ANNUAL REVIEW BY LABORATORY DIRECTOR OR DESIGNEE:

Signature

Date

REVIEW BY LABORATORY EMPLOYEES:

I have read and understood the following procedure.

I agree to comply with all stated methods and policies.

Date

Signature

Date

Signature
**UT HEALTH EAST TEXAS - The University of Texas Health Science Center at Tyler**

**SECTION:** Public Health Laboratory of East Texas  
**SOP#**

**PROCEDURE:** PHLET Submission Information and Instructions 2018/2019 updates  
**MANUAL:** LRN Policies and Procedures

**PAGE:**

**REPLACES:** PHLET Submission Information and Instructions 2017 updates

**EFFECTIVE DATE:**

**RETIRE DATE:**

**PREPARED BY:** Janine Yost BS, MT (ASCP)  
**COPIES TO:**

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<th>APPROVAL SIGNATURE:</th>
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<td>Richard J. Wallace Jr., M.D.</td>
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**Commented [YJ]: Made minor changes to the document for clarity**

UTHealth  
The University of Texas Health Science Center at Tyler

UT Health East Texas-The University of Texas Health Science Center at Tyler-  
Public Health Laboratory of East Texas  
1
PHLET Submission Information and Instructions 2018/2019

PHLET SUBMISSION FORM INSTRUCTIONS

Submitter: Complete ALL the submitter information including submitter name, address, city, state, zip, phone number and fax number. For BT and Flu submissions, add DSHS submitter number (if known).

Emergency Contact: Please give the name of the person to contact at the submitting facility if additional information about the specimen/isolate is needed. This is not the person collecting the sample; this is a person in the laboratory. If the submitter does not want to be called with panic values, the submitter must include the contact name and numbers for the ordering physician.

Date/Time of collection: Give the date and time the specimen was collected from the patient or other source. Do not give the date it was sent to PHLET. This date must be on the sample submitted as well as the request form. USE the acronym DOC to clearly mark the date on the sample.

Patient information: Complete all the patient information including first and last name, address, city, state, zip, sex, and SSN. You may use pre-printed patient label, if all the information is provided.

DOB: Give both the date of birth and the age. If DOB is not available, give the age of the patient and tell us whether the age is in days, months, or years.

Patient ID Number: Provide the submitter identification number for matching purposes.

Specimen Source or Type: Indicate the kind of material you are submitting or the source of the specimen or isolate.

Date of Onset/ outbreak association: Required for BT and Flu submissions.

Test(s): Check or specify the specific test(s) to be performed by PHLET.

If you have questions, want to request additional copies of the order forms or would like additional information on a specific assay, please call PHLET at 903-877-5071.

Forms are available on the web at https://www.uthct.edu/phlet-forms-procedures

If the form is not completed correctly, PHLET reserves the right to reject any sample. This may delay testing services and adversely affect the quality of the submitted sample and testing results.
**PHLET Submission Information and Instructions 2018/2019**

**EXAMPLE_ SEE WEBSITE FOR FORM**

<table>
<thead>
<tr>
<th>Public Health Laboratory of East Texas</th>
<th>CLIA# 45D1011121</th>
</tr>
</thead>
<tbody>
<tr>
<td>The University of Texas Health Science at Tyler</td>
<td>PHLET</td>
</tr>
<tr>
<td>11949 US Highway 271 N Tyler, Texas 75708</td>
<td>Laboratory Director</td>
</tr>
<tr>
<td>Phone 903-677-5071 Fax 903-677-5259</td>
<td>Richard J. Wallace Jr., M.D.</td>
</tr>
<tr>
<td>24 hour Emergency phone</td>
<td>903-312-3537</td>
</tr>
</tbody>
</table>

**SUBMITTER INFORMATION**

**SUBMITTER**

**ADDRESS**

**CITY** | **STATE** | **ZIP CODE**

**PHONE** | **FAX**

**LABORATORY CONTACT NAME AND NUMBER (FOR QUESTIONS)**

**PANIC VALUE-CONTACT NUMBER**

**PATIENT INFORMATION**

**PATIENT NAME (LAST, FIRST, MI)**

**DATE OF BIRTH** | **AGE** | **SEX** Male/Female | **SSN**

**ADDRESS**: | **CITY** | **STATE**/ZIP CODE

**DATE AND TIME OF COLLECTION** | **PHONE**:

**DATE OF ONSET** | **DIAGNOSIS/SYMPTOMS** | **RISK**

**OUTBREAK ASSOCIATION**: Y/N | **SURVEILLANCE**: Y/N | **CIRCLE ONE**: INPATIENT/OUTPATIENT

**ORDERING PHYSICIAN**

**SPECIMEN SOURCE OR TYPE** (CIRCLE ONE)

<table>
<thead>
<tr>
<th>PLASMA</th>
<th>WHOLE BLOOD</th>
<th>NASOPHARYNGEAL SWAB/ASPIRATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOUND SWAB</td>
<td>SOURCE-THROAT SWAB</td>
<td>SPUTUM</td>
</tr>
<tr>
<td>TRACHEAL ASPIRATES</td>
<td>PLEURAL FLUID</td>
<td>SERUM</td>
</tr>
<tr>
<td>BACTERIAL ISOLATE</td>
<td>VIRAL CULTURE</td>
<td>OTHER (describe)</td>
</tr>
</tbody>
</table>

**TEST requested**

Place a check mark in the box to the left of the test requested

- QUANTIFERON TB GOLD PLUS Sample incubated? Yes no
- BIOTERRORISM RULE IN/ RULE OUT* - SUSPECTED ORGANISM
- INFLUENZA BY RT-PCR
- AVIAN FLU *
- EBOLA PCR *
- ARBOVIRUS PCR PANEL * (INCLUDES DENGUE, CHIKUNGUNYA, ZIKA)
- ZIKA IgM Serology *

**OTHER TESTS**: CALL PHLET FOR APPROVAL

**SPECIMEN RECEIVED BY**

**DATE/TIME**

**CONDITION**: REFRIGERATED ROOM TEMPERATURE FROZEN

*FOR ALL SUBMISSIONS and tests marked with an * NOTIFY DISH AT 1-866-310-9698

IF APPLICABLE, PLEASE DESCRIBE ANY EXPOSURES RELATED TO THIS SUBMISSION.
PHLET Submission Information and Instructions 2018/2019

Instructions for Specimens

1. Clearly label each specimen with the patient’s first and last name and date of birth exactly the way it is written on the request form.
2. Place the date and time of collection on the specimen label.
3. Retain a copy of submission form for your records.
4. Triple-contain specimens with sufficient absorbent materials to avoid breakage.
5. Specimens may be sent at room (ambient) temperature unless otherwise noted.
6. Include a completed request form for each patient with corresponding specimen tube.
7. Mark specimen source or type on form.

For isolates that are submitted from a suspected bioterrorism event, PHLET must be notified prior to sending the samples. All possible information as to the origin of the sample must be retained at the submitting hospital. The original sample must be submitted as well as the isolate to be tested.

In order to insure the satisfactory receipt and proper testing of your specimens in our laboratory, it is necessary that:

1. Each specimen container is labeled with the name of the patient exactly the way it is written on the request form.
2. Some absorbent material, such as paper towels, is placed in the bottom of the secondary plastic liner, and then put the labeled specimen container in the plastic liner on the absorbent material. Add sufficient absorbent material on top on the blood tubes so that when the cap is tightened, and the container is shaken the specimen containers do not rattle.
3. The properly completed request form(s) {must have the name of the patient(s) and a correct return address} is wrapped around the secondary plastic liner. If a “master copy” is used, please submit on an 8 ½ “x 11” pieced of paper. Please do not cut the form into smaller individual forms. Place the secondary container in the fiberboard container.
4. The proper label is attached to the outside container before the specimens are mailed.
PHLET Submission Information and Instructions 2018/2019

ONLY PROPERLY TRAINED AND CERTIFIED SHIPPERS MAY LEGALLY SHIP SAMPLES

In order to insure the satisfactory receipt and proper testing of your specimens in our laboratory, it is necessary that:

5. Each specimen container is labeled with the name of the patient exactly the way it is written on the request form.

6. Some absorbent material, such as paper towels, is placed in the bottom of the secondary plastic liner, and then put the labeled specimen container in the plastic liner on the absorbent material. Add sufficient absorbent material on top on the blood tubes so that when the cap is tightened, and the container is shaken the specimen containers do not rattle.

7. The properly completed request form(s) (must have the name of the patient(s) and a correct return address) is wrapped around the secondary plastic liner. If a “master copy” is used, please submit on an 8 1/2 “x 11” piece of paper. Please do not cut the form into smaller individual forms. Place the secondary container in the fiberboard container.

8. The proper label is attached to the outside container before the specimens are mailed.

Call the lab prior to shipping samples.

Mailing Instructions and Information

Submitters are responsible for shipping specimens in conformity with all safety and labeling regulations. Be aware that many commercial carriers no longer accept specimens. When using any carrier, including courier services, package specimens to avoid leakage or breakage. Specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquids. The shipper is responsible for assuring the correctness of all packages prior to shipment. Follow all the applicable state and regional guidelines for proper shipping and transportation.

Always exert the maximum precaution for the sake of those who handle parcels, and to avoid jeopardizing the system for shipping specimens.

Ship specimens to:

Public Health Laboratory of East Texas
The University of Texas Health Science at Tyler
Attention: Janine Yost
11949 US Highway 271N
Tyler, Texas 75708
Phone: 903-877-5071
Attention: Janine Yost
<table>
<thead>
<tr>
<th>Test</th>
<th>Required Specimen Type</th>
<th>Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantiferon TB Gold Plus Assay</td>
<td>Special tubes supplied by PHLET</td>
<td>Follow Quantiferon TB Gold Plus Collection Procedure special collection and sample handling required</td>
</tr>
<tr>
<td>Seasonal Influenza typing, RT- PCR</td>
<td>Nasopharyngeal wash, aspirate or swab; bronchial lavage; throat swab, notify lab for other sample types</td>
<td>Collect samples in Viral transport media and refrigerate immediately. Transport to lab within 72 hours of collection on cold packs or freeze at -70°C and ship on dry ice.</td>
</tr>
<tr>
<td>Bioterrorism Chemical or Environmental Sample</td>
<td>Refer to BT or CT Specimen Collection Guide. Call for further instructions.</td>
<td>All samples submitted must have a Chain of Custody- Receipt of Property Form and submission form for each sample. Original samples must be retained for further investigation purposes or transferred to PHLET.</td>
</tr>
<tr>
<td>Avian Influenza (Influenza A H5 and H7)</td>
<td>Nasopharyngeal wash, aspirate or swab; bronchial lavage; throat swab. Call PHLET regarding other specimen types.</td>
<td>All samples must be approved by health department prior to shipment. Contact PHLET prior to shipment. Collect samples in Viral transport media and refrigerate immediately. Transport to lab within 72 hours of collection on cold packs or freeze at -70°C and ship on dry ice. Send on wet ice (cold packs).</td>
</tr>
<tr>
<td>Ebola PCR</td>
<td>Whole blood in plastic EDTA tube, two tubes, 4 mls each. Do not open or centrifuge sample. Refrigerate sample.</td>
<td>All samples must be approved by health department prior to shipment. Contact PHLET prior to shipment. Send on wet ice (cold packs). If delay in testing is expected (&gt;24 hours) store at 2 to 8°C for up to 7 days.</td>
</tr>
<tr>
<td>Arbovirus testing</td>
<td>Serum separated and refrigerated. (3-5 mls preferred, 2 mls minimum) CSF or urine may be submitted along with a serum sample (PCR only).</td>
<td>All samples must be approved by health department prior to shipment. Contact PHLET prior to shipment. Send on wet ice (cold packs). If delay in testing is expected (&gt;24 hours) freeze sample and ship on dry ice.</td>
</tr>
</tbody>
</table>

See pages 10-26 for additional information.
Directions to PHLET

Address: Public Health Laboratory of East Texas, 11557 US Highway 271 N, Building 558, Tyler, TX 75791

1A. Entering from Highway 271 Tyler: turn left at the main UTHTC entrance onto Health Center Drive. Stay on Health Center Drive through the 4-way stop.

1B. Entering from Highway 59 Tyler: turn right onto University Drive at the UTHTC sign. Continue through the campus in front of the Medical Center (large white and glass building). You will reach Health Center Drive. Turn right. Go to Health Center Drive. Drive through the 4-way stop.

2. From the large red arrow (goal): continue on Health Center Drive. PHLET is the building on the left next to the Credit Union. Deliveries must be received at the back door.
APPENDIX A: QUANTIFERON TESTING

Test Name: Quantiferon TB Gold Plus
CPT Code: 86480

Test Includes: Quantiferon TB reported as negative, positive, or indeterminate

Method: Enzyme linked Immunosorbent Assay (ELISA)

Reporting: Samples are tested on Monday, Wednesday and Friday. Reports are generated Monday, Wednesday and Friday by 4 pm.

Critical values: n/a

Specimen requirements: Whole Blood. Special collection kits are required. Follow instructions from the kit. Important- The tubes fill slowly. If using a butterfly needle a discard tube must be drawn before collecting the QuantiFERON tubes.

COLLECT BLOOD USING KIT PROVIDED BY PHLET

4 tubes required

Quantiferon TB Gold Plus Blood Collection Tubes

Proper training in specimen collection is necessary to ensure accurate results. New employees should be trained in the proper technique to collect a QuantiFERON sample and demonstrate proper sample collection and handling 5 times before collecting the specimens without supervision.

Training materials are available from PHLET.

Sample rejection criteria: Mislabeled specimens, insufficient or excess volume in the QFT tubes, specimens not processed according to provided instructions including: Specimens not incubated for the time specified by the Quantiferon TB gold in Tube procedure (16-24 hours at 37C) and specimens not received by the laboratory within 72 hours of incubation. Refer to Mycobacterium tuberculosis Determination using the QuantiFERON TB Gold Plus. The whole blood IFN-γ test measuring responses to ESAT-6 and CFP-10 peptide antigens Collection and Processing Instructions contained in this document
Limitations:

1. A negative QFT result does not preclude the possibility of Mycobacterium tuberculosis infection or tuberculosis disease: false negative results can be due to stage of infection (e.g. specimen obtained prior to the development of cellular immune response), co-morbid conditions which affect immune function, or other immunological factors

2. A false negative QFT result can be caused by incorrect blood sample collection or improper handling of the antigens affecting lymphocyte function. Blood tubes must be incubated at 37°C +/- 1C with stimulation antigens within 16 hours of collection: delay in incubation may cause false negative or indeterminate results (refer to Package insert, Technical information section) and other technical parameters may affect ability to detect a significant IFN-γ response.

3. Incorrect performance of the assay may cause false negative results

4. Incorrect performance of the assay may cause false positive QFT responses. A positive QuantiFERON test should not be the sole or definitive basis for determining infection with M. tuberculosis.

5. The effect of lymphocyte count on reliability of QFT results is unknown. Lymphocyte counts may vary over time for an individual person, and from person to person. The minimum number of lymphocytes required for a reliable test result has not been established and may also be variable.

6. A positive QFT result should be followed by further medical evaluation for active tuberculosis disease (e.g. Acid-fast bacilli (AFB) smear and culture, chest x-ray)

7. A positive QFT result can support and the diagnosis tuberculosis disease. ESAT-6, CFP-10, AND TB 7.7(p4) are present in Mycobacterium tuberculosis, but infection by other mycobacteria, including M. kansasii, M szulgai, and M. marinum may also cause positive results. Other diagnostic evaluations (e.g. AFB smear and culture, chest x-ray) besides QFT are needed to confirm tuberculosis disease.

8. The predictive value of a negative QFT result in immunosuppressed persons has not been determined.

9. The performance of the QFT test has not been extensively evaluated with specimens from the following groups:
   - Individuals who have impaired or altered immune function such as those who have HIV infection or AIDS, those who have transplant managed with immunosuppressive treatment or others who receive immunosuppressive drugs (e.g. corticosteroids, methotrexate, azathioprine, chemotherapy) and those who have other clinical conditions: diabetes, silicosis, chronic renal failure, hematological disorders (e.g. leukemia and lymphomas), and other specific malignancies (e.g. carcinoma of the head or neck or lung)
   - Individuals younger than 17 years of age
APPENDIX A: QUANTIFERON TESTING

Mycobacterium tuberculosis Determination using the QuantiFERON TB Gold Plus.

The whole blood IFN-γ test measuring responses to ESAT-6 and CFP-10 peptide antigens.

Collection and Processing Instructions

Blood Collection Tubes
QuantiFERON Nil Tube (gray cap, white ring) Nil
QuantiFERON TB1 Tube (green cap, white ring) TB1
QuantiFERON TB2 Tube (yellow cap, white ring) TB2
QuantiFERON Mitogen Tube (purple cap, white ring) Mitogen

1. Label tubes appropriately.
Ensure each tube (Nil, TB1, TB2, and Mitogen) is identifiable by its label or other means once the cap is removed.

2. For each patient, collect 1 ml of blood by venipuncture directly into each of the QFT-Plus Blood Collection Tubes.
This procedure should be performed by a trained phlebotomist. Important note: Tubes should be between 17°C to 25°C at the time of blood filling. As 1 ml tubes draw blood relatively slowly, keep the tube on the needle for 2–3 seconds once the tube appears to have completed filling. This will ensure that the correct volume is drawn. The black mark on the side of the tubes indicates the validated range of 0.8–1.2 ml. If the level of blood in any tube is outside the range of the indicator mark, a new blood sample should be obtained.

Figure 1. Under- or over-filling of the tubes outside of the 0.8 mL (bottom of black mark) to 1.2 mL (top of black mark) range may lead to erroneous results. Specimens with volumes outside of black mark will be rejected.
3. Immediately after filling tubes, shake them ten (10) times just firmly enough to ensure the entire inner surface of the tube is coated with blood, to dissolve antigens on tube walls.

![Figure 2. Entire inner surface of tube must be coated with blood.](image)

Important note: Tubes should be between 17°C to 25°C at the time of shaking. Overly vigorous shaking may cause gel disruption and could lead to aberrant results.

4. Following labeling, filling, and shaking, the tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. Prior to incubation, maintain and transport the tubes at room temperature (22°C ± 5°C).

**SAMPLE HANDLING incubation and centrifugation.**

1. If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation.

2. Incubate all 4 tubes UPRIGHT at 37°C ± 1°C for 16 to 24 hours. The incubator does not require CO2 or humidification.

3. After incubation, blood collection tubes may be held between 4°C to 27°C for up to 3 days prior to centrifugation.

4. After incubation, centrifuge tubes for 15 minutes at 2000 to 3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be centrifuged again.

5. After centrifugation, refrigerate tubes at 4°C until testing is performed (up to 28 days).

**Transportation and sample handling requirements:**

Samples must be maintained at room temperature and received by the laboratory within 16 hours of collection.

If the sample will not be received within 16 hours of collection it must be incubated on site and centrifuged. Incubated samples must be sent on cold packs. (see **SAMPLE HANDLING incubation and centrifugation**)

---

UT Health - The University of Texas Health Science Center at Tyler

Public Health Laboratory of East Texas
PHLET Submission Information and Instructions 2018/2019

Ship samples to:

Public Health Laboratory of East Texas
The University of Texas Health Science at Tyler
Attention: Janine Yost
11937 US Highway 271N, Building 558
Tyler, Texas 75708
Phone: 903-877-5071

Collection notes:

If a “butterfly needle” is being used to collect blood, a “purge” tube should be used to ensure that the tubing is filled with blood prior to the QFT-Plus tubes being used. If using QFT-Plus Blood Collection tubes at an altitude higher than 810 meters (2650 ft), but not between 1020 m (3350 ft) and 1875 m (6160 ft), or if low blood draw volume occurs, users can collect blood with a syringe and immediately transfer 1 ml of blood to each of the 4 QFT-Plus tubes. For safety reasons, this is best performed by removing the syringe needle, ensuring appropriate safety procedures, removing the caps from the 4 QFT-Plus tubes, and adding 1 ml of blood to each tube (to the center of the black mark on the side of the tube label). Replace the caps securely and mix as described in Collection and Processing Instructions step 3.

Alternatively, blood may be collected in a single generic blood collection tube containing lithium heparin as the anticoagulant and then transferred to the QFT-Plus tubes. Only use lithium heparin as a blood anticoagulant because other anticoagulants interfere with the assay. Fill a blood collection tube (minimum volume 5 ml) and gently mix by inverting the tube several times to dissolve the lithium heparin. Blood tubes must be maintained and transported at room temperature (22°C ± 5°C) before transfer to QFT-Plus tubes for incubation, which must be initiated within 16 hours of blood collection. If blood has been collected in a lithium heparin tube, samples must be evenly mixed by gentle inversion before dispensing into QFT-Plus tubes. Dispensing should be performed aseptically (ensuring appropriate safety procedures) by removing the caps from the 4 QFT-Plus tubes and adding 1 ml of blood to each (to the center of the black mark on the side of the tube label). Replace the tube caps securely and mix as described in Collection and Processing Instructions step 3.

INFLUENZA RT-PCR

Laboratory Testing Protocol: Influenza Surveillance

Texas is following traditional influenza seasonal surveillance protocols for the identification of influenza cases and the emergence of novel or variant influenza strains using participants in the Texas Department of State Health Services (DSHS) Influenza Laboratory Surveillance Program. Public health laboratory testing for influenza conducted by the DSHS Austin Laboratory and Texas Laboratory Response Network laboratories is done primarily to:

- Detect the distribution and spread of the virus
- Detect new variants of the virus and
Lab testing for clinical disease management purposes in individual patients is not a primary function of public health laboratory testing. Such diagnostic testing, if desired, should be performed by commercial laboratories.

For avian flu see “SPECIAL INSTRUCTIONS FOR AVIAN INFLUENZA LAB TESTING”

COLLECTION OF SPECIMENS

Specimens acceptable for influenza testing include:

- Nasopharyngeal swabs (Preferred)
- Nasal swabs
- Throat swabs
- Nasal aspirates
- Nasal washes
- Dual nasopharyngeal/throat swabs
- Bronchoalveolar lavage
- Bronchial wash
- Tracheal aspirate
- *Sputum
- *Lung tissue
- *Please call before submission.

Use sterile, polyester-tipped, plastic shaft swabs and viral transport media (VTM) for specimen collection. Any commercially available VTM is acceptable for specimen transport. Dacron or rayon-tipped swabs with a plastic shaft or any other commercially available sterile collection system intended for virus isolation may be used. Calcium alginate swabs, cotton swabs or swabs with wooden shafts are not acceptable for specimen collection as they may inhibit recovery of the virus. Supplies used for Genprobe testing are not acceptable. Specimens submitted using these supplies will be rejected.

Viral transport media (VTM) tubes should be stored at the specified temperature according to the product storage requirement(s) or product insert. If the viral transport media (VTM) tubes have been stored frozen, the media should be thawed (at either refrigeration or room temperature) completely before specimen collection. Do not heat, microwave, or incubate the media prior to use as this may cause inactivation of the virus. Be sure to check the expiration date of the media prior to specimen collection. Specimens submitted in expired media will be rejected.

After the specimen has been collected, insert the fiber tip of the swab immediately into the VTM and break off the shaft so that the swab fits completely within the tube. Please tighten the cap securely and place at 4°C immediately in an upright position.
PHLET Submission Information and Instructions 2018/2019

- Ship specimen tubes to PHLET as soon as possible after collection. Specimens not shipped to be received at the lab within 72 hours of collection should be frozen in an upright position at -70°C. Specimens must be received cold on ice packs at the laboratory within 72 hours of collection.

- If specimens are received greater than 72 hours after collection, they must be frozen on dry ice.

- Ensure that the patient name and date of birth are written on each specimen tube that is submitted.

- Please record the date and time of collection on the PHLET submission form.

- Add DFSIS submitter number to the PHLET submission form

NOTE: If you are not a current submitter please contact us so that we may establish you as a submitter to prevent testing delays. Surveillance specimens will only be received from current submitters.

REJECTION CRITERIA:

1. Swabs with calcium alginate or cotton tips and wooden shafts
2. Specimens not refrigerated or frozen
3. Insufficient specimen volume
4. Incomplete labeling or documentation

SPECIMEN TESTING

Specimens submitted for influenza surveillance will be initially screened for Influenza A and Influenza B using the CDC real time RT-PCR assay for detection of influenza. All positive influenza A specimens will be subtyped for seasonal H3 or 2009 Influenza H1N1. All positive Influenza B samples will be genotyped for Victoria and Yamagata lineages. Viral Isolation will be performed during off peak influenza months (i.e., summer months or relevant to the timing of circulating influenza virus).

PACKING AND SHIPMENT OF SPECIMENS TO LABORATORY:

Boxes containing clinical specimens must be labeled, “Biological Substance, Category B”. Air shipments must display the UN3373 label with the adjoining words, “Biological Substance, Category B”. The phone number and name of a contact person must be listed on the box or air bill for both the shipper and the recipient.
PHLET Submission Information and Instructions 2018/2019

Note:

Please refer to the detailed diagrams of packing and shipping instructions.

To avoid specimen warm-up during packing and shipping, it is helpful if the plastic liner (secondary container) is cold before placing the specimen inside. The recommended method of shipment is to use a carrier that will deliver the next day. Next day deliveries cannot be accepted on Saturday, Sunday or state holidays unless coordinated with the receiving laboratory.

It is your responsibility as the shipper to make sure that all packaging and labeling meet the current criteria.

Sending samples PHLET Laboratory Response Network (LRN) LABORATORY

Please use the PHLET specimen submission form when submitting specimens to the PHLET laboratory. Add your submitter number to the form under comments.

If you are not a current submitter to DSHS, please contact us so that we may establish you as a submitter to prevent testing delays. Specimens will only be received from current submitters.

Ship to: UTHSCT/PHLET Attn: Janine Yost 11949 US Highway 271 Tyler, TX 75708

For shipping to the DSHS Austin laboratory, use the G-2A Specimen Submission Form. If you wish to submit a specimen for flu surveillance testing, please contact the DSHS Emerging and Acute Infectious Diseases Branch (flutexas@dshs.state.tx.us) for approval and instructions regarding payor source.
SPECIAL INSTRUCTIONS FOR AVIAN INFLUENZA LAB TESTING

TESTING INDICATIONS:

Testing for avian influenza A (H5) or (H7) is indicated for hospitalized patients with:

1. Radiographically confirmed pneumonia, acute respiratory distress syndrome (ARDS), or other severe respiratory illness for which an alternative diagnosis has not been established, and
2. History of travel within 10 days of symptom onset to a country with documented avian influenza (such as H5N1) infections in poultry and/or humans.

Testing for avian influenza A (H5 or H7) should be considered on a case-by-case basis in consultation with state and local health departments for hospitalized or ambulatory patients with:

1. Documented temperature of >100.4°F (>38°C), and
2. One or more of the following: cough, sore throat, or shortness of breath, and
3. History of close contact either with poultry (e.g., visited a poultry farm, a household raising poultry, or a bird market) in an H5 or H7 affected country, or with a known or suspected human case of influenza A H5 or H7 within 10 days prior to onset of symptoms.

SPECIMENS

ACCEPTABLE SPECIMENS:

HUMAN RESPIRATORY SPECIMENS

1. Nasopharyngeal swabs
2. Nasopharyngeal aspirates
3. Oropharyngeal aspirates or washes
4. Throat swabs
5. Sputum
6. Tracheal aspirates
7. Bronchoalveolar lavage
8. Pleural fluid
9. Viral culture

Swab specimens must be collected using swabs with a Dacron® tip and aluminum or plastic shaft. Swabs must be submitted in viral transport media. ALL specimens must be immediately placed on wet ice and transported at 4-8°C.
Collecting specimens from the upper respiratory tract

Nasopharyngeal wash/aspirate

- Have the patient sit with head tilted slightly backward.
- Instill 1 ml–1.5 ml of non-bacteriostatic saline (pH 7.0) into one nostril. Flush a plastic catheter or tubing with 2 ml–3 ml of saline. Insert the tubing into the nostril parallel to the palate. Aspirate nasopharyngeal secretions. Repeat this procedure for the other nostril.
- Collect the specimens in sterile vials. Label each specimen container with the patient’s ID number and the date collected.

Nasopharyngeal or oropharyngeal swabs

- Use only sterile Dacron® or rayon swabs with aluminum or plastic shafts. Do not use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit PCR testing.
- To obtain a nasopharyngeal swab, insert a swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions. Swab both nostrils.
- To obtain an oropharyngeal swab, swab the posterior pharynx and tonsillar areas, avoiding the tongue.
- Place the swabs immediately into sterile vials containing 2 ml of viral transport media. Break the applicator sticks off near the tip to permit tightening of the cap. Label each specimen container with the patient’s ID number and the date the sample was collected.

Collecting specimens from the lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate, or pleural fluid tap

- During bronchoalveolar lavage or tracheal aspirate, use a double-tube system to maximum shielding from oropharyngeal secretions.
- Place the un-spun fluid in sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with the patient’s ID number and the date the sample was collected.

Sputum

- Educate the patient about the difference between sputum and oral secretions.
- Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap sputum collection cup or sterile dry container.

If shipping, use cold packs to keep the sample at 4°C. If sample will not reach laboratory within 72 hours or collection, freeze and ship on dry ice.
LIMITATIONS TO RT-PCR TESTING

1. Current reports indicate that patients infected with a novel Influenza A/H5 virus may shed fewer viral particles than patients infected with other Influenza viruses. Collection of multiple specimens from the same patient may be necessary to detect the virus. Collect the specimens as early in the illness as possible (within 4-5 days of symptom onset).

2. Additional testing for Influenza A or B or other respiratory infections may be required when the test results are negative for Influenza A/H5 virus.

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

4. False-positive results are more likely to occur when disease prevalence in the community is low.

5. If inhibitors are present during the RNA extraction, PCR assay may produce a false negative result. This may occur with specimens collected on swabs with calcium alginate or cotton tips or wooden shafts.

LABORATORY BIOSAFETY GUIDELINES FOR HANDLING & PROCESSING SPECIMENS OR ISOLATES OF NOVEL INFLUENZA STRAINS

1. Commercial antigen detection testing for influenza may be conducted under BSL-2 containment conditions if a Class II Biological Safety Cabinet is used.

2. Clinical specimens from suspected novel influenza cases should be tested by RT-PCR using standard BSL-2 work practices in a Class II Biological safety cabinet for initial processing of patient specimens.

3. If a specimen is confirmed positive for Influenza A (H5N1) by RT-PCR, additional testing should be performed only under BSL-3 conditions with enhancements.

4. A detailed description of recommended facilities, practices, and protective equipment for the various laboratory safety levels can be found in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual at www.cdc.gov/od/ohs/biosfty/bml4toc.htm

5. State and local public health laboratories may test clinical specimens from suspected novel influenza cases by RT-PCR using standard BSL-2 work practices in a Class II Biological Safety Cabinet. Commercial rapid antigen detection testing may also be conducted under BSL-2 biocontainment conditions.

6. Highly pathogenic Avian Influenza A (H5) and A (H7) viruses are classified as select agents. USDA regulations require that these viruses be handled under BSL-3 laboratory containment conditions, with enhancements, including but not limited to:
   - All BSL-3 practices
   - Use of negative air pressure
   - Controlled-access double-door entry with change room and shower to include clothing change and personal showering protocols upon exit
   - HEPA-filtered respirators or positive air-purifying respirators
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- Decontamination of all waste
- Registration of personnel and facility with the Select Agent Program
- USDA-APHIS permit

7. Any laboratory should not perform virus isolation on respiratory specimens from patients who may be infected with Avian Influenza unless stringent BSL-3 enhanced containment conditions can be met. Diagnostic work must be kept separate from studies with human influenza A viruses (H1 or H3). Therefore, respiratory virus cultures should not be performed in most clinical laboratories.
Figure 1: Shipping Diagram for Influenza Testing
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Health department approval required for testing. There is no fee for testing.

Bioterrorism Rule out submissions (Select agent rule outs)

Refer to PHLET procedure: “Collecting and Submitting Biothreat and Chemical Threat Samples” for complete instructions. (Available upon request to qualified Sentinel Laboratories)

Specimen Submission:

All specimens must be triple contained in accordance with federal shipping regulations. All clinical specimens must be accompanied by a specimen submission form.

Call PHLET at 903-877-5071 or 903-312-3537 prior to submission.

Sentinel laboratories are asked to perform rule out testing before submission. If you are not able to perform rule to protocol or need training contact PHLET for assistance.

Environmental samples are accepted from Law enforcement only -Sentinel laboratories should not accept environmental or animal specimens; such specimens should be forwarded directly to the State Public Health Laboratory

For assistance with rule outs a guidance document is available at https://www.uthct.edu/d/PHLET/Clincial_Laboratory_Preparedness_and_Response_Guide%5B2%5D.pdf

ASM Sentinel testing protocols can be found at 

Submission forms can be found in this publication and at https://www.uthct.edu/phlet

Biological Threat Fact Sheets Texas department of State Health Services 
http://www.dshs.state.tx.us/lab/BioTFactSheets.shtm

TRAINING:

As part of our Hospital Preparedness Program, PHLET offers training in Sentinel Rule out Protocols and Packaging and Shipping of Dangerous Goods.

Contact PHLET at 903-877-5071 to request training.

Refer to PHLET procedure: Collecting and Submitting Biothreat and Chemical Threat Samples
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Testing of Persons under Investigation for Dengue, Chikungunya or Zika virus

PHLET Laboratory submission information

Overview

This document is intended to provide guidance for health care providers and local and regional health departments with approval to test specimens from a Person under Investigation (PUI) for, dengue, chikungunya and Zika virus. More information can be found at http://www.texaszika.org/labs.htm

Document Details

- Zika and related virus PCR and ZIKA MAC IgM Serology testing will be performed at the Public Health Laboratory of East Texas by the Biothreat Team. Laboratory specific questions, coordination and updates should be directed to 903-877-5071, or the 24/7 phone 903-312-3537 or by emailing janine.vost@uthct.edu
- Before sending any samples for testing, please call your local health department to coordinate testing.  http://www.dshs.texas.gov/idcu/investigation/conditions/contacts/
- The patient name and date of birth should be referenced on all communication related to the sample. (Information on submission form and sample must match)
- Samples should be packaged as Category B infectious substance and shipped on cold packs or dry ice as appropriate.
- Testing is available free of charge when pre-approved by local health department.

Required forms: The PHLET submission form and DSHS Supplemental form must be completed. Submitter information and DSHS Submitter Number (if available) must be completed. If the hospital is not an existing DSHS submitter and the sample needs to be sent after normal business hours, the hospital can use the submitter number from the local health department. Under tests requested- Choose chikungunya, dengue and Zika virus PCR or ZIka IgM serology as appropriate.

Samples types accepted:

Serum Aliquot: Please ship a minimum of 3-5 mls. Centrifuge sample and separate serum as soon as possible.

Urine Aliquot: For PCR only. Please ship a minimum of 1-2 mls A serum sample must be submitted in parallel.

Contact the PHLET team regarding testing of other specimen types.

Specimens should be placed in a biohazard bag and stored at 4°C or -20°C as indicated below:
- Specimens that are shipped the same day of collection and will arrive at the lab within 48 hours of collection should be stored at 4°C and should be shipped with cold packs.
- Specimens that will be stored and arrive at the lab more than 48 hours after collection should be stored at -20°C and shipped on dry ice.
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Reporting: PCR Testing will take 6-24 hours from sample receipt. Serology testing will take 2-7 days from sample receipt. Turn-around times are estimates and are dependent on workload at the time of sample receipt. Verbal results will be given to the local and regional health department via email or phone. The final report could take up to 48 hours to generate. For surveillance samples, results will only be sent to the health department.

- All samples must be accompanied by a PHLET submission form available at: https://www.uthct.edu/phlet-forms-procedures
- For specimen types and testing criteria, PHLET will follow the DSHS Chikungunya, Dengue, and Zika PCR and Serology Specimen Criteria
- All samples must be accompanied by a DSHS-Chik-Den-Zika-Supplemental Form.
- These documents are available at: https://www.texaszika.org/labs.htm
- The name on the tube should match the name on the form exactly

PRIOR to shipping: Contact your local Health Department Service Region to ensure patient meets criteria for testing. http://www.dshs.state.tx.us/Regions/lhds.shtm

Fax copy of submission form to 903-877-5259 Attn: Janine Yost, Microbiology Supervisor or send via secure email to janine_yost@uthct.edu
Include a copy with the specimen
The following must be provided to the laboratory by phone or email:
- Method of delivery
- Estimated time of arrival
- Tracking number for the package or courier phone number
- Complete the PHLET form for each specimen
- Check “Zika Serology IgM” and or Zika Trioplex PCR
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Ship to the physical address:
Public Health Laboratory of East Texas
Attention: Janine Yost
11949 US Highway 271N
Tyler, Texas 75708
Phone: 903-877-5071

- Email form to: Janine.yost@uthct.edu or Fax 903-877-5259
- PHLET Submission forms can be downloaded from www.phlet.org
- Record the shipping tracking number and notify your local health department that a specimen is being shipped.
- A map and driving directions to the PHLET laboratory follows.

For more information regarding these assays consult the fact sheets located at:
https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm
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Testing of Persons Under Investigation for Ebola

PHLET Laboratory submission information

Overview
This document is intended to provide guidance for health care providers and local and regional health
departments with approval to test specimens from a Person Under Investigation (PUI) on PHLET
laboratory sample submission

Testing must be approved by health department. Approval to test is granted from: DSHS EAIDS
Branch Epidemiologist AND CDC Emergency Operation Center.

• Testing will be performed at the Public Health Laboratory of East Texas by the Biothreat Team.
  Laboratory specific questions, coordination and updates should be directed to the 24/7 phone 903-312-
  3537 or emailing janine.yost@uthct.edu

• The unique CDC PUI number should be referenced on all communication related to the sample.
  Collect two purple top EDTA plastic tubes of blood with a minimum volume of 4 mls each. Do
  not centrifuge or open the tubes
  Samples should be kept cold (4 °C).
  If the tube expiration date is not clearly visible, write it on the submission form

The following must be provided to the laboratory by phone or email:
  Method of delivery
  Estimated time of arrival
  Tracking number for the package or courier phone number

Reporting:
Testing will take 4-6 hours from sample receipt.
Verbal results will be given to the local and regional health department via email or phone. The final report
could take up to 24 hours to generate and will be automatically sent to the submitter by PHLET.

Result interpretation:
• Positive results are presumptive and require CDC confirmation
• Negative DSHS results are considered final and do not require CDC confirmation. However additional
tests including Lassa fever can be performed at the CDC from the blood ETDA tube.

Submission Forms and Shipping
  Complete and submit the PHLET Submission Form.
  Submission forms can be downloaded from https://www.uthct.edu/phlet-forms-procedures
  Provide all patient information, including full address and medical history.
  Write “Ebola virus” as the disease suspected in the “Patient Medical History” section.
  Complete Shipper’s Declaration Form (must have red border)

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If the hospital is not an existing DSHS submitter and the sample needs to be sent after normal business hours, the hospital can use the submitter number from the local health department. Under tests requested- Choose BT RULE-OUT and for suspected organism, write Ebola

Fax copy to 903-877-5259 Attn: Biothreat Team or send via secure email to
janine.yost@uthct.edu

Include a copy with the specimen

Samples should be packaged as Category A infectious substance. Identify the material as a “Suspected Category A infectious substance” Do not identify the package as containing Ebola unless confirmatory testing has been done. If patient is confirmed Ebola positive and you must ship samples, contact shipper before attempting to ship to ensure the package will be accepted.

NOTE: The Shipper’s Declaration form must to be completed by a certified Category A shipper using compliance checking software. Form can be prepared at www.saripsak.com individual registration is required. Place 3 copies (two must be printed in color) of the printed shippers declaration in the plastic sleeve that is attached to the outermost insulated shipper.

Arrange shipping with an approved courier that will accept Select Agent shipments.

Shipping Address:

Public Health Laboratory of East Texas
Attention: Janine Yost
11949 US Highway 271N
Building 558
Tyler, Texas 75708