

UT HEALTH EAST TEXAS-	PHLET
SECTION: Public Health Laboratory of East Texas	SOP# 5-0004.1
PROCEDURE: Collecting and Submitting Biothreat and Chemical Threat Samples	
MANUAL:	
PAGE: _____ of _____	
REPLACES: 5-0004 Collecting and Submitting Biothreat and Chemical Threat Samples 2023	
EFFECTIVE DATE:	RETIRED DATE:
PREPARED BY: Janine Yost BS, MT (ASCP) and Jessica Lisenbe, BS, M(ASCP) ^{CM}	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
_____	_____	_____	_____
_____	_____	_____	_____
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SPECIMEN SUBMISSION AND PACKING/SHIPPING

PRINCIPLE:

The LRN sentinel laboratory responsibilities include specimen collection for clinical specimens, packaging, and shipment of suspected biothreat agents to a Texas LRN laboratory for confirmatory testing. The Public Health Laboratory of East Texas (PHLET) is the confirmatory LRN facility for Public Health Region 4/5 North. In order to better assist the sentinel laboratories in correctly performing these tasks, this procedure has been compiled for their use. The Texas DSHS website is a valuable resource which may be used as a guide for shipping infectious substances as well as determining appropriate samples for submission to PHLET, DSHS, the CDC or other entity. See the links below:

<https://www.uttyler.edu/academics/colleges-schools/health-science-center/public-health-lab-of-east-texas-overview/>

<http://www.dshs.state.tx.us/lab/epr.shtm>

http://www.dshs.state.tx.us/lab/mrs_shipping.shtm

DEFINITIONS:

- A. Reference Labs** sometimes referred to as “confirmatory reference,” can perform tests to detect and confirm the presence of a threat agent. These labs ensure a timely local response in the event of a terrorist incident. Rather than having to rely on confirmation from labs at CDC, reference labs are capable of producing conclusive results. This allows local authorities to respond quickly to emergencies.
- B. Sentinel Labs** represents the thousands of hospital-based labs that are on the front lines. Sentinel labs have direct contact with patients. In an unannounced or covert terrorist attack, patients provide specimens during routine patient care. Sentinel labs could be the first facility to spot a suspicious specimen. A sentinel laboratory’s responsibility is to refer a suspicious sample to the right reference lab.
- C. Infectious Substances Category A** is an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.
- D. Category B** – An infectious substance, which does not meet the Category A criteria.
- E. Exempt Human/Animal Specimens** – Human and Animal specimens that are not known to be infectious and are not being tested for anything infectious.
- F. Dry Ice**- Carbon dioxide (solid), CO₂(s). Commonly used refrigerant in transport that is considered a hazardous material when transported by aircraft and requires the UN1845 hazmat label.

Proper Shipping Names

- 1 UN3373 *Biological substance Category B*
- 2 UN2814 *Infectious Substance, Affecting Humans*
- 3 UN2900 *Infectious Substance, Affecting animals only*
- 4 UN1845 *Dry Ice*
- 5 Exempt Human Specimen
- 6 Exempt Animal Specimen

SPECIMEN/SAMPLE HANDLING

A. BIOLOGICAL THREATS

1. Environmental Samples

- a. Environmental samples must be coordinated with the FBI and/or other law enforcement agencies. Sentinel laboratory personnel should **not** accept any suspicious environmental sample in the hospital setting. Immediately contain a suspicious substance and notify your local law enforcement and PHLET personnel. All environmental samples that are collected for biological testing in response to a real or perceived threat must be coordinated through law enforcement. The FBI must be notified and will coordinate the activities involved with the testing of the specimens. HAZMAT is trained in the collection, labeling, screening and packaging of environmental specimens. The Federal Bureau of Investigation is the lead federal agency tasked with directing the interagency response to acts of terrorism. Any and all information pertaining to the analysis of potential evidence samples is not to be released to the public and should only be conveyed to the appropriate law enforcement officials.

2. Clinical Samples

- a. Sentinel laboratories are expected to follow LRN rule-out protocols. Any isolates that cannot be ruled-out of a possible biothreat agent should be submitted to an LRN laboratory for further testing. The isolates should be inoculated to an agar slant or placed into a transport medium in accordance with package insert instructions.
- b. In the case of an overt threat, the sentinel laboratories not capable of completing rule-out protocols should submit clinical specimens for testing. See Appendix D.
- c. All biological threat specimens must be triple contained in an approved shipping container and packed according to the regulations in 49-CFR class 6.2. Specimens must be accompanied by a PHLET Specimen Submission Form and submitted by overnight delivery. Submitting laboratory personnel must contact PHLET prior to shipment of any biological threat specimens and a chain of custody and a receipt of property forms must be completed and included with the specimen (See Appendix H). Labelling on specimen and paperwork must match exactly and contain patient name and at least one other unique identifier. (such as date of birth, medical record number)
- d. In response to a real or perceived threat, the sentinel laboratory should preserve the original specimens, plates, cultures, and subcultures pursuant to a potential criminal investigation, and notify an LRN laboratory.
- e. See Appendix B for a list of sample types and storage requirements.

B. CHEMICAL THREATS

1. Specimen Types (collect the following from each potentially exposed adult person):

- a. **Whole blood**
See Appendix C.
 - b. **Urine**
FREEZE IMMEDIATELY (-70°C, dry ice, or -50°C gel packs preferred) See Appendix C.
 - c. **Specimen Types/Controls**
In addition, for **each lot number** of tubes and urine cups used for collection, please provide two empty unopened purple-top tubes, two empty unopened green-top (or gray-top) tubes, and two empty unopened urine cups to serve as blanks for measuring background contamination. See Appendix C.
- Must be triple contained in an approved shipping container and packaged according to Category B biological substances. Unless otherwise specified by CDC, these specimens must be submitted to the Texas Department of State Health Services Laboratory, 1100 West 49th Street, Austin, TX 78756 and accompanied by a Specimen Submission Form (G-2B).
 - PHLET personnel are trained and able to assist in Chemical threat specimen collection. PHLET personnel are certified shippers and can assist in packaging and shipping those samples to Austin for testing.

C. FOODS

PHLET does not perform food testing. All food testing must be submitted through Public Health Sanitarians. Please contact your local health department or regional/state health department agency for assistance in referring samples to the appropriate agency for food testing.

D. RADIOLOGICAL SAMPLES

If a patient or sample is suspected of being radioactively contaminated, laboratory personnel should contact the facility's Radiation Safety Officer or the DSHS Radiation Control Program at 512-834-6770.

E. WATER SAMPLES

1. For routine testing of drinking water, including testing for coliforms and *E. coli*, contact the local health department
2. In requesting water testing for possible biological agents or chemical agents, contact PHLET for assistance with collection and shipping.
3. Water samples are not considered to pose serious infection risk may be exempt from dangerous goods requirements and regulation.

F. MILK

All milk and dairy products must be collected and shipped by a sanitarian. Test requests are coordinated by the sanitarian. Contact local health department for testing.

INSTRUCTIONS FOR USE OF MATERIALS AND FORMS**A. Packaging Materials****1. Primary Packaging**

- Primary receptacle(s) must be watertight, e.g., screw cap sealed with Parafilm or adhesive tape or similar positive means to prevent the cap from loosening and leaking.
- Multiple primary receptacles must be wrapped individually to prevent breakage. Multiple primary receptacles may be individually wrapped and secured together to cushion them and prevent their movement within the secondary container.
- Primary receptacle(s) must not contain more than not more than 50 ml or 50 g of Category A infectious substances by passenger aircraft, 4 kg or 4L / of Category A infectious substances by cargo aircraft. Category B must not contain more than 1kg or 1L of infectious material per primary container and not more than 4L or 4kg of total infectious material per package. It is a good practice to enclose all primary containers within a biohazard labeled ziplock bag before placing into the secondary container.

2. Secondary Packaging

- Use enough absorbent material in the secondary container to absorb the entire contents of all primary receptacles in case of leakage or damage.
- Secondary packaging must be leak-proof. Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.
- Secondary packaging for Category A, B, and Exempt specimens may be sealed in IATA/CFR approved secondary containers, which may be ridged screw-top containers or sealed leak-proof bags capable of withstanding without leakage, an internal pressure of 95 kPa (0.95 bars).

3. Outer Packaging

- The outer package may be made of cardboard or paper fiberboard and must meet the IATA packaging requirements including the 1.2 meter (for diagnostic specimens)/9 meter (for infectious specimens) drop test procedure.
- Either dry ice or wet ice must be placed outside the secondary packaging for samples that must be transported cold or frozen.
- **Dry ice:** packaging must permit the release of carbon dioxide gas and not allow a build-up of pressure that could rupture the packaging. The packaging must also meet general requirements for packages under IATA and DOT regulations.
- **Wet ice:** packaging must be leak-proof. Ice packs are preferred for Category B, Exempt Human/Animal Specimens and infectious substances.
- The outer packaging must be no less than 100 mm (4 inches) in the smallest overall external dimension and must be large enough for shipping documents.
- **See Appendix "D" for packaging diagrams of Category A, B, and Exempt Human/Animal Specimens.**

C. Forms

1. Public Health Laboratory of East Texas (PHLET) Submission Forms

Biological threat samples that are sent to PHLET must have a completed submission form for each patient. A copy of the submission form and instructions for completing the form can be found in Appendix "I" or at <https://www.utt Tyler.edu/academics/colleges-schools/health-science-center/forms-procedures/>

2. Form G-2B

Chemical threat samples that are sent to DSHS in Austin must have a completed G-2B form for each patient. DSHS Austin assigns each laboratory a unique submitter number, so the submitting laboratory must obtain the form from DSHS. Call 512-458-7661 to order forms by phone or go to http://www.dshs.state.tx.us/lab/MRS_forms.shtm for instructions on ordering forms by email. A sample form and ordering instructions are also available at the website listed above. Form G-2B can also be used to submit specimens for bacteriology or parasitology exams.

3. Receipt for Property Received/Returned and Chain of Custody

When a sample is transferred from law enforcement, a sanitarian or a sentinel laboratory, a Receipt for Property Received/Returned form must be filled out by the submitter and the receiver. An example of this form can be found in Appendix "H".

4. Chain of Custody

If a clinical specimen or isolate is known or suspected to be associated with a biological or chemical attack, or if suspicious circumstances are involved regarding the patient from whom the sample was collected, all persons who have contact with the specimen must document their involvement with that specimen. This documentation is maintained on a Chain of Custody form. The sentinel laboratory is responsible for maintaining its own chain of custody documentation. The sentinel laboratory would retain the original form(s) and submit a copy of the form(s) with the specimen. In the event that a carrier/courier is used to transfer a sample, the name of the carrier/courier and the shipping/reference number should be recorded in this documentation. An example of this form can be found in Appendix "H".

5. Shipper's Declaration

Documentation of shipping infectious substances is accomplished by properly completing a Shipper's Declaration. A Shipper's Declaration is **required** for Category A shipments and is **NOT required** for Category B or Exempt Human/Animal specimens. A Shipper's Declaration can be downloaded from a carrier's website. Generalized Shipper's Declarations are available, however, most carriers require the use of their specific Shipper's Declaration. In addition, the shipping declaration **MUST** be printed in color and produced using Fed EX approved computer software. Handwritten declarations are not allowed. The Shipper's Declaration is completed and signed by the shipper and is a legal contract between the shipper and the carrier. Carrier and Federal Aviation Administration inspectors have a duty and the right to examine the Shipper's Declaration and the contents of package to determine the degree to which the shipper complied with regulations. Only the shipper may complete the document. All corrections in a Shipper's Declaration must be neatly "lined out" and any changes must be signed (not initialed) by the same person who signed the document. Do not use whiteout. A Shipper's Declaration contains 20 fields that must be complete and absolutely correct. Appendix "G" contains instructions for filling out a Shipper's Declaration, an example of a Shipper's Declaration and a checklist.

SHIPPING OPTIONS:

A Guidance document for Packing and Shipping Procedures is available online

[LRN Sentinel Level Clinical Laboratory Protocols \(asm.org\)](https://asm.org/Articles/CPHMC/Laboratory-Response-Network-LRN-Sentinel-Level-C) (<https://asm.org/Articles/CPHMC/Laboratory-Response-Network-LRN-Sentinel-Level-C>)

The DSHS laboratory and Texas LRNs will provide packing and shipping protocols. Each sentinel laboratory is responsible for the development of a plan for the submission of samples outside of routine work hours. Cost and method of shipping will depend on location, distance, and time of day the specimen/sample will have to travel. Several options are available to submitter:

- FedEx has services that can handle a Category A shipment. The white gloves section at [1.866.274.6117](tel:18662746117) has dedicated charter shippers that can transport by air or ground as fast as needed. See <http://customcritical.fedex.com/> for details
- World Courier can provide Category A shipping to Texas laboratories. <http://www.worldcourier.com/>
Or call 408-871-1862
- Courier services that are available for the regional area must be capable of delivering dangerous, diagnostic or infectious goods. It is important to remember that it is the responsibility of the shipper to ensure that the courier is approved for the type of shipment that is being transported.
- Laboratories not able to find an appropriate shipping service may contact their local or regional health departments or PHLET laboratories for assistance. PHLET will NOT provide shipping for sentinel laboratories, however, we may be able to assist you with finding a carrier, courier, or other means through our many partner that could aid you in shipping your sample.

NOTE: For suspected Biothreat samples, a shipper may choose to ship a sample suspected of containing a select agent using the technical name "Suspected Category A". At the time of this writing, FedEx will **not** accept shipments of confirmed Select Agent shipments. World Courier will accept all Category A including select agent shipments.

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: Microbiologist or send via secure email to Jessica.lisenbe@uttyler.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

NOTES:

- Any suspected case of bioterrorism organism should be reported immediately to the local state health department and laboratory for review. Transport should be arranged immediately to facilitate diagnosis.***
- * If smallpox is suspected, CDC's Poxvirus Section @ 404-639-2184 will be notified for approval prior to packaging and shipping of sample. Sample should be held at submitting institution until CDC's approval is gained.***
- If Ebola is suspected, contact Texas DSHS EAIDS Branch Epidemiologist; and CDC Emergency Operation Center. . Sample should be held at submitting institution until CDC's approval is gained.***

APPENDIX "A" – Contact Information

Public Health Laboratory of East Texas (PHLET)

11949 US Hwy 271

Tyler, TX 75708

Phone 903-877-5071

Fax 903-877-5259

Texas Department of State Health Services- Laboratory Services Section

1100 W. 49th Street MC-1947

Austin, TX 78756-3199

Phone 512-458-7318

Fax 512-458-7294

Toll Free 888-963-7111, ext. 7318

HEALTH DEPARTMENTS AND HEALTH DISTRICTS OF EAST TEXAS<http://www.dshs.texas.gov/regions/default.shtm>

HEALTH SERVICE REGION 4/5 NORTH - Tyler

Sharon Huff, M.D., M.S., Regional Medical Director

Regional Headquarters: 2521 West Front Street, Tyler, Texas 75702, Mail Code 1901

Phone: (903) 595-3585 FAX: (903) 593-4187

A list of Texas Local Public Health Organizations can be found at:

<https://www.dshs.texas.gov/regional-local-health-operations/public-health-regions/texas-local-public-health>**Poison Control (for Chemical and Radiological Events)***"Texas Poison Center Network and Terrorism", contact your poison center at 1-800-222-1222*Emergency Number 1-800-222-1222 <http://www.poisoncontrol.org/>

APPENDIX "B" – Biological Specimen Collection Guide

Refer to ASM Sentinel protocols and call PHLET at 903-877-5071 for specific sample questions.

DISEASE/AGENT	SPECIMEN SELECTION		Time & Temp	
			Transport	Storage
Anthrax (<i>Bacillus anthracis</i>)	Cutaneous	Vesicular Stage: collect fluid from intact vesicles on sterile swab(s). The organism is best demonstrated in this stage.	≤2 h RT	≤24 h RT
		Eschar Stage: without removing eschar, insert swab beneath the edge of eschar, rotate and collect lesion material.	≤2 h RT	≤24 h RT
	Gastro-intestinal	Stool: collect 5-10 g in a clean, sterile, leakproof container.	≤1 h RT	≤24 h 2-8°C
		Blood: collect per institution's procedure for routine blood cultures.	≤2 h RT	Incubate per lab protocol
	Inhalation	Sputum: collect expectorated specimen into a sterile, leakproof container.	≤2 h RT	≤24 h RT
		Blood: collect per institution's procedure for routine blood cultures.	≤2 h RT	Incubate per lab protocol
Brucellosis (<i>Brucella</i> spp.)	Acute, Subacute or Chronic	Serum: collect 10-12 cc acute phase specimen as soon as possible after disease onset. Followed by a convalescent specimen, obtained 14 to 21 days later	≤2 h RT	≤-20°C
		Blood: collect per institution's procedure for routine blood culture.	≤2 h RT	Incubate per lab protocol
		Bone Marrow: collect per institution's surgical/ pathology procedure	≤2 h RT	≤24 h 2-8°C
		Tissue, Spleen or Liver: Submit in sterile container, may add 1-2 drops of saline to keep moist Other specimen types may be accepted-see ASM protocols		≤24 h RT

Plague (<i>Yersinia pestis</i>)	Pneumonic	Sputum/throat: collect routine throat culture using a swab or expectorated sputum collected into a sterile, leakproof container.	≤2 h RT	≤24 h 2-8°C
		Bronchial/tracheal wash: collect per institution's procedure in an area dedicated to collecting respiratory specimens under isolation/ containment circumstances, i.e., isolation chamber/ "bubble".	≤2 h RT	≤24 h 2-8°C
		Blood: collect per institution's procedure for routine blood cultures.	≤2 h RT	Incubate per lab protocol
	Bubonic	Tissue or aspirate: Submit in sterile container, may add 1-2 drops of saline to keep moist	≤2 h RT	≤24 h 2-8°C
Tularemia (<i>Francisella tularensis</i>)	Pneumonic	Sputum/throat: collect routine throat culture using a swab or expectorated sputum collected into a sterile, leakproof container.	≤2 h RT	≤24 h 2-8°C
		Bronchial/tracheal wash: collect per institution's procedure in an area dedicated to collecting respiratory specimens under isolation/ containment circumstances, i.e., isolation chamber/ "bubble".	≤2 h RT	≤24 h 2-8°C
		Blood: collect per institution's procedure for routine blood cultures.	≤2 h RT	Incubate per lab protocol
		Biopsy, tissue, scrapings, aspirate or swab: Submit in sterile container. For small tissue samples add several drops of sterile normal saline to keep tissue moist. Swabs are collected by obtaining firm sample of advancing margin of the lesion. Place swab in transport package to keep swab moist with the transport medium inside packet.	≤2 h RT	≤24 h 2-8°C

Glanders & Melioidosis (<i>Burkholderia mallei</i> & <i>pseudomallei</i>)		Blood or Bone Marrow: collect using standard automated blood culture system per institution's procedure for routine blood culture.	≤2 h RT	≤24 h 2-8°C
		Sputum/Bronchial: collect into sterile leakproof container	≤2 h RT	≤24 h 2-8°C
		Abscess material and wounds: tissue aspirate, tissue fluid preferred to swab alternative	≤2 h RT	≤24 h 2-8°C
		Urine:	≤2 h RT	≤24 h 2-8°C
		Serum: collect (≥1 mL) acute phase specimen as soon as possible after disease onset. Followed by a convalescent specimen, obtained 14-21 days. Specimens should be collected if serologic diagnosis is available in the United States.		
Smallpox (<i>Variola virus</i>) PHLET will test low and medium risk samples, high risk samples will be forwarded to CDC	Required consult with health department Pustular Rash Illness	Biopsy specimens: aseptically place two to four portions of tissue into a sterile, leakproof, freezable container.	~6 h 2-8°C	-20°C to -70°C
		Scabs: aseptically place scrapings/material into a sterile, leakproof, freezable container.	~6 h 2-8°C	-20°C to -70°C
		Vesicular fluid: collect fluid from separate lesions onto separate sterile swabs. Be sure to include cellular material from the base of each respective vesicle.	~6 h RT	-20°C to -70°C
Mpox (<i>Non-variola orthopoxvirus</i>)	Required consult with health department	Dry swab: collect 2 swabs from each lesion, preferably from different sites on the body or from lesions that differ in appearance. Vigorously swab each lesion, avoiding contamination of gloved hands, to ensure adequate viral DNA is collected.	2-8°C ASAP	2-8°C up to 7 days. ≤-20°C for 60 days.
Unknown virus	Required consult with health department	Specimen and storage/shipping will depend on health department assessment	TBD	TBD

APPENDIX “C” – Chemical Specimen Collection and Submission Diagrams

For guidance on Chemical terrorism events refer to CDC web link:

<https://emergency.cdc.gov/chemical/lab.asp>

Required Specimens for Chemical threat testing

Unless otherwise directed, collect the following specimens from each person who may have been exposed:

Whole blood

- Collect blood specimens from adults only unless you receive specific instruction from CDC to collect blood from pediatric patients.
- Collect a minimum of 12 mL of blood.
- Use three 4-mL or larger vacuum-fill only (unopened), non-gel, purple-top (EDTA) tubes; use four tubes if using 3-mL tubes.
- Using indelible ink, mark each purple-top tube of blood *in the order collected* (e.g., # 1, # 2, # 3, # 4 [if using 3-mL tubes]).
- In addition, collect another specimen using one 3-mL or larger, vacuum-fill only (unopened), non-gel, green- or gray-top tube. Allow the tube to fill to its stated capacity.

Urine

- Collect at least 40-60 mL from potentially exposed adults and children.
- Use a screw-cap plastic container; do not overfill.
- Freeze specimen as soon as possible (–70 °C or dry ice preferred).
- If other than “clean catch”, note method of collection on the specimen cup (e.g., obtained by catheterization).

Blanks

For each lot number of tubes and urine cups used for collection, provide the following to be used as blanks for measuring background contamination:

- Two (2) empty, unopened purple-top tubes.
- Two (2) empty, unopened green- or gray-top tubes.
- Two (2) empty, unopened urine cups.

Chemical Specimens may be sent to DSHS Austin for testing or to the CDC depending on the agent. To refer a sample to DSHS Austin Chemical threat response team, call (512) 634-6730. If required, the DSHS Austin Chemical threat team will be able to assist you in submitting samples to the CDC for chemical testing. Patient Samples sent for chemical testing regardless of the chemical are going to be category B and should be shipped according to Category B regulations regardless of which agency they are sent to.

CDC Specimen-Collection Protocol for a Chemical-Exposure Event

For detailed instructions see CDC's Shipping Instructions for Specimens Collected from People Who May Have Been Exposed to Chemical-Terrorism Agents.

Collect blood and urine samples for each person involved in the chemical-exposure event.

Note: For children, collect only urine samples unless otherwise directed by CDC.

Blood-Sample Collection

For each person, collect blood in glass or plastic tubes in the following order: 1st: collect specimens in three (3) EDTA (purple-top) 4 mL or larger plastic or glass tubes; 2nd: collect another specimen in one (1) gray- or green-top tube. Collect the specimens by following the steps below:

1 Collect a minimum of 12 mL of blood in three (3) 4 mL or larger glass or plastic tubes. If using 3 mL tubes, use four tubes.



Do not use gel separators.

2 Mix contents of tubes by inverting them 5 or 6 times.



Label tubes in order of collection. #1, #2, #3

3 Place bar-coded labels on each tube, so that when the tubes are upright, the barcodes look like a ladder.



Store samples at 1°C to 10°C. Do not freeze.

4 After collecting samples in the purple-top tubes, collect one (1) sample in a gray- or green-top tube (gray-top tube shown). Allow the tube to fill to its stated capacity.



Do not use gel separators.

5 Mix contents of the tube by inverting it 5 or 6 times.



6 Place bar-coded labels on the tube, so that when the tube is upright, the barcodes look like a ladder.



Store samples at 1°C to 10°C. Do not freeze.

Urine-Sample Collection

For each person, collect 25 mL- 50 mL of urine in a screw-cap urine cup.



Label the urine cup with the appropriate bar-coded label as shown. Indicate on the cup how the sample was collected if the method was other than "clean catch" (i.e., catheterization).
Freeze samples (optimally at -70°C).



Place bar-coded labels on all cups so that when the cup is upright, the barcodes look like a ladder.

11/2008



Instructions for Shipping Urine Specimens to CDC after a Chemical-Exposure Event

Guidance in Accordance with Packaging Instructions International Air Transport Authority (IATA) 650 Biological Substance Category B

For detailed instructions, see CDC's Shipping Instructions for Specimens Collected from People Who May Have Been Exposed to Chemical-Terrorism Agents.



1 Use a gridded box or individually wrapped cups sealed with evidence tape to separate urine cups. Place absorbent material in the bottom of the box and insert the cups.



2 Use one continuous piece of evidence tape to seal the gridded box or Saf-T-Pak liner leak-proof polybag (or equivalent) containing wrapped urine cup(s). Write initials half on the evidence tape and half on the box or bag.



3 Wrap the gridded box with absorbent material and secure with tape. Seal the box inside a Saf-T-Pak liner leak-proof polybag (or equivalent).



4 Place the sealed Saf-T-Pak liner leak-proof polybag (or equivalent) inside a white "tyvek" outer envelope (or equivalent). **Note: If primary receptacles do not meet the compact secondary packaging materials,**



5 Seal the opening of this envelope with a continuous piece of evidence tape. Write initials half on the evidence tape and half on the envelope.



6 Use polystyrene foam-insulated, corrugated fiberboard shipper to ship boxes to CDC. Place absorbent pad in the bottom of the shipper.



7 Place a layer of dry ice in the bottom of the shipper on top of the absorbent material. **DO NOT** use large chunks or flakes of dry ice.



8 Place the packaged urine cups in the shipper. Use absorbent material or cushioning material to minimize shifting while box is in transit. Place additional dry ice on top of samples.



9 Place the urine shipping manifest in a sealable plastic bag and put on top of the sample boxes inside the shipper. Keep your chain-of-custody documents for your files. Place lid on the shipper.



10 Secure the outer container lid with fiberboard shipping tape. Place your return address in the upper left-hand corner of the shipper top and put the CDC Laboratory receiving address in the center.



11 Add the UN 3373 label and the words "Biological Substance Category B" on the front of the shipper. UN 3373 is the code identifying the shipper's contents as "Biological Substance, Category B."



12 Place a Class 90UN 1845 label on the front of the shipper. This label for dry ice **MUST** indicate the weight of dry ice (in kg) in the shipper and the proper name (either dry ice or carbon dioxide, solid).



13 Send shipment via FedEx to:
Centers for Disease Control and Prevention
Alan L. Ernest McGabine
4770 Buford Hwy.
Building 110 Loading Dock
Atlanta, GA 30341
(770) 488-7579

For questions concerning this process, please contact:
Centers for Disease Control and Prevention
Alan C. Cecilia Sanders, Chemical Emergency Response Team Leader
4770 Buford Hwy.
Building 110 Loading Dock
Atlanta, GA 30341
Office: (770) 488-4034
Cell: (770) 294-4126



Department of Health and Human Services
Centers for Disease Control and Prevention

10/2007

Instructions for Shipping Blood Specimens to CDC after a Chemical-Exposure Event

Guidance in Accordance with Packaging Instructions International Air Transport Authority (IATA) 650 Biological Substance Category B
 For detailed instructions see CDC's Shipping Instructions for Specimens Collected from People Who May Have Been Exposed to Chemical-Terrorism Agents.



1 Place purple- and gray- or green top tubes by patient number into grid-like-type box lined with an absorbent pad. If using an alternative packaging method, pack all tubes from the same patient together while preventing tube-to-tube contact.



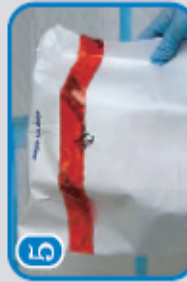
2 Seal gridded box or alternative secondary container with one continuous piece of evidence tape. The individual making the seal must initial half on the tape and half on the packaging.



3 Wrap gridded box in absorbent pad and tape to seal. Seal gridded box or alternative container inside a Sar-T-pak clear, inner, leak-proof polybag (or equivalent).



4 Place the sealed Sar-T-pak inner leak-proof polybag (or equivalent) inside a white Tyvek® outer envelope (or equivalent). **Note: If primary receptacles do not meet the minimal pressure requirement of 95 psia, use compliant secondary packaging materials.**



5 Seal the opening of this envelope with a continuous piece of evidence tape. Write initials half on the evidence tape and half on the envelope.



6 Use polystyrene foam-insulated, corrugated fiberboard shipper to ship boxes to CDC. Place absorbent material in the bottom of the shipper.



7 Place refrigerator packs in a single layer on top of the absorbent material.



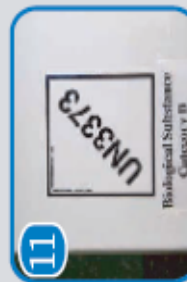
8 Place the packaged specimens in the shipper. Use cushioning material to minimize shifting while box is in transit. Place additional refrigerator packs on top of samples.



9 Place the blood shipping manifest in a sealable plastic bag and put on top of the sample boxes inside the shipper. Keep your chain-of-custody documents for your files. Place lid on the shipper.



10 Secure the shipper lid with filamentous shipping tape. Place your return address in the upper left-hand corner of the shipper box and put the CDC Laboratory receiving address in the center.



11 Add the UN 3373 label and the words "Biological Substance, Category B" on the front of the shipper. UN 3373 is the code identifying the shipper's contents as "Biological Substance, Category B."



12 Send shipment via FedEx to:
 Centers for Disease Control and Prevention
 Attn: Lt. Ernest McGehee
 4770 Buford Hwy.
 Building 110 Loading Dock
 Atlanta, GA 30341
 (770) 485-1575

For questions concerning this process, please contact:

Centers for Disease Control and Prevention
 Attn: Cecelia Sanders, Chemical Emergency Response Team Leader
 4770 Buford Hwy.
 Building 110 Loading Dock
 Atlanta, GA 30341
 Office: (770) 488-4034
 Cell: (770) 294-4124



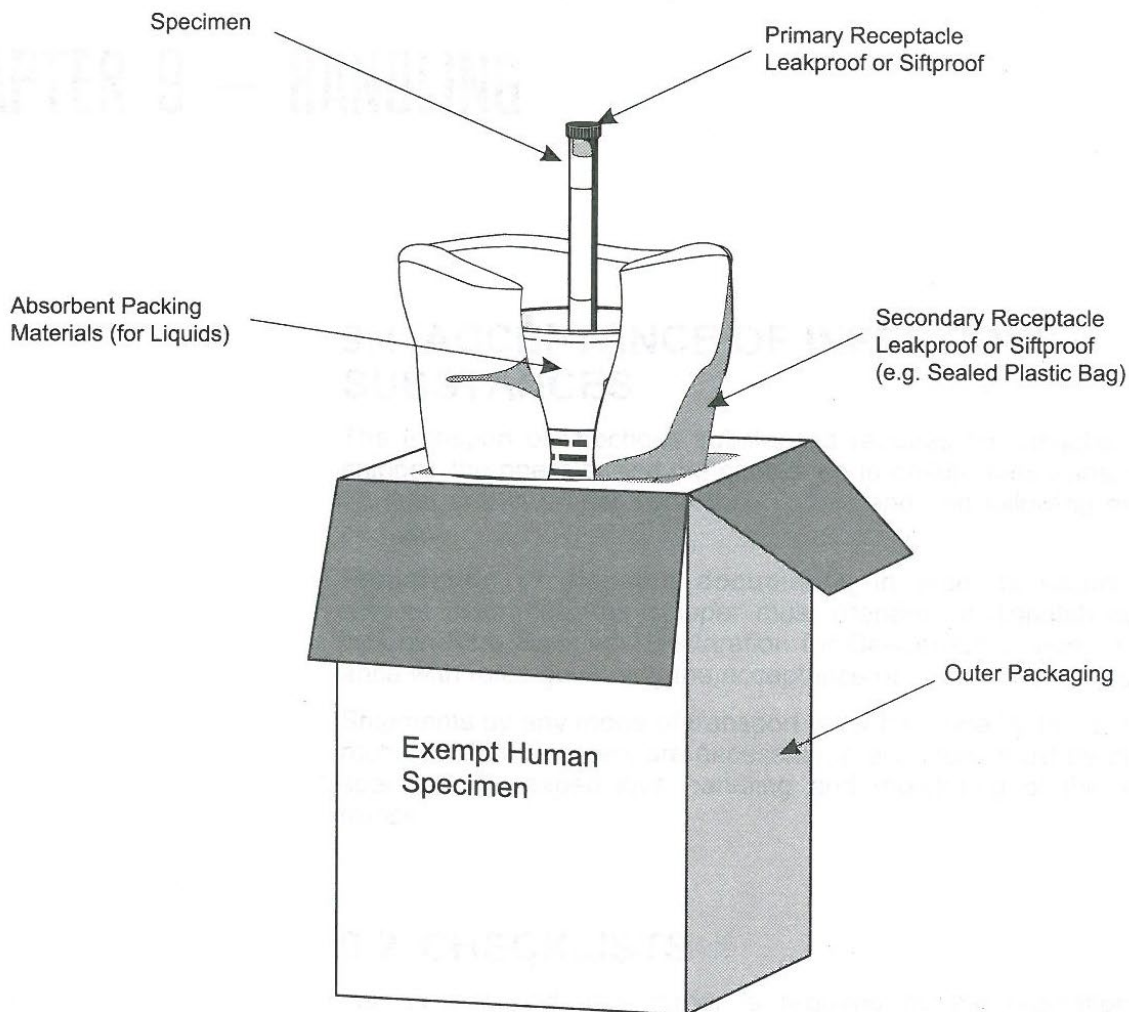
Department of Health and Human Services
 Centers for Disease Control and Prevention

05/2008

Appendix "D" – Triple Packaging and Proper Labeling Guides

Packing and labeling diagram of an Exempt Human/Animal Specimen.

**Figure 8.4.6.C
Sample Packaging & Labelling**

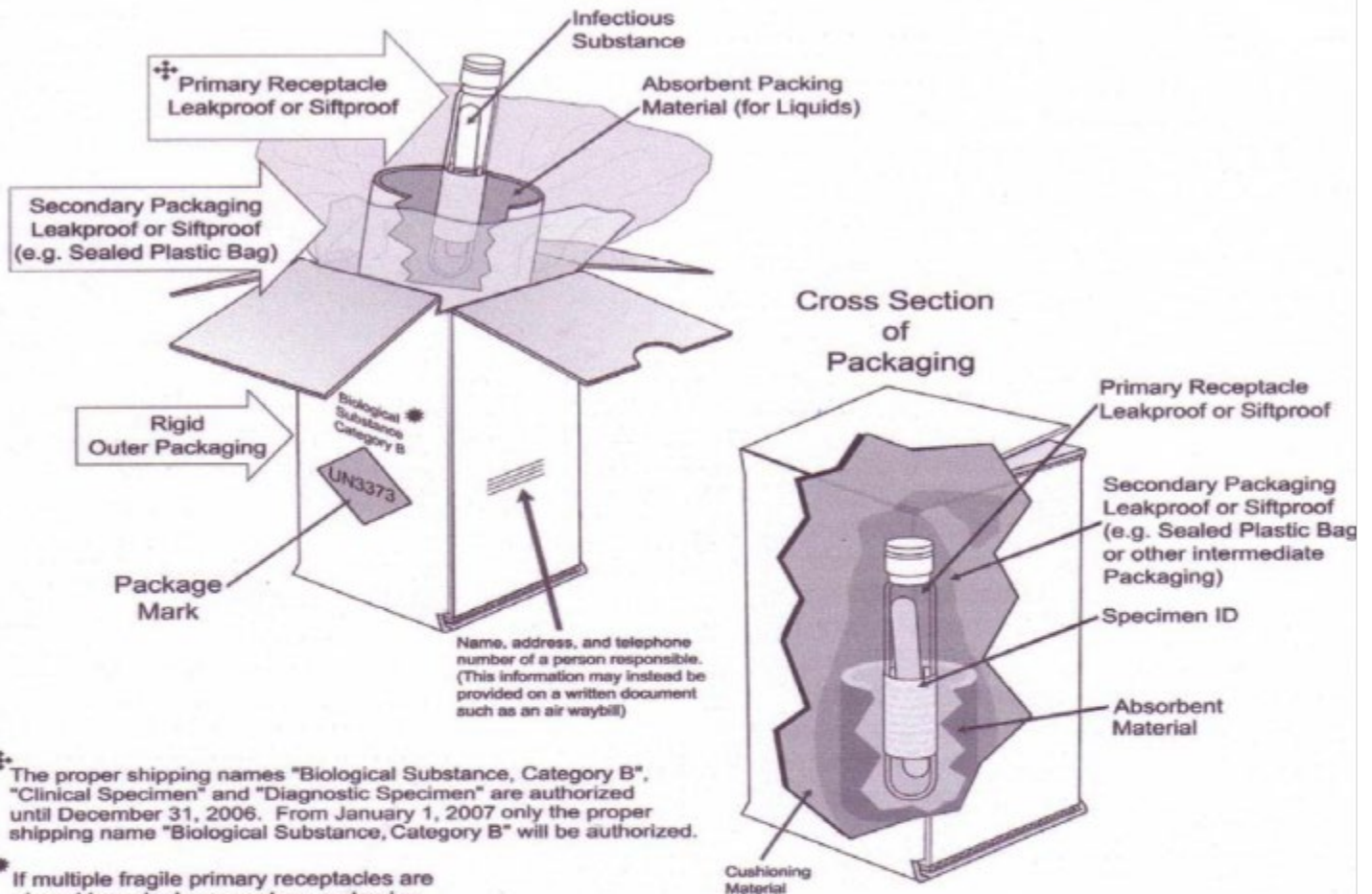


The package must be marked "Exempt human specimens" or "Exempt animal specimens", as appropriate.

Packing and Labeling of Category B

UN3373 Biological Substance, Category B – Packing Instructions 650

(See Packing Instruction 650 for additional requirements; e.g. drop test)



⚠ The proper shipping names "Biological Substance, Category B", "Clinical Specimen" and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.

⚠ If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact.

Note: 1-At least one surface of the outer packaging must have a minimum dimension of 100 mm X 100 mm

Note: 2-The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 KPa

8.4.4 Sample Documentation and Labelling for a Shipment of Infectious Substances in Category B

**Figure 8.4.4.A
Shipper's Declaration**

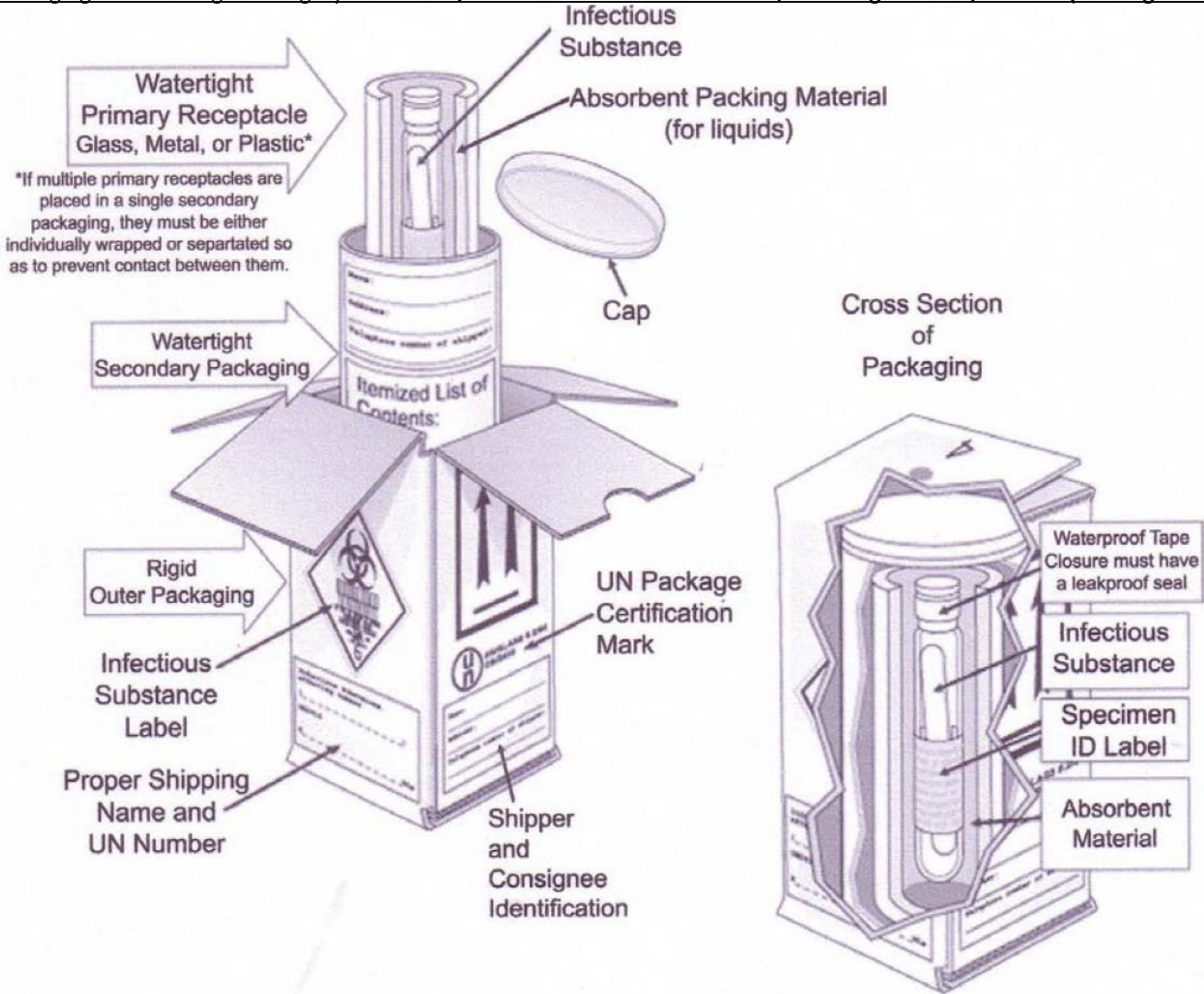
NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Pack-ing Group	Subsidiary Risk	Quantity and type of packing	Packing Inst.	Authorization
NOT Required							

**Figure 8.4.4.B
Air Waybill**

Airport of Destination		Requested Flight/Date		Amount of Insurance		INSURANCE – If carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures in box marked "Amount of Insurance".	
Handling Information Responsible person: Dr. I. M Able, 1 rue St-Antoine, Montreal Tel.: +1 (514) 103-4567							
No. of Pieces RCP	Gross Weight	kg lb	Rate Class Commodity Item No.	Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)
							BIOLOGICAL SUBSTANCES CATEGORY B UN 3373, 1 PACKAGE

Source: Infectious Substance Shipping Guidelines, Ref No. 9052-11, IATA, 11th Edition,

Packaging and Labeling of Category A: UN2814/UN2900 Infectious Substances, Affecting Humans/Animals (Packing Instructions 620)



Note: 1-The smallest external dimension of the outer packaging must not be less than 100 mm

Note: 2-The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 KPa

8.4.2 Sample Documentation and Labelling for a Shipment of Infectious Substances in Category A with Dry Ice

**Figure 8.4.2.A
Shipper's Declaration**

UN2814	Infectious substance, affecting humans (Suspected category A infectious substance)	6.2	10 ml	620
UN1845	Dry Ice	9	3 kg All packed in one Fibreboard box.	954

A way to show an infectious substance shipment packed together with dry ice inside a UN Class 6.2 specification package. Note that a "Q" value is not required, and the Air Waybill will require the statement as shown in 8.3.

**Figure 8.4.2.B
Air Waybill**

Airport of Destination		Requested Flight/Date		Amount of Insurance		INSURANCE – If carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures in box marked "Amount of Insurance".		
Handling Information								
Dangerous Goods as per attached DGD							SCI	
No. of Pieces RCP	Gross Weight	kg lb	Rate Class		Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)
			Commodity Item No.					
								Infectious substance

Source: Infectious Substance Shipping Guidelines, Ref No. 9052-11, IATA, 11th Edition,

Appendix "E" - Infectious Substance Packaging Checklist**Category A UN 2814 or UN2900 Packaging Checklist**

- Primary containers – leak proof/ watertight
- Multiple primary containers – separated to prevent breakage
- Absorbent material – sufficient to absorb entire contents
- Secondary packaging – UN Specification Packaging for infectious substances; watertight

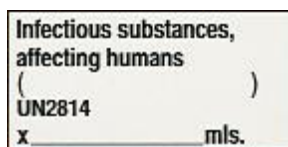


**4GU/CLASS 6.2/07
USA/SHIPPINGCO**

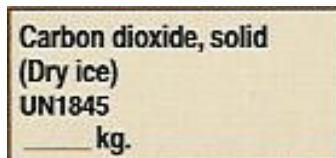
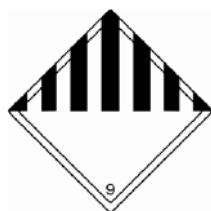
- Itemized list of contents – between secondary container and outer packaging
- Rigid outer packaging

Marking and Labels

- Name, facility name, complete shipping address and telephone number of shipper
- Name, facility name, complete shipping address and telephone number of recipient
- Name and telephone number of person responsible for shipment
- Class 6.2: Infectious Substance black on white diamond label
- UN 2814 Infectious substance, affecting humans (Liquid or solid) in parenthesis and the quantity in ml. or grams. (or UN 2900 Infectious substance, affecting animals only)
- (Technical name in parentheses **ONLY on Shipping Declaration**,// **NOT** on box)



- If packed with dry ice - Class 9: Black on white diamond label and UN 1845 Carbon dioxide, dry ice amount label (to convert to kg divide pounds by 2, use whole numbers) Dry ice hazardous material label is only required when transporting by air.



Category B UN3373 Packaging Checklist

- Primary containers – leak proof/ watertight
- Multiple primary containers – separated to prevent breakage
- Absorbent material – sufficient to absorb entire contents
- Secondary packaging – UN Specification Packaging for infectious substances; watertight

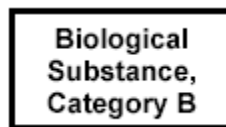


**4GU/CLASS 6.2/07
USA/SHIPPINGCO**

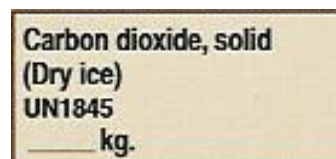
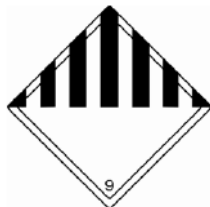
- Itemized list of contents – between secondary container and outer packaging
- Rigid outer packaging

Marking and Labels

- Name, facility name, complete shipping address and telephone number of shipper
- Name, facility name, complete shipping address and telephone number of recipient
- Name and telephone number of person responsible for shipment
- Class 6.2: UN 3373 Diagnostic specimen black on white diamond label and additional labeling indicating Biological Substance, Category B



- If packed with dry ice - Class 9: Black on white diamond label and UN 1845 Carbon dioxide, dry ice amount label (to convert to kg divide pounds by 2, use whole numbers).



Exempt Specimens: No Packing instructions are available. Regulations state packaging must have adequate strength for the contents mass and intended use. Packaging must be such that there is no leakage.

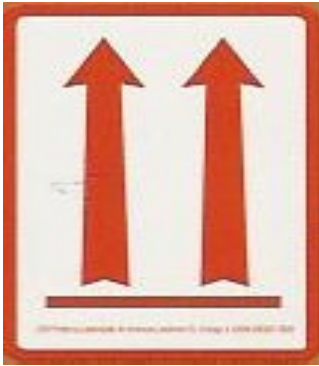
Required labels:

Exempt Human Specimen

OR

Exempt Animal Specimen

This label is only required if shipping liquids.



Appendix “F” – Training Requirements

The U.S. Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations (HMR), 49 CFR, parts 171-180, as well as IATA DGR, require training for all persons involved in the packaging, shipping, etc. of hazardous materials (including infectious substances). Training can be accomplished by lecture, demonstration, seminars, workshops, self-study, or other means, as long as the goal is met. Private consultants and commercial suppliers of packaging products are good sources of training and training materials. Persons (including supervisors) must be trained if they are considered a shipper, pack at the origination site, pick up for the airline, handle the package as cargo during transport, deliver the goods, etc. Training must consist of the following three components:

- A. General familiarization: presentation of governing regulations and provisions
- B. Function-specific training: detailed instructions of how to perform what the employee/shipper is supposed to do (e.g., package infectious substances, label packages, and prepare documentation)
- C. Safety training: presentation of the hazards of dangerous goods and emergency Procedures.
- D. Security training: security protocols and preventative measures to limit unauthorized access to hazardous materials.

A person is considered trained only when the person’s employer creates a written Record of Training that states the person has been trained to the satisfaction of the employer.

The Record of Training must contain the following:

- 1) Employee name
- 2) Date of the training
- 3) A description or copy of the training
- 4) Location of the training
- 5) Name and address of the trainer
- 6) Statement of certification

Training of new employees must be accomplished within 90 days of start of employment or reassignment to shipping duties. Training is valid for two (IATA) or three (DOT) years. Records of training must be kept for two years (IATA) or the duration of employment plus 90 days (DOT).

Training

LRN laboratories will provide packaging and shipping training without cost to your personnel. Please contact your local LRN listed in Appendix A for more information. Contact PHLET at 903-877-5071 to schedule training.

Appendix “G” – Shipper’s Declaration Instructions, Forms and Checklist**Shipper’s Declaration Instructions**

Shipping Declaration forms may vary. These instructions are intended to provide examples. These fields are extremely important and must be completed fully, accurately and legibly! Failure to do so may result in the rejection of a package by a carrier.

- **Shipper:** Name and address of the shipper, telephone number, responsible person (name and telephone number)
- **Consignee:** Name and address of the consignee (recipient), and the name and telephone number of a responsible person in case of an emergency
- **Air Waybill Number:** can be entered by the carrier or the shipper
- **Page __ of __:** number of pages of the *Shipper’s Declaration* (usually only one)
- **Aircraft Limitations:** “mark out” the limitation that does **NOT** apply
- **Airport of Departure:** can be entered by the carrier or the shipper
- **Airport of Destination:** can be entered by the carrier or the shipper
- **Shipment Type:** “mark out” the type that does **NOT** apply (mark out radioactive usually)
- **Nature and Quantity of Dangerous Goods:**
- **Proper Shipping Name:** proper shipping name [Ex. UN2814 Infectious Substance, Affecting Humans, (*Bacillus spp.*)] and technical name in parenthesis (A comma *must* be placed immediately after the proper shipping name, and parenthesis *must* enclose the technical name! The word “substance” must be singular, not plural. There are NO exceptions!)
***Important note:** When shipping BT or Select Agents, on the Shipper’s Declaration of Dangerous Goods form under Proper Shipping Name, you may use the “*Genus spp.*” instead of the specific genus and species name for the technical name. For example: “**Bacillus anthracis**” or “**Bacillus spp.**”
- **Class or Division:** Enter 6.2 if the substance is an infectious substance. Enter 9 for dry ice or genetically modified microorganisms.
- **UN Identification Number:** The number must be preceded by the prefix “UN”.
Examples:
 - UN 2814 Infectious substance, affecting humans (liquid/solid)
 - UN 2900 Infectious substance, affecting animals (liquid/solid)
 - UN 3245 Genetically modified microorganisms
 - UN 1845 Dry ice
- **Packing Group:** packing group II applies to regulated biomedical waste, for dry ice use packing group III
- **Subsidiary Risk:** not applicable to infectious substances
- **Quantity and Type of Packaging:**
 1. The type of packaging must be labeled on the shipping declaration. If using a cardboard container, the shipping declaration must be labeled with all packed in one “**Fiberboard box**” (this spelling is required).
 2. Total net quantity of infectious substances. The number of primary containers (how the substance is divided). Some carriers require total quantity while others need the quantity broken out. Example: **5 ml x 2** (or **10 ml**) or **1g x 2 (2g)**. Check with individual carrier for specific requirements.
 3. If using dry ice, it must be weighed in kilograms and labeled on the box as well as the shipping declaration when transported by air. Example: 2 kg
- **Packing Instructions:** applicable packing instructions
For example:
 - PI 620 Infectious Substances (Category A)
 - PI 650 Biological Substance (Category B)
 - PI 959 Genetically Modified Organisms
 - PI 954 Dry Ice
- **Authorization:** Enter any special provisions or exceptions used to bypass usual regulations (e.g., A81 and A82).
 - **Authorization A140-The infectious substance should be packaged according to Category A regulations (packing instructions 620)**
 - **When infectious substances to be transported are unknown but suspected of meeting the criteria for inclusion in Category A, the words “Suspected Category A Infectious Substance” must be shown in parentheses following the proper shipping name instead of the technical name on the shipping declaration, but not on the outer packaging.**

- **Additional Handling Information:** Required notices regarding special responsibilities must be given in this field:
An emergency contact number, including area code: The number *must* be monitored as long as the shipment is in transit [including during incidental storage] and be the number of a person knowledgeable of the substance and who has, or has available, incident mitigation information or has direct access to someone who has such information. Must be able to be reached using one phone call, pagers and beepers are acceptable as long as calls can be returned promptly.
 - **Name and Title of Signatory:** name and title of person who signs the document (the shipper)
 - **Place and Date:** place and date of signing
 - **Signature:** signature of person who completes the document (the shipper)
- IMPORTANT: Shipper's Declaration for Dangerous Goods is a legal contract/document, you must sign this form. If originating and destination is in US, you may type your name in all CAPS electronically.**
- NOTE: Many carriers will **NOT** accept handwritten documents and may require additional copies of the *Shipper's Declaration*. Check with individual carriers to determine their requirements. Appendix G shows a completed and acceptable *Shipper's Declaration*.

Important Considerations in Completing a Shipping Declaration:

- Shipping Declaration is only required for Category A shipments.
- All hazardous materials contained in the shipment must be listed on the form.
 - Must be in **color**.
- FedEx requires the use of their approved Computer generated forms.
- FedEx will not accept hand written Shipping Declaration forms.
- At least 4 copies of the Shipping Declaration form should be printed,
5 COPIES ARE NEEDED FOR FEDEX SHIPMENTS.
- One copy should be included inside the box but outside the secondary container for the recipient.
- One copy should be kept in the sender's records for at least 2 years.
- Two copies (**3 FOR FEDEX**) should be included with the shipping documentation for the carrier.

The Emergency Contact number listed on the Shippers declaration must be answered 24/7. It is best to use a commercial service in this role.

EXAMPLE: Created using free software at: <https://www.saftpak.com/default.aspx>

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Shippers Name Shippers Workplace Shippers workplace address Tyler, Texas 75708 United States 903-877-5071		Air Waybill No. _____ Page <u>1</u> of <u>1</u> Pages Shipper's Reference Number <u>111</u> <i>(optional)</i>				
Consignee Recipients Name Recipients workplace Recipients workplace address Tyler, Texas 75702 United States 111-221-3333						
<p><i>Three completed and signed copies of this Declaration must be produced. One is retained by the shipper and two handed to the operator.</i></p> <p>TRANSPORT DETAILS</p> <p>The packages in this shipment are within the quantity limitations prescribed for: <i>(strike-out non-applicable)</i></p> <table border="1"> <tr> <td>PASSENGER AND CARGO AIRCRAFT</td> <td>CARGO AIRCRAFT ONLY</td> </tr> </table> <p>Airport of Departure: _____ enter if known</p> <p>Airport of Destination: _____ enter if known</p> <p>WARNING</p> <p>Only trained and certified shippers can sign this form. Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.</p> <p>Shipment type: <i>(strike-out non-applicable)</i></p> <table border="1"> <tr> <td>NON-RADIOACTIVE</td> <td>RADIOACTIVE</td> </tr> </table>			PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	NON-RADIOACTIVE	RADIOACTIVE
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY					
NON-RADIOACTIVE	RADIOACTIVE					
<p>NATURE AND QUANTITY OF DANGEROUS GOODS</p> <p><i>UN Number or Identification Number, Proper shipping name, Class or Division (subsidiary risk) Packing Group (if required) and all other required information.</i></p> <p>UN 2814, Infectious substance, affecting humans (Bacillus anthracis), 6.2 1 Fibreboard box x 20.000 mL 620</p> <p>UN 1845, Dry ice, 9 1.000 kg 954</p> <p>All packed in one Fibreboard box</p>						
<p>Additional Handling Information</p> <p>24-Hour Emergency Contact: Infotrak 123-445-1345 Person Responsible: Jan Lab 123-45-6789</p>						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.		Name/Title of Signatory Shippers Name / Microbiologist Place and Date Tyler, TX, 04-Aug-2014 Signature <i>(see warning)</i>				

APPENDIX “H” –**RECEIPT FOR PROPERTY RECEIVED/RETURNED AND CHAIN OF CUSTODY FORMS****GUIDANCE FOR PROPER USE OF FORMS****General**

- The custodian is responsible to maintain and collect additional chain of custody documentation generated at the laboratory.
- The laboratory will maintain originals (copies if necessary) of all chain of custody documentation and provide originals to law enforcement officials upon transfer of evidence. Copies should be maintained by the laboratory for its records.
- In the event that custodianship of the evidence is split, due to sampling of a specimen or the transfer of one or more items, the chain of custody forms must be imitated, maintained, and transferred with that portion of evidence. The custodians receiving and releasing the sample or item will keep a copy of the Receipt of Property Form.
- The chain of custody documentation should be considered confidential/classified information. This form should be maintained in a secure location.

Receipt for Property Received/Returned

- The form must be completed, signed, providing date and time, upon receipt of evidence. Both the laboratory and the law enforcement official will retain a copy of the completed form.
- This form must be completed, signed and dated upon the release of evidence to a law enforcement official. Both the laboratory and the law enforcement official will retain a copy of the completed form.
- Description information should include the following information for each and every item.
 - Unique identifier for each item
 - Number/quantity
 - Type/description
- If multiple items are received, all items must be listed on the form. Each item should be assigned a unique identifier. The original identifier should be maintained on the chain of custody records for any sample/portion of that item.
- The person that packages the sample must complete the packing information section.
- The name of the carrier/courier and the shipping/reference number should be recorded if items are delivered by carrier/courier.
- Additional information may be attached as appropriate (e.g., original source/submitter, collected by, emergency contacts, situational information).

Chain of Custody Form

This form must be signed and dated when transferring custody within the laboratory, from the initial receipt of the evidence, through the processing, storage, and release of the evidence to a law enforcement official.

RECEIPT FOR PROPERTY RECEIVED/RETURNED

Case ID: _____ Date: _____ Page ____ of ____

	<input type="checkbox"/> Received from	<input type="checkbox"/> Released to <input type="checkbox"/> Returned to
Name (print):		
Organization:		
Street Address:		
City, State, Zip:		
Phone:		

Description of Property (identifier, number/quantity, and type/description):

Packaging Information:

Packaged by (name):	
Date packaged:	
Time packaged:	

Received from: (sign/date/time)
Received by: (sign/date/time)

CHAIN OF CUSTODY

Case ID: _____

Page _____ of _____

Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		
Received by (Print/Sign):	Date:	Time:
Organization:		
Reason:		

APPENDIX "I" - PHLET Specimen Submission Forms

REMINDERS

All specimens must be triple contained in accordance with federal shipping regulations.

All clinical specimens must be accompanied by a specimen submission form.

Prior to submission, please call (903) 877-5071 or (903)-312-3537

All specimens must include a PHLET submission form listing the sender's name and telephone number to contact for the preliminary report and additional information. If Bioterrorism is suspected, a Chain of Custody Form must also accompany the sample.

Level A (Sentinel) laboratories should not accept environmental or animal specimens; such specimens should be forwarded directly to the State Health Laboratory.

Submission forms and instructions are available online at <https://www.uthct.edu/phlet>

CLINICAL SUBMISSION FORM available at <https://www.uthct.edu/phlet>

Public Health Laboratory of East Texas at the University of Texas Health Science at Tyler		CLIA# 45D1011121 SAP# C20140110-1537
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	ZIP CODE		
PHONE	FAX			
LABORATORY CONTACT NAME AND NUMBER (FOR QUESTIONS)				
PANIC VALUE-CONTACT	Example see website for form			
PATIENT INFORMATION				
PATIENT NAME (LAST, F				
DATE OF BIRTH				SSN
ADDRESS :				
DATE AND TIME OF COL				
DATE OF ONSET				IK
OUTBREAK ASSOCIATON				INPATIENT/OUTPATIENT
ORDERING PHYSICIAN				
SPECIMEN SOURCE OR T				B/ASPIRATE
PLASMA	SPUTUM			
WOUND SWAB	TRACHEAL ASPIRATES	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				
<input type="checkbox"/>	QUANTIFERON TB GOLD In Tube : Sample incubated? Yes/no			
<input type="checkbox"/>	BIOTERRORISM RULE IN/ RULE OUT* - SUSPECTED ORGANISM			
<input type="checkbox"/>	INFLUENZA BY RT-PCR			
<input type="checkbox"/>	AVIAN FLU *			
<input type="checkbox"/>	EBOLA PCR *			
<input type="checkbox"/>	ARBOVIRUS PCR PANEL *(INCLUDES DENGUE, CHIKUNGUNYA, ZIKA)			
<input type="checkbox"/>	ZIKA MAC IgM Serology			
TO BE FILLED OUT BY PHLET EMPLOYEE				
SPECIMEN RECEIVED BY		DATE/TIME		
CONDITION: REFRIGERATED ROOM TEMPERATURE FROZEN				

*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:

ENVIRONMENTAL SUBMISSION FORM- available at <https://www.uthct.edu/phlet>

Law Enforcement and FBI only *Sample will be screened using unknown environmental agents panel*

Public Health Laboratory of East Texas
 11949 US Highway 271N Tyler, Texas 75708
 Phone -903 877-5071 Fax 903-877-5259
 CLIA # 45D1011121
 Lab Director: Dr. Richard Wallace / Supervisor: Janine Yost
 24 hour emergency# 903-312-3537



ENVIRONMENTAL SUBMISSION FORM

Sample will be screened using unknown environmental agents panel.

Suspected agent: _____

<i>Submitting Lab or Agency Information</i>		
Agency name	Address	City/State/ Zip code
Representative/ Title	Phone #	Fax#
Date/time released or shipped to LRN Laboratory		<div style="background-color: yellow; text-align: center; padding: 5px;"> Example see website for form </div>
<div style="background-color: yellow; text-align: center; padding: 5px;"> Example see website for form </div>		
<i>Submitted Sample Information</i>		
Sample Container Description and Identifying Marks:		
Sample Description		
Tamper evident seal present and intact? Yes/ No comments:		
Was the sample screened for Radiation? Yes/ No		
Field tests performed and results: _____		
Equipment used: _____		
Name of Agency and tech that performed test: _____		
If this is a letter: Has it been opened? Yes/ No - Was there powder present? Yes/ No/ unknown		

To be filled out by LRN Laboratory

LRN Lab ID# _____ PHLIMS ID# _____

Rec'd by _____ Date/ Time Rec'd _____

Appendix J:

Summary and Utilization of Select Agent Forms by LRN Sentinel Level Laboratories

LRN Sentinel Level Laboratories are not required to register or be certified with the Select Agent Rule but are required to be compliant under specific conditions. An area of confusion for Sentinel Level Laboratories has been the completion of specific forms related to select agents. The purpose of this document is to provide information on the utilization of Forms 2, 3, and 4A by the Sentinel Level Laboratory, specifically the conditions under which such forms may require completion as directed by the LRN Reference Laboratory or following authorization by the Centers for Disease Control and Prevention (CDC). Additional information regarding the aforementioned forms can be obtained at: <http://www.selectagents.gov>.

Form 2: Request to Transfer Select Agents and Toxins

Sentinel (Diagnostic) Laboratories are not required to be registered with- or certified to handle select agents and, with few exceptions, are exempt from the need to comply with the Select Agent Rule. For example, the Rule Out or Refer responsibility of the Sentinel Level Laboratory applies to specimens or proficiency samples that are suspected of containing a select agent based on the results obtained following the application of the LRN Sentinel Level Testing Protocols. If the isolate cannot be “ruled out” it is then referred to the nearest LRN Reference Laboratory (usually the State Health Department) for confirmatory identification. Unless directed otherwise, within 7 calendar days following notification that the isolate submitted to the LRN Reference is a select agent, the agent/specimen must be destroyed on-site by a recognized sterilization (autoclave) or inactivation process. Completion of Form 2 would not normally be required of Sentinel Level Laboratories however, be advised that the form does contain an option for “nonregistered entities” under Section B, Sender Information. It would be an unusual circumstance for a nonregistered laboratory (Sentinel Laboratory) to request transfer of a select agent but if the Sentinel Laboratory’s autoclave or other form of destruction (chemical inactivation) is nonfunctional, Form 2 would be initiated to facilitate the transfer of the agent. Form 2 can be found here: <http://www.selectagents.gov>.

Form 3: Report of Theft, Loss, or Release of Select Agents and Toxins

All laboratories must complete Form 3 if there is a theft, loss or release of a select agent or toxin. The CDC Select Agent program considers a release any activity with a select agent outside of the biosafety cabinet. This form is also used to capture any laboratory exposures. Therefore, if a Sentinel Laboratory knowingly has a select agent on site (confirmatory testing conducted by the LRN Reference laboratory), Form 3 must be sent to the CDC within 7 days after the discovery of a theft, loss, or release. For theft or loss, the laboratory must also notify the appropriate local, state, or federal law enforcement agencies. For a release only, the laboratory should notify the local or state health agencies.

Summary: Form 3 is initiated by the laboratory that knowingly harbors a confirmed select agent in the event of a theft, loss or release. For the CAP Laboratory Preparedness Exercise (LPX), the Sentinel Laboratory **DOES NOT** complete Form 3 because the challenge organisms are **exempt** from the Select Agent Regulations. Form 3 can be found here: <http://www.selectagents.gov>.

Form 4: Reporting the Identification of a Select Agent or Toxin from a Clinical/ Diagnostic Specimen.

There are four parts to Form 4. After a select agent has been confirmed by the LRN Reference Laboratory, it is required to complete Parts A and B and send to the CDC. The CDC then calls the Reference laboratory and provides a Case Identification Number for the Sentinel Laboratory to use. The Sentinel Laboratory completes Parts C and D and Form 3 if there was an occupational exposure. For the CAP Laboratory Preparedness Exercise (LPX), the Sentinel Laboratory **DOES NOT** complete Form 4 because the challenge organisms are **exempt** from the Select Agent Regulations.

Summary: The Sentinel Laboratory is required to complete Form 4A **only** if notified by the LRN Reference laboratory following its having been contacted and required by the CDC.

Form 4 can be found here: <http://www.selectagents.gov>

References:

- 1) ASM Sentinel Laboratory Guidelines Available on the web at [LRN Sentinel Level Clinical Laboratory Protocols \(asm.org\)](#)
- 2) SENTINEL LEVEL CLINICAL LABORATORY GUIDELINES FOR SUSPECTED AGENTS OF BIOTERRORISM AND EMERGING INFECTIOUS DISEASES Packing and Shipping Infectious Substances American Society for Microbiology Previous Version: December 20, 2012, Current Version: revised April 20, 2021
[CPHMC PackAndShip Guideline \(3\).pdf](#)
- 3) Chemical terrorism Clinical Specimen Handling Guidelines, available at cdc.gov
<https://emergency.cdc.gov/chemical/lab.asp>
- 4) Clinical Laboratory Preparedness and Response Guide. APHL and ASM. Available on the web at:
https://www.aphl.org/aboutAPHL/publications/Documents/WORK_BlueBook.pdf
- 5) MMWR, Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories, January 6, 2012 available on the web at
<http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
- 6) CDC/NIH BMBL – [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition | CDC Laboratory Portal | CDC](#)
- 7) US Department of Transportation Pipeline and Hazardous Materials Safety Administration. *Transporting Infectious Substances Safely*. Available at
<http://www.phmsa.dot.gov>
- 8) CDC Guidelines for collecting and handling specimens for Mpox testing, 1/3/2025 available on the web at https://www.cdc.gov/mpox/hcp/diagnosis-testing/collecting-specimens.html#cdc_generic_section_2-collection