



Bureau of Laboratory Services
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Guidelines for the Submission of Clinical Samples

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Storage of Supplies and Reagents

In order to ensure that the laboratory is able to provide you with results that are of appropriate quality for patient care it is important that all supplies and reagents are stored appropriately and according to manufacturer's guidelines prior to use. Temperature should be recorded in any area used for storage of reagents and supplies that have a temperature range designated by the manufacturer. Humidity should be monitored as well where appropriate.

If out of range storage conditions are noted it is important to address the situation as soon as possible. Improper storage of supplies or reagents prior to testing could result in erroneous lab results. Some possible means of corrective action are:

- Remove the stored items to a different location
- Increase the frequency of monitoring until the conditions are back in range
- Repair equipment
- Perform QC on items in question to ensure they were not compromised

NOTICE: For tests that require serum or plasma the laboratory requires that the serum or plasma be transferred to a separate transport tube prior to being transported to the lab.

Serum or Plasma samples that have been separated by centrifugation but remain in the sample collection tube will not be accepted.

Un-separated whole blood samples (un-centrifuged) will not be accepted by the laboratory. **(Exception:** Whole blood is accepted for *Mycobacterium tuberculosis* testing and Blood Lead testing)

Suggested Procedure for Serum or Plasma Transfer

The serum pour-off process should be performed as follows after the blood sample has been collected:

- Prepare your area by gathering all needed supplies and comfortably arranging them
 - Supplies
 - Test tube rack
 - Transfer pipettes
 - Transport tubes and caps
 - Absorbent mat
 - 10% bleach solution in spray bottle or commercial disinfectant
 - Biohazard waste disposal container
 - Gloves
 - Lab coat
 - Face shield
 - Permanent Marker (for labeling tube if needed)
- Put on personal protective equipment (lab coat, gloves, face shield)
- Centrifuge your whole blood specimen
 - Whole blood drawn in redtop tubes should be inverted five times then allowed to sit still and upright in a rack for 60 minutes before centrifuging
 - Whole blood drawn in serum separator tubes (gold top, tiger top or any of the tubes that contain gel) should be inverted five times then allowed to sit still and upright in a rack for 30 minutes before centrifuging
 - Centrifuge Process
 - Place tubes in the centrifuge. Place even number of tubes in balance across from each other. If you have an odd number you may use a tube of water to balance the centrifuge so that it runs smoothly and does not rock while it is spinning the tubes
 - Make sure the centrifuge is set for a minimum speed of 1200g
 - Close the lid securely
 - Centrifuge for 10 minutes

- Transfer serum to transport tube
 - **NOTE:** Each labeled specimen should have an empty transfer tube paired with it that is labeled with the same identifying information. There should always be two forms of identification on the tube (e.g. name, DOB, ID number, etc.)
 - Place a test tube rack on an absorbent pad on the countertop
 - Remove tubes from the centrifuge and place them in a test tube rack
 - Place the labeled transport tube in the test tube rack next to the original blood draw tube
 - Uncap the blood draw tube
 - **NOTE:** Uncap and transfer only one tube at a time to prevent contamination or specimen mix-up
 - Take the transfer pipette and insert it into the tube and aspirate the serum by squeezing the bulb and allowing the pipette to fill with serum
 - Place the filled transfer pipette into the empty transport tube that matches the original tube and release the serum into the tube by squeezing the bulb of the pipette
 - **NOTE:** The transfer process may take more than once depending on the volume of serum in the original tube. Be careful not to touch the red blood cell layer. Only transfer the straw colored serum
 - Discard the transfer pipette into a suitable biohazard waste container
 - Place a cap on the serum specimen that is now in the transport tube
 - Discard the original blood tube
 - Perform the process for the next specimen
- Specimens are now ready for transport and may be placed in a refrigerator until ready for transport
- Specimens **MUST** be transported to the laboratory in an ice chest that contains cold ice packs or wet ice
- Disinfect the work space
 - Discard the absorbent pad and any other materials that may have been used in a suitable biohazard waste disposal container
 - Spray the work area with a 10% bleach solution or a suitable commercial disinfectant
 - Wipe the sprayed area with absorbent paper towels and discard the towels immediately after use

Specimen Collection Guidelines

AFB Culture and Smear

- All specimens should be stored at 2-8°C.
- Specimens should be transported to the laboratory on ice packs; within 24 hours of collection whenever possible.
- Exceptions (temperature) are blood and bone marrow specimens which should be maintained at room temperature during storage and transport.
- Specimens received greater than 24 hours after collection or at room temperature may be accepted for testing at the laboratory's discretion.
- The following sample types and collection methods are recommended by the laboratory. Other sample types or collection methods may be accepted at the laboratory's discretion.
 - Abscess, exudates- Collect fluid/ abscess material with syringe and/or remove tissue aseptically. A swab is discouraged unless it is the only specimen available. Submit swabs in 2-3 ml saline.
 - Sputum, expectorated- Collect specimen under direct supervision of nurse/healthcare worker. Have patient rinse with water to remove excess bacteria. Instruct patient to cough deeply to produce a lower respiratory specimen
 - Sputum, induced- Collect specimen under direct supervision of nurse/healthcare worker. Have patient rinse with water to remove excess bacteria. With aid of nebulizer have patient inhale approximately 25ml of 3-10% sterile saline
 - Fluids (abdominal, amniotic, bile, joint, paracentesis, pericardial, peritoneal, pleural, synovial, thoracentesis) - Obtain specimen via percutaneous needle aspiration or surgery; submit as much fluid as possible. Swabs dipped in fluid are not acceptable.
 - Tissue/lymph node- Add 2-3ml of 0.85% sterile saline to tissue for transport
 - Gastric lavage- Collect in early morning before patients eat. Introduce nasogastric tube into stomach. Perform wash with 25-50 ml chilled, sterile water. Recover sample and place in 50ml conical tube. Neutralize pH with 100mg sodium carbonate within 4 hrs of collection.
 - Bronchial lavage or brush, Endotracheal aspirate, lower BAL- Collect washing or aspirate in sputum trap, place brush in 5ml saline.
 - CSF-collect aseptically
 - Blood, bone marrow- Direct smears are not performed on blood. Do not refrigerate. Collect specimen in 10ml SPS yellow top collection tube. SPS is preferred but heparinized blood is also acceptable. Fill according to manufacturer's instructions to ensure proper dilution.
 - Stool- Pass specimen directly into container. Do not use transport medium. Rectal swabs are not acceptable.

AFB ID (MALDI-TOF)

- Pure cultures on solid or broth media are accepted by the laboratory.

AFB Antimicrobial Drug Susceptibility

- Pure cultures on solid or broth media are accepted by the laboratory.

Arbovirus Microsphere Immunoassay

- Serum or CSF samples are accepted for testing
- Store specimens at 2-8°C

- Specimens should arrive at the lab on ice within 48 hours of collection.
- Frozen specimens may be accepted greater than 48 hours after collection at the laboratory's discretion.

Blood Lead Testing

Specimen Collection and Receiving:

1. The whole blood specimen is drawn for blood lead testing according to the policy and procedure designed by the HHD Medical Professionals.
2. Only venous blood is accepted since they are considered appropriate for diagnostic evaluation and medical management.
3. Blood specimens are collected in 2mL plastic vacutainer lavender top tubes (Becton Dickinson 2mL Vacutainer K2EDTA 3.6mg Tube)
4. The following tubes will be used for this procedure:
 - a. Becton Dickinson (BD) 2mL Vacutainer K2EDTA 3.6mg Tube
5. Collected specimens must follow federal regulations and are placed individually in tertiary containment with enough absorbent material in case of leaks, which are then placed in biohazard bags with ice/cold pack and are sealed properly.
6. Specimens must be labeled properly: at least, 2 identifiers on each tube and each specimen must be accompanied by a test request from an authorized provider.
7. Patient blood specimen are transported to the laboratory in person, preferably on the date of collection. Specimens must be stored on ice or kept cold with cold packs until they are delivered to the laboratory. Temperature of the specimen must be 5 ± 3 °C. Proficiency Test specimens can be shipped via commercial courier (ice pack not needed for PT specimens).
8. On receipt at the laboratory, temperature of specimens is taken and it must be within 5 ± 3 °C. Specimens are then logged into the laboratory information system (LIS), labeled with a unique lab ID generated by the LIS, and placed in the refrigerator (at temperature 5 ± 3 °C) until they are retrieved and analyzed.
9. Samples must be received in the lab within 3 days of collection to allow the laboratory to complete the analysis before the end of the seven-day holding time requirement. Samples delivered on Friday should be within 2 days of sample collection because the laboratory is closed on Saturday and Sunday.

Specimen Rejection Criteria:

- Samples submitted in any tubes other than those specified above;
- Samples not placed individually in biohazard bags;
- Samples over or under the required fill volume;
- Samples delivered without having sufficient time for analysis to meet the seven-day holding time requirement.
- Samples transported and received without cold packs or ice.
- Samples where specimen label and data entry information are different;
- Samples missing date & time collected (after failed attempts to get the required information)
- Sample tubes that are broken or leaking;
- Clotted samples;
- Proficiency samples coming from another laboratory. The lab does not communicate with any other lab about proficiency testing/samples.

***Bordetella pertussis* by Direct Fluorescent Antibody or Culture**

- Do not use fixatives or preservatives for collection of any samples.

- Swabs should be transported to the lab in Amies transport media or a similar appropriate media.
- Specimens should be transported to the laboratory on ice or ice packs within 24h of collection whenever possible. If transport will take more than 24 hours specimens should be incubated at 35°C for 48 hours prior to shipment.
- Cultures, inoculated media or slides should be transported at room temperature

The laboratory will accept the following appropriately collected sample types:

- Nasopharyngeal swabs collected on calcium alginate or Dacron fiber tip swabs transported in appropriate media.
- Nasal Washes; 1-5 ml total volume flushed into a sterile leak proof container with 1-1.5ml of sterile saline.
- Nasal aspirates collected on calcium alginate or Dacron fiber tip swabs transported in appropriate media.
- For DFA only a slide prepared from any of the above sample types is acceptable.
- Cultures on Blood Agar or Regan-Lowe media. Other appropriate media may be accepted at the laboratory's discretion. Cultures should be inoculated bedside for maximum recovery.

***Campylobacter* Reference Culture Identification**

Culture isolates on *Campylobacter* blood agar stored and transported under microaerophilic conditions area accepted by the laboratory.

Carbapenemase Producing Enterobacteriaceae and *Pseudomonas aeruginosa*

Sealed isolates on solid media are accepted by the laboratory

Chlamydia Culture

Cervical Specimens

- Wipe the cervix prior to collection to remove WBC and mucus debris
- Insert a sterile, large tipped polyester swab into the endocervix, rotate and remove. Discard this swab.
- Insert a sterile, polyester swab into the cervical to collect cells from the transitional zone. Rotate the swab vigorously in firm contact with the cervix surface to facilitate the collection of columnar epithelial cells.
- Withdraw swab without contacting surfaces.
NOTE: Recovery rate for females can be improved if the urethra is also sampled

Urethral Specimens

- Insert a sterile, fine tipped polyester swab 2 to 4 cm into the male urethra or 1 cm into the female urethra and hold in place for 5 seconds.
- Rotate the swab several times to obtain columnar epithelial cells and withdraw.
Note: patient should not have urinated within one hour of collection.

Eye

- Gently swab the lower conjunctiva with a sterile, fine-tipped polyester swab, collecting patient mucous membrane cells.

Nasopharynx and Throat

- Gently insert a sterile nasopharyngeal fine-wire polyester swab into one or both anterior nares to the posterior pharynx; rotate to collect mucous membrane cells and withdraw.
- Swab the posterior pharynx vigorously with a large-tipped, sterile polyester swab.

Note: Nasal aspirates collected by intubation are a superior source of the agent in infants with pneumonia.

Rectal Mucosa

- To collect cells from the mucosal surface, insert a sterile polyester swab 1-cm past the anal sphincter, rotate in firm contact with the mucosal surface and withdraw.

TIPS

- When swabs are used for collection use cotton or polyester swabs, do not use calcium alginate swabs as they have been shown to inhibit replication.
- Immerse swab immediately in appropriate transport medium. This will serve to stabilize Chlamydiae, if present, and inhibit undesirable bacterial and fungal overgrowth.
- Place swab in transport tube, break off shaft, and tightly secure cap.

Transport

- Specimens should be transported to the laboratory on wet-ice or ice packs and processed and tested as soon as possible.
- Specimens can be stored at 2-8°C for up to 48H.
- If longer storage is required , the sample should be stored at -70°C or lower

Chlamydia by Nucleic Acid amplification (APTIMA Combo 2)

- The following specimen types are accepted for testing: endocervical and male urethral specimens, vaginal swab specimens, PreserveCyt Solution liquid Pap specimens, female and male urine specimens, oral swabs, and rectal swabs.
- Only the following specimen collection kits are approved for use:
 - APTIMA Unisex Specimen Collection Kit for endocervical and Male Urethral Swab specimens
 - APTIMA Urine collection kit for Male and Female Urine Specimens
 - APTIMA Vaginal Swab Specimen Collection Kit
 - APTIMA Specimen Transfer Kit(for use with gynecological samples processed with the ThinPrep 2000 System)
- Refer to the appropriate specimen collection kit package insert for collection instructions
- The APTIMA Combo2 assay has not been evaluated for use on patients under the age of 16 with specimen types other than urine. The laboratory will only accept urine samples for patients under the age of 16.
- The performance of the vaginal swab has not been evaluated in pregnant women. Vaginal swabs from pregnant women should not be submitted for testing.
- Swab specimens should be stored and transported to the lab at 2-30°C within 30 days
- Urine samples should be transferred to the APTIMA urine specimen transport tube within 24 hours of collection.
- Urine samples should be stored and transported to the lab at 2-30°C within 30 days of collection.
- Oral and Rectal swabs should be stored and transported to the lab at 2-30°C within 30 days of collection.
- PreserveCyt Solution liquid Pap specimens intended for CT and/or GC testing must be processed for cytology within 30 days of collection when stored at 2-30°C
- Process the PreserveCyt Solution liquid Pap specimen in accordance with the *Thin Prep 2000 Processor Operator's Manual* and the APTIMA Specimen Transfer Kit package insert. Transfer 1 ml. of the fluid remaining in the PreserveCyt Solution vial into an APTIMA Specimen Transfer tube according to the instructions in the APTIMA Specimen Transfer Kit package insert.

- PreservCyt Solution liquid Pap specimens in APTIMA Specimen transfer tubes stored and transported at 2-8°C must arrive at the laboratory within 30 days of collection, or within 14 days of collection if stored and transported at 15-30°C.

***Clostridium botulinum*, typing, isolation, and toxin detection**

Requires pre-approval by the Texas Department of State Health Services, call state epidemiologist at 512-776-6352 or 512-776-6648 for instruction.

Dengue Detection and Serotype by Real Time RT-PCR

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative results. Training in specimen collection is highly recommended due to the importance of specimen quality.

To diagnose dengue, the laboratory requires a blood sample taken during the acute period of the disease (first 7 days of symptoms). If the patient makes the first visit to the physician on or after day 7 of onset of the symptoms that sample is likely to not render a positive RT-PCR result.

- Once there is a clinical diagnosis of suspected dengue, take a venous, whole blood sample.
- Follow serum or plasma specimen collection devices manufacturer instructions for proper collection, separation and storage methods.
- Serum or plasma should be transferred to a separate transport tube as soon as possible.
- Separated serum or plasma samples should be frozen at -20°C and sent or shipped in dry ice to the laboratory.
- If dry ice is not available separated serum or plasma can be transported to the laboratory on ice or ice packs within 2 hours of collection.

***E. coli* O157:H7 Reference Culture Identification**

Sealed isolates on solid media are accepted by the laboratory.

EHEC Shiga-Toxin Assay

- Stool samples in an appropriate enteric transport medium such as Cary-Blair are accepted by the laboratory.
- Fill transport media according to manufacturer's label instructions.
- Store samples at 2-8°C prior to transport.
- Transport samples to the laboratory on wet ice or ice packs.

Gonorrhea by Nucleic Acid Amplification (APTIMA Combo 2)

- The following specimen types are accepted for testing: endocervical and male urethral specimens, female and male urine specimens, oral swabs, and rectal swabs.
- Only the following specimen collection kits are approved for use:
 - APTIMA Unisex Specimen Collection Kit for endocervical and Male Urethral Swab specimens
 - APTIMA Urine collection kit for Male and Female Urine Specimens
- Refer to the appropriate specimen collection kit package insert for collection instructions
- The APTIMA Combo2 assay has not been evaluated for use on patients under the age of 16 with specimen types other than urine. The laboratory will only accept urine samples for patients under the age of 16.

- Swab specimens should be stored and transported to the lab at 2-30°C within 30 days
- Urine samples should be transferred to the APTIMA urine specimen transport tube within 24 hours of collection.
- Urine samples should be stored and transported to the lab at 2-30°C within 30 days of collection.
- Oral and Rectal swabs should be stored and transported to the lab at 2-30°C within 30 days of collection.

***Haemophilus influenzae* Typing**

- Cultures collected from sterile body sites such as blood or CSF are accepted by the laboratory.
- Culture isolates inoculated onto chocolate agar slants are preferred

For the serology assays, the package inserts say the assay can be performed on serum and plasma; however, plasma was not performed on our verification of the assay.

Hepatitis A (Anti-HAV EIA)

- The laboratory will accept serum or plasma samples for testing.
- EDTA, citrate, ACD or heparin-based anticoagulants are acceptable for plasma collection
- Specimens collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution.
- Serum or plasma should be transferred to a separate transport tube as soon as is practicable and stored at 2-8°C for up to 7 days.
- Specimen should be received frozen at the laboratory.

Hepatitis A (Anti-HAV IgM EIA)

- The laboratory will accept serum or plasma samples for testing.
- EDTA, citrate, ACD or heparin-based anticoagulants are acceptable for plasma collection
- Specimens collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution.
- Serum or plasma should be transferred to a separate transport tube as soon as is practicable and stored at 2-8°C for up to 7 days.

Hepatitis B (Anti-HBc EIA)

- The laboratory will accept serum or plasma for testing
- The following glass or plastic tubes are suitable for specimen collection: SST, potassium EDTA, sodium citrate, ACD, and sodium and lithium heparin.
- Specimens collected in anticoagulant tubes should be filled as labeling indicates to avoid improper dilution
- The volume of anticoagulant in sodium citrate tubes causes a specimen dilutional effect. Individuals with borderline results from specimens collected in sodium citrate tubes should be retested using serum specimens.
- Serum/plasma should be transferred to a separate transport tube as soon as is practicable.
- Specimens should be stored at 2-8°C.
- Specimens should be transported to the laboratory on ice or frozen within 7 days of collection.
- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.

Hepatitis B (HBsAg EIA)

- Serum, plasma, or cadaveric specimens are accepted by the laboratory.
- The following anticoagulants in glass tubes are acceptable for specimen collection: EDTA, sodium heparin, sodium citrate, CPDA-1, and ACD.
- Plastic tubes with serum, serum separators, or the following anticoagulants are acceptable for specimen collection: EDTA, lithium heparin, and sodium citrate.
- Samples collected into anticoagulant tubes should be filled as labeling indicates to ensure proper dilution.
- Serum or Plasma samples should be transferred to a separate transport tube as soon as is practicable and stored at 2-8°C.
- Specimens must arrive at the laboratory within seven days of collection and may be shipped at ambient temperature or under refrigeration
- Frozen specimens may be accepted greater than seven days after collection at the laboratory's discretion

Hepatitis B (Anti-HBs EIA)

- The laboratory will accept serum or plasma samples for testing
- The following glass or plastic tubes are acceptable for specimen collection: SST, EDTA, sodium citrate, lithium heparin, and sodium heparin
- Specimens filled into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution.
- The volume of anticoagulant in sodium citrate tubes causes a specimen dilutional effect. Individuals with borderline results from specimens collected in sodium citrate tubes should be retested using serum specimens.
- The volume of anticoagulant in sodium citrate tubes causes a specimen dilutional effect. Individuals with borderline results from specimens collected in sodium citrate tubes should be retested using serum specimens.
- Serum or Plasma samples should be transferred to a separate transport tube as soon as is practicable and stored at 2-8°C.
- Samples should be transported to the lab frozen or on ice within 7 days.
- Frozen specimens may be accepted greater than seven days after collection at the laboratory's discretion

Hepatitis B (Anti-HBc IgM EIA)

- The laboratory will accept serum or plasma for testing
- The following glass or plastic tubes are suitable for specimen collection: SST, EDTA, sodium citrate, ACD, and sodium and lithium heparin.
- Specimens collected in anticoagulant tubes should be filled as labeling indicates to avoid improper dilution
- The volume of anticoagulant in sodium citrate tubes causes a specimen dilutional effect. Individuals with borderline results from specimens collected in sodium citrate tubes should be retested using serum specimens.
- Serum/plasma should be transferred to a separate transport tube as soon as is practicable.
- Specimens should be stored at 2-8°C.
- Specimens should be transported to the laboratory on ice or frozen within 7 days of collection.
- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.

Hepatitis C Virus ELISA

- Blood specimens collected in glass, plastic, or serum-separator tubes are accepted.
- Plasma specimens collected in EDTA (glass and plastic tubes, plasma preparation tubes), lithium heparin, CPD, CP2D,
- CPDA-1, ACD, or 4% citrate anticoagulants may be used. Plasma collected with an improper ratio of specimen to anticoagulant should not be used.
- Whole blood may be stored up to 25°C for 24 hours from time of draw and serum and EDTA plasma specimens may be stored up to 10 days from time of draw at 2-8°C prior to centrifugation. Do not freeze whole blood.
- Specimens may be stored for up to 10 days from time of draw at 2-8°C following centrifugation and transfer, or up to 4 weeks at -20°C undergoing 5 freeze/thaw cycles. Store specimens in appropriately qualified freezers. Mix specimen thoroughly after thawing and before testing.
- Studies have demonstrated that specimens may be shipped at ambient temperature (up to 37°C) for up to seven days or refrigerated (2 to 8°C) for up to seven days. Upon arrival, specimens should be stored at 2 to 8°C.
- For shipments requiring extensive transit times (greater than seven days), specimens should be kept frozen (-20°C or below).
- If specimens are to be shipped, they must be packaged in compliance with International Air Transport Association (IATA) and other applicable guidelines and regulations.^{20,23}
- No special preparation of the donor is required prior to specimen collection. Blood should be collected by approved medical techniques. Proper sample handling techniques should be employed to avoid microbial contamination.

Hepatitis C Virus RNA Qualitative Assay (APTIMA)

- Take universal blood borne pathogen precautions with all samples
- Samples can be collected in BD Vacutainer serum collection tubes (red tops)
- Whole blood samples may be stored and shipped at room temperature if they arrive at the lab within 24 hours of collection. Do not freeze.
- Samples that will arrive greater than 24 hours after collection should be centrifuged at 1,000x G for 10 to 15 minutes and transferred to a separate transport tube.
- Serum or plasma can be stored at 2-8°C for up to 48 hours or for longer periods at below -20°C

Herpes Simplex Virus (HSV) Culture

- Specimens should be collected by appropriately trained personnel from lesions in the acute or vesicular stage, as the lesion ulcerates, crusts, and heals the number of viable viruses decrease.
- Creams, ointments, lotions, ice, alcohol, Betadine solution, zinc, or recent sitz bath all significantly diminish viral load, and should be avoided prior to sample collection or recorded at time of collection.
- Try not to draw blood; antibodies in plasma may inhibit viral replication in cell culture.
- Exercise care to avoid contamination from body sites other than the lesion to be sampled.
- Use a sterile, dry cotton, Dacron, or rayon swab to absorb fluid and collect cells from the base of the lesion.
- Store samples between 2-8°C; transport to the laboratory on ice or ice packs within 48 hours.

BioPlex HIV Ag-Ab

- Serum specimens may be submitted for testing
- Samples may be stored for no longer than 4 days at room temperature or 7 days at 2-8°C, including the time that samples are in transit.
- For longer storage of samples, keep at -20°C or colder.
- Specimens must be removed from the clot, red blood cells, or separator gel prior to transport to the lab.
- If specimens are to be shipped, they should be packed in compliance with applicable local, regional, and international regulations covering the transportation of etiologic agents.
- Specimens may be shipped at 2-8°C or frozen (e.g., dry ice). For shipments that are in transit for more than 7 days, specimens should be kept at -20°C or lower.

HIV Combo Ag/Ab

- Serum specimens may be used in the test
- The following tube types and anticoagulants, including those in both glass and plastics tubes, may be used: serum tubes, serum separator tubes (SSTs) with and without activator, potassium EDTA, sodium citrate, sodium and lithium heparin, and plasma separator tubes (PSTs). Samples that are collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution.
- Specimens with observable particulate matter should be clarified by centrifugation prior to testing.
- Do not heat-inactivate the samples
- Samples, separated from the clot or cells, may be stored for no longer than 2 days at room temperature or 7 days at 2°-8° C, including the time that samples are in transit.
- For long term storage, the specimens should be removed from the clot, red blood cells, or separator gel and should be frozen at -20° C or colder.
- Samples should not be used if they have incurred more than 4 freeze/thaw cycles. Mix samples thoroughly after thaw.
- if specimens are to be shipped, they should be packed in compliance with Federal Regulations covering the transportation of etiologic agents. Specimens may be shipped at 2°-8° C (wet ice) or frozen (dry ice), after removal from the clot, red cells, or separator gel. Do not exceed the storage time limitations described above.

HIV GEENIUS

- Fresh or frozen serum or plasma collected by standard phlebotomy procedures may be submitted for testing. SST tubes are acceptable.
- The tube of serum must be well mixed after collection and before testing
- Specimens may be stored at 2-8°C for up to seven days, or at room temperature (20-30°C) for up to 48 hours.
- Specimens stored longer than seven days should be frozen at -20°C or colder
- If specimens are to be shipped they should be packed in compliance with regulations covering the transportation of etiologic agents.
- Serum specimens can be shipped at ambient conditions (18-30°C) for up to 2 days or samples can be shipped refrigerated with cold packs or wet ice.

HIV-1 RNA Qualitative Assay (Aptima)

- Handle all specimens as if they are potentially infectious agents
- Take care to avoid cross-contamination during the sample handling steps. For example, discard used material without passing over open tubes.

- Blood specimens may be collected in glass or plastic tubes.
- Specimens collected in K₂EDTA, K₃EDTA, ACD, sodium citrate, BD PPT, or serum tubes may be used. Follow sample tube manufacturer's instructions.
- Whole blood, plasma, or serum can be stored for up to 72h prior to testing at ≤25°C
- Centrifuged specimens can be stored up to 8 days after collection at 2-8°C.
- Plasma separated from the cells can be stored at ≤-20°C for longer periods of time
- Long term storage of serum has not been evaluated.
- Do not freeze whole blood.

HIV Western Blot

- Serum or dried blood spots are the only acceptable specimen types.

Serum or Plasma

- The following anticoagulants are acceptable for blood collection: EDTA, heparin, sodium citrate, CPDA-1, and ACD. Samples collected into anticoagulant tubes should be filled as labeling indicates to avoid improper dilution.
- Serum or plasma may be stored at 2-8°C for up to seven days.
- Specimens should be shipped refrigerated (2-8°C) or at ambient (≤37°C) and be received at the lab no more than 7 days after collection.
- Specimens that will arrive at the lab greater than 7 days after collection should be stored and shipped frozen (-20C or lower)

Dried Blood Spots

- Specimens should be obtained by using a licensed collection kit, or collected according to the national Committee for Clinical Laboratory Standards, by either finger puncture or heel stick.
- Label a separate piece of filter paper for each specimen with the appropriate specimen identification. Use a ball point pen or other water-indelible marker. Handle the filter paper by the edges; do not touch the areas that will be used to collect specimens.
- Prepare the area (either finger or heel) for puncture. The puncture must be performed with sufficient force and penetration to sustain a flow of at least several drops of blood. Allow a large drop of free flowing blood to collect at the puncture site. Touch the filter paper to the edge of the drop to collect the drop, and allow another large drop to form at the puncture site. Continue to collect drops in this manner until the wound ceases to bleed or until collection is sufficient.
- Collect each drop of blood in a separate area of the filter paper (if the filter paper is marked with several circles, place each drop of blood in a different circle). Do not layer successive drops of blood in the same spot. In addition to the sample that is required to perform the EIA (i.e. one spot of blood ≥1/4 of an inch in diameter), at least one spot of blood that is ≥1/4 of an inch in diameter must be obtained to perform the Western Blot.
- If the wound stops flowing before sufficient blood has been obtained, a second puncture should be performed. The wound may be massaged very gently to encourage formation of large blood droplets. Do not squeeze the wound to obtain more blood as this may result in hemolysis of the specimen or a mixture of other body fluids with the specimen.
- After the blood has been absorbed into the filter paper, it should be dried at room temperature for at least three hours. The filter paper may be allowed to dry at room temperature overnight. When dry, the spots will be a uniform dark brown. No areas of red coloration should be seen; the appearance of the spots should be similar to that of a dried blood stain.
- Dried blood specimens should be enclosed and sealed in a moisture barrier container, such as a heavy duty zip-lock bag with dessicant, or a high quality bond-envelope for transport to the lab.

- Dried blood spots can be stored for up to one week at room temperature ($\leq 37^{\circ}\text{C}$) or up to two months refrigerated or frozen.
- If specimens are stored at $\geq 60\%$ humidity a desiccant should be used.

Influenza (Real-Time RT-PCR)

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results, Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-P may be referenced as an appropriate resource

Respiratory samples are accepted by the laboratory

Specimen Collection

- Follow the specimen collection devices manufacturer instructions for proper collection methods
- Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron[®], and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.
- Respiratory specimens should be collected and placed into viral transport media (VTM)

Specimen Transport

- Samples should be stored at 2-8 $^{\circ}\text{C}$
- Samples should be transported to the lab on ice or ice packs within 72 hours after collection.
- Frozen specimens may be accepted at greater than 72 hours post collection at the laboratory's discretion.

***Legionella* by Direct Fluorescent Antibody or Culture**

- Cultures or sputum, bronchial washes, nasotracheal aspirate, transtracheal aspirate, percutaneous lung aspirate, endobronchial aspirate, bronchoscopy, biopsy, CSF, pericardial fluid, peritoneal fluid, pleural fluid and tissue are accepted by the laboratory.
- Clinical specimens can be fresh or fresh frozen
- Collect dense gray or reddish consolidated areas for respiratory samples
- Collect samples in sterile leak proof containers without fixative or preservative
- Use only sterile water for washings as saline is inhibitory to *Legionella* growth.
- Isolates should be stored at 2-8 $^{\circ}\text{C}$ prior to transport on ice or ice packs to the laboratory
- Specimens should be submitted on buffered charcoal yeast extract agar or another appropriate solid media to ensure viability.

***Listeria* Reference Culture Identification**

Culture isolates on Heart Infusion Agar, Brain Heart Infusion Agar, or Tryptic Soy Agar with 5% sheep blood are accepted by the laboratory.

Measles EIA

- Only serum samples are accepted by the laboratory
- Serum should be separated from the clot and transferred to a separate transport tube prior to storage and transport.
- Specimens should be stored at 2-8 $^{\circ}\text{C}$
- Specimens should be transported to the lab on ice or ice packs within 48 hours.
- Frozen specimens may be accepted at greater than 48 hours at the laboratory's discretion.
- Do not heat inactivate samples.

Mumps IgG EIA

- Only serum samples are accepted by the laboratory
- Serum should be separated from the clot and transferred to a separate transport tube prior to storage and transport.
- Specimens should be stored at 2-8°C
- Specimens should be transported to the lab on ice packs within 48 hours.
- Frozen specimens may be accepted at greater than 48 hours at the laboratory's discretion.
- Do not heat inactivate samples.

***Mycobacterium avium* complex by DNA Probe**

- *Solid Media*- Growth on appropriate solid media such as Lowenstein-Jensen slants or Middlebrook 7H10 or 7H11 plates suggestive of *M. avium*
- *Liquid Media*- Growth in BacTec Mycobacterium Growth Indicator Tube (MGIT) or Middlebrook 7H9 broth with turbidity equivalent to or greater than a McFarland 1 Nephelometer standard

***Mycobacterium gordonae* by DNA Probe**

- *Solid Media*- Growth on appropriate solid media such as Lowenstein-Jensen slants or Middlebrook 7H10 or 7H11 plates suggestive of *M. gordonae*
- *Liquid Media*- Growth in BacTec Mycobacterium Growth Indicator Tube (MGIT) or Middlebrook 7H9 broth with turbidity equivalent to or greater than a McFarland 1 Nephelometer standard

***Mycobacterium kansasii* by DNA Probe**

- *Solid Media*- Growth on appropriate solid media such as Lowenstein-Jensen slants or Middlebrook 7H10 or 7H11 plates suggestive of *M. kansasii*
- *Liquid Media*- Growth in BacTec Mycobacterium Growth Indicator Tube (MGIT) or Middlebrook 7H9 broth with turbidity equivalent to or greater than a McFarland 1 Nephelometer standard

***Mycobacterium tuberculosis* complex antimicrobial susceptibility (MGIT)**

- Pure cultures of *Mycobacterium tuberculosis* are accepted for testing.

***Mycobacterium tuberculosis* complex by DNA Probe**

- *Solid Media*- Growth on appropriate solid media such as Lowenstein-Jensen slants or Middlebrook 7H10 or 7H11 plates suggestive of *M. tuberculosis*
- *Liquid Media*- Growth in BacTec Mycobacterium Growth Indicator Tube (MGIT) or Middlebrook 7H9 broth with turbidity equivalent to or greater than a McFarland 1 Nephelometer standard

***Mycobacterium tuberculosis* complex by nucleic acid amplification (Cepheid Xpert MTB/RIF)**

- The Xpert MTB/RIF test is intended for use only with specimens from patients showing signs and symptoms consistent with active pulmonary tuberculosis (TB). Xpert MTB/RIF is to be used as an adjunctive test for evaluating either AFB smear positive or negative sediments prepared using NALC-NaOH digestion-decontamination of respiratory specimens. Patients who are suspected of having pulmonary TB based on clinical evaluation and who have received no anti-tuberculosis therapy, less than 3 days of therapy, or have not received such therapy in the last 12 months may be evaluated with the test. The Xpert MTB/RIF test must be performed in conjunction with mycobacterial culture.
- Specimens can be stored at 2-8° for up to seven days

- Specimens should be transported to the laboratory as soon as possible

***Neisseria meningitidis* serotyping**

- Cultures collected from sterile body sites such as blood or CSF are accepted by the laboratory.
- Culture isolates inoculated onto chocolate agar slants are preferred

Norovirus

- Stool or vomitus specimens should be collected during the acute phase of illness (i.e., within 48-72 hours after onset). In specific cases, specimens may be collected later in the illness (i.e., 7-10 days after symptom onset), if testing is necessary for either determining the etiology of the outbreak or for epidemiological purposes (e.g., a specimen obtained from an ill food handler who might be the source of the infection).
- Ideally, stool or vomitus specimens from at least 7-10 ill persons should be obtained during the acute phase of the illness for testing. Depending on the outbreak or cooperation of the patients involved, it may be difficult to collect the ideal number of samples. If this is the case, the number of samples collected will be determined by Epidemiology. 10-50 mL of stool or vomitus should be collected and placed in a tightly capped (leak-proof) stool or urine sample cup.
- Stool or vomitus specimens should be kept refrigerated at 4°C. This temperature allows for the specimens to be stored without compromising diagnostic yield for 2-3 weeks from collection. Freezing can destroy the characteristic viral morphology and may preclude a preliminary diagnosis by electron microscopy (EM). Specimens can be frozen for PCR testing if the test cannot be done within 2-3 weeks. Prior to being shipped, specimen cups should be individually sealed and bagged. Specimens should be shipped in an appropriately labeled, insulated, waterproof shipping container with refrigerant packs

Respiratory Viral Panel

- Collect one nasopharyngeal swab according to standard technique,
- Place swab in Viral transport Media.
- At least 200µl of nasopharyngeal swab specimen in viral transport media is required for testing.
- Specimens stored between 2-8°C must be transported to the lab within 3 days on ice or ice packs.
- Specimens stored below -15°C must arrive at the lab within 25 days after collection on dry ice. If sample is transported to the lab >5 days after collection, storage temperature less than -15°C must be documented.

Respiratory Viral Screen Culture

- Aspirates and Washes containing secretions from the nasopharyngeal epithelium provide the best specimens for direct specimen testing since they will contain large numbers of epithelial cells.
- Aspirates can be collected using a sterile, soft polyethylene #8 infant feeding tube attached to a disposable aspiration trap connected to a suction device. Washes can be collected by instilling and aspirating 1 to 2 ml of saline in the patient's nostril while the patient is in a supine position.
- Aspirates and washes should be diluted with equal volumes of transport medium contained in a centrifuge tube with several sterile glass beads.
- Swabs from nasal, throat, and nasopharyngeal areas often do not contain sufficient numbers of columnar epithelial cells to allow for direct specimen detection of respiratory viruses.
- Specimens should be stored and transported between 2-8°C

- Specimens should arrive at the lab within 48 hours after collection.

Rubella IgG EIA

- Only serum samples are accepted by the laboratory
- Serum should be separated from the clot and transferred to a separate transport tube prior to storage and transport.
- Specimens should be stored at 2-8°C
- Specimens should be transported to the lab on ice packs within 48 hours.
- Frozen specimens may be accepted at greater than 48 hours at the laboratory's discretion.
- Do not heat inactivate samples.

***Salmonella* serotyping**

Sealed isolates on solid media are accepted by the laboratory.

***Shigella* serotyping**

Sealed isolates on solid media are accepted by the laboratory.

Stool Culture

- Stool samples in an appropriate enteric transport medium such as Cary-Blair are accepted by the laboratory.
- Fill transport media according to manufacturer's label instructions.
- Samples should be collected prior to antibiotic treatment whenever possible
- Store samples at 2-8°C prior to transport.
- Transport samples to the laboratory on ice or ice packs.

Syphilis RPR

- Heated or unheated serum samples or plasma specimens containing EDTA, CPD, CPDA-1, heparin or sodium citrate as an anticoagulant.
- If anticoagulant tubes are used they should be filled according to label instructions to ensure proper dilution.
- Specimens should be free from bacterial contamination, gross hemolysis, or lipemia.
- Store specimens at 2°-8°C prior to transport
- Serum or plasma samples sent to the lab for testing should arrive within five days of collection
- The samples should be transported on ice or ice packs
- If refrigerated stored samples will exceed five days, freeze at -20°C or below in a non-defrosting freezer

Syphilis TP-PA

- Serum specimens are preferred, but plasma samples collected in EDTA, sodium citrate, or heparin are acceptable.
- Store specimens at 2°-8°C prior to transport
- Serum or plasma samples sent to the lab for testing should arrive within five days of collection
- The samples should be transported on ice or ice packs
- If refrigerated stored samples will exceed five days, freeze at -20°C or below in a non-defrosting freezer

TB detection by Quantiferon®-TB Gold Plus (QFT®) ELISA

- Only samples in Quantiferon®-TB Gold collection tubes will be accepted
- Four tubes are required for testing: Nil tube (gray cap with white ring), TB1 (green cap with white ring), TB2 (yellow cap with white ring), and mitogen tube (purple cap with white ring)
- Collect 1ml of blood by venipuncture directly into each of the QFT collection tubes
- If a "butterfly needle" is being used to collect blood, a "purge" tube should be used to ensure that the tubing is filled with blood prior to the QFT tubes being used.
- Immediately after filling the tubes, shake them ten times just firmly enough to ensure the entire surface of the tube is coated with blood, to dissolve antigens on tube walls.
- Option 1-Store samples at ambient temperature ($22 \pm 5^{\circ}\text{C}$). Transport samples to the laboratory at ambient temperature ($22 \pm 5^{\circ}\text{C}$) within 16 hours of collection
- Option 2- Place tubes in a $37 \pm 1^{\circ}\text{C}$ incubator within 16 hours of collection. Incubate tubes upright for 16-24 hours. Store and transport sample tubes between $4-27^{\circ}\text{C}$. The laboratory must receive samples within three days of incubation.

Varicella IgG EIA

- Only serum samples are accepted by the laboratory
- Serum should be separated from the clot and transferred to a separate transport tube prior to storage and transport.
- Specimens should be stored at $2-8^{\circ}\text{C}$
- Specimens should be transported to the lab on ice packs within 48 hours.
- Frozen specimens may be accepted at greater than 48 hours at the laboratory's discretion.
- Do not heat inactivate samples.

Vibrio Reference Culture Identification

Culture isolates on Heart Infusion Agar, Brain Heart Infusion Agar, or Tryptic Soy Agar are accepted by the laboratory.

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