UT HEALTH EAST TEXAS-	**The University of Texas Health Science Center at Tyler-**
SECTION:	**Public Health Laboratory of East Texas** **SOP#**
PROCEDURE*:*	PHLET Lab Manual 2023
MANUAL:	**LRN Policies and Procedures**
PAGE:	**of**
REPLACES:	PHLET Submission Information and Instructions 2018/2019
EFFECTIVE DATE:	**RETIRED DATE:**
PREPARED BY: Janine Yost MPH, BS CLS/ASCP	**COPIES TO:**

APPROVAL SIGNATURE: _____ DATE: _____

Richard J. Wallace Jr., M.D.

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
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Public Health Laboratory of East Texas

LABORATORY MANUAL

2023

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's 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/public-health-lab-of-east-texas-resources/

If the form is not completed correctly or the sample is deemed unacceptable, testing services may be delayed and adversely affect the quality of the submitted sample and testing results.

Insructions 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. Be sure to check the expiration date of the media prior to specimen collection. Specimens submitted in expired media will be rejected.
3. Place the date and time of collection on the specimen label and submission form.
4. Retain a copy of submission form for your records.
5. Triple-contain specimens with sufficient absorbent materials to avoid breakage.
6. Specimens must be sent at appropriate temperature.
7. Include a completed request form for each specimen.
8. 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. It is recommended for highly suspicious cases that original sample and all subcultures be submitted as well as the isolate to be tested.

In order to ensure 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.
5. The sample is transported and arrives at the appropriate temperature.
6. Each specimen container is labeled with the name of the patient exactly the way it is written on the request form.
7. 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.
8. 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.
9. Call the lab prior to shipping samples.

Rejection criteria

1. The specimen is mislabeled or not labelled
2. The submission form is not sent or is incomplete
3. The sample is stored and/or arrives at the incorrect temperature
4. The sample arrives after the required time limit for the test requested
5. Specimen container is not labeled with the name of the patient and date of birth exactly the way it is written on the request form.
6. Check the expiration date of the media prior to specimen collection. Specimens submitted in expired media will be rejected.
7. The laboratory must follow established manufacturer and CLIA guidelines. Samples that do not meet acceptance criteria will be rejected.

Mailing Instructions and Information

ONLY PROPERLY TRAINED CERTIFIED PERSONNEL MAY LEGALLY SHIP SAMPLES

Submitters are responsible for shipping specimens in conformity with all safety and labeling regulations. Be aware that many commercial carriers may not accept certain 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

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.

SEE WEBSITE FOR EDITABLE COPY

Public Health Laboratory of East Texas The University of Texas Health Science Center at Tyler	CLIA# 45D1011121
11949 US Highway 271 N Tyler, Texas 75708	Laboratory Director Richard J. Wallace Jr., M.D.
Phone 903-877-5071 Fax 903-877-5259	24-hour Emergency Phone 903-312-3537

SUBMITTER INFORMATION			
SUBMITTER			
ADDRESS			
CITY	STATE TX	ZIP CODE	
PHONE	email-	FAX	
LABORATORY CONTACT NAME AND NUMBER (FOR QUESTIONS)			
PANIC VALUE-CONTACT NUMBER (24/7)			
PATIENT INFORMATION		**PLACE LABEL HERE**	
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 ASSOCIATON: Y/N	SURVEILLANCE: Y/N	CIRCLE ONE: INPATIENT/OUTPATIENT	
ORDERING PHYSICIAN			
SPECIMEN SOURCE OR TYPE (Circle one)			
PLASMA	WHOLE BLOOD	NASOPHARYNGEAL SWAB/ASPIRATE	
WOUND SWAB/ SOURCE-		THROAT SWAB	SPUTUM
TRACHEAL ASPIRATE	PLEURAL FLUID	SERUM	CSF/SPINAL FLUID
BACTERIAL ISOLATE	VIRAL CULTURE	OTHER (describe)	

TEST REQUESTED (Place a check mark in the box to the left of the test requested)

- ☐ ***BIOTERRORISM RULE IN/RULE OUT SUSPECTED ORGANISM_____***
- ☐ ***INFLUENZA BY RT-PCR***
- ☐ ***AVIAN FLU***
- ☐ ***ARBOVIRUS PANEL (includes Zika, dengue, and Chikungunya***
- ☐ ***COVID-19 PCR***
- ☐ ***OTHER (specify)***

TO BE COMPLETD BY PHLET PERSONNEL:

OTHER TESTS: CALL PHLET FOR APPROVAL

SPECIMEN RECEIVED BY DATE/TIME

CONDITION: Refrigerated 2-8 Celsius Room Temp 15-30 Celsius Frozen less than -20 Celsius

FOR ALL BT SUBMISSIONS and tests marked with an * NOTIFY DSHS at 1-866-310-9698

IF APPLICABLE, PLEASE DESCRIBE ANY EXPOSURES RELATED TO THIS SUBMISSION:

Summary of tests available		
Test	**Required Specimen Type**	**Special Instructions**
Seasonal Influenza typing, SARS COV-2 RT-PCR	Nasopharyngeal wash, aspirate, or swab; bronchial lavage; throat swab, Call PHLET regarding other specimen types.	Collect samples in Viral transport media and refrigerate immediately. Transport to lab within 72 hours of collection on cold packs If sample will not arrive within 72 hours then freeze sample and ship on dry ice.
Bioterrorism Chemical or Environmental Sample	Sample types depend on suspected agent and sample type. Refer to " Collecting and Submitting Biothreat and Chemical Threat Samples". Call for further instructions. Call 903-877-5071 for assistance	All samples submitted must have a Chain of Custody- Receipt of Property Form and submission form for each sample. Refer to " Collecting and Submitting Biothreat and Chemical Threat Samples" for storage conditions. Original samples must be retained for further investigation purposes or transferred to PHLET.
Avian Influenza (Influenza A H5 and H7)	Nasopharyngeal wash, aspirate, or swab; bronchial lavage; throat swab. Call PHLET regarding other specimen types.	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 If sample will not arrive within 72 hours then freeze sample and ship on dry ice.
Arbovirus testing (Dengue, Chikungunya and Zika PCR)	Serum separated and refrigerated. (3-5 mls preferred, 2 mls minimum) CSF or urine may be submitted along with a serum sample (PCR only). (1 ml minimum).	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 (>24 hours) freeze sample and ship on dry ice.

Refrigerated- 2-8 Celsius

RT- Room temp 15-30 Celsius

Frozen less than or = -20 Celsius

For questions, please contact:

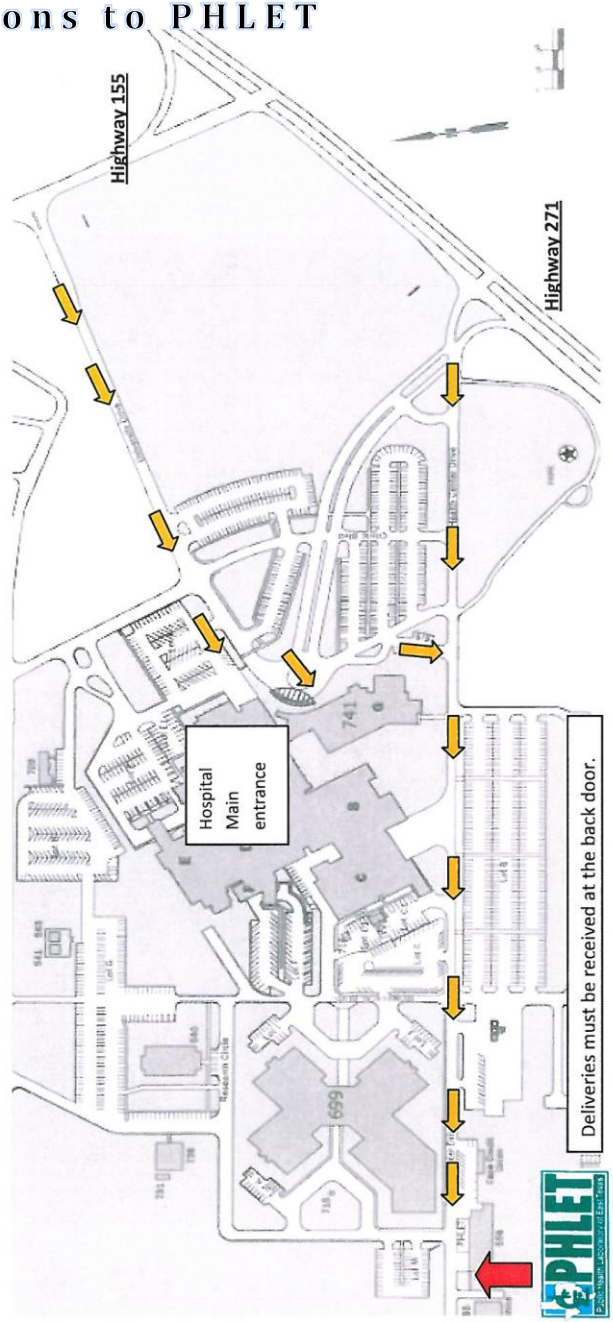
Public Health Laboratory of East Texas

Tyler, Texas 75708

Phone: 903-877-5071

On call technician: 903-312-3537

Directions to PHLET



Directions to The PHLET on the UTHSCT Campus: SAMPLE DELIVERIES

Address: Public Health Laboratory of East Texas, 11937 US highway 271N, Building 558, Tyler, TX 75791

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

1B-Entering from Highway 155: Turn right onto University Drive at the UTHSCT sign. Continue through the campus in front of the Academic Center (large white and glass awning) until you reach Health Center Drive. Turn right on Health Center Drive. Stay on Health Center Drive, through the 4-way stop.

2- From the 4 way stop, 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 (large red arrow).

Laboratory Testing Protocol: Influenza and SARS COV-2 Surveillance

Health department approval required for testing. There is no fee for testing.

Texas is following traditional influenza seasonal surveillance protocols for the identification of influenza cases and the emergence of novel or variant influenza and SARS COV-2 strains using participants in the Texas Department of State Health Services (DSHS) Influenza Laboratory Surveillance Program. Public health laboratory testing for respiratory viruses conducted by the laboratory is done primarily to:

- Detect the distribution and spread of the virus
- Detect new variants of the virus and
- Assist in outbreak investigations.

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.

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. Specimens submitted using unacceptable collection supplies will be rejected.

Viral transport media (VTM) tubes should be stored at the specified temperature according to the manufacturer product storage requirement(s) or product insert. If the viral transport media (VTM) tubes have been stored frozen, the media should be thawed completely before specimen collection. **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.

- 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's 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 DSHS 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 received after 72 hours of collection
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 and SARS COV-2 using the CDC real time RT-PCR assay. 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 Yamaguta lineages.

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.

Note:

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.

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 questions, please call 903-877-5071

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 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 2-8°C.

For guidance regarding collecting specimens from the upper respiratory tract and surveillance information refer to Texas Influenza Surveillance Handbook | Texas DSHS

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 Testing Protocol: 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/wp-content/uploads/clinical-laboratory-preparedness-and-response-guide-2.pdf

ASM Sentinel testing protocols can be found at https://asm.org/Articles/CPHMC/Laboratory-Response-Network-LRN-Sentinel-Level-C

Submission forms can be found in this publication and at https://www.uthct.edu/public-health-lab-of-east-texas-overview/

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

Laboratory Testing Protocol: 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.yost@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's 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.

Sample types accepted:

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

CSF aliquot: Please ship a minimum of **1-2 ml**s A serum sample must be submitted in parallel.

Urine Aliquot: For ***PCR*** only. Please ship a minimum of **1-2 ml**s 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.

Reporting: PCR Testing will take 6-24 hours from sample receipt Monday to Friday. Samples received after 10 am will be tested the next business day. 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: http://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

In March 2020, Texas DSHS updated testing guidance for asymptomatic and symptomatic persons based on local and national trends. There is now increased scientific knowledge of the disease and the limitations of available tests.

- **Zika virus testing is no longer recommended for asymptomatic persons, regardless of travel history or pregnancy status.**
  - Previously, DSHS recommended testing asymptomatic pregnant women by PCR if they:
    - Recently traveled to a Zika virus risk area outside Texas or their sexual partner had done so, or

        - Resided in Cameron, Hidalgo, Kinney, Maverick, Starr, Val Verde, Webb, Willacy, and Zapata counties.
    - DSHS continues to not recommend any Zika testing for asymptomatic, non-pregnant persons.
- **Test symptomatic pregnant women with possible Zika exposure using PCR only. Zika IgM testing is not recommended.***
    - Possible exposure to Zika includes:
        - Recent travel to or residence in a Zika virus risk area outside the US and its territories, or sexual exposure to a traveler to a risk area, or
        - Residence in Cameron, Hidalgo, Kinney, Maverick, Starr, Val Verde, Webb, Willacy, and Zapata counties.
    - Zika virus symptoms may include:
        - Rash
        - Fever
        - Conjunctivitis (red eyes)
        - Joint pain
    - Previously, DSHS recommended testing symptomatic pregnant women with Zika exposure by both PCR and IgM.
- **Zika testing is no longer recommended for symptomatic non-pregnant persons with exposure to a Zika risk area.**
    - Evaluate these people for other possible infectious diseases, especially dengue virus, which causes similar symptoms and is a common infection in areas with a history of Zika transmission.
    - Many countries reported large dengue outbreaks recently, and dengue risk remains high in these areas.

**Zika IgM testing is still recommended alongside PCR for pregnant women with ultrasound evidence of fetal abnormalities consistent with Zika after possible Zika. Specimen will be referred to the Texas Department of State Health Services.*

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

For more information regarding these assays consult the fact sheets located at:

Fact Sheet for Healthcare Providers: Interpreting Trioplex Real-Time RT-PCR Assay (Trioplex rRT-PCR) Results (fda.gov)

Fact Sheet for Patients: Understanding Results from the (fda.gov)

LABORATORY BIOSAFETY GUIDELINES FOR HANDLING & PROCESSING SPECIMENS OR ISOLATES OF NOVEL INFLUENZA STRAINS AND SELECT AGENTS (BIOTHREAT) SAMPLES

1. 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.
2. If a specimen is confirmed positive for a select agent including Influenza A (H5 or H7) additional testing should be performed only under BSL-3 conditions with enhancements.
3. 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 Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratory Portal | CDC www.cdc.gov/od/ohs/biosfty/bmbl4toc.htm
4. 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.
5. 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
    - Decontamination of all waste
    - Registration of personnel and facility with the Select Agent Program
    - USDA-APHIS permit
6. A 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.

CHANGE RECORD

:

02/2023- UPDATED MANUAL, replaced PHLET Submission Information and Instructions 2018/2019

"SUBMISSION FORM updated, ADDED REJECTION CRITERIA, REMOVED QuantiFERON test

Added guidelines for sample acceptance and rejection including acceptable temperature ranges.