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Guidelines for the Submission of Clinical Samples

Revised May 2022

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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
- Specimen 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 in10ml 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 5 days of collection.
- Frozen specimens may be accepted greater than 5 days after collection at the laboratory's discretion.

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 are accepted on *Campylobacter* blood agar or TSA with 5% sheep blood agar then stored and transported to the laboratory under microaerophilic conditions.

Candida auris

Culture isolates are accepted on Sabouraud dextrose agar or TSA with 5% sheep blood agar

Carbapenemase Producing Enterobacteriacea 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 cervix 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 14 with specimen types other than urine. The laboratory will only accept urine samples for patients under the age of 14.
- 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.
- PreservCyt 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 PreservCyt 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**
Culture isolates are accepted in properly sealed HAI slants, TSA with 5% sheep blood agar, or selective media

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 within 3 days from the collection date.

Note: If samples are unable to be transported within 3 days from the collection date, freeze samples until transported and transport on dry ice.

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 14 with specimen types other than urine. The laboratory will only accept urine samples for patients under the age of 14.
- Swab specimens should be stored ant 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 influenza **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 for testing.
- Serum should be transferred to a separate transport tube as soon as is practicable and can be stored at 2°-8°C for up to 7 days.
- Specimen should not be used if they have incurred more than 5 freeze-thaw cycles.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.

Hepatitis A (Anti-HAV IgM EIA)

- The laboratory will accept serum for testing.
- Serum should be transferred to a separate transport tube as soon as is practicable and can be stored at 2°-8°C for up to 7 days.
- Specimen should not be used if they have incurred more than 5 freeze-thaw cycles.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.

Hepatitis B (Anti-HBc EIA)

- The laboratory will accept serum for testing

- The following glass or plastic tubes are suitable for specimen collection: SST.
- Serum can remain at room temperature for no longer than eight hours.
- Serum should be transferred to a separate transport tube as soon as is practicable.
- Specimens can be stored at 2°-8°C for 7 days.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.
- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.
- Specimens should not be used if incurred more than 5 freeze/thaw cycles.

Hepatitis B (HBsAg EIA)

- The laboratory will accept serum for testing
- The following plastic tubes are suitable for specimen collection: SST.
- Serum should be transferred to a separate transport tube as soon as is practicable.
- Specimens can be stored at 2°-8°C for 7 days.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.
- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.
- Specimens should not be used if incurred more than 5 freeze/thaw cycles.

Hepatitis B (Anti-HBs EIA)

- The laboratory will accept serum for testing
- The following glass or plastic tubes are suitable for specimen collection: SST.
- Serum can remain at room temperature for no longer than eight hours.
- Serum should be transferred to a separate transport tube as soon as is practicable.
- Specimens can be stored at 2°-8°C for 7 days.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.
- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.
- Specimens should not be used if incurred more than 5 freeze/thaw cycles.

Hepatitis B (Anti-HBc IgM EIA)

- The laboratory will accept serum for testing
- The following glass or plastic tubes are suitable for specimen collection: SST.
- Serum can remain at room temperature for no longer than eight hours.
- Serum should be transferred to a separate transport tube as soon as is practicable.
- Specimens can be stored at 2°-8°C for 7 days.
- Specimens should be transported to the laboratory on ice or frozen within 5 days of collection. If they are in transit for more than 7 days, specimens should be kept frozen at ≤-20°C in compliance with federal regulations covering the transportation of etiologic agents.

- Frozen specimens received greater than seven days after collection may be accepted at the laboratory's discretion.
- Specimens should not be used if incurred more than 5 freeze/thaw cycles.

Hepatitis C Virus ELISA

- Blood specimens collected in glass or plastic serum-separator tubes are accepted.
- Whole blood may be stored up to 25°C for 24 hours from time of draw. 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.
- 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.
- 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 Aptima HCV Quant Dx Assay (Qualitative reporting)

- Take universal blood borne pathogen precautions with all samples
- Whole blood specimens collected in serum tubs or SST tube can be used, and they must be centrifuged withing 6 hours of collection.
- Separate serum from the pelleted red blood cells following the manufacturers instructions.
- To obtain the 500uL reaction volume, the minimum volume of serum for primary collection tubes is up to 1200uL and for secondary tubes 700uL.
- Serum can stored in the secondary pour off tube at 2° to 8°C for five days or at -20°C for up to 60 days
- Only plastic secondary tubes are recommended.

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.

HIV Ag-Ab (BioPlex)

- Serum specimens may be submitted for testing
- Serum separator tubes may be used.

- 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.
- 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 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 (20°-30°C) for up to 2 days or samples can be shipped refrigerated with cold packs or wet ice.

HIV Aptima HIV-1 Quant Dx Assay (Qualitative Reporting)

- Take universal blood borne pathogen precautions with all samples
- Whole blood specimens collected in serum tubs or SST tube can be used. They must be centrifuged withing 24 hours of collection.
- Separate serum from the pelleted red blood cells following the manufacturer's instructions.

- To obtain the 500uL reaction volume, the minimum volume of serum for primary collection tubes is up to 1200uL and for secondary tubes 700uL.
- Serum can be stored in the secondary pour off tube at 2° to 8°C for five days or at -20°C for up to 90 days
- Only plastic secondary tubes are recommended.

HIV Aptima HIV-1 Quant Dx Assay (Quantitative Reporting)

- Take universal blood borne pathogen precautions with all samples
- Whole blood specimens collected in tubes containing EDTA or Acid Citrate Dextrose (ASC) anticoagulants or Plasma Preparation Tubes (PPTs)
- Separate plasma from the pelleted red blood cells following the manufacturer's instructions withing 24 hours of collection and prior to transport.
- To obtain the 500uL reaction volume, the minimum volume of plasma for primary collection tubes is up to 1200uL and for secondary tubes 700uL.
- Only plastic secondary tubes are recommended.
- Separated Plasma should be transported to the lab on ice or ice packs.
- Plasma may be stored at 2-8C in secondary pour off tube for up to 5 days, or frozen at -20C or -70C for up to 90 days

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°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°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 transported to the lab on ice packs within 48 hours.
- Specimens can be stored at 2°-8°C for up to 48 hours or frozen at -20°C or below
- Avoid multiple freeze thaw cycles.
- Samples that are hemolyzed, icteric, or grossly contaminated will not be used.
- 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 transported to the lab on ice packs within 48 hours.
- Specimens can be stored at 2°-8°C for up to 48 hours or frozen at -20°C or below
- Avoid multiple freeze thaw cycles.
- Samples that are hemolyzed, icteric, or grossly contaminated will not be used.
- 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 gordoane **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 Panel 2 (RP2)

- 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.
- Samples submitted for analysis for both RP2 and RT-PCR can be stored at 2°-8°C and must be transported to the lab within 72 hours on ice or ice packs.

- If specimens are only submitted for RP2 testing they can be stored at room temperature for up to 12 hours or refrigerated @ 2°– 8°C for up to 10 days after collection.
- Specimens can be stored @ -70°C or below and delivered on dry ice.

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 78 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 transported to the lab on ice packs within 48 hours.
- Specimens can be stored at 2°-8°C for up to 48 hours or frozen at -20°C or below
- Avoid multiple freeze thaw cycles.
- Samples that are hemolyzed, icteric, or grossly contaminated will not be used.
- Do not heat inactivate samples.

Salmonella **ID**

Culture isolates are accepted in properly sealed HAI slants, TSA with 5% sheep blood agar, or selective media

Shigella **serotyping**

Culture isolates are accepted in properly sealed HAI slants, TSA with 5% sheep blood agar, or selective media

SARS-CoV-2 - Aptima®

- Specimen type: NP, nasal, mid-turbinate and OP swab specimens, or nasopharyngeal wash/aspirate and nasal aspirate specimen collection in viral transport medium (VTM/UTM), saline, Liquid Amies, or specimen transport medium (STM). The following types of VTM/UTM can be used.
    - Remel MicroTest M4, M4RT, M5 or M6 formulations
    - Copan Universal Transport Medium
    - BD Universal Viral Transport Medium
- Aptima Multitest Swab Specimen Collection Kit and Hologic Direct Load Collection Kit may be used for the collection of OP and nasal swab samples.
- VTM/UTM can be stored at 2°C to 8°C up to 96 hours.

- Aptima Multitest Tube, the Hologic Direct Load Tube, and the Hologic Direct Load Capture Cap Tube, may be stored at 2°C to 30°C up to 6 days

SARS-CoV-2 - PerkinElmer Real-Time RT-PCR

Use only synthetic fiber swabs with plastic shafts, DO NOT use calcium alginate swabs or swabs with wooden shafts, these substances may inactivate some viruses and inhibit PCR testing.

- Anterior Nasal swab (NS), sample both nostrils with the same swab
- Nasopharyngeal swab (NP)
- Oropharyngeal swab (OP)

Store specimens at 2-8^{o}C for up to 72 hours after collection. If a delay in testing or shipping is expected to exceed 72 hours, store specimens at -70^{o}C or below

SARS-CoV-2 - Platelia Assay

- Serum specimens are preferred.
- Store specimens at 2^{o}-8^{o}C prior to transport
- Serum samples sent to the lab for testing should arrive within four days of collection
- The samples should be transported on ice or ice packs
- If testing is not completed within four days, freeze at -20^{o}C or below, and sample can only be frozen and thawed once.
- Do not heat specimens

SARS-CoV-2 (Flu SC2) CDC Multiplex Assay (Influenza/COVID Assay)

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, these substances may inactivate some viruses and inhibit PCR testing.

- Nasal swab (NS)
- Nasopharyngeal swab (NP)
- Oropharyngeal swab (OP)
- Sputum
- Lower respiratory tract aspirates
- Bronchoalveolar lavage
- Nasopharyngeal wash/aspirate
- Nasal aspirate

Store specimens at 2-8^{o}C for up to 72 hours after collection. If a delay in testing or shipping is expected to exceed 72 hours, store specimens at -70^{o}C or below.

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

- Serum or plasma specimens containing EDTA, CPD, CPDA-1, heparin or sodium citrate as an anticoagulant can be used.
- 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.
- Once poured off store specimens at 2°-8°C prior to transport for a maximum of five days
- **Serum** samples sent to the lab for testing should arrive within five days of collection or frozen at -20°C or below in a non-defrosting freezer
- **Plasma** samples can be stored for up to five days at 2°-8°C maximum.
- The samples should be transported on ice or ice packs.

Syphilis TP-PA

- Serum specimens are preferred.
- Store specimens at 2°-8°C prior to transport
- Serum samples sent to the lab for testing should arrive within five days of collection and can only be frozen and thawed once.
- 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®) LIAISON®XL

- 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 ± 5°C). Transport samples to the laboratory at ambient temperature (22 ± 5°C) within 16 hours of collection
- Option 2- Place tubes in a 37±1°C incubator within 16 hours of collection. Incubate tubes upright for 16-24 hours. Store and transport sample tubes between 4-27°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°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.

References

Elvis HSV ID Test System, A Test for the Culture and Identification of Herpes simplex virus using the Enzyme Linked Virus Inducible System®, ref PI-030en v2010SEP22, ©2006 Diagnostic Hybrids

*eSensor Respiratory Viral panel Package Insert,*Clinical Micro Sensors, Inc. dba Gen Mark Diagnostics

D^3 Ultra^{TM} DFA Respiratory Virus Screening & ID Kit, Ref:01:010000,v2, ©2006 Diagnostic Hybrids

D^3 DFA Chlamydiae Culture Confirmation Kit, Ref: 01-040000, v2014Feb17, ©2014 Diagnostic Hybrids

Mycobacterium avium Complex Culture Identification Test, 102902 Rev. L, Gen-Probe AccuProbe

Multispot HIV-1/HIV-2 Rapid Test, Rev. March 2013 506507, Bio-Rad Laboratories

CDC DENV-1-4 Real-Time RT-PCR Assay, 2013 Centers for Disease Control and Prevention

Aptima HIV-1 RNA Qualitative Assay, 501623 Rev. 001, Hologic Aptima

APTIMA Combo 2 Assay, 502487 Rev. A , Hologic Aptima

Human Immunodeficiency Virus Type I (GS HIV-1 Western Blot) Rev. October 2012 506571, Bio-Rad Laboratories

Rubella IgG EIA, Rev. February 2015 503923C, Bio-Rad Laboratories

Serodia TP-PA-Reagents for the Detection of Antibodies to Treponema pallidum, 093131.00 Rev. 001, Fujirebio Inc.

ASI RPR Card for Syphilis, 6004-900 03-2016, Arlington Scientific Incorporated

Aptima HCV RNA Qualitative Assay, 500237 Rev. 001, Hologic Aptima

VZV IgG EIA, 503930C Rev. February 2015, Bio-Rad Laboratories

Mumps IgG EIA, 203932C Rev. February 2015, Bio-Rad Laboratories

Measles IgG EIA, 503931C Rev. February 2015, Bio-Rad Laboratories

Antibody to Hepatitis B Surface Antigen, 506588 Rev. January 2013, Bio-Rad Laboratories

MONOLISA™ Anti-HBC IgM EIA, 506545 Rev. September 2013, Bio-Rad Laboratories

MONOLISA™ Anti-HBc EIA, 50623 Rev. September 2013, Bio-Rad Laboratories

MONOLISA™ Anti-HAV EIA, 883553 Rev. November 2008, Bio-Rad laboratories

Quantiferon®-TB Gold Plus (QFT-Plus®) Package Insert, July 2018, Quiagen

*BACTEC MGIT 960 PZA KIT Package Insert,*L005486JAA, Beckton, Dickinson and Company

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (CDC Flu rRT-PCR Dx Panel), Centers for Disease Control and Prevention