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Texas Department of State Health Services (DSHS)
Protocol for Laboratory Testing of Symptomatic Responders who Participated in an
Avian Influenza Outbreak Response

Key Reminders

1. **Human testing for avian influenza and other novel strains must be performed at the DSHS Laboratory or a LRN Laboratory.**
2. **Please use the appropriate laboratory specific submission form when submitting specimens for avian influenza testing to a public health laboratory.**
3. **All specimens must arrive at the DSHS or a LRN Laboratory within 72 hours of collection if refrigerated at 2–8 °C. If specimens will arrive more than 72 hours after collection, the specimens must be frozen at -70 °C.**
 - Include date and time of collection on the laboratory submission form.
 - One submission form must be submitted for each specimen.
 - The name and date of birth on the form must match the name and date of birth on the specimen tube.
4. **For avian influenza testing of patients with an upper respiratory illness, a nasopharyngeal (NP) swab, nasal aspirate or wash, or two swabs combined into one viral transport media vial (i.e., nasal or nasopharyngeal swab combined with an oropharyngeal swab) is the preferred specimen for testing.**
 - Submit specimens in unexpired viral transport medium.
5. **For patients with lower respiratory tract illness, a lower respiratory specimen should also be collected and submitted to the DSHS or a LRN Laboratory.**
6. **For persons under monitoring for avian influenza who develop symptoms, complete the Avian Influenza Initial Case Investigation Form.**

SPECIMEN TESTING

1. Specimens from symptomatic responders who participated in an avian influenza outbreak response should be sent to a qualified public health laboratory with the capability to test for novel influenza viruses (i.e. DSHS or Laboratory Response Network [LRN] Laboratory).
2. Real-time reverse transcription polymerase chain reaction (rRT-PCR) testing using CDC-approved primers should be performed.
 - a. Seasonal influenza testing (the CDC Influenza rRT-PCR Diagnostic Panel) should be performed along with H5. This includes the following primer/probe sets: InfA, InfB, H1, H3, Pdm InfA, Pdm H1, H5a, H5b, and RNase P
3. Specimens that are positive for unsubtypeable influenza A will be sent to the CDC for lab confirmation.
 - a. Specimens positive for unsubtypeable influenza A are considered “presumptive” positive until there is lab confirmation from the CDC.

SPECIMEN COLLECTION

1. For persons under monitoring for avian influenza who develop symptoms, complete the Avian Influenza Initial Case Investigation Form. Local health departments should fax the completed form to their Health Service Region (HSR). DSHS HSRs should fax completed forms to DSHS EAIDB at 512-776-7616.
2. Specimens should be collected and submitted for novel/avian and seasonal influenza testing from incident responders who report having new onset or worsening of the following signs or symptoms:
 - Fever or feeling feverish/chills
 - Cough
 - Runny or stuffy nose
 - Eye tearing, redness, irritation
 - Sneezing
 - Sore throat
 - Difficulty breathing
 - Shortness of breath
 - Fatigue (very tired)
 - Muscle or body aches
 - Headaches
 - Nausea
 - Vomiting
 - Diarrhea
 - Seizures
 - Rash

3. If VTM is frozen, thaw frozen VTM (either by refrigeration or at room temperature) completely before specimen collection. *Do not heat, microwave, or incubate media prior to use as this may cause inactivation of the virus.*

Use sterile, polyester-tipped, plastic shaft nasopharyngeal swabs and viral transport medium for specimen collection. Dacron or rayon-tipped swabs with a plastic shaft or any other commercially available sterile collection system intended for virus isolation also may be used.

Note: Calcium alginate swabs or swabs with wooden shafts are not acceptable for specimen collection as they may inhibit recovery of the virus.

4. **For patients with upper respiratory tract illness**, please collect:
 - a. A nasopharyngeal swab, or
 - b. A nasal aspirate or wash, or
 - c. Two swabs combined into one viral transport media vial (i.e., nasal or nasopharyngeal swab combined with an oropharyngeal swab).If these specimens cannot be collected, a single nasal, or oropharyngeal swab is acceptable.
5. **For patients with lower respiratory tract illness**, please collect a lower respiratory tract specimen (e.g., an endotracheal aspirate or bronchoalveolar lavage fluid) in addition to an upper respiratory tract specimen.
6. Additional specimens may be requested depending on the patient's symptoms (e.g., a conjunctival swab maybe requested if the patient reports eye redness, tearing, or irritation).
7. If possible, in order to increase the potential for novel virus detection, multiple respiratory specimens from different sites may be obtained from the same patient on at least two consecutive days.
8. After specimen collection, insert the fiber tip of the swab into the VTM specimen vial and break off the shaft so that the swab fits completely within the tube. Please tighten the cap securely and refrigerate or freeze immediately.
 - a. The VTM specimen vial should contain at least 2-3 ml of viral transport medium (e.g., containing protein stabilizer, antibiotics to discourage bacterial and fungal growth, and buffer solution).

SPECIMEN STORAGE

1. Refrigerate (2–8 °C) or freeze (-70 °C) specimen vials immediately after collection.
2. Specimens should be stored in an upright position with caps tightened.
3. If collected specimens will arrive at the DSHS or LRN Laboratory within 72 hours of collection, store at 2–8 °C. If collected specimens will arrive more than 72 hours after collection, freeze at -70 °C. Specimens received by the DSHS or LRN Laboratory more than 72 hours after collection (including those received cold) will be rejected as unsatisfactory for testing unless those specimens are frozen after collection (recommended at -70 °C), shipped on dry ice, and received frozen by the DSHS or LRN Laboratory.
4. Ship specimens to the DSHS or LRN Laboratory as soon as possible after collection. Timely transport to the laboratory will increase the likelihood of recovering the influenza virus from specimens.

SPECIMEN LABELING AND LABORATORY SUBMISSION FORM COMPLETION

For submission to Laboratory Response Network (LRN) Laboratory

1. Each submitter should use the appropriate LRN submission forms when submitting specimens to a specific LRN.
2. If submitters do not have the appropriate LRN submission forms for a particular LRN then the submitter should contact the specific LRN to which they want to submit the specimen(s) to obtain LRN-specific lab submission forms.

For submission to DSHS Laboratory

1. Each submitter should have a “master” G-2V Specimen Submission Form that includes their unique submitter number, name, and address. This master G-2V form should be reserved to make copies for future specimen submissions. If submitters have not yet established a unique submitter number with DSHS, they must contact Laboratory Reporting at (512)776-7578. Laboratory Reporting can also provide current copies of submission forms—including a copy of the new G-2V form—to existing submitters.
2. Ensure that the patient name and date of collection are written on each specimen vial. A corresponding DSHS G-2V laboratory submission form must accompany **each** specimen vial. *The patient name and date of collection on the specimen vial must match the name and date on the corresponding laboratory form.*
3. Fill out the G-2V laboratory form as thoroughly as possible (see page 6 for more information). The following items are **required**:
 - Section 1, Submitter Information:
 - Submitter/TPI Number
 - NPI Number
 - Submitter name, address, and contact information
 - Section 2, Patient Information:
 - Patient name, date of birth, sex, and full address
 - Date and **time** of specimen collection
 - ICD diagnosis code(s)
 - Section 3, Specimen Source or Type (please check appropriate box or boxes)
 - Section 4, Virology
 - Check the box labeled “Influenza surveillance {Influenza real-time RT-PCR}”
 - Please indicate if the patient received the current season’s influenza vaccine and the date it was received

- Please indicate if the patient has had recent travel (especially international) or animal contact (i.e., avian or swine)
- Section 5, Ordering Physician Information
 - Ordering Physician's Name and NPI Number
- Section 6, Payor Source
 - Check the box labeled "IDEAS".

Note: Submitters who do not complete the form correctly and are billed will not be reimbursed.

PACKAGING SPECIMENS FOR SHIPMENT

Note: Please refer to pages 7–8 of this document for detailed diagrams of packing and shipping instructions.

1. **If the specimens will arrive at the DSHS or LRN Laboratory within 72 hours of the time of collection, specimens can be shipped on cold or freezer packs.** Specimens that arrive at room temperature will be rejected as unsatisfactory for testing. No exceptions will be made for specimens that are unexpectedly delayed in transit.
2. **If the specimens will arrive at the DSHS or LRN Laboratory more than 72 hours after the time of collection, ship specimens frozen on dry ice. If dry ice is used, a dry ice label should be placed on the outer cardboard box.** Specimens that are shipped on dry ice, but are not received frozen by the DSHS or LRN laboratory will be rejected as unsatisfactory for testing.

Note: DSHS does not provide dry ice boxes or labels designating dry ice shipments. Submitters who ship using dry ice are responsible for ensuring that their shipments meet regulations. Contact the local LRN about the shipping supplies they provide.

3. Pack enough coolant (i.e., cold/freezer packs or dry ice) in the Styrofoam box to ensure that the specimens remain at the appropriate temperature until they arrive at DSHS or the LRN.
4. Follow the triple containment rules for specimen shipments.
 - Primary container = the VTM specimen vial in which the patient swab is placed
 - Secondary container = leak proof container with absorbent material
 - Tertiary container = sturdy outer container (e.g., cardboard shipping box with internal Styrofoam box)
5. Ensure that the tertiary shipping container (i.e., the outer cardboard shipping box) is properly labeled for "Biological Substance, Category B" shipments. The required labels include:
 - UN 3373/Category B Biological Substances label
 - Directional arrows label
 - Submitter's address and contact person's information
 - Shipping address and contact person's information
 - Dry ice label (if applicable)

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

6. Be sure that the cap on the specimen vial (primary container) is tightened and the secondary container is sealed.

Place the primary container (the specimen in the VTM vial) into the secondary container with enough absorbent material (e.g., paper towels) to absorb the entire contents if leakage/breakage occurs. Place the secondary container inside the tertiary container (e.g., cardboard shipping box with internal Styrofoam box). Do not tape the Styrofoam lid. Place a completed laboratory

submission form for **each** specimen in the shipment on top of the lid of the Styrofoam box, inside the outer cardboard box. Tape the cardboard shipping box to close it.

Note: If dry ice is used, do not tape the Styrofoam box; this allows venting of the carbon dioxide as the dry ice evaporates.

SHIPPING SPECIMENS

1. Collect specimens early in the week (i.e., Monday through Wednesday) and ship them to the laboratory no later than the day after collection. Any specimens collected on Thursday must be delivered to the laboratory on the same day as collection. This practice ensures that specimens are delivered to the laboratory before the weekend so they can be properly stored and testing procedures can begin as soon as possible. **Do not ship specimens on a Friday or the day before a holiday unless special arrangements have been made in advance with the DSHS or LRN Laboratory.**
2. Ship specimens using overnight shipping.
 - a. **Inform your testing laboratory and epidemiology staff that specimens are being sent.**
 - i. If sending to DSHS Austin, contact the DSHS Virology Laboratory (512-776-2452) and DSHS Emerging and Acute Infectious Disease Branch (512-776-7676).
 - ii. If sending to an LRN, contact the specific LRN (<https://www.dshs.state.tx.us/lab/eplrncontact.shtml>) and the local health department (<https://www.dshs.state.tx.us/idcu/investigation/conditions/contacts/>).
 - b. **Provide a tracking number** for the shipment.
 - c. Transport temperature: Store the specimen at 2^o-8^oC if the specimen will be received at the laboratory within 72 hours of collection; ship the specimen on cold packs. Otherwise, the specimen must be stored frozen (-70^oC) and shipped on dry ice.
3. If shipping specimens to DSHS Austin Laboratory, ship specimens to:

Texas Department of State Health Services
Laboratory Services Section
Attn: Walter Douglass (512) 776-7569
1100 West 49th Street
Austin, TX 78756-3194

4. If shipping specimens to an LRN Laboratory, contact that LRN for shipping information.

Instructions for Completing the G-2V Specimen Submission Form* for Human Testing for Avian Influenza Viruses at DSHS

*Note: Instructions in this document refer to the DSHS G-2V Specimen Submission Form (SEP 2015).

Complete Section 5, "Ordering Physician Information," by providing the physician's name and NPI number.

Ensure Section 1, "Submitter Information," has the correct submitter name, address, phone, and contact information. This section should be pre-populated on your master form**.

Complete Section 2, "Patient Information," with **date and time** of specimen collection, patient name, address, date of birth, and any other pertinent information (e.g., diagnosis or symptoms).

Complete Section 3, "Specimen Source or Type," by checking the appropriate box or boxes.

Complete Section 4, "Virology," by selecting the box marked "Influenza surveillance {Influenza real-time RT-PCR}". In the blank space to the left of Influenza surveillance, write "suspect avian influenza" or "suspect novel influenza". If applicable, indicate patient travel history and/or animal contact.

Suspect avian influenza

Influenza surveillance {Influenza real-time RT-PCR}
 Vaccine received: Yes No
 Date vaccine received: _____
 Travel history (if known): _____
 Animal contact (if known): _____

Complete Section 6, "Payor Source," by selecting the box marked "IDEAS". **The submitter will be billed if the box is not checked.**

Medicaid/Medicare #:

<input type="checkbox"/> Submitter (3)	<input type="checkbox"/> Private Insurance (4)
<input type="checkbox"/> BIDS (1720)	<input type="checkbox"/> TB Elimination (1619)
<input type="checkbox"/> BT Grant (1719)	<input type="checkbox"/> Title X (12)
<input type="checkbox"/> HIV / STD (1608)	<input type="checkbox"/> Title XX (13)
<input checked="" type="checkbox"/> IDEAS (1610)	<input type="checkbox"/> TX CLPPP (9)
<input type="checkbox"/> Immunizations (1609)	<input type="checkbox"/> Zoonosis (1620)
<input type="checkbox"/> Refugee (7)	<input type="checkbox"/> Other: _____

TEXAS
Department of
State Health Services
Specimen Acquisition: (512) 776-7598

G-2V Virology Specimen Submission Form (SEP 2015)
 CAP# 3024401 CLIA #45D060644
 Laboratory Services Section, MC-1947
 P. O. Box 149347, Austin, Texas 78714-9347
 Courier: 1100 W. 49th Street, Austin, Texas 78756
 (512) 963-2111 x2318 or (512) 776-7318
<http://www.dshs.state.tx.us/lab/>

For DSHS Use Only
Place DSHS Bar Code Label Here

Section 1. SUBMITTER INFORMATION - (REQUIRED)**

Submitter/FPI Number ** Submitter Name **

NPI Number ** Address **

City ** State ** Zip Code **

Phone ** Contact

Fax ** Clinic Code

Section 2. PATIENT INFORMATION - (REQUIRED)**

NOTE: Patient name on specimen is **REQUIRED & MUST** match name on this form & Medicare/Medicaid card.

Last Name ** First Name ** MI

Address ** Telephone Number

City ** State ** Zip Code ** Country of Origin / Bi-National ID #

DOB (mm/dd/yyyy) ** Age Sex ** SSN Pregnant? Yes No Unknown

Race White Black or African American Hispanic
 American Indian / Native Alaskan Asian Non-Hispanic
 Native Hawaiian / Pacific Islander Other Unknown

Ethnicity: Other: _____

Date of Collection ** (REQUIRED) Time of Collection AM PM Collected By

Medical Record # Alien # / CUI / CDC ID Previous DSHS Specimen Lab Number

ICD Diagnosis Code ** (1) ICD Diagnosis Code ** (2) ICD Diagnosis Code ** (3)

Date of Onset Diagnosis / Symptoms Risk

Inpatient Outpatient Outbreak association Surveillance

Section 3. SPECIMEN SOURCE OR TYPE

Abscess (site) Nasopharyngeal: wash swab aspirate
 Blood Nasal Swab
 Bone marrow Nasal Wash Throat swab
 Bronchial washings Oral fluid Tissue (site)
 Buccal swab Rectal swab Urethral
 CSF Serum: Urine
 Eye Acute date: _____ Vaginal
 Feces/stool Convul. date: _____ Wound (site)
 Lesion (site) Sputum: Induced Other: _____
 Lymph node (site) Sputum: Natural

Section 4. VIROLOGY

Electron Microscopy

Culture: Reference (Virus ID)
 Virus suspected: _____
 Submitted on (cell type): _____

Chikungunya, real time RT-PCR
 Date of onset: _____
 Travel history: _____
 *** Information required prior to testing. ***
 Performed only if specimen is collected within 5 days or less of symptom onset.

Dengue, real time RT-PCR
 Date of onset: _____
 Travel history: _____
 *** Information required prior to testing. ***
 Performed only if specimen is collected within 5 days or less of symptom onset.

NOTES: All dates must be entered in mm/dd/yyyy format. * = Justification is required.
 § = Requires acute and convalescent specimens.
 ▲ = Document time & date specimens were INCUBATED or removed from FREEZER/REFRIGERATOR in the bottom box. @ = Provide patient history on reverse side of form to avoid delay of specimen processing.
 Please see the form's instructions for details on how to complete this form. Visit: <http://www.dshs.state.tx.us/lab/>

FOR LABORATORY USE ONLY

Specimen Received: FREEZER REFRIGERATOR INCUBATOR Room Temp. Cold Frozen

Section 5. ORDERING PHYSICIAN INFORMATION - (REQUIRED)**

Ordering Physician's NPI Number ** Ordering Physician's Name **

Section 6. PAYOR SOURCE - (REQUIRED)

1. Reflex testing will be performed when necessary and the appropriate party will be billed.
 2. If the patient does not meet program eligibility requirements for the test requested and no third party payor will cover the testing, the submitter will be billed.
 3. Medicare generally does not pay for screening tests-please refer to applicable Third party payor guidelines for instructions regarding covered tests, benefit limitations, medical necessity determinations and Advanced Beneficiary Notice (ABN) requirements.
 4. If Medicaid or Medicare is indicated, the Medicaid/Medicare number is required. Please write it in the space provided below.
 5. If private insurance is indicated, the required billing information below is designated with an asterisk (*).
 6. Check only one box below to indicate whether we should bill the submitter, Medicaid, Medicare, private insurance, or DSHS Program.

Medicaid (2) Medicare (6)

Medicaid/Medicare #:

Submitter (3) Private Insurance (4)
 BIDS (1720) TB Elimination (1619)
 BT Grant (1719) Title X (12)
 HIV / STD (1608) Title XX (13)
 IDEAS (1610) TX CLPPP (9)
 Immunizations (1609) Zoonosis (1620)
 Refugee (7) Other: _____

HMO / Managed Care / Insurance Company Name *

Address * City * State * Zip Code *

Responsible Party (Last Name, First Name) *

Insurance Phone Number * Responsible Party's Insurance ID Number *

Group Name Group Number

I hereby authorize the release of information related to the services described here and hereby assign any benefits to which I am entitled to the Texas Department of State Health Services, Laboratory Services Section.
 Signature of patient or responsible party. Date *

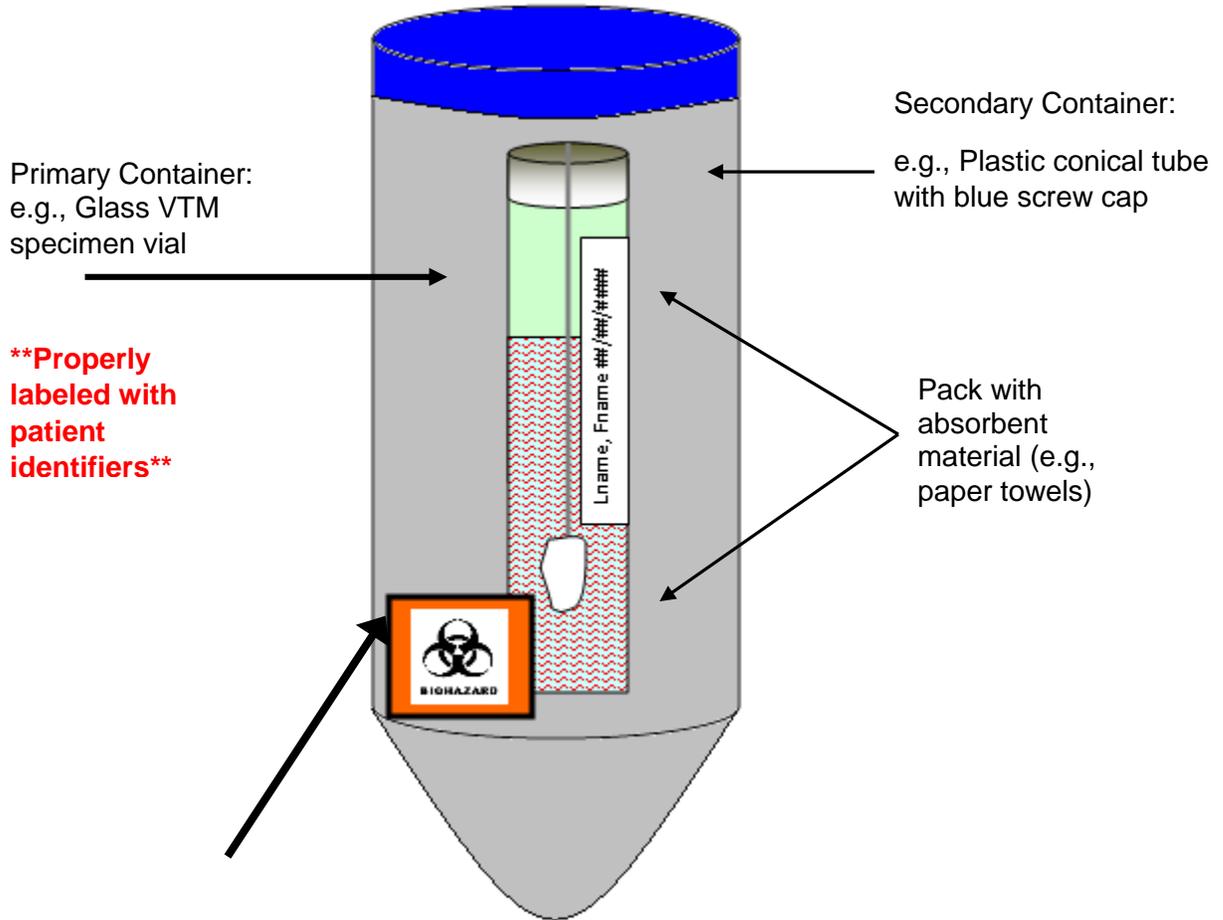
REQUIRED for cold/frozen/incubated shipments.

Indicate removal from: FREEZER REFRIGERATOR INCUBATOR DATE TIME

6

Packaging and Labeling of Biological Substances, Category B

Do not put any patient information on outer or secondary containers or lids



Biohazard label should already be on secondary container.

DO NOT put biohazard label on outer container.

