedEx) that will assure prompt service and meet IATA shipping guidelines.

4. Any bite case in which the history reveals a strong probability of rabies should be handled with utmost speed. Hand deliver emergency specimens to the laboratory after calling ahead to inform the laboratory manager of the emergency situation and the estimated time of arrival.

5. Do not ship specimens on the weekends unless prior approval has been obtained from the lab manager. Store specimens in refrigerator until Monday.

**REPORTING AND INTERPRETATION OF RESULTS**

1. Rabies testing is available Monday through Friday excluding official state holidays. Due to the required period of tissue fixation, reports will be issued the day following the
receipt of the specimen. Reporting will be delayed on specimens that are received frozen. **Note:** Specimens involved in emergency situations, and Monday and Friday morning specimens will receive only four hours of fixation; and reports will be issued the same day if received by 10:00. Otherwise, reporting will be next day or following the weekend.

2. If the brain material found inside the skull is decomposed or damaged to the point of uncertainty about its being brain tissue, no slides will be prepared unless human exposure to the suspected rabid animal is involved.

   **No Exposure** – Reported “Unsatisfactory” and comment is made "Test requires at least two identifiable brain parts."

   **Exposure** - Routine testing is performed. If the test result is positive, a report is issued as positive. If the test result is Negative, a report of Unsatisfactory is made and the comment "Test requires at least two identifiable brain parts" is added.

3. All Rabies reports are telephoned immediately to the submitter listed on the history form. Copies of all reports are mailed to the submitter, County Environmentalist (county of the animal) and to the State Epidemiology Office.

4. Test results may be given to concerned individuals, such as owners of animals, persons bitten, etc.

**UNACCEPTABLE SPECIMENS**

Rabies specimens will be reported as Unsatisfactory for the following reasons:

1. There is no documented exposure to humans or domestic animals.
2. Brain tissue is damaged or decomposed beyond recognition of at least two principal parts.
3. Tissue in preservative, such as formalin.

**Note:** See #2 under Reporting/Interpretation Section above.
INTRODUCTION

All serologic services provided by the Waycross Public Health Laboratory are available to both the public and private sector customers.

Currently the Rapid Plasma Reagin (RPR) 18mm Circle Card Test (a nontreponemal test) is the screening procedure for the diagnosis of syphilis. All reactive RPR tests will be confirmed by the Enzyme Immunoassay (EIA) unless the requisition form is marked “No Confirmatory Test Needed.” Further testing will be performed only on specimens when the EIA results are equivocal, or the RPR results are reactive 1:16 or greater with a negative EIA.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

For routine testing, whole blood from a venipuncture or serum transferred to a clean, leak resistant, non-breakable tube may be used. **Note:** Plasma is not approved for use.

1. No special preparation for the patient is required prior to specimen collection.
2. Using Universal Precautions and standard venipuncture technique collect approximately five (5) milliliters of blood in a plain (no additive) redtop vacuum blood collection tube. Use appropriate size needle (large enough to prevent hemolysis of the red blood cells) for the vein location and age of the patient.
3. Properly label with patient identifier (name, first and last, or number), collection date, and name of submitter. Use a waterproof marker that will not fade, smear, or run during transportation.
4. Allow blood specimen to clot undisturbed at room temperature for 20-30 minutes before transporting or storing.

**Requisition Form:**

Legibly complete laboratory requisition form in full providing:

1. Unique patient identifier (name);
2. Tests requested;
3. Race, sex, and date of birth;
4. Collection date;
5. Complete and accurate mailing address of submitter; and
6. Any information the submitter needs for patient identification, e.g., chart number, address. Use Submission Form #3583.
SHIPMENT OF SPECIMENS

In order to expedite the testing of all of the blood samples, and to insure the integrity of the sample, all specimens should be sent to the Waycross Public Health Laboratory on the day of collection by a courier or a shipping vendor with a traceable system.

1. Transport specimens using the doubled-walled mailing containers (biohazard bag and cardboard mailer provided by the Waycross Public Health Laboratory) or package in a cardboard box using U. S. postal regulations.
2. Tyvek bags are used to ensure impact resistance. Bags hold 3-5 specimens.
3. Wrap each specimen with absorbent material to cushion it from breakage or in case of breakage, to absorb the leakage. Multiple specimens may be placed in each bag.
4. Place the requisition form or multiple forms into the pocket of biohazard bag and place specimen or specimens inside the biohazard bags.
5. Biohazard bag then goes into cardboard mailer or place tyvek biohazard bags directly into a cardboard box with the following:
   a. The outer cardboard mailer with the Waycross Public Health Laboratory address. Reinforce the metal cover of the can with tape around the circumferential seam. To aid the laboratory in removing the tape, do not use reinforced tape.
   b. A cardboard box sealed with plastic tape with a Waycross Public Health Laboratory label. Labels are available from Waycross Public Health Laboratory (912) 338-7050. U.S. postal regulations allow up to 50 ml of blood to be transported in one package.
6. Transport specimen promptly to the laboratory. When mailing is delayed, refrigerate at 2-8°C pending transport.
7. Transport by U.S. mail, or courier.
8. Note: If U.S. mail is used, precautions should be taken that specimens are put in mail boxes that have a daily pick-up.
9. While refrigeration during transport is not necessary, avoid exposure to extreme temperatures and avoid mailing over long weekends and holidays.

INTERPRETATION AND REPORTING OF RESULTS

Turn-around-time for a RPR specimen is same day if received by 9:00 am, otherwise testing and reporting will be next business day. Arrangements may be made however, for "special request specimens," that are received after 9:00 am for same-day testing and reporting.

Results will be reported as follows:

<table>
<thead>
<tr>
<th>RPR</th>
<th>Nonreactive</th>
<th>negative RPR test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive</td>
<td>positive RPR test</td>
<td></td>
</tr>
<tr>
<td>Titer</td>
<td>Endpoint (highest dilution giving a reactive result)</td>
<td></td>
</tr>
</tbody>
</table>
Unsatisfactory     Specimen was compromised in a way that might render the test results invalid. The reason for the unsatisfactory report will be indicated on each requisition form.

**Note:** All reactive RPR specimens will be confirmed by the EIA unless the requisition form is marked “NO CONFIRMATORY TEST NEEDED.” RPR test is performed on all specimens submitted for EIA.

### CONFIRMATORY EIA

<table>
<thead>
<tr>
<th>Nonreactive</th>
<th>Negative EIA (if greater than 1:16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equivocal</td>
<td>+/- EIA (if specimen is equivocal, it will be retested)</td>
</tr>
<tr>
<td>Reactive</td>
<td>Positive EIA</td>
</tr>
</tbody>
</table>

Unsatisfactory     Specimen was compromised in a way that might render the test results invalid. The reason for the unsatisfactory report will be indicated on each requisition form.

### UNACCEPTABLE SPECIMENS

The Waycross Public Health Laboratory specimen acceptance policy requires that all specimens must be properly labeled with unique patient identifier (name) with matching identifier on requisition form, in acceptable testing condition, and accompanied by a completed requisition form. Failure to provide proper patient information may result in testing/reporting delays. Plasma is not approved for many procedures. Therefore, submit only one venous blood or serum sample without anticoagulants.

In order to expedite testing and to insure the integrity of the sample, all specimens should be mailed or delivered to the Waycross Public Health Laboratory on the day of collection. If kept refrigerated at 2-8°C until ready for transport, specimens can be tested satisfactorily for 14 days before the red blood cells lyse to the extent that tests cannot be accurately interpreted.

The submitter will be notified of all specimens unacceptable for testing with the reason for the unsatisfactory report indicated on the requisition form. When possible, the unacceptable specimen will be held in the refrigerator for 14 days. At the end of 14 days the specimen will be discarded without further notification.

Specimens will be reported “Unsatisfactory for Testing” for the following reasons:

1. No patient identifier on specimen (first and last name must be legible);
2. Discrepancy between identifier on specimen and identifier on requisition form;
3. Insufficient quantity for testing;
4. Specimen broken or leaked in transit;
5. Specimen grossly hemolyzed, lipemic, turbid or contaminated; and
6. Plasma samples.
INTRODUCTION

The Waycross Public Health Laboratory has an intergovernmental agreement with the Georgia Department of Natural Resources (DNR) Coastal Resources Division for the analysis of enterococci in water from coastal areas (beach water). Enterococci serve as indicators of the bacterial contamination of water. Therefore, their presence or absence is often used to measure the safety of coastal water areas. Specimens which are not submitted by DNR environmentalists or environmental health specialists will not be tested.

Currently the Waycross Public Health Laboratory uses a membrane filtration method for surface water testing. Direct observation of these membrane filters after 24 hours on mEI medium provides a direct test, for the detection of enterococcus bacteria in water samples.

SPECIMEN COLLECTION/LABELING/REQUISITION FORM

1. Samples are collected from coastal areas by the department of natural resources environmentalists or by environmental health specialists.
2. The Laboratory will provide 100ml sterile sample bottles containing the appropriate head space. The laboratory will provide the bottles with sample labels for the collection bottles. The forms for the bacteriological analysis of water are provided by DNR.
3. Samples should be collected from an area free of aerators, strainers, hose attachments, water purifiers or other devices.
4. Samples should be aseptically collected using grab sample method, without splashing.
5. The bottle should be filled up to the fill line of 100-mL. Do not overfill: leave ample airspace (about one inch) above the water line in the bottle.
6. All specimens must be accompanied by the bacteriological analysis of water form (requisition/report form). The upper portion of the form should be completed by the submitter. The bottle containing the specimen should also be labeled with matching information, including date and time of collection, and name of the person responsible for the collection. Use indelible ink to complete the sample information.
7. Specimen should be delivered to the laboratory preferably by 1:00 p.m. on the day of collection, Monday through Thursday. Do not deliver after 3:00 p.m., unless prior approval has been obtained from the laboratory manager. Samples will not be accepted by the laboratory on Friday.
8. To comply with State and Federal Regulations, the time from sample collection to initiation of analysis may not exceed 6 hours. Any specimen exceeding 6 hours at the time of delivery to the laboratory will be reported as UNSATISFACTORY.
SHIPMENT OF SPECIMENS

According to State and Federal Regulations, submitters of water samples for coliform analysis are encouraged but not required to hold samples below 10°C during transit to the laboratory. For hand delivered samples, an iced cooler can be used for this purpose. No mailed samples will be accepted. When arranging for a delivery, remember that the time from sample collection to initiation of analysis cannot exceed 6 hours.

Hand delivery
1. Place the water sample container inside the polyfoam box, and include the bacteriological analysis of water form on the outside.
2. Place the sample inside an iced cooler. This would assure that the temperature of the specimen is below 10°C during transit to the laboratory.
3. Transport specimen promptly to the laboratory. Keep in mind that the maximum time allowed between sample collection and initiation of analysis is 6 hours.
4. Deliver the specimens to the laboratory on the day of collection preferably before 1:00 p.m. and not later than 3:00 p.m.
5. Do not deliver specimens on Friday. No specimens will be accepted by the laboratory on Friday or the day before a state holiday.

REPORTING AND INTERPRETATION OF RESULTS

Water analysis is available Monday through Thursday. The analysis will be initiated on the day of receipt. The mEI medium test requires at least 24 hours for the availability of results. Results will be sent to the submitter within one to four days after receipt in the laboratory.

Results for the mEI medium test will be reported as follows: Number of Colony forming units per 100 milliliters. #CFU/100ml.

UNACCEPTABLE SPECIMENS
1. Specimens received without a completed bacteriological analysis of water form and/or without a sample label on the bottle containing the specimen.
2. Specimens where the information (name) on the bacteriological analysis of water form does not match the information on the sample label (bottle).
3. Samples collected more than 6 hours before they are received by the laboratory.
4. Samples in collection bottles other than the sterile bottles provided by the laboratory.
5. Samples delivered to the laboratory with a volume of less than 100-mL.
6. Samples delivered to the laboratory in cracked, broken or improperly sealed bottles.
7. Samples received by the laboratory on Friday.
8. Specimens which are not submitted by DNR environmentalists or environmental health specialists.
9. Samples containing too much chlorine. This situation may occur after disinfection using bleach. The presence of elevated levels of chlorine suggests the need for longer time between chlorine disinfection and collection of the sample.
10. Samples containing too much sulfur and/or iron.
LABORATORY OPERATIONS

INTRODUCTION

Non-technical laboratory functions are performed by several specialized units that comprise Laboratory Support Services. This section is supervised and administratively represented by the Director, Administrative Operations.

The Support Services Section exists to provide the support necessary to enable the Georgia Public Health Laboratory perform the testing that it does. It is responsible for the pre- and post- analytical processes for specimen testing and reporting, and it acquires and warehouses the supplies needed. Additionally, budget, personnel, purchasing, contracts, building security and the reception desk are also managed in this unit.

Components of the Georgia Public Health Laboratory Support Services Unit are briefly described below:

Central Accessioning and Data Processing
With few exceptions, specimens sent to the Public Health Laboratory are received in the Central Accessioning area. Packages are opened and each specimen is numbered with a bar code label. The patient’s demographic information and requested tests are entered into the Laboratory Information System (LIS).

Reports and Records Office
This office distributes laboratory test result reports electronically, by U.S. Mail and courier services (when provided by submitters). Electronic copies of reports are kept on file for reference in accordance with record retention schedules that are coordinated through DPH.

Service and Supply Unit
This unit provides all purchasing services for the Laboratory and oversees all equipment maintenance and agency contracts. It also includes warehouse operations, the mail room, the outfit room, and courier service for outbound deliveries.

The Support Services Unit’s goal is to provide the administrative support necessary to its internal and external customers to ensure the efficient and effective delivery of laboratory services to the residents of Georgia.

Bill Shea
Director, Administrative Operations
CENTRAL ACCESSIONING / DATA PROCESSING (CA/DP)

The Accessioning Unit is the entry point for specimens submitted for testing at any of the Georgia Public Health Laboratory locations.

The Decatur CA/DP Unit consists of two sections. Central Accessioning is where the specimens are opened and sorted, and a numbered bar code label is affixed to the both specimen and the submission form that accompanies the specimen. Georgia Public Health Laboratory policy dictates that all specimens are accessioned the day they are received, without exception. All specimens must have a submission form indicating the test(s) requested. Central Accessioning staff checks to see that a name or unique identifier on the specimen matches the name and identifier on the submission form.

It is critically important that all of the information on the submission form is complete and legible, and that the data on the submission form is an exact match of the data on the specimen. If the information does not match, or if it is missing, the specimen is not delivered to the laboratory for testing and a report of “unsatisfactory” is sent to the submitter.

Customers are strongly encouraged to include a specimen manifest for multiple specimens with every shipment. This enables Central Accessioning to identify any discrepancies quickly so they can notify the sender of any missing or additional specimens in the shipper. It is important to remember that proof of delivery provided by UPS, the USPS or other couriers, documents only that a package arrived, it does not account for the contents of that box.

The second area is the Data Entry Section where the patient and testing information for each specimen is entered into the Laboratory Information System (LIS). The Data Entry section is responsible for entering patient demographics and requested tests into the LIS in an accurate and timely manner.

The two regional laboratories have accessioning areas arranged to meet their specific requirements.

For information concerning the receipt of specimens, or accessioning information, please contact:

Decatur Laboratory 404-327-2281
Waycross Laboratory 912-338-7050
REPORTS AND RECORDS UNIT

The Reports and Records Units in the Public Health Laboratories in Decatur and Waycross perform three essential functions:

1. Generating laboratory test result reports in electronic and paper formats.
2. Maintaining laboratory records and statistical data.
3. Serving as liaisons to clinicians, Public Health officials and the general public regarding test results.

Each GPHL location produces its own test result reports. Questions regarding reports should be directed to the location that performed the testing.

The Reports and Records Unit in the Decatur Laboratory reports laboratory findings for the majority of the tests performed at this location. To inquire about the status of a particular specimen, please contact the Reports and Records Unit at 404-321-2241. If testing has not been completed and reported, or if you have technical questions regarding the test, your call will be referred to the testing unit for further information.

Note: Test results will be provided only to the official submitter of record; we cannot release results to the patient or other health care provider that was not the submitter, with or without the patient’s permission.

Laboratory test records are retained by the Georgia Public Health Laboratory for two years and are then destroyed. The Health Insurance Portability and Accountability Act (HIPAA) requires that paper records are cross-cut shredded to ensure complete privacy. Electronic records are purged from the LIS. Duplicate copies of laboratory test reports can be provided upon request from the original submitting clinician with proper identification. All requests for more than five duplicate reports must be requested in writing.

For additional information about Reports and Records, please contact:

Decatur Laboratory: 404-321-2241

Waycross Laboratory 912-338-7050
LABORATORY SERVICES AND SUPPLY UNIT

The Laboratory Services and Supply Unit provides support services in the areas listed below to the Decatur and Waycross Public Health Laboratories. Additionally, employees in this unit assemble and distribute specimen collection outfits to customers of the Decatur Laboratory.

Purchasing: The Laboratory Services and Supply Manager oversees purchasing for all laboratory testing materials and reagents used in both public health laboratories. These purchases are accomplished with state and federal funds, adhering to strict purchasing guidelines imposed by the Department of Administrative Services (DOAS or State Purchasing) and the Department of Public Health (DPH). This unit maintains a large supply warehouse to ensure availability of the items used by the GPHL and it responsible for all of the agency contracts for equipment maintenance, reagents, and reagent/rental agreements.

Mail Handling: All incoming and outgoing mail is processed through the Service & Supply Unit. Incoming mail is processed through the new modular mail screening facility, sorted, and delivered to the appropriate areas. Outbound mail is processed twice daily to coincide with USPS pick-up schedules, and UPS packages are shipped daily.

Shipping and Receiving: All deliveries for the Decatur laboratory are received and signed for in the mail screening facility. Outgoing shipments are also prepared for shipment by the Services and Supply staff.

The Services & Supply Unit provides the courier service for the Decatur facility. This service is for deliveries between the laboratory and the state office and for other outbound deliveries. The GPHL does not currently provide specimen pick-up service for our submitters.

The “Outfit Room” recycles used specimen shippers that have been sterilized and refurbishes them so that they may be used again. They also provide specimen collection outfits.
**SPECIMEN COLLECTION OUTFIT INFORMATION**

<table>
<thead>
<tr>
<th>ITEM NO</th>
<th>TYPE TESTS</th>
<th>OUTFIT COMPONENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>BACTERIOLOGY</strong></td>
<td></td>
</tr>
<tr>
<td>505</td>
<td>Cultural Referral</td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag/tyvek envelope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - absorbent packing paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>555</td>
<td>Stool Culture</td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag/tyvek envelope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - vial preservative (Para-Pak)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>525</td>
<td>Pertussis</td>
<td>1 – medium mailing can &amp; lid</td>
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<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - slide holder w/2 glass-etched ring slides</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>560</td>
<td>Streptococcus</td>
<td>1 - preaddressed #10 envelope #3547</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - pack preservative (Dripaz)</td>
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<tr>
<td></td>
<td></td>
<td>1 - Self-seal HS Envelope</td>
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<tr>
<td></td>
<td></td>
<td>1 - cotton tip applicator Dacron swab</td>
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<tr>
<td></td>
<td></td>
<td>1 - requisition form # 3583</td>
</tr>
<tr>
<td></td>
<td><strong>MICROBIAL IMMUNOLOGY OUTFITS</strong></td>
<td></td>
</tr>
<tr>
<td>500</td>
<td>Microbial Immunology with Blood</td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td>Tubes</td>
<td>1 - biohazard transport bag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - absorbent packing paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - 5ml plastic blood collection tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>501</td>
<td>Microbial Immunology without Blood</td>
<td>Same as #0500 without 5ml blood tube</td>
</tr>
<tr>
<td></td>
<td>Tubes</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Contents</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>502</td>
<td>HCV Viral Load</td>
<td>1 – 12x75mm screw capped cryovial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag/tyvek envelope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - absorbent packing paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 – serum SST-Tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>550</td>
<td>MYCOBACTERIOLOGY (TB) OUTFITS</td>
<td>Sputum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag/tyvek envelope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - absorbent packing paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - 50ml conical tube</td>
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<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>585</td>
<td>Identification</td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - absorbent packing paper</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
<tr>
<td>3491</td>
<td>NEWBORN SCREENING OUTFITS</td>
<td>Metabolic Disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - 4 part snap-out form #3491 w/filter paper attached</td>
</tr>
<tr>
<td>3603</td>
<td>Mailing Envelope</td>
<td>1 - preaddressed envelope</td>
</tr>
<tr>
<td>520</td>
<td>PARASITOLOGY OUTFITS</td>
<td>Intestinal Parasites/PVA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - tall mailing can/lid (large)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag/tyvek envelope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - prepackaged kit (2 vials preservative)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 - requisition forms #3583</td>
</tr>
<tr>
<td>521</td>
<td>Amebiasis/E. Histolytica PCR</td>
<td>1 - medium mailing can/lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - biohazard transport bag</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - 5% Potassium dichromate/absolute ethanol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 - requisition form #3583</td>
</tr>
</tbody>
</table>
Pinworms

1 - preaddressed Kraft envelope #3602
1 - slide holder w/1 glass slide w/tape attached
1 - wooden depressor
1 - requisition from #3583

Blood Smears

1 - medium mailing can/lid
1 - double slide holder w/2 glass slides
1 - requisition form #3583

VIROLOGY OUTFITS

HIV (AIDS)

1 - Biohazard transport bag
1 - Absorbent packing paper
1 - 5ml Vacutainer® gold serum separator tube
1 - Requisition form #3583
1 – Freezer Pack
1 – Styrofoam specimen container w/ outer fiberboard box (labeled UN3373 BIOLOGICAL SUBSTANCE CATEGORY B).

Viral Culture**

1 – Biohazard transport bag
1 – Absorbent packing paper
1 – Specimen collection vial w/ preservative
2 - 6" polyester swabs
1 - Requisition form #3583

Viral Load

1 – Biohazard transport bag
1 - Absorbent packing paper
1 - Vacutainer® PPT - Tube
1 - 12 x 75mm (306 ml) screw-capped cryovial
1 – Plastic 6” transfer pipette
1 – Requisition form #3583
LABORATORY INFORMATION MANAGEMENT SYSTEM

The Georgia Public Health Laboratory IT infrastructure is managed by Public Health Information Technology group (PH/IT.) The Laboratory Information Management System (LIMS) Unit provides the support function for all of the information and data system needs at the GPHL. The laboratory IT unit responsibilities include:

- Integrating the technical aspects of laboratory operation with LIMS
- Maintaining the web portal
- Supporting, maintaining and helping to continually develop LIMS
- Managing outsourced IT infrastructure needs

The Laboratory Information Management System (LIMS) is the key element for maintaining integrity, availability, authenticity, and confidentiality for all records on all specimens handled by GPHL. LIMS, displays, collects and reports all test information that is received from the testing of specimens.
**BILLING UNIT**

The Laboratory Billing Unit is a part of the Department of Public Health Finance Division and is located in the Georgia Public Health Laboratory’s Decatur Facility. It prepares and mails invoices for infectious disease and newborn metabolic screening tests.

**INFECTIONOUS DISEASE FEES**

Effective April 1, 2010 the fee schedule at the Georgia Public Health Laboratory was revised for infectious disease tests. The changes are summarized below:

1. Fee stamps are no longer sold for laboratory testing. Customers receive a monthly invoice from the GPHL at the end of each month for their billable tests. Customers may continue to use any fee stamps already purchased. Invoices will be sent for any billable test not accompanied by the appropriate fee stamp.

2. Laboratory test fees increased for the four tests listed below. These tests are billable to all GPHL customers, including Public Health providers.

   - Blood Lead Test $10.00
   - Hepatitis C Test $10.00
   - Routine HIV Test $10.00
   - Syphilis Serology Test $10.00

3. The fees for all other billable infectious disease tests remain $8.00 and are billable to private health care providers only.

4. As of November 1, 2011 a late interest charge of 1.5% per month will be charged on unpaid balances over thirty (30) days old as per O.C.G.A. Section 7-4-16.

**NEWBORN SCREENING FEES**

Effective July 1, 2010 the fee for Newborn Screening is increased to $50.00 per specimen submitted, subject to exclusions for mandated repeats. The Medicaid and PeachCare reimbursement rates have been increased accordingly.

As of November 1, 2011 a late interest charge of 1.5% per month will be charged on unpaid balances over thirty (30) days old as per O.C.G.A. Section 7-4-16. **Note:** Well water testing, offered in Albany and Waycross Public Health Laboratories, is charged at $30/test.

Please call the Georgia Public Health Laboratory Billing Unit at (404) 327-7933 with any questions.

Marcel Russell,
Billing Supervisor