Section VI: Laboratory Support

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Viral Transport Medium (VTM)

The majority of the viral transport medium (VTM) shipped to providers throughout the season is prepared in July or August each year by the DSHS Media Preparation Group in the DSHS Austin Laboratory. Usually 2,500 to 3,000 tubes of VTM are prepared each season with an expiration date of September 30 of the following year. Quality control is performed on the VTM by the Viral Isolation Team in August or September, prior to the beginning of the official influenza season. DSHS-prepared VTM may be supplemented with commercially-prepared VTM.

VTM is designed to maintain the stability and viability of viruses while outside of the host organism or laboratory tissue culture. Most VTM contains antibiotics to inhibit the overgrowth of viruses by bacteria that also may be present in clinical respiratory specimens. The DSHS VTM, also called influenza transport medium, is specifically made for use in influenza surveillance.

VTM prepared by DSHS contains tryptose-phosphate broth, gelatin, penicillin and streptomycin sulfate. Quality control for DSHS-prepared VTM is performed using only influenza viruses. In theory, DSHS VTM should be able to successfully transport other viruses besides influenza virus; however, this is not recommended except in an urgent or outbreak situation. When in doubt, check with the specific disease program and laboratory to which you wish to submit the specimen. For commercially-prepared VTM, refer to the package insert for approved uses. Because VTM contains antibiotics, it is not an appropriate medium to use for bacterial testing; this also applies in outbreak situations in which viral and bacterial testing will need to be performed on specimens from each patient.

DSHS-prepared VTM should be stored frozen, preferably at -20˚C or below, until needed. If a freezer is not available, VTM should be stored for no longer than one month in a refrigerator (2–8˚C). The antibiotics contained in the medium will not remain effective when VTM is stored for a long period of time at refrigeration temperatures. If the VTM is stored frozen, it should be allowed to thaw either at room temperature or at refrigeration temperature prior to specimen collection. Avoid incubating, microwaving or heating the VTM to speed the thawing process. For commercially-prepared VTM, refer to the package insert for approved storage conditions and timeframes.

Appropriate types of VTM for influenza surveillance include DSHS-prepared VTM, any commercially prepared VTM approved for general viral transport and universal transport medium (UTM). Inappropriate transport types for influenza surveillance specimens include dry swabs, swabs in saline and transport medium used for gonorrhea and Chlamydia testing.

Beginning in the 2012-2013 influenza season, media provided to influenza surveillance submitters may be commercially prepared. This media should be stored according to the manufacturer's instructions. Specimen collection and shipping instructions will remain the same as those listed for DSHS-prepared VTM.

Receiving and Storing DSHS VTM

1. DSHS removes the sterile, viral transport medium (VTM) vials from freezer storage and sends them to the surveillance sites overnight with frozen cold packs in a Sterile Media Shipper ("X Box"). **Please return the Sterile Media Shippers, enclosed freezer bricks, and gel packs to the DSHS laboratory according to the instructions on the box**.

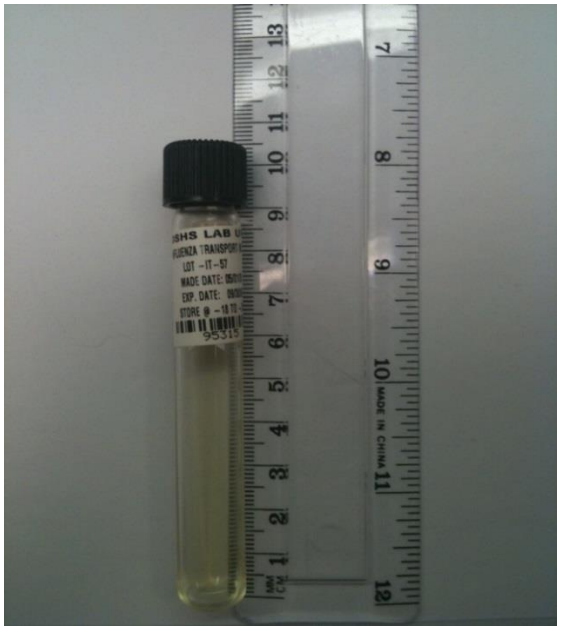
2. When received at the sites, the VTM vials should be stored frozen (-20 ºC or below). It is preferable to store the VTM in the upright position. The caps on the VTM may loosen and result in leakage if stored horizontally.

3. If a freezer is not available at the site, then the VTM vials should be refrigerated (2–8 ºC) and used within one month. Avoid storing the vials for a long period of time in a refrigerator; instead, shipments of media can be mailed as needed during the season.

4. **Regularly check the expiration date on the VTM and discard expired media.** Unused expired VTM should be discarded according to your health department's policies and procedures. If your health department does not have policies and procedures for discarding expired VTM, DSHS recommends using the following procedure:
   a. Place unused expired media into a cardboard box.
   b. Tape the cardboard box shut.
   c. Write "Do Not Recycle" on the outside of the cardboard box.
   d. Throw the cardboard box containing the expired media into a trashcan.

   Expired media should not be returned to the DSHS Laboratory.

5. The plastic conical tubes with white or blue screw caps and the specimen boxes (if ordered) provided by DSHS should be used to ship influenza surveillance specimens back to DSHS. Do not use the DSHS-provided containers for other specimens, or to ship specimens to non-public health laboratories.



Ordering Supplies

Influenza surveillance related supplies should be ordered prior to the beginning of the official influenza season (referred to as an "initial" order) and throughout the season as needed (referred to as "replenishment" orders). Influenza surveillance supplies are maintained, packaged and shipped to submitters by the Container Preparation Group in the DSHS Austin Laboratory.

Typical influenza surveillance supplies that can be ordered from DSHS include the following:

- Nasopharyngeal (NP) swabs
- Viral transport medium (VTM)
- Plastic conical tubes with blue or white screw caps—labeled with a biohazard sticker—that serve as secondary containment for specimens
- Specimen shipping boxes (aka "cold boxes") of various sizes
- Cold packs, two per cold box supplied
- Current DSHS Influenza Laboratory Surveillance Protocol
- FedEx waybills (for DSHS Austin submitters who already have shipping boxes onsite)

Supply type	**Automatically included in "initial" preseason orders**	**Automatically included in all VTM replenishment orders**	**Included upon request**
Nasopharyngeal (NP) swabs	Yes	Yes	N/A
Viral transport medium (VTM)	Yes	Yes	N/A
Specimen shipping boxes* (various sizes)	No	No	Yes
Cold packs	No	No	Yes
Plastic conical tubes with blue or white screw caps (secondary containment)	Yes	Yes	N/A
Current DSHS influenza surveillance protocol	Yes	No	Yes
FedEx waybills**	No, unless shipping boxes ordered	No	Yes

*Please instruct submitters to reuse remaining shipping boxes from previous seasons if they still have them onsite.

**FedEx waybills are provided to DSHS Austin submitters when they order shipping boxes or upon request. LRNs are expected to cover shipping costs for their submitters.

Orders for VTM and supplies must include the following information:

- Name of ordering agency
- Shipping address of ordering agency
- Name of a contact person who will receive the order at the ordering agency
- Phone number and email address for the contact person at the ordering agency

- Number of VTM tubes requested
- Number of cold boxes requested
- If the bulk order will cover several agencies, the number of agencies to which the order will be distributed
- Whether the site is a high, medium or low volume submitter:
    - low = fewer than 8 specimens per shipment
    - medium = 9–25 specimens per shipment
    - high = more than 25 specimens per shipment

See page VI.20 for an example of the VTM and supplies order form.

Preseason or "initial" orders should be placed with the DSHS Emerging and Acute Infectious Disease Branch (EAIDB) Influenza Surveillance Coordinator prior to the beginning of influenza season, if possible. Regional health departments (RHDs) should collect orders from their RHD submitters as well as orders from their local health departments and forward those to flutexas@dshs.state.tx.us. Initial orders are typically made in August.

Replenishment orders for influenza surveillance submitters, initial orders for new sites recruited during the season and special orders for respiratory outbreaks should also be forwarded to the DSHS EAIDB Influenza Surveillance Coordinator throughout the season at flutexas@dshs.state.tx.us. DSHS Austin reserves the right to make changes to VTM and supply orders as needed. Please note that orders sent directly to the DSHS Laboratory's Container Preparation Group may be rerouted to the DSHS EAIDB Influenza Surveillance Coordinator for approval before being filled. Please double-check the shipping address for the submitter before placing the VTM or supply order. For all VTM and supply orders, the agency/site ordering the supplies needs to have a person onsite during normal business hours to receive the order. This person should be instructed to store the VTM in the refrigerator or freezer immediately upon arrival.

VTM orders shipped by the Container Preparation Section of the DSHS Laboratory are always shipped via overnight mail; other supplies (e.g., shipping boxes) may be shipped by overnight mail or another shipping method. VTM and supplies are shipped according to the following policy: VTM orders received by the Container Preparation Section on Monday through Wednesday are shipped out the same week they are received; orders received after Wednesday are shipped out the following week. Orders will not be shipped on Fridays except in an emergency. In an emergency situation, the receiving site will need to provide the name and phone number of the person who will be present at the shipping address to receive the shipment on Saturday. Please contact DSHS EAIDB and the DSHS Container Preparation Section in the case of an emergency order (see contact information in the appendix).

Testing Performed by DSHS Austin

The DSHS Austin Laboratory performs a real time RT-PCR (reverse transcription polymerase chain reaction) test on all influenza surveillance specimens using PCR kits supplied annually by CDC. Multiplex PCR respiratory virus panel testing and pyrosequencing are other tests available upon request when supplies are available at the DSHS Austin Laboratory.

Acceptable specimens for routine influenza surveillance include nasopharyngeal (NP) swabs (generally considered the best specimen for routine influenza surveillance), nasal swabs, nasal aspirates, nasal washes and throat swabs. Lower respiratory specimens may be submitted as needed and include bronchoalveolar lavages, bronchial washes, and tracheal aspirates. This is due to the requirements of the RT-PCR test kits supplied by CDC, which are the main screening tests used for influenza surveillance in Texas public health laboratories. Submission of influenza surveillance specimen types other than those listed above may result in the specimen being rejected as "unsatisfactory for testing."

Specimens tested for influenza virus via RT-PCR at Texas public health laboratories are identified by type (i.e., A or B) and subtype [i.e., 2009 A (H1N1), seasonal A (H1N1) or A (H3N2)], if applicable. Specimens found to be positive for unsubtypeable influenza A are forwarded to CDC for identification and confirmation. The DSHS Austin Laboratory can also perform PCR testing for influenza A (H5N1) and (H7N9) upon request. If you wish to request testing for non-seasonal influenza A viruses, please contact the DSHS EAIDB Influenza Surveillance Team at 512-776-7676.

Specimens tested for influenza by viral culture, which will only be done for CDC purposes, are identified by type (A or B) through immunofluorescence testing. Viral isolation (i.e., culture) using a rhesus monkey kidney cell line is performed on 5–10 randomly selected positive influenza surveillance specimens every two weeks during the season, or according to the current CDC sampling protocol. Some influenza negative specimens may also be cultured as time and supplies allow.

Beginning in the 2010-2011 influenza season, the DSHS Austin Laboratory began testing a subset of influenza positive specimens via pyrosequencing for mutations that confer antiviral resistance. Currently the only testing capability is for oseltamivir resistance of H1N1 subtypes and results will only be released to public health.

The DSHS Laboratory also has the capability to run a multiplex PCR respiratory virus panel (RVP) assay. The RVP assay testing of influenza surveillance or other respiratory virus specimens is usually performed on a monthly basis as testing depends upon the number of specimens submitted to the DSHS Laboratory for testing, availability of time, supplies and reagents. Beginning in the 2013-2014 season, nasopharyngeal specimens collected during outbreak investigations will be tested on the respiratory virus panel.

In general, RT-PCR testing results should be available within 1–4 business days from the date the specimen is received at the laboratory. Pyrosequencing results are available 1–2 weeks after the specimen is received; these results are not reported to the submitter. Multiplex PCR RVP assay

testing results for respiratory virus specimens are usually available 2-4 weeks after the specimens are received. However, RVP assay testing results could be available 5 business days after the specimen is received if pre-approval is obtained from an epidemiologist in EAIDB. The multiplex PCR RVP assay test used by the DSHS Laboratory has been fully validated and individual patient results may be released to providers. Situations and factors that may cause a turnaround time to fall outside of these ranges include having to rerun a test for various reasons, extremely high numbers of influenza specimens received at the laboratory, staffing shortages or other unforeseen laboratory or public health emergencies.

The DSHS Laboratory sends a representative sample of influenza viruses to the CDC throughout the influenza season. This sample includes a variety of specimens from different geographic areas in Texas, different types and subtypes of influenza detected by Texas public health laboratories, cases of apparent vaccine failure, isolates possibly resistant to antiviral agents and other isolates from unusual cases. The CDC influenza laboratory performs additional tests on these influenza isolates such as antigenic characterization and antiviral resistance. Antigenic characterization identifies the specific influenza strain; data from this test are used to monitor circulating viruses and inform the decision of which viruses are recommended for inclusion in the vaccine for the upcoming year. CDC typically characterizes from 50–100 influenza isolates sent from DSHS each season.

Antiviral resistance testing determines whether or not an influenza isolate is resistant to the neuraminidase inhibitors—oseltamivir, zanamivir and peramivir—or the adamantanes (rimantadine and amantadine). Influenza A viruses are tested for resistance to both classes of antiviral agents, and the majority of currently circulating influenza A viruses are typically resistant to the adamantanes. Because influenza B viruses lack an M2 protein, adamantanes are ineffective against them; therefore, influenza B viruses are only tested for resistance to the neuraminidase inhibitors.

Both antigenic characterization and antiviral resistance results can be found in the Texas Weekly Flu Report. The typical turnaround time for results from CDC's antigenic characterization testing or antiviral resistance testing is 1–3 months; however, resistant viruses are reported to the state health departments immediately for investigation. Antigenic characterization and antiviral resistance testing results are not reported to submitters.

Summary of DSHS Influenza Testing Methods

Testing Method	Also known as	Tests for	Notes
Real-time Reverse Transcription Polymerase Chain Reaction	rRT-PCR or PCR	Influenza A and B; influenza A subtypes 2009 H1, seasonal H1, H3 (H5 and H7 upon request)	Primary surveillance test at DSHS and LRN laboratories
Multiplex PCR assay	Multiplex PCR respiratory virus panel (RVP) assay	Parainfluenza viruses 1, 2 and 3; respiratory syncytial viruses A and B; influenza A unspecified, H1, 2009 H1, H3, influenza B; rhinovirus; adenoviruses B/E and C; and human metapneumovirus	This is an expensive test and supplies are limited. This test is fully validated and results on individual patients may be released.
Pyrosequencing	Antiviral resistance testing	Resistance to oseltamivir only for seasonal H1N1 and 2009 H1N1	Performed on a subset of specimens that are positive for 2009 H1N1 influenza by PCR; PCR positive influenza specimens are sent to CDC regularly for full antiviral resistance testing according to the CDC sampling protocol

Specimen Collection

Nasopharyngeal (NP) specimens are the preferred specimen type for influenza surveillance. NP specimens are the only acceptable specimens for multiplex PCR RVP assay testing. Limited influenza testing can be performed on other respiratory specimen types but prior approval is required. Non-nasal/non-NP swab specimens should only be submitted if no other specimens are available and there is a strong public health need for the results (such as confirming influenza in a pediatric death investigation).

For seasonal influenza surveillance, collect specimens from patients who present with clinical symptoms resembling acute influenza infection or an influenza-like illness (one swab per patient). Please do not include patients with allergy symptoms, strep throat, or any other confirmed diagnosis that explains the symptoms. Typical symptoms of influenza infection generally include fever (typically $\geq$ 100 ºF), malaise, myalgia (muscle aches), cough, rhinorrhea (runny nose), sore throat, chills and headache. Select patients who present with recent onset (i.e., patients whose symptom onset was within 3–4 days of presenting to the clinic).

Texas public health laboratories are also interested in receiving the following priority specimens and specimens of interest for influenza surveillance:

- Patients with an extremely severe or unusual illness presentation
- Patients who received an influenza vaccine at least 2 weeks prior to illness onset
- Patients not responding to antiviral treatment
- Patients with a history of animal contact (avian/swine)
- Patients with a history of international travel
- Early and late season specimens
- Outbreak specimens
- Specimens from influenza-associated pediatric deaths
- Unsubtypeable influenza A specimens detected in a laboratory that can perform subtyping

Thaw frozen VTM (at either refrigeration or room temperature) completely before specimen collection. Use sterile, polyester-tipped, plastic shaft nasopharyngeal swabs and viral transport media (VTM) 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. Cotton-tipped or calcium alginate swabs are not acceptable because they can inhibit the PCR test. After specimen collection, insert the fiber tip of the swab into the VTM (be sure to fully submerge the fiber tip inside the VTM) in the specimen tube and break off the shaft so that the swab fits completely within the tube. Please tighten the cap securely.

Nasopharyngeal specimen collection

Basic instructions for collecting NP specimens are available in the appendix of this handbook. A video demonstrating proper technique for nasopharyngeal collection for pertussis testing can be found on the CDC website at http://www.cdc.gov/pertussis/clinical/diagnostic-testing/specimen-collection.html. Though the video demonstrates specimen collection for pertussis, the basic technique for collecting a specimen for influenza testing is the same. Two swabs are recommended for pertussis testing but only one swab is needed for influenza testing.

Additional videos are also available on the COPAN website at http://www.copanusa.com/index.php/education/videos/. DSHS recommends that providers wear appropriate personal protective equipment including gloves, a mask and eye protection when collecting nasopharyngeal specimens.

How to Submit Influenza Specimens

Specimen Storage
At a minimum, all influenza surveillance specimens must be kept cold (2–8˚C) from the time of collection until testing. Specimens may also be stored frozen (-70˚C) after collection. Avoid multiple freeze/thaw cycles as this may inhibit recovery of virus in culture. Specimens should be stored in an upright position with caps tightened. Ship specimens to a Texas public health laboratory as soon as possible after collection. Timely transport to the laboratory will increase the likelihood of recovering the influenza virus from specimens.

Specimen Shipping
Specimens maintained at refrigerated temperatures (2–8˚C) before and during shipping must be received at the laboratory no more than 72 hours after the specimen collection time. Please include a sufficient number of cold packs to keep the specimen at the appropriate temperature until it is received at a Texas public health laboratory. For the DSHS Austin lab, if no collection time is specified on the G-2V Specimen Submission Form, the assumption will be made that the specimen was collected at 12:01am on the date of collection specified on the G-2V form. Specimens maintained in a frozen (-70˚C) state before and during shipping and shipped on dry ice are not subject to these time requirements. Please include a sufficient amount of dry ice to keep frozen specimens frozen until they are received at a Texas public health laboratory.

Each specimen should be submitted to the laboratory using the DSHS G-2V Specimen Submission Form or the appropriate specimen submission form for the local LRN laboratory. For the DSHS Austin Lab, each submitter must have a submitter identification number on file with the DSHS Austin Laboratory and must submit specimens using copies of the personalized, master G-2V form. The submitter identification number and contact information are pre-filled on each submitter's personalized G-2V form. For help obtaining a submitter ID or a personalized G-2V form for the DSHS Austin Laboratory, please contact Laboratory Reporting at 512-776-7578. For more information, see http://www.dshs.texas.gov/lab/MRS_forms.shtm.

Please complete the following sections of the DSHS G-2V Specimen Submission Form for **each** influenza surveillance specimen sent to the DSHS Laboratory:

- 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
    - If date of birth is not provided, an alternate approved secondary identifier must be provided
      - Alternate approved secondary identifiers include: medical record number, social security number, Medicaid number, or CDC number
  - Date and **time** of specimen collection
  - ICD diagnosis code(s)

- Section 3, Specimen Source or Type (please check appropriate box)

- 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 recent travel (especially international)
  - Please indicate if the patient has had animal contact (i.e., avian or swine) by writing "Animal contact" and the type of animal with which the patient had contact within the blank space on the G-2V form, section 4.

- Section 5, Ordering Physician Information
  - Ordering Physician's Name and NPI Number

- Section 6, Payor Source
  - Check with your Regional Influenza Surveillance Coordinator for instructions on completing payor source. See the appendix for contact information.

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

See the example G-2V form on page VI.17. The patient and specimen identifiers must match between the specimen tube and the G-2V form.

Effective September 1, 2016: All specimens must be labeled with at least two patient specific identifiers; both a primary and a secondary identifier. The identifiers must appear on both the primary container and the associated submission form. Please see the specimen acceptance criteria update letter at www.dshs.texas.gov/lab/PDF/SpecAcceptCriteria-TwoPatientIdentifiers-072516.pdf for additional details and acceptable patient identifiers.

Specimens must be packed in triple containment. When using influenza surveillance shipping supplies provided by DSHS, the VTM tube is the primary container, the plastic conical tube with a blue or white screw cap (labeled with a biohazard sticker) in which the VTM tube is placed is the secondary container, and the Styrofoam cold box is the tertiary container. Non-DSHS shipping supplies must meet IATA and other shipping regulations. Place enough paper towels or other absorbent material in the secondary container to absorb the entire contents of the VTM tube if leakage or breakage should occur. Be sure to tighten caps on the primary and secondary containers. Then place the Styrofoam box in a corrugated cardboard box (provided), and tape it for shipping. **Do not seal the Styrofoam lid.** (The cardboard shipping boxes provided by DSHS have a Styrofoam liner inside. Please keep these two units together; do not separate the Styrofoam box from the outer cardboard box.) Place a completed G-2V laboratory form for **each** specimen in the shipment on top of the Styrofoam box inside the cardboard box. If dry ice is used, do not tape the Styrofoam box; this allows venting of the carbon dioxide as the dry ice melts.

Influenza surveillance specimens fall under Category B shipping regulations; a specimen submitter must be familiar with the regulations for Category B in order to ship specimens in this category. For Category B shipments, the shipping box must be labeled with the following:

- 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)

Do not place a biohazard sticker on the outer mailing container. Category B shipments are accepted by FedEx and Lone Star Overnight. If it can be avoided, try not to use more than 5 pounds of dry ice in a shipping container because of limits for some of the shipping companies. It is the responsibility of the shipper to make sure that all packaging and labeling meet the current criteria.

Specimens should be shipped as soon as possible after collection and should arrive at the laboratory within 72 hours of collection (unless they are maintained frozen throughout shipping). It is recommended to collect specimens Monday through Wednesday and to ship Monday through Thursday. Please do not ship specimens to the DSHS or LRN laboratories on Friday unless it is an emergency and you have received approval from the appropriate laboratory, the DSHS Emerging and Acute Infectious Disease Branch (see the appendix for contact information) and the local health department (if applicable). Specimens should always be shipped using overnight mail.

The shipping address is:

Texas Department of State Health Services
Walter Douglass (512) 776-7569
Laboratory - MC 1947
1100 West 49th Street
Austin, TX 78756-3194

Specimen Rejection

Please be aware of the most common reasons for specimen rejection:

- Unfrozen specimens received at the laboratory more than 72 hours after specimen collection
- Submission of specimen types other than those listed on page VI.6
- Specimens arriving at ambient temperature
- Specimens collected with calcium alginate or wooden shaft swabs
- Specimens submitted in expired medium
- Broken or leaking specimen tubes
- Absence of patient identifiers on the specimen and/or the laboratory submission form
- Mismatch of patient identifiers between the specimen and the laboratory submission form
- No date of collection on submission form
- No specimen included with the submission form

Overview of the Texas Laboratory Response Network (LRN)

The Laboratory Response Network (LRN) was established in 1999 by the Department of Health and Human Services Centers for Disease Control and Prevention (CDC), in response to Presidential Decision Directive 39.

This network is comprised of state and local public health, federal, military and international laboratories. The main function of the LRN is to ensure that these laboratories have the capacity to respond to biological and chemical threats as well as other public health emergencies.

The LRN laboratories are categorized as either national, reference or sentinel laboratories based on their respective testing capabilities. National laboratories, such as the CDC, perform definitive testing of specimens that cannot be tested or confirmed by a reference laboratory due to its Biosafety Level rating. Reference laboratories, which include state public health, veterinary and international laboratories, provide confirmatory testing for many select agents. The sentinel laboratory category contains the largest number of laboratories and is composed of hospital, clinical and commercial diagnostic laboratories that perform routine diagnostic and rule-out testing in addition to referring specimens to reference laboratories.

In Texas there are ten LRN laboratories, one in each of the following cities: Corpus Christi, Dallas, El Paso, Fort Worth, Harlingen, Houston, Lubbock, San Antonio and Tyler. The DSHS Laboratory in Austin also functions as an LRN. The primary function of these laboratories is to respond to biological threats, emerging infectious disease and other public health emergencies; additionally, since 2008 the LRNs have performed influenza surveillance testing for select providers in their local areas.

The LRN laboratories perform a real time RT-PCR test to identify influenza types (A or B) and subtypes [2009 H1N1, seasonal A (H1N1), A (H3N2)], if applicable. The LRN laboratories also have the capability to test for influenza A (H5N1) and (H7N9) by RT-PCR. The typical turnaround time for influenza surveillance RT-PCR testing is 2–5 business days. Viral isolation and other testing for influenza is not available through the LRNs.

The LRN laboratories have different testing capacities and most assist in the recruiting of their influenza surveillance submitters. Please contact the local LRN laboratory for more information about its testing capacity, role in influenza surveillance and LRN-specific laboratory specimen submission form. Contact information for the LRNs is located in the appendix.

Frequently Asked Questions

General

Q1: Are supplies, shipping and testing provided free of charge for influenza surveillance specimens?

A1: Yes. Supplies (e.g., VTM and swabs) are available at no cost to influenza surveillance specimen submitters identified by the regional and local health departments; shipping (via FedEx) for influenza surveillance specimens is also free from designated submitters to the DSHS Laboratory in Austin. Influenza surveillance testing is provided free of charge as long as the approved submitter fills out the billing information correctly on the G-2V Specimen Submission Form.

Viral Transport Medium (VTM)

Q1: If I have expired VTM on hand that has not been used, what should I do with it?

A1: Unused expired VTM should be discarded according to your health department's policies and procedures. If your health department does not have policies and procedures for discarding expired VTM, DSHS recommends using the following procedure:

a. Place unused expired media into a cardboard box.
b. Tape the cardboard box shut.
c. Write "Do Not Recycle" on the outside of the cardboard box.
d. Throw the cardboard box containing the expired media into a trashcan.

Please do not send the expired VTM back to DSHS Austin.

Q2: If I don't have any VTM, can I submit an influenza specimen in saline?

A2: No. Influenza surveillance specimens must be submitted in medium suitable for viral transport like FTM, VTM or UTM.

Rapid Influenza Tests

Q1: The patient had a negative rapid influenza test result. Should I still submit a specimen from this person for influenza surveillance testing?

A1: Rapid influenza tests are less reliable than viral culture and PCR testing. If the rapid influenza test is negative but the physician strongly suspects influenza based on the clinical presentation, then we highly recommend submitting a nasopharyngeal specimen for confirmatory laboratory testing.

Swabs

Q1: Can I use a throat swab as a NP swab?

A1: NP swabs are typically smaller and more flexible than throat swabs and are more comfortable for patients.

Q2: Why can't I use a calcium alginate swab or a swab with a wooden shaft?

A2: The testing protocol for the rRT-PCR test performed in the DSHS Laboratory prohibits use of these types of swabs because they can inhibit the test.

Shipping

Q1: It is Friday and I want to submit an influenza specimen on a patient. Can I ship it today?

A1: It is better to freeze the specimen and ship it frozen on dry ice on Monday. Some shipping companies do not deliver on Saturday, and there are no laboratory staff members on duty during the weekend to ensure that the specimen is stored properly over the weekend. If there is an urgent need for testing, contact the Influenza Surveillance Team to coordinate shipping.

Instructions for Completing the G-2V Specimen Submission Form* for Influenza Laboratory Surveillance

*Note: Instructions in this document refer to the DSHS G-2V Specimen Submission Form (JUL 2016).

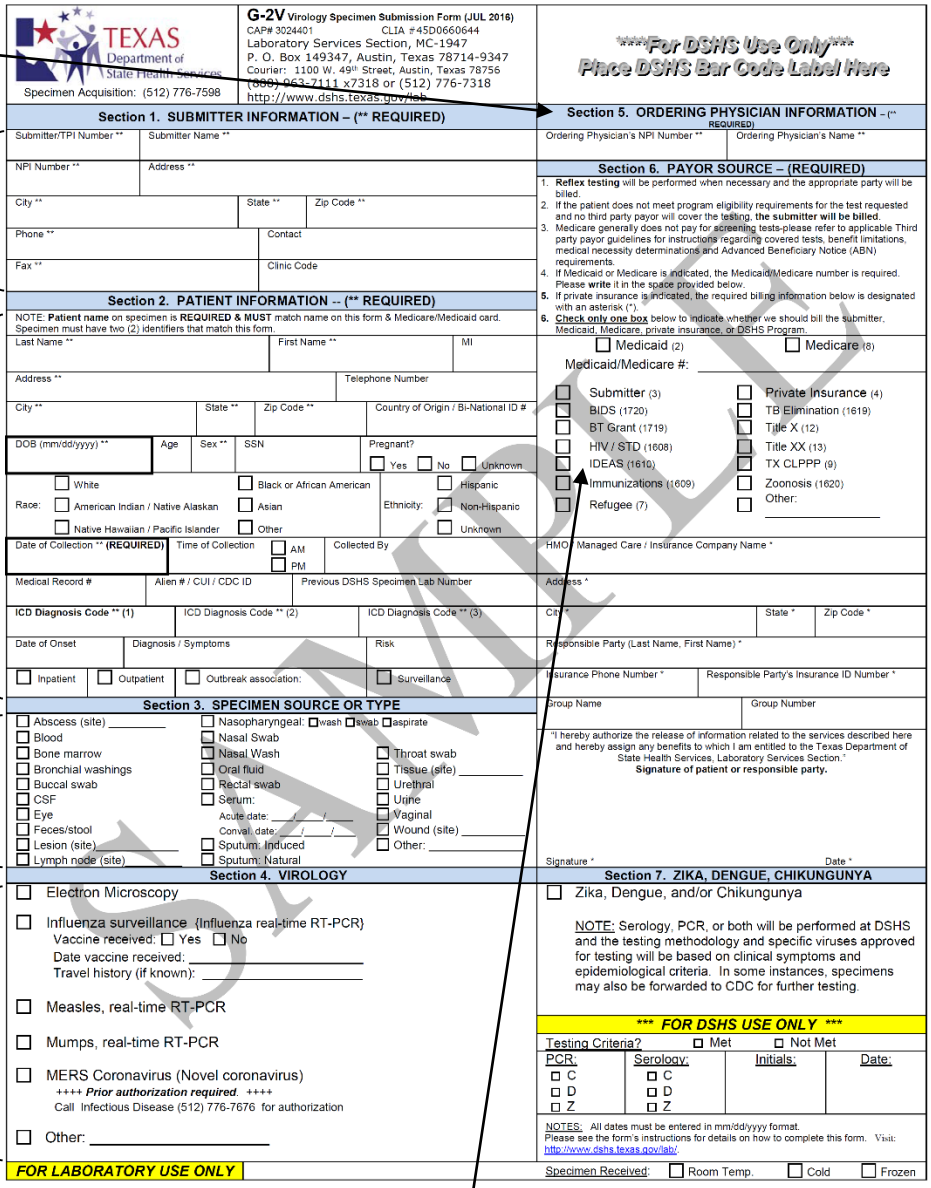
Complete Section 5, "Ordering Physician Information," by providing the physician's name and NPI number.

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 (or other approved secondary identifier** [see page VI.11]), 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}". Indicate patient's flu vaccination status for the current season and date of vaccination, if known. If applicable, indicate patient travel history. If applicable, in the blank space write "Animal contact" and the type of animal with which the patient had contact.



TEXAS Department of State Health Services

Specimen Acquisition: (512) 776-7598

G-2V Virology Specimen Submission Form (JUL 2016)
CAP# 3024401 CLIA #45D0660644
Laboratory Services Section, MC-1947
P. O. Box 149347, Austin, Texas 78714-9347
Courier: 1100 W. 49th Street, Austin, Texas 78756
(888) 963-7111 x7318 or (512) 776-7318
http://www.dshs.texas.gov/lab

*** For DSHS Use Only ***
Place DSHS Bar Code Label Here

Section 1. SUBMITTER INFORMATION – (REQUIRED)**
Submitter/TPI 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. Specimen must have two (2) identifiers that match this form.
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 ☐ American Indian / Native Alaskan ☐ Asian ☐ Native Hawaiian / Pacific Islander ☐ Other
Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown
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) _____
☐ Blood
☐ Bone marrow
☐ Bronchial washings
☐ Buccal swab
☐ CSF
☐ Eye
☐ Feces/stool
☐ Lesion (site) _____
☐ Lymph node (site) _____
☐ Nasopharyngeal: ☐wash ☐swab ☐aspirate
☐ Nasal Swab
☐ Nasal Wash
☐ Oral fluid
☐ Rectal swab
☐ Serum:
Acute date: __/__/__
Convalescent date: __/__/__
☐ Sputum: Induced
☐ Sputum: Natural
☐ Throat swab
☐ Tissue (site) _____
☐ Urethral
☐ Urine
☐ Vaginal
☐ Wound (site) _____
☐ Other: _____

Section 4. VIROLOGY
☐ Electron Microscopy
☐ Influenza surveillance {Influenza real-time RT-PCR}
Vaccine received: ☐ Yes ☐ No
Date vaccine received: _____
Travel history (if known): _____
☐ Measles, real-time RT-PCR
☐ Mumps, real-time RT-PCR
☐ MERS Coronavirus (Novel coronavirus)
++++ *Prior authorization required.* ++++
Call Infectious Disease (512) 776-7676 for authorization
☐ Other: _____

FOR LABORATORY USE ONLY

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.
Signature * | Date *

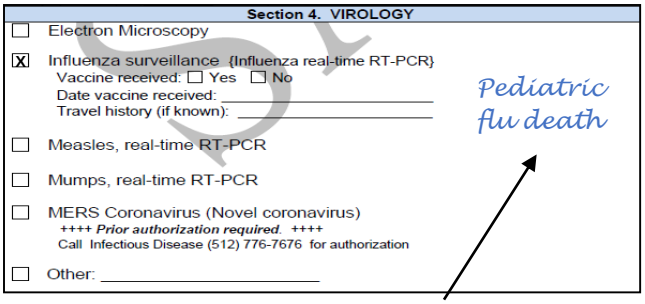
Section 7. ZIKA, DENGUE, CHIKUNGUNYA
☐ Zika, Dengue, and/or Chikungunya
NOTE: Serology, PCR, or both will be performed at DSHS and the testing methodology and specific viruses approved for testing will be based on clinical symptoms and epidemiological criteria. In some instances, specimens may also be forwarded to CDC for further testing.

*** FOR DSHS USE ONLY ***
Testing Criteria? ☐ Met ☐ Not Met

PCR:	Serology:	Initials:	Date:
☐ C	☐ C		
☐ D	☐ D		
☐ Z	☐ Z		

NOTES: All dates must be entered in mm/dd/yyyy format.
Please see the form's instructions for details on how to complete this form. Visit: http://www.dshs.texas.gov/lab/

Specimen Received: ☐ Room Temp. ☐ Cold ☐ Frozen

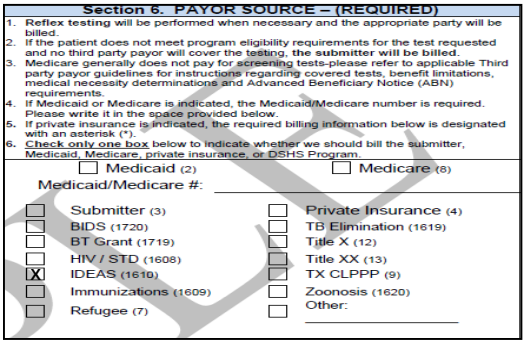


Section 4. VIROLOGY
☐ Electron Microscopy
☒ Influenza surveillance {Influenza real-time RT-PCR}
Vaccine received: ☐ Yes ☐ No
Date vaccine received: _____
Travel history (if known): _____
☐ Measles, real-time RT-PCR
☐ Mumps, real-time RT-PCR
☐ MERS Coronavirus (Novel coronavirus)
++++ *Prior authorization required.* ++++
Call Infectious Disease (512) 776-7676 for authorization
☐ Other: _____

Pediatric flu death

When submitting priority specimens, indicate reason for submission in blank space to the right of the Influenza Surveillance information in Section 4 (e.g., "pediatric flu death", "severe illness", "travel to China", etc.).

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



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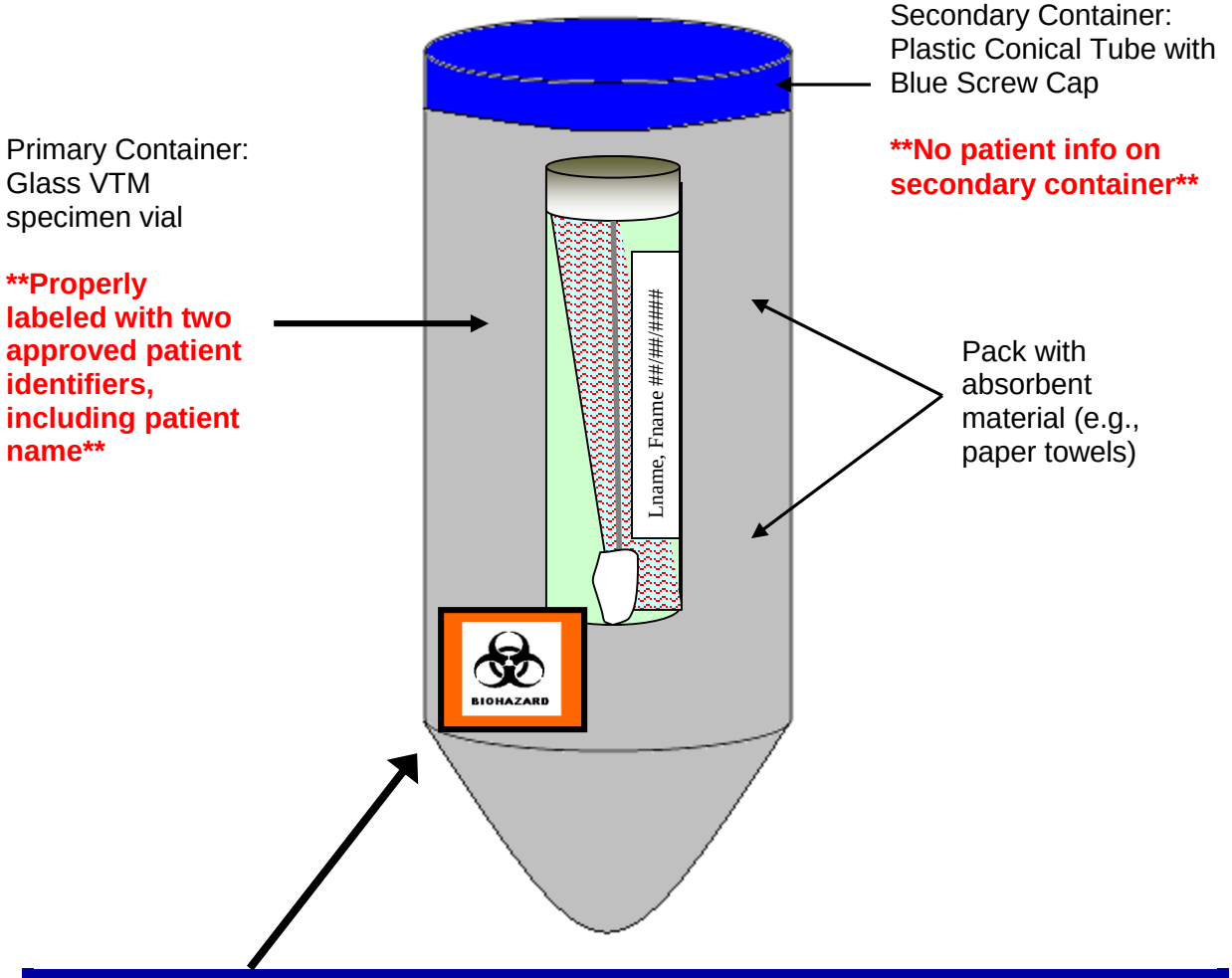
☐ HIV / STD (1608) ☐ Title XX (13)
☒ IDEAS (1610) ☐ TX CLPPP (9)
☐ Immunizations (1609) ☐ Zoonosis (1620)
☐ Refugee (7) ☐ Other: _____

Packaging Diagram 1

Packaging and Labeling of Biological Substances, Category B

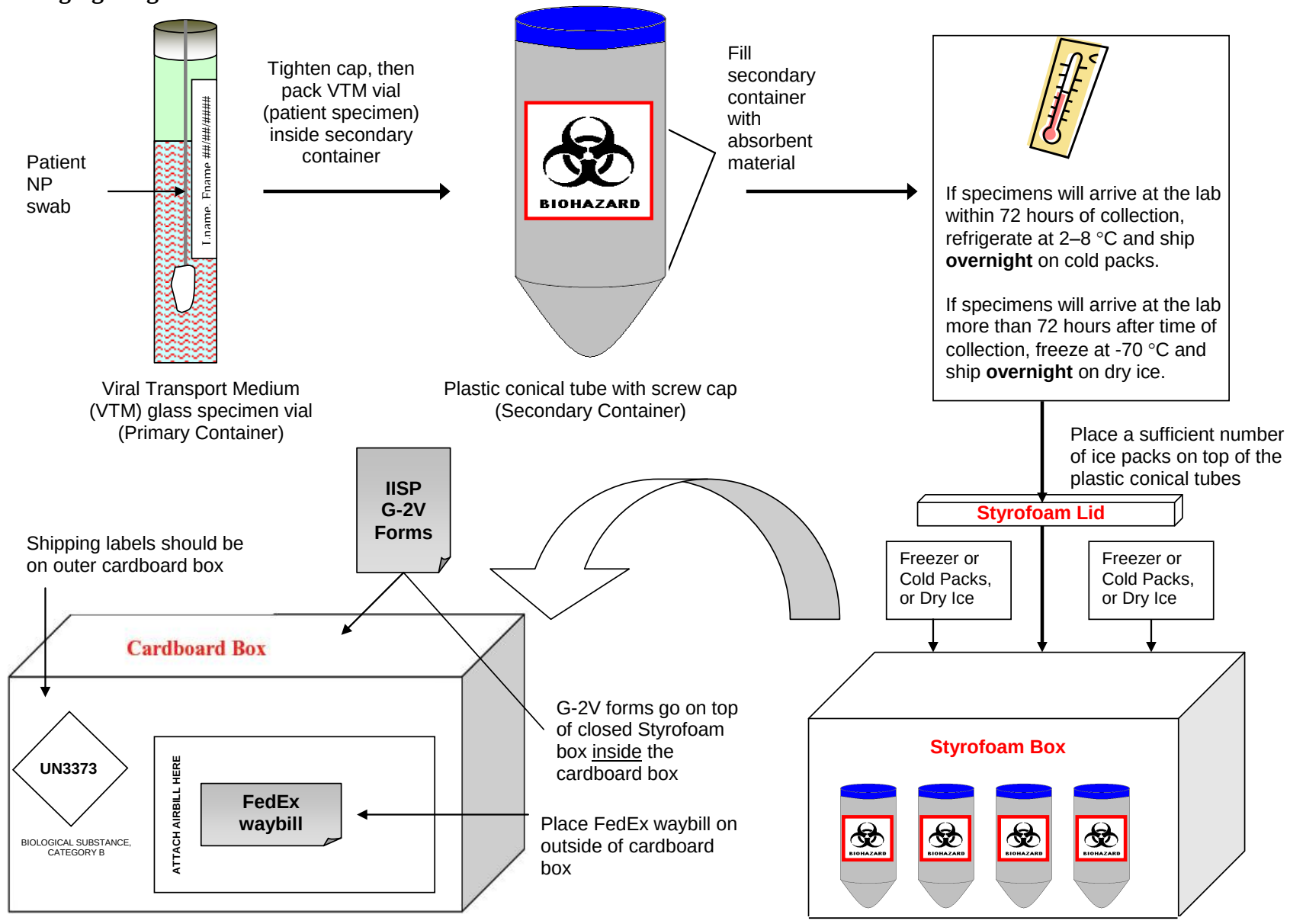
Do not put any patient information on outer or secondary containers or lids



Biohazard Label should already be on outside of secondary container

DO NOT put biohazard label on outer container

Packaging Diagram 2



Viral Transport Medium (VTM) glass specimen vial (Primary Container)

Plastic conical tube with screw cap (Secondary Container)

VTM Order Form Example

Information for site that will receive the VTM							Information on person ordering VTM (if different from person receiving VTM)			VTM Order--Initial Shipment			
Facility/Culture Surveillance Site Name	Shipping Address	City	Zip	Name of person receiving order	Phone number of person receiving order	E-mail for Person receiving order	Name of person placing order	Phone Number of person placing order	E-mail of person placing order	Number of VTM tubes requested	If this order is for multiple sites, how many sites?	Large or small volume site? (small is <8 specimens submitted to lab weekly; large is >8 specimens	Number of specimen shipping boxes (aka cold boxes) requested
Health Clinic A	111 Any Street	Austin	78758	Mary Smith	512-299-1111	mary.smith@healthclinic.com	Jake Doe	512-678-9999	jake.doe@dshs.state.tx.us	20	n/a	small	2