Specimen Collection, Packaging, and Shipment of Suspect Agents for Biological or Chemical Threat Testing from Sentinel Laboratories to LRN Laboratories, Revision 3, For Official Use Only, Sensitive but Unclassified - Version: 3.0. Index: EPG 1. Printed: 10-Jun-2013 10:48

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Specimen Collection, Packaging, and Shipment of Suspect Agents for Biological or Chemical Threat Testing from Sentinel Laboratories to Laboratory Response Network (LRN) Laboratories

Standard Operating Procedure
Emergency Preparedness Branch
EP 3001 Revision ~~4~~ 3
RP 8-3-11

Action	Signature	Date
Prepared by: Andrea Cole, Response Coordination Team	Andrea Cole	7/29/11
Reviewed by: Rahsaan Drumgoole, Biothreat Team Leader		7.29.11
Approved by: Cathy Edmonson, QA Officer Quality Control Unit		8.5.11
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Approved by: Manager Susan Tanksley Lab Operations Unit Acting	Susan Tanksley	8/5/11
Approved by: Dr. Grace Kubin, Director Laboratory Services Section	Grace Kubin	08/10/2011
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Title	Signature	Date
Branch Manager		
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Standard Operating Procedure
Response Coordination Team, Emergency Preparedness Branch
Document # EP 3001 Revision 4 3

RP 8-3-11

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1) PURPOSE

The LRN sentinel laboratory responsibilities include collection, packaging, and shipment of clinical specimens suspected of containing biological threat (biothreat) agents to a Texas LRN reference laboratory for confirmatory testing. The LRN Level 3 laboratory responsibilities include collection, , packaging, and shipment of blood and urine specimens to the Texas LRN Chemical Threat Laboratory in Austin. In order to better assist the sentinel and Level 3 laboratories in correctly performing these tasks, this procedure has been compiled for their use. This document does not substitute for training in collection, packaging and shipment of specimens.

2) DEFINITIONS

A. LRN Level 3 laboratory: A laboratory that has the capabilities of performing phlebotomy procedures. These laboratories would be used in a chemical terrorism event for collecting blood and urine specimens on clients that had been exposed or possibly exposed to the chemical threat agent.

B. LRN sentinel laboratory: Sentinel laboratories are private, commercial, or public health laboratories that have microbiological capabilities and play a key role in the early detection of biothreat agents. Sentinel laboratories provide routine diagnostic services, rule-out, and referral steps in the identification process of possible biothreat agents.

C. LRN reference laboratory: A laboratory that has been accepted into the Laboratory Response Network and is capable of performing standardized confirmatory tests for biothreat agents. In Texas there are ten LRN laboratories, geographically dispersed, serving an assigned number of counties.

D. Dangerous goods: articles or substances capable of posing a risk to health, safety, property or the environment; IATA (International Air Transport Association) and DOT (Department of Transportation) have defined nine classes of dangerous goods to be used when items are transported by air:

1) Class 1: explosives

2) Class 2: gasses

3) Class 3: flammable liquids

4) Class 4: flammable solids

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5) Class 5: oxidizing substances

6) Class 6: toxic/infectious substances

   a. Division 6.1 – toxic substances

   b. Division 6.2 – infectious substances and diagnostic specimens

7) Class 7: radioactive substances

8) Class 8: corrosive substances

9) Class 9: miscellaneous substances (includes dry ice and genetically modified organisms)

E. Diagnostic specimen: human or animal material (e.g., tissue, tissue fluid, serum, urine, secreta, excreta, body fluids, blood, and blood components) being shipped for diagnostic or investigational purposes but excluding live, infected animals.

F. Division 6.2 infectious substance: a material known to contain or reasonably expected to contain a pathogen, including, but not limited to, the following:

1) pathogens and cultures of pathogens

2) diagnostic specimens suspected to contain a pathogen

3) diagnostic specimens from patients with serious disease of unknown etiology

G. Categories of Infectious Substances

1) **Category A** - An infectious substance in a form capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. These specimens will be assigned the UN 2814 (or UN 2900) designation and packaged in accordance..

2) **Category B** – An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. These substances must be described as "Biological substance, Category B", assigned identification number UN 3373 and packaged in accordance.

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3) SPECIMEN/SAMPLE HANDLING AND STORAGE

H. BIOLOGICAL THREATS

1) Specimen Types

a. **Environmental samples** must be coordinated with the FBI or law enforcement. HAZMAT is trained in sample collection, labeling and transport as well as coordination of activities with law enforcement. Contact your local LRN to assist with notification of the appropriate authorities (see Appendix A).

b. **Clinical samples**

i. Sentinel laboratories are expected to follow LRN rule-out protocols. Any isolates that cannot be ruled-out as possibly being a 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.

ii. Sentinel laboratories not capable of completing rule-out protocols should submit clinical specimens for testing (see Appendix B).

iii. All biothreat specimens must be triple contained in an approved shipping container and have biohazard labels (see Appendix D). Specimens must be submitted to the LRN designated for the area (see Appendix A) and accompanied by an LRN-specific Specimen Submission Form.

I. CHEMICAL THREATS

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

a. **Whole blood**

i. **Adult Patients**: Three 4 ml or larger purple-top (EDTA) tubes, vacuum-fill only. Please number the tubes in order of collection using permanent ink, for example, the first tube drawn will be labeled "1", second tube "2", etc. One 3 ml or larger green-top tube (Heparin), vacuum-fill only. If green-top tube is not available, a 3 ml gray-top tube (Heparin) may be substituted.

ii. **Pediatric Patients**: Collect urine only unless otherwise directed.

b. **Urine**

Adult or Pediatric Patients: Collect at least 25 ml in a screw-capped plastic container (urine cup). Please do not overfill. FREEZE IMMEDIATELY (-70°C, dry ice, or –50°C gelpacks preferred)

c. **Controls**

In addition, for **each lot number** of tubes and urine cups used for collection,

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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.

2) Labeling of Chemical Threat specimens: (See Appendix C)

a. Label specimens with labels generated by your facility. These labels should include the following information:

i. medical records number

ii. specimen identification number

iii. collector's initials

iv. date and time of collection

Follow your facility's procedures for proper specimen labeling. The collector's initials and date and time of collection will allow law enforcement officials to trace the specimen back to the collector should the case go to court and the collector is needed to testify that they collected the specimen.

b. Place a single, unbroken strip of waterproof, tamper-evident forensic evidence tape over each specimen top, being careful not to cover the specimen ID labels. This tape must make contact with the specimen container at two points. The individual placing the evidence tape must identify himself by writing his initials half on the container and half on the evidence tape using a permanent marker.

c. Maintain a list of names with corresponding specimen identification numbers at the collection site to enable results to be reported to the patients.

d. All chemical threat specimens must be triple contained in an approved shipping container and packaged according to Category B infectious substances guidelines. Unless otherwise specified by CDC, these specimens must be submitted to the Texas Department of State Health Services (TDSHS) Laboratory, 1100 West 49th Street, Austin, TX 78756 and accompanied by a Specimen Submission Form (G-2B). The G-2B form and instructions are in Appendix G.

J. FOODS

1) **No food samples will be accepted from individuals**. A sanitarian or health authority must collect food samples. A chain of custody form must accompany food samples suspected of being involved in a terrorist event. (See Appendix I) Food items should be refrigerated and maintained at 0°C to 4.0°C prior to arrival at the laboratory. Do not freeze refrigerated foods. If possible, submit samples to the laboratory in the original unopened containers. Dry or canned foods that are not perishable should be collected and shipped at ambient temperature. Frozen foods should be shipped frozen. Collect at least 100 grams of each sample unit. (Four quarters and one penny weigh approximately 25 grams.)

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2) Shellfish samples should be shucked and packed in crushed ice immediately and transported to the laboratory maintaining an ambient temperature of 0°C to 10°C. **Do not freeze. Samples must be shipped overnight.**

3) Food samples not considered to pose a serious infection risk may be exempt from dangerous goods requirements and regulations.

K. 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 512-458-7460.

L. WATER SAMPLES

1) Drinking Water

a. Routine testing for drinking water samples includes testing for coliforms and *E. coli.* Drinking water samples do not require refrigeration but it is recommended. Samples (at least 100 ml) must be collected in EPA-approved containers (available at TDSHS), which contain sodium thiosulfate (a dechlorinating agent). Testing must begin within 30 hours of collection.

b. If requesting water testing for possible biological chemical threat agents, contact the LRN in your area for assistance with collection and shipping.

c. Water samples not considered to pose a serious infection risk may be exempt from dangerous goods requirements and regulation.

M. MILK

All milk and dairy products must be collected and shipped by a sanitarian. Test requests are coordinated by the sanitarian.

4) MATERIALS AND FORMS

N. Packaging Materials

As mentioned earlier, category A and B infectious substances must be packaged under "triple pack" conditions. The three following packaging descriptions detail components of the "triple pack" system. See Appendix D for diagrams.

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1) Primary Packaging

a. Primary receptacle(s) must be water tight, e.g., screw cap sealed with Parafilm, adhesive tape, or similar positive means, to prevent the cap from loosening.

b. Multiple primary receptacles must be wrapped individually to prevent breakage. The volumes of the multiple specimens will be added to find the total volume of the package and determine whether it is within the maximum allowable limits below.

c. The total package volume **must not** be more than: 1.0 L or 1 kg (air transport) for diagnostic specimens; and not more than 50 ml or 50 g (passenger aircraft), 4 kg or 4 L (cargo aircraft), and 400 kg or 450 L (ground transport) for infectious substances.

2) Secondary Packaging

a. Use enough absorbent material in the secondary container to absorb the entire contents of all primary receptacles in case of leakage or damage.

b. Secondary packaging must be watertight. Follow the packaging manufacturer or other authorized party's packing instructions included with the secondary packaging.

c. Secondary packaging for infectious substances should be a rigid screw-top container; secondary packaging for Category B specimens may be a sealed plastic bag.

d. Secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bars).

3) Outer Packaging

a. The outer package may be made of cardboard or paper fibreboard and must meet the IATA packaging requirements including the 1.2 meter (for diagnostic specimens)/9 meter (for infectious specimens) drop test procedure.

b. Either dry ice or wet ice must be placed outside the secondary packaging for samples that must be transported cold or frozen.

c. **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.

d. Wet ice: packaging must be leak-proof. Ice packs are preferred for diagnostic specimens and infectious substances.

e. 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.

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O. Documentation and Labeling

1) Form G-2B

An itemized list of contents (use Form G-2B for Chemical Threat samples; see Appendix G for instructions for completing this form) must be enclosed between the secondary packaging and the outer packaging. Place the document in a sealed plastic bag to protect from moisture.

2) Required Labeling

4G/CLASS 6.2/10
USA/6-20 SHIPPCO

a. The outer packaging will have the required UN specification markings. A circle containing a "U" over an "N" indicates United Nations specifications have been met. The additional text indicates: the type of package, class of goods the package may carry, last two digits of year of manufacture, authorizing country, and the manufacturer, respectively.

b. **For Category B specimens**, each package and the air waybill must be marked with the following exact wording**:

UN 3373
BIOLOGICAL SUBSTANCE, CATEGORY B

A Shipper's Declaration for Dangerous Goods is **NOT** required for Category B specimens. If Category B specimens are packed in dry ice, the dry ice can be entered onto the waybill. A separate Shippers Declaration for only the dry ice is not necessary.

****As of January 1, 2007, we will no longer accept samples with the shipping name list as "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS".**

c. **For Category A infectious substances**, each package must be marked with the UN ID number and proper shipping name. A technical name should not be marked on the outer package of a Division 6.2 material. For example, a package containing plague:

Infectious Substance, affecting humans
UN2814

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A Shipper's Declaration for Dangerous Goods is also required for Category A infectious substances when transported via air. In addition to the UN ID number and proper shipping name, a technical name (*Genus* spp.) must also be included on the form. The species name should not be included. If the agent is unknown, then "Suspected category A infectious substance" should be used as the technical name.

See Appendix D for packaging diagrams of diagnostic specimens and infectious substances. Appendix E contains checklists for packaging diagrams of diagnostic specimens and infectious substances.

d. **Additional Packaging Labels**

Address label – must have name of person, complete facility name, shipping address and telephone number of both shipper and consignee (no toll-free numbers). The shipper's phone number must be a 24/7 number answered by a person. This information must be on the inner and outer containers.

Shipper's Name *Shipper's Organization* *Shipper's Address* *Shipper's Telephone Number*
Consignee's Organization *Consignee's Address* *Consignee's Telephone Number*

e. **Responsible person label – (for Category B specimens shipped via air or Category A infectious substances only)** the name and telephone number of the person responsible for the shipment. This person could be the shipper, consignee, or other trained and certified person. This person must be knowledgeable of the package contents and be able to provide emergency information in case the package is damaged. The telephone number must be answered 24 hours a day, otherwise a large fine may be assessed.

Person Responsible for Shipment *(Name of person)* *(24/7 telephone number)*

f. **Cargo Aircraft Only label** – use this label if an infectious substance package contains more than 50 ml or 50 g but less than 4 L or 4 kg and must be transported by a cargo plane.

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See Appendix D for a table listing the proper labels to use for diagnostic specimen and infectious substance packaging. In addition, this appendix shows an example of overpack (one or more complete triple packs in the same box).

3) Receipt of Property/Chain of Custody

a. 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. 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. A receipt of property/chain of custody form (Appendix I) must be completed.

b. 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 (Appendix I) and the sentinel/level 3 laboratories would retain the original and submit a copy of the chain of custody with the specimen.

c. Specimens that are considered to be involved in a legal investigation or could result in legal investigation should be secured with evidence tape. All specimens submitted for chemical threat analysis must be secured with evidence tape (Appendix C).

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. The LRN laboratory will coordinate with the FBI or law enforcement and secure the transport of the specimens to the LRN laboratory. The sentinel/level 3 laboratories will need to complete a receipt of property/chain of custody form (Appendix I).

e. Sentinel/Level 3 laboratories are responsible for maintaining their own chain of custody documentation. In the event that a carrier/courier is used for transfer of the samples, the name of the carrier/courier and the shipping/reference number should be recorded on this documentation.

f. If your facility is instructed to ship samples directly to CDC in response to a chemical terrorism event, contact your local LRN reference laboratory listed in Appendix A to receive the required shipping manifest documentation and other instructions.

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5) SHIPPING OPTIONS

P. The DSHS laboratory and Texas LRNs will provide packaging and shipping protocols and training as well as proper shipping containers to sentinel/Level 3 laboratories (see Appendix F for training requirements). 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 the submitter:

1) FedEx Custom Critical has three services that can handle any shipment: CharterAir Dedicated, Blended Services and Point-to-Point Air-Freight offer different plans. The white gloves section at 1-800-255-2421 has dedicated charter shippers that can transport by air or ground as fast as needed. See www.customcritical/fedex.com for details.

2) 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.

3) Laboratories not able to find an appropriate shipping service may contact their local or regional health departments or regional LRN laboratories for assistance.

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APPENDICES

Appendix A
Texas LRN 24/7 Contact Information

LRN	Name	Position	Office Phone	Email Address	24/7 Phone
Austin	Rahsaan Drumgoole	BT Coordinator	512-776-7185	Rahsaan.Drumgoole@dshs.state.tx.us	512-689-5537
	David Klein	CT Coordinator	512-776-3486	David.Klein@dshs.state.tx.us	512-689-9945
	Dan Bost	Emergency Preparedness Branch Manager	512-776-6171	Dan.Bost@dshs.state.tx.us	512-634-6727
Corpus Christi	Donna Rosson	BT Coordinator	361-850-1323	DonnaR@cctexas.com	361-533-3500
Dallas County	Joey Stringer	BT Coordinator	972-692-2762	jstringer@dallascounty.org	972-342-5605
El Paso	Minerva Cutter	BT Coordinator	915-543-3255	Minerva.Cutter@elpasotexas.gov	915-543-9984
Fort Worth/Tarrant County	Rebecca McMath	BT Coordinator	817-321-4755	rbmcmath@tarrantcounty.com	817-929-4720
Harlingen/South Texas	Kristina Zamora	BT Coordinator	956-364-8369	Kristina.Zamora@dshs.state.tx.us	512-694-9306
Houston	Jane O'Brien	BT Coordinator	713-558-3490	Jane.Obrien@cityofhouston.net	713-376-0484
Lubbock	Trisha Jenkins	BT Coordinator	806-775-3087	tjenkins@mylubbock.us	806-775-3774
San Antonio	Patricia Blevins	BT Coordinator	210-207-5883	Patricia.Blevins@sanantonio.gov	210-854-2594
Tyler/PHLET	Janine Yost	BT Coordinator	903-877-5056	Janine.Yost@uthct.edu	903-312-3537

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LRN/Full Service Local Health Departments and Districts for Texas Counties

Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Andrews County	Andrews City-CO Health Dept	208 NW 2nd Street	Andrews	79714	432-524-1434	432-524-1461	Lubbock
Angelina County	Angelina CO & Cities Health Dist	503 Hill Street	Lufkin	75904	936-632-1139	936-632-2640	Tyler
Archer County							Tarrant
Anderson County							Tyler
Angelina County							Tyler
Aransas County							Corpus Christi
Armstrong County							Lubbock
Atascosa County							San Antonio
Austin County							Houston
Bailey County							Lubbock
Bandera County							San Antonio
Bastrop County							Austin
Baylor County							Tarrant
Bee County							Corpus Christi
Bell County	Bell CO Public Health Dist	201 North 8th Street	Temple	76501	254-773-4457	254-773-7535	Austin
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Bexar County	San Antonio Metropolitan Hlth Dist	332 W Commerce, Ste 307	San Antonio	78205-2489	210-207-8730	210-207-8999	San Antonio
Blanco County							Austin
Borden County							Lubbock

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Bosque County							Austin
Bowie County	Texarkana-Bowie CO Fam Hlth Cntr	902 West 12th	Texarkana	75501	903-798-3255	903-793-2289	Tyler
Brazoria County	Brazoria CO Health Department	432 East Mulberry	Angleton	77515-4736	281-756-1484	979-864-1456	Houston
Brazos County	Brazos CO Health Dist	201 North Texas Ave	Bryan	77803-5317	979-361-4440	979-823-2275	Austin
Brewster County							El Paso
Briscoe County							Lubbock
Brooks County							South Texas
Brown County	Brownwood-Brown CO Health Dept	510 East Lee	Brownwood	76801	325-646-0554	325-643-8157	Tarrant
Burleson County							Austin
Burnet County							Austin
Caldwell County							Austin
Calhoun County	Calhoun CO Health Dept	117 West Ash	Port Lavaca	77979	361-552-9721	361-552-9722	Corpus Christi
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Callahan County							Tarrant
Cameron County	Cameron CO Health Dept	1390 W. Expressway 83	San Benito	78586	956-247-3685	956-361-8230	South Texas
Camp County							Tyler
Carson County							Lubbock
Cass County	Cass County Health Dept	123 South Kaufman	Linden	75563	903-756-7051	903-756-5146	Tyler
Chambers County	Chambers CO Health Dept	1107 Wilcox	Anahuac	77514	409-267-8356	409-267-4276	Houston

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Cherokee County	Cherokee CO Health Dept	593 N Main Street	Rusk	75785	903-683-4688	903-683-4899	Tyler/East Texas
Childress County							Lubbock
City of Beaumont	Beaumont Public Health Dept	950 Washington Blvd	Beaumont	77705	409-832-4000	409-832-4270	Houston
City of Dallas	Dallas Envirn & Hlth Svcs Dept (City of)	1500 Marilla Street, Ste 7AN	Dallas	75201	214-670-5711	214-670-3863	Dallas
City of El Paso Department of Public Health	Michael Hill	5115 El Paso Drive	El Paso	79905	915-771-5702	915-771-5729	El Paso
City of Fort Worth	Fort Worth (City of) Public Health Dept	1800 University Dr, Rm 232	Fort Worth	76107	817-871-7201	817-871-7335	Tarrant
City of Houston	Houston Dept of HHS	8000 N Stadium Drive, 8th Flr	Houston	77054	713-794-9311	713-798-0862	Houston
City of Laredo	Laredo (City of) Health Dept	2600 Cedar Avenue	Laredo	78043	956-795-4901	956-726-2632	San Antonio
City of Port Arthur	Port Arthur City Health Dept	449 Austin Avenue	Port Arthur	77640	409-983-8800	409-983-8870	Houston
Clay County							Tarrant
Cochran County							Lubbock
Coke County							Lubbock
Coleman County							Tarrant
Collin County	Collin CO Health Care Servcs	825 N McDonald St, Ste 130	McKinney	75069	972-548-5500	972-548-5550	Dallas
Collingsworth County							Lubbock
Colorado County							Houston
Comal County							San Antonio
Comanche County							Tarrant
Concho County							Austin
Cooke County							Tarrant

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Corvell County							Austin
Cottle County							Lubbock
Crane County							Lubbock
Crockett County							Austin
Crosby County							Lubbock
Culberson County							El Paso
Dallam County							Lubbock
Dallas County excluding City of Dallas	Dallas CO Health & Human Servcs	2377 N Stemmons Freeway	Dallas	75207	214-819-6070	214-819-6022	Dallas
Dawson County	South Plains Public Health Dist	919 East Main Street	Brownfield	79316-0112	806-637-21644	806-637-4295	Lubbock
Deaf Smith County							Lubbock
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Delta County							Tyler
Denton County	Denton CO Health Dept	535 S Loop 288, Ste 1003	Denton	76209	940-349-2900	940-349-2905	Tarrant
DeWitt County	Cuero-DeWitt CO Health Dept	106 N Gonzales Street	Cuero	77954	361-275-3461	361-275-5732	San Antonio
Dickens County							Lubbock
Dimmit County							San Antonio
Donley County							Lubbock
Duval County							San Antonio
Eastland County							Tarrant
Ector County	Ector CO Health Dept	221 North Texas	Odessa	79761	432-498-4141	432-498-4143	Lubbock

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Edwards County							San Antonio
Ellis County							Dallas
El Paso County	El Paso City-CO Hlth & Envirn Dist	5115 El Paso Drive	El Paso	79905	915-771-5702	915-771-5729	El Paso
Erath County							Tarrant
Falls County							Austin
Fannin County							Dallas
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Fayette County							Austin
Fisher County							Lubbock
Floyd County							Lubbock
Foard County							Tarrant
Fort Bend County	Fort Bend CO Health Dept (HHS)	4520 Reading Road, Ste A	Rosenberg	77471	281-342-6414	281-342-7371	Houston
Franklin County							Tyler
Freestone County							Austin
Frio County							San Antonio
Gaines County	South Plains Public Health Dist	919 East Main Street	Brownfield	79316-0112	806-637-2164	806-637-4295	Lubbock
Galveston County	Galveston CO Health Dist	1207 Oak Street	La Marque	77568-5925	409-938-2401	409-938-2243	Houston
Garza County							Lubbock

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Gillespie County							San Antonio
Glasscock County							Lubbock
Goliad County							Corpus Christi
Gonzales County							San Antonio
Gray County							Lubbock
Grayson County	Grayson CO Health Dept	515 North Walnut	Sherman	75090	903-893-0131	903-892-3776	Dallas
Gregg County	Gregg County Health Department	405 East Marshall	Longview	75601	903-237-2620	903-237-2608	Tyler
Grimes County							Austin
Guadalupe County							San Antonio
Hale County	Plainview-Hale CO Health Dist	111 East 10th Street	Plainview	79072	806-293-1359	806-293-5741	Lubbock
Hall County							Lubbock
Hamilton County							Austin
Hansford County							Lubbock
Hardeman County							Tarrant
Hardin County	Hardin CO Health Dept	440 West Monroe	Kountze	77625	409-246-5188	409-246-4373	Houston
Harris County excluding City of Houston	Harris CO Public Health & Envirn Servcs	2223 West Loop South	Houston	77027	713-439-6016	713-439-6080	Houston
Harrison County	Marshall-Harrison CO Health Dist	805 Lindsey Dr.	Marshall	75670	903-938-8338	903-938-8330	Tyler

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Hartley County							Lubbock
Haskell County							Tarrant
Hays County	Hays CO Health Dept	401-A Broadway Drive	San Marcos	78666	512-393-5520	512-393-5530	Austin
Hemphill County							Lubbock
Henderson County							Dallas
Hidalgo County	Hidalgo CO Health Dept	1304 South 25th Street	Edinburg	78539	956-383-6221	956-383-3229	South Texas
Hill County							Austin
Hood County							Tarrant
Hockley County							Lubbock
Hopkins County							Tyler
Houston County							Tyler
Howard County							Lubbock
Hutchinson County							Lubbock
Hudspeth County							El Paso
Hunt County	Greenville-Hunt CO Health Dept	4815 King St., Suite B	Greenville	75401	903-455-4433	903-455-4956	Dallas
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Irion County							Lubbock
Jack County							Tarrant

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Jackson County	Jackson CO Health Dept	411 N Wells, Rm 206	Edna	77957	361-782-5221	361-782-7312	Corpus Christi
Jasper County	Jasper-Newton CO Public Health Dist	139 West Lamar Street	Jasper	75951	409-384-6829	409-384-7861	Tyler
Jeff Davis County							El Paso
Jefferson County							Houston
Jim Hogg County							South Texas
Jim Wells County							San Antonio
Johnson County							Tarrant
Jones County							Tarrant
Karnes County							San Antonio
Kaufman County							Dallas
Kendall County							San Antonio
Kenedy County							South Texas
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Kent County							Lubbock
Kerr County							San Antonio
Kimble County							Austin
King County							Lubbock

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Kinney County							San Antonio
Kleberg County							Corpus Christi
Knox County							Tarrant
La Salle County							San Antonio
Lamar County	Paris-Lamar CO Health Dept	740 SW 6th	Paris	75460	903-785-4561	903-737-9924	Tyler
Lamb County							Lubbock
Lampasas County							Austin
Lavaca County							San Antonio
Lee County							Austin
Leon County							Austin
Liberty County							Houston
Limestone County							Austin
Lipscomb County							Lubbock
Live Oak County	Live Oak CO Health Dept	301 Houston Street P.O. Drawer 670 Crths Annex	George West	78022	361-449-2733 x119	361-449-1013	San Antonio
Llano County							Austin
Loving County							Lubbock
Lubbock County	Lubbock City Health Dept	1902 Texas Avenue	Lubbock	79411	806-775-2945	806-775-3959	Lubbock

Lynn County							Lubbock
Madison County							Austin
Marion County							Tyler
Martin County							Lubbock
Mason County							Austin
Matagorda County							Houston
Maverick County							San Antonio
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
McCulloch County							Austin
McLennan County	Waco-McLennan CO Public Health Dist	225 West Waco Drive	Waco	76707	254-750-5450	254-750-5452	Austin
McMullen							San Antonio
Medina County	Medina CO Health Dept	3103 Avenue G	Hondo	78861	830-741-6191	830-426-4202	San Antonio
Menard County							Austin
Midland County	Midland Health Dept	3303 W Illinois, Space 22	Midland	79703	432-681-7613	432-681-7634	Lubbock
Milam County	Milam CO Health Dept	209 South Houston Street	Cameron	76520	254-697-7039	254-697-4809	Austin
Mills County							Austin
Mitchell County							Lubbock
Montague County							Tarrant
Montgomery County	Montgomery CO Health Dept	701 East Davis, Suite A	Conroe	77301	936-525-2800	936-539-4668	Houston

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
Moore County							Lubbock
Morris County							Tyler
Motley County							Lubbock
Nacogdoches County							Tyler
Navarro County	Corsicana-Navarro Public Health Dist	618 North Main	Corsicana	75110	903-874-6731	903-872-7215	Dallas
Newton County	Jasper-Newton CO Public Health Dist	139 West Lamar Street	Jasper	75951	409-384-6829	409-384-7861	Tyler
Nolan County	Sweetwater-Nolan CO Health Dept	301 East 12th Street	Sweetwater	79556	325-235-5463	325-236-6856	Lubbock
Nueces County	Corpus Christi-Nueces CO PH Dist	1702 Horne Road	Corpus Christi	78416	361-851-7200	361-851-7295	Corpus Christi
Ochiltree							Lubbock
Oldham							Lubbock
Orange County	Orange CO Health Dept	2014 North 10th Street	Orange	77630	409-883-6119	409-883-3147	Houston
Palo Pinto County							Tarrant
Panola County							Tyler
Parker County							Tarrant
Parmer County							Lubbock
Pecos County	Pecos County Health Department	461 S. Highway 285, Suite 2	Ft. Stockton	79735	432-336-2738	432-336-3552	El Paso
Polk County							Tyler

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Potter County	Amarillo (City of) Dept of Health	1411 Amarillo Blvd, East	Amarillo	79105	806-351-7220	806-351-7275	Lubbock
Presidio County							El Paso
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Rains County							Dallas
Randall County	Amarillo (City of) Dept of Health	1411 Amarillo Blvd, East	Amarillo	79105	806-351-7220	806-351-7275	Lubbock
Reagan County							Lubbock
Real County							San Antonio
Red River County							Tyler
Reeves County							El Paso
Refugio County							Corpus Christi
Roberts County							Lubbock
Robertson County							Austin
Rockwall County							Dallas
Runnels County							Tarrant
Rusk County	Rusk County Health Unit	115 North Main St., Ste 500A	Henderson	75652	903-657-0304	903-657-0304	Tyler
Sabine County							Tyler
San Augustine County							Tyler/East Texas
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**

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Area Served	Local Health Dept.	Address	City	Zip Code	Telephone	Fax	LRN region
San Jacinto County							Houston
San Patricio County	San Patricio CO Dept of Health	313 North Rachal Street	Sinton	78387	361-364-6208	361-364-6117	Corpus Christi
San Saba County							Austin
Schleicher County							Austin
Scurry County	Scurry CO Health Unit	911 26th Street	Snyder	79549	325-573-3508	325-573-0380	Lubbock
Shelby County							Tyler s
Smith County	Smith CO Public Health Dist	815 North Broadway	Tyler	75702-4507	903-535-0036	903-535-0052	Tyler s
Shackleford County							Tarrant
Sherman County							Lubbock
Somervell County							Tarrant
Starr County							South Texas
Stephens County							Tarrant
Sterling County							Lubbock
Stonewall County							Lubbock
Sutton County							Austin
Swisher County							Lubbock
Tarrant County excluding City of Fort Worth	Tarrant CO Public Health Dept	1101 S. Main, Rm 2412	Fort Worth	76104	817-321-5300	817-321-5302	Tarrant
Taylor County	Abilene-Taylor CO Health Dept	850 N. 6th St.	Abilene	79601	325-692-5600	325-734-5390	Tarrant

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Terrell County							El Paso
Terry County	South Plains Public Health Dist	919 East Main Street	Brownfield	79316-0112	806-637-2164	806-637-4295	Lubbock
Throckmorton County							Tarrant
Titus County							Tyler
Tom Green County	SanAngelo-TomGreen CO Hlth Dept	2 City Hall Plaza	San Angelo	76903	325-657-4235	325-657-4553	Lubbock
Travis County	Austin-Travis CO HHS	7201 Levander Loop, Bldg. E	Austin	78767	512-972-5010	512-972-5016	Austin
Trinity County							Tyler
Tyler County							Tyler
Upshur County							Tyler
Upton County							Lubbock
Uvalde County	Uvalde CO Health Dept	1021 Garnerfield Road	Uvalde	78801	830-278-1705	830-278-1881	San Antonio
Val Verde							San Antonio
Area Served	**Local Health Dept.**	**Address**	**City**	**Zip Code**	**Telephone**	**Fax**	**LRN region**
Van Zandt County							Dallas
Victoria County	Victoria City-CO Health Dept	2805 North Navarro	Victoria	77901	361-578-6281	361-578-7046	Corpus Christi
Walker County							Houston
Waller County							Houston
Ward County							Lubbock

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Washington County							Austin
Webb County	Laredo (City of) Health Dept	2600 Cedar Avenue	Laredo	78043	956-795-4901	956-726-2632	San Antonio
Wharton County							Houston
Wheeler County							Lubbock
Wichita County	Wichita Falls-Wichita CO PH Dist	1700 Third Street	Wichita Falls	76301-2113	940-761-7805	940-767-5242	Tarrant
Wilbarger County							Tarrant
Willacy County							South Texas
Williamson County	Williamson CO & Cities PH Dist	100 West 3rd Street	Georgetown	78626-5030	512-930-3600	512-943-1499	Austin
Wilson County	Wilson County	#2 Library Lane, Ste #4 PO Box 396	Floresville	78114	830-393-8503	830-393-6031	San Antonio
Winkler County							Lubbock
Wise County							Tarrant
Wood County	Wood CO Health Dept	213 Bermuda Road	Quitman	75783	903-763-5406	903-763-5407	Tyler
Yoakum County Young County Zapata County	South Plains Public Health Dist	919 East Main Street	Brownfield	79316-0112	806-637-2164	806-637-4295	Lubbock Tarrant South Texas
Zavala County							San Antonio

Specimen Collection, Packaging, and Shipment of Suspect Agents for Biological r Chemical Threat Testing from Sentinel Laboratories to LRN Laboratories ev sion 3, For Official Use Only ensit ve but Unclassified - Version: 3.0. Index: EPG 1. Printed: 10-Jun-2013 10:48

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Authorized on: 11-Jun-2012. Authorized by: Richard Po. SOP Unique Reference: 645-2668710. Due for review on: 10-Aug-2013
Author(s): Andrea Cole
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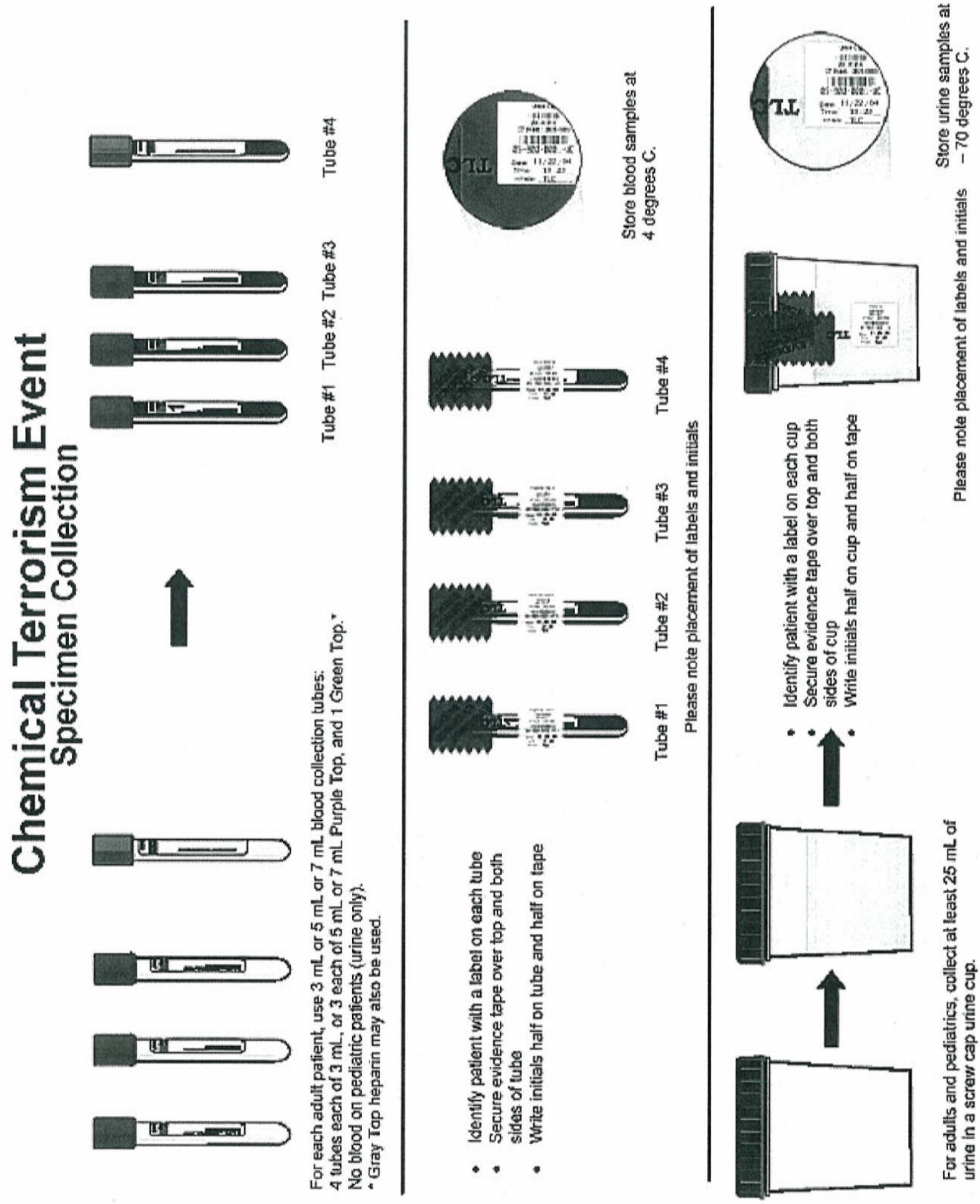
Appendix B
Table of specimen type collection procedures and transport and storage conditions

Specimen Selection	Transport Conditions	Storage Conditions
Sputum/throat: Collect routine throat culture using a swab or expectorated sputum collected into sterile, leak-proof container.	_< 2 h/room temp.	_< 24 h/4°C
Bronchial/tracheal wash: Collect per institution's procedure in an area dedicated to collecting respiratory specimen under isolation/containment circumstance, i.e., isolation chamber "bubble".	_< 2 h/room temp.	_< 24 h/4°C
Blood: Collect per institution's procedure for routine blood culture.	_< 2 h/room temp.	Delayed entry may depend on instrument
Biopsy specimen: Aseptically place two to four portions of tissue into a sterile, leak-proof, freezable container.	~1 h/4°C	-20°C to -70°C
Scabs: Aseptically place scrapings/material into a sterile, leak-proof, freezable container.	~6 h/4°C	-20°C to -70°C
Vesicular fluid: Collect fluid from separate lesions onto separate sterile swabs. Be sure to include cellular materials from the base of each respective vesicle.	_< 2 h/room temp.	< 4°C
Serum: Collect 10-12 cc of serum (additional specimen handling protocols are still under development).	_< 2 h/room temp.	_< 4°C

Appendix C



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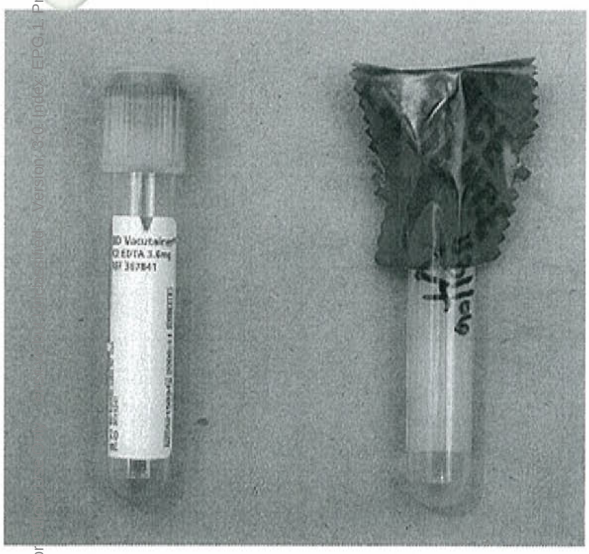
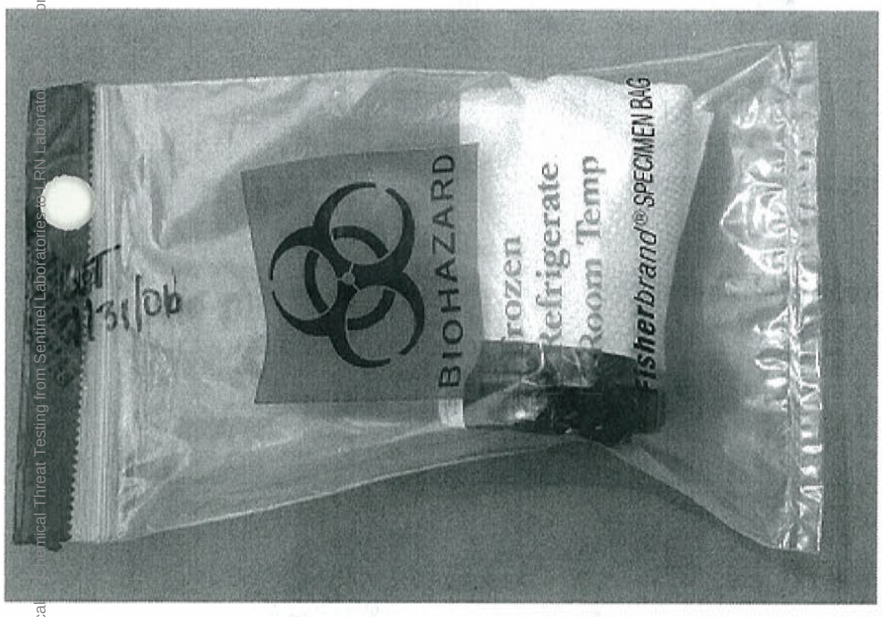
Chemical Threat Specimen Packaging





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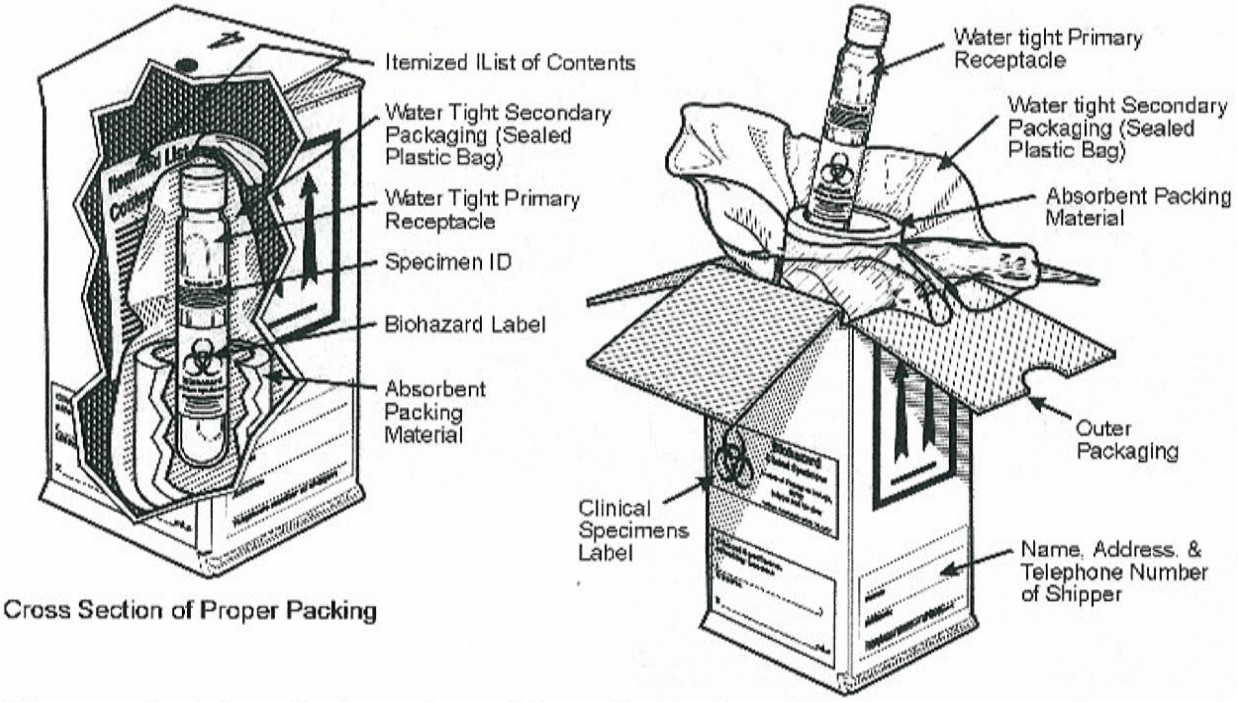
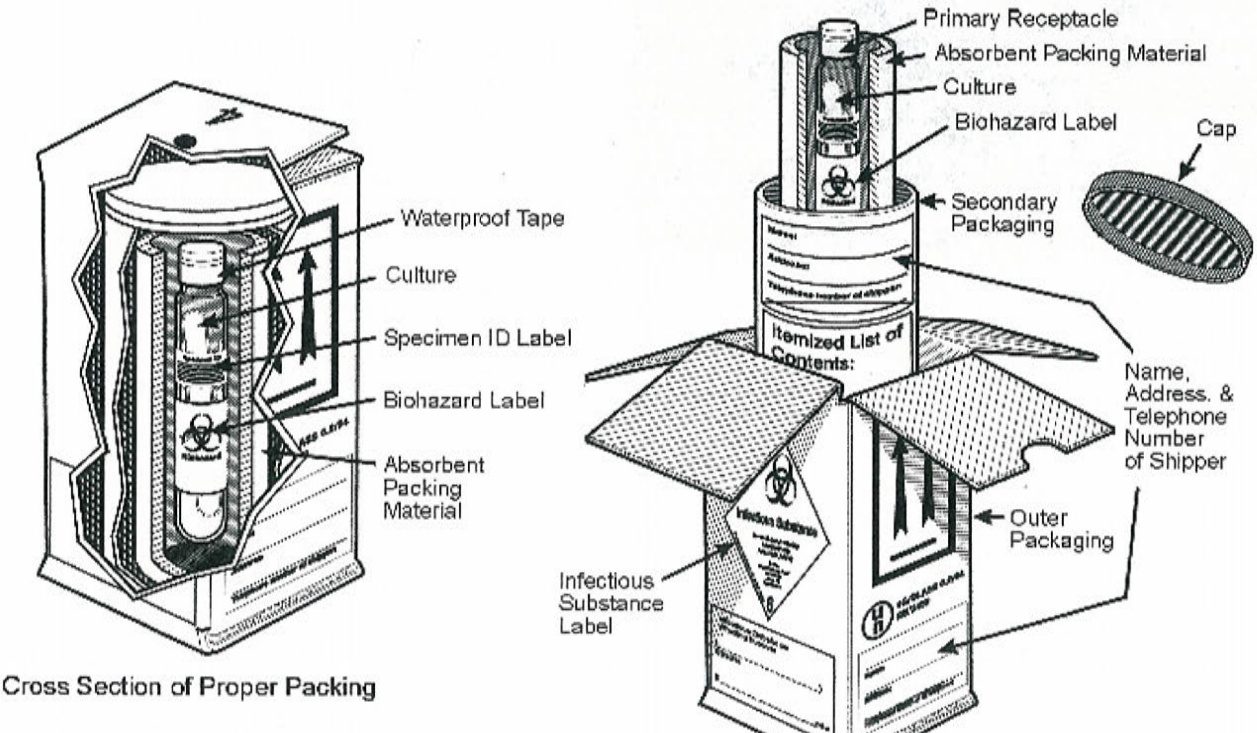
Appendix D



Cross Section of Proper Packing

Diagram of a triple packed parcel containing a diagnostic specimen.

Diagram of triple packed parcel containing for an infectious substance.



Cross Section of Proper Packing

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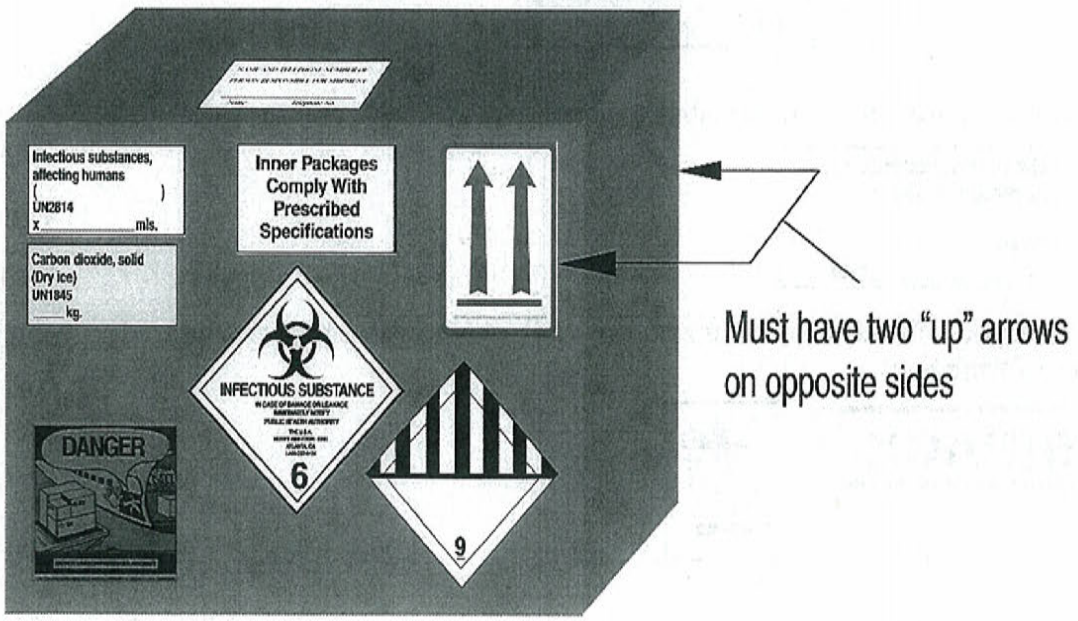
Table of required labels for diagnostic specimens and infectious substances.

	NAME AND TELEPHONE NUMBER OF PERSON RESPONSIBLE FOR SHIPMENT NAME NUMBER	Infectious substances, affecting humans ( ) UN2814 x mls.	UN3373 Biological Substance, Category B	Carbon dioxide, solid (Dry ice) UN1845 kg.	Inner Packages Comply With Prescribed Specifications		
Diagnostic Specimens	✓ (Air only)		✓			✓	
Infectious Substance ***< 50 ml***	✓	✓			✓		
Infectious Substance ***> 50 ml***	✓	✓			✓		✓
For Diagnostic Specimens and Infectious Substances							
Dry Ice used in shipment				✓		✓	
Overpack used					✓	✓	

Example of overpack with infectious substance and dry ice (over 50 ml)



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Appendix E

Infectious Substance 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

4G/CLASS 6.2/2001
USA/6-20 SHIPPCO

- ☐ 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 consignee
- ☐ Name and telephone number of person responsible for shipment
- ☐ Class 6.2: Infectious Substance black on white diamond label

- ☐ 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)

Carbon dioxide, solid
(Dry ice)
UN1845
_____ kg.

- ☐ UN 2814 Infectious substance, affecting humans label and amount

Infectious substances, affecting humans
( )
UN2814
x_____mls.

- ☐ If Overpack used – "Overpack" label and double up arrows label with arrows being black or red on white (2 labels on opposite sides of the box)

OVERPACK

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Diagnostic Specimen Packaging Checklist

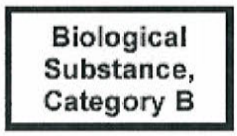
- ☐ Primary containers – leak-proof/ watertight
- ☐ Multiple primary containers – separated to prevent breakage
- ☐ Absorbent material – sufficient to absorb entire contents
- ☐ Secondary packaging – UN Specification Packaging for diagnostic specimens; watertight

4G/CLASS 6.2/2001
USA/6-20 SHIPPCO

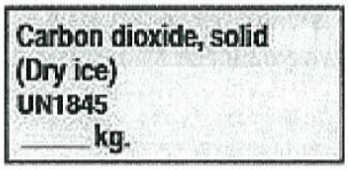
- ☐ Itemized list of contents – between secondary container and outer packaging
- ☐ Rigid outer packaging

Marking and Labels

- ☐ Name, facility name, complete shipping address and telephone number of shipper
- ☐ Name, facility name, complete shipping address and telephone number of consignee
- ☐ 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)



- ☐ If Overpack used – "Overpacks" label and double up arrows label with arrows being black or red on white (2 labels on opposite sides of the box)

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Appendix F

Training requirements

The U.S. Department of Transportation (DOT) Hazardous Materials (HazMat) Regulations (HMR) and 49 CFR (parts 171-180), as well as IATA regulations, 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 Awareness training
E. In-depth security training

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) most recent completion date of training
3) description copy, or location of the training materials used to meet the requirements
4) name and address of the trainer
5) certification that the hazmat employee has been trained and tested

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.

Appendix G

G-2B Specimen Submission Form Instructions

The specimen submission form ***must*** accompany each specimen.
The patient's name listed on the specimen ***must*** match the patient's name listed on the form.
If the Date of Collection field is not completed, the specimen will be rejected.

For mailing and specimen packaging information, visit DSHS Laboratory Services Section's web page at http://www.dshs.state.tx.us/lab/.

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TEXAS Department of State Health Services

Specimen Acquisition: (512) 458-7598

G-2B Specimen Submission Form (Dec 2010) Rev. 4
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) 458-7318
http://www.dshs.state.tx.us/lab

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 / Collected By **
Fax ** | Clinic Code

Section 2. PATIENT INFORMATION -- (** REQUIRED)

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

Last Name ** | First Name ** | MI
Address ** | Telephone Number
City ** | State ** | Zip Code ** | Country of Origin / Bi-National ID #
DOB (mm/dd/yyyy) ** | 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
Medical Record # | Alien # / CUI / CDC ID | Previous DSHS Specimen Lab Number
ICD Diagnosis Code ** (1) | ICD Diagnosis Code ** (2) | ICD Diagnosis Code ** (3)
of Onset | Diagnosis / Symptoms | Risk

☐ Inpatient ☐ Outpatient ☐ Outbreak association: ☐ Surveillance

Section 3. SPECIMEN SOURCE OR TYPE -- (**REQUIRED)

☐ Abscess (site) _____
☐ Blood
☐ Bone marrow
☐ Bronchial washings
☐ Cervical
☐ CSF
☐ Eye
☐ Feces/stool
☐ Gastric
☐ Lesion (site)_____
☐ Lymph node (site)_____
☐ Nasopharyngeal
☐ Plasma
☐ Rectal swab
☐ Serum
☐ Sputum: Induced
☐ Sputum: Natural
☐ Throat swab
☐ Tissue (site) _____
☐ Urethral
☐ Urine
☐ Vaginal
☐ Wound (site) _____
☐ Other:

Section 4. BACTERIOLOGY

Clinical specimens:
☐ Aerobe isolation
☐ Amplified probe (for Gonorrhea/Chlamydia only)
☐ Anaerobe isolation
☐ Botulism @
☐ Diphtheria screen
☐ Enteric pathogens
☐ Gonorrhea culture
☐ Pertussis culture
☐ Strep screen (Group B only)
☐ Toxin / EHEC
☐ Toxin / Other: _____

Pure cultures:
☐ Aerobe ID only
Organism suspected: _____
☐ Anaerobe ID only
Organism suspected: _____
☐ Campylobacter ID only

Special studies:
☐ Toxin studies
☐ Other: _____

ID and typing:
☐ E. coli (EHEC confirmation)
☐ Haemophilus influenzae
☐ Neisseria meningitides
☐ Salmonella
☐ Shigella
☐ Other:

Section 5. MOLECULAR STUDIES

☐ PCR for:
☐ PFGE for:
☐ Other:

Section 6. ENTOMOLOGY

☐ Insect ID
☐ Other:

▲ REQUIRED for cold shipments.
Indicate REMOVAL from:
☐ FREEZER ☐ REFRIGERATOR
DATE | TIME

NOTES: For pure culture ID and typing, please provide biochemical reactions on reverse side of form or attach copy of biochemistry printout. Each test block (ex. Bacteriology) requires a separate form and specimen. Please see the form's instructions for details on how to complete this form. Visit our web site at http://www.dshs.state.tx.us/lab/.

@ = Provide patient history on reverse side of form to avoid delay of specimen processing.
▲= Document **time & date** specimens were **removed from FREEZER / REFRIGERATOR** in the bottom box.

Section 7. ORDERING PHYSICIAN INFORMATION – (** REQUIRED)

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

Section 8. 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 payer guidelines for instructions regarding covered tests, benefit limitations, medical necessity determinations and Advanced Beneficiary Notice (ABN) requirements.
4. If Medicaid, Medicare, or THSteps 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 (8)
Medicaid/Medicare #: _____

☐ Submitter (3)
☐ Medicaid HMO
☐ BIDS
☐ BT Grant (1917)
☐ ELC Grant
☐ HIV / STD (1608)
☐ IDEAS (1620)
☐ Immunizations (1609)
☐ NBS CCC (11)
☐ Refugee (7)
☐ TB Elimination (1619)
☐ Private Insurance (4)
☐ Medicare HMO
☐ Title V - Child Health (5142)
☐ Title V - Dysplasia
☐ Title V - Family Planning (6)
☐ Title V - Prenatal (5143)
☐ Title X (12)
☐ Title XX (13)
☐ TX CLPPP (9)
☐ Zoonosis (1620)
☐ Other: _____

HMO / Managed Care / Insurance Company Name **
Address **
City ** | State ** | Zip Code **
Responsible Party **
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 9. CHEMICAL TERRORISM (CT)

☐ CT Panel (blood and urine)
Justification: _____

Section 10. MYCOBACTERIOLOGY / MYCOLOGY

*** Is drug resistant MTB suspected? ☐ Yes ☐ No ***

Clinical specimens:
☐ AFB smear & culture
☐ Direct Testing Only of ***Processed Specimen Sediment***
☐ T-Spot

Pure cultures:
☐ AFB ID
☐ MTB 1° Drug Panel
☐ MTB 2° Drug Panel
☐ MTB PZA
☐ MTB Genotyping Only/for Compliance
☐ Fungus ID for: ☐ Mold ☐ Yeast
☐ Other Aerobic Actinomycetes ID
☐ Other:

Section 11. PARASITOLOGY

☐ Blood/Tissue parasites @
☐ Intestinal parasites @
☐ Worm ID @
☐ Pin Worm Prep
☐ Fixative: _____
☐ Stain: _____
☐ Other:

NOTE: All dates must be entered in mm/dd/yyyy format.

FOR LABORATORY USE ONLY Specimen Received: ☐ Room Temp. ☐ Cold ☐ Frozen

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Place DSHS Bar Code Label Here: Place the specimen bar code label that will be used to identify and track the specimen in the DSHS laboratory information management system (LIMS). If you are performing remote entry, place DSHS LIMS specimen bar code label here.

Section 1. SUBMITTER INFORMATION

All submitter information that is required is marked with double asterisks (**).

Submitter/TPI number, Submitter name and Address: The submitter number is a unique number that the Texas Department of State Health Services (DSHS) Laboratory Services Section assigns to each of our submitters. To obtain a Texas Provider Identifier (TPI) number, contact Texas Medicaid and Healthcare Partnership (TMHP) at 1-800-925-9126.

To request a DSHS Laboratory Services Section submitter number, a master form, or to update submitter information, please call (888) 963-7111 x7578 or (512) 458-7578, or fax (512) 458-7533 or visit http://www.dshs.state.tx.us/lab/mrs_forms.shtm#email.

NPI Number: Indicate the facility's 10-digit NPI number. All health care providers must use the National Provider Identifier (NPI) number. To obtain an NPI number, contact the National Plan and Provider Enumeration System (NPPES) toll free at (800) 465-3203 or via their web site at https://nppes.cms.hhs.gov/NPPES/Welcome.do.

Indicate the submitter's name, address, city, state, and zip code. Please print clearly, use a pre-printed label, or use a legible photocopy of a master form provided by the Laboratory Services Section.

Contact Information/Collected By: Indicate the name, telephone number, and fax number of the person to contact at the submitting facility in case the laboratory needs additional information about the specimen/isolate.

Clinic Code: Please provide, if applicable. This is a code that the submitter furnishes to help them identify which satellite office submits a specimen and to help the submitter identify where the lab report belongs, if the submitter has a primary mailing address with satellite offices.

Section 2. PATIENT INFORMATION

Complete all patient information including date of collection, time of collection, previous DSHS specimen lab number, last name, first name, middle initial, address, city, state, zip code, country of origin, telephone number, date of birth (DOB), date and time of collection, sex, social security number (SSN), pregnant, race, ethnicity, medical record number, ICD diagnosis code, date of onset, diagnosis/symptoms, risk, and mark either inpatient/outpatient, outbreak association, and/or surveillance.
NOTE: The patient's name listed on the specimen ***must*** match the patient's name listed on the form.

Information that is required to bill Medicare, Medicaid, or private insurance has been marked with double asterisks (**). These fields must be completed. You may use a pre-printed patient label.

Patient Name: If patient is covered by Medicaid, Medicare, or Private Insurance, the name on the specimen form and specimen must match the name on the Medicaid, Medicare, and insurance card, respectively.

Date of birth (DOB): Please list the date of birth. **If the date of birth is not provided, the specimen may be rejected.**

Pregnant: Indicate if female patient is pregnant by marking either Yes, No, or Unknown.

Date of collection/Time of collection: Indicate the date and time the specimen was collected from the patient or other source. Do not give the date the specimen was sent to DSHS. **IMPORTANT: If the Date of Collection field is not completed, the specimen will be rejected.**

Medical Record # / Alien # / CUI: Provide the identification number for matching purposes. CUI is the Clinic Unique Identifier number.

Previous DSHS Specimen Lab Number: If this patient has had a previous specimen submitted to the DSHS Laboratory, please provide the DSHS specimen lab number.

ICD Diagnosis Code(s), Country of Origin, Date of Onset, Diagnosis/Symptoms, and Risk (if applicable): Indicate the diagnosis code or findings that would help in processing, identifyin and billing of this specimen/isolate. If the patient's country of orig. is not the U.S., then please provide the patient's country of origin.

Inpatient or Outpatient (if applicable): Indicate if the patient is currently admitted to a hospital (required for TB patients).

Outbreak/Surveillance (if applicable): Tell us whether the specimen/isolate is part of an outbreak or cluster, or if the specimen is for routine surveillance. If the specimen is being submitted because of an outbreak, write in the associated name of the outbreak next to the outbreak box.

Section 3. SPECIMEN SOURCE OR TYPE

Specimen Source or Type: Indicate the kind of material you are submitting or the source of the specimen or isolate. **For mycobacteriology specimens, complete this section or the specimen will be rejected.**

For tuberculosis treatment, a specimen source or type MUST be provided for specimens used for the diagnosis or monitoring of TB. *DO NOT leave this section blank.* For specimens other than those listed, check the "Other" box and write in the site and source selected from the TB Elimination Division's list of Anatomic Sites and Corresponding Specimen Sources, which can be obtained from your local or regional health department.

TEST

Test Requested: You **MUST** check or specify the specific test(s) be performed by the DSHS Laboratory Services Section. Each tes block requires a separate form AND a separate specimen. Examples of separate blocks are "Bacteriology" or "Mycobacteriology/Mycology" or "Parasitology". For specific test

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Author(s): Andrea Cole

instructions, see the Laboratory Services Section Manual of Reference Services. ***Still waiting on group's response*

Section 4. BACTERIOLOGY

Gonorrhea (GC)/Chlamydia: Please follow the instructions listed below when submitting *Neisseria gonorrhoeae* and *Chlamydia trachomatis* specimens.

Under the "Bacteriology" section of the form:

1. Under "Clinical specimens:"
   a. Check the box marked "Gonorrhea culture", if the specimen is a clinical sample submitted on a transport media such as Remel Transgrow, Remel GC transport media, GemBec Plates, etc.
2. Under "Pure cultures:"
   a. If *Neisseria gonorrhoeae* is isolated and a pure culture is being submitted, please check the box "Aerobe ID only" under "Pure Cultures". Please either hand write in GC or *Neisseria gonorrhoeae* next to the "Aerobe ID: Organism suspected" or attach a copy of any lab work performed at your facility.

Toxin/Other: If requesting Clostridium toxin, please be aware that this test is performed on *Clostridium species, not C. perfringens*.

Section 5. MOLECULAR STUDIES

PCR for: / PFGE for: Write the name of the organism requested for testing.

Other: Write any other special test request.

For special test requests, contact Molecular Biology at (888) 963-7111 x7735 or (512) 458-7735 prior to submitting specimens.

Section 7. ORDERING PHYSICIAN INFORMATION

Ordering Physician's name and NPI Number: Give the name of the physician and the physician's NPI number. **This information is required to bill Medicaid, Medicare, and insurance.**

Section 8. PAYOR SOURCE

THE SUBMITTER WILL BE BILLED, if the required billing information is not provided, is inaccurate, or if multiple payor boxes are checked.

Indicate the party that will receive the bill by marking only one box.

Please do not use this form for THSteps or medical check ups; use the G-THSTEPS form.

If selecting Medicaid or Medicare:
- Mark the appropriate box.
- Write in the Medicaid or Medicare number.
- If the patient name on the form does not match the name on the card, the submitter will be billed.
- Patient's DOB and address must be provided.

If selecting Private Insurance, Medicaid HMO, or Medicare HMO:
- Mark the appropriate box.
- Complete all fields on the form that have an asterisk (*).
- If the private insurance information is not provided on the specimen form or is inaccurate, the submitter will be billed.
- Patient's DOB and address must be provided.

If selecting a DSHS Program:
- If you are contracting and/or approved by a DSHS program to provide services that require laboratory testing, please indicate which program. For program descriptions, see the Laboratory Services Section's Manual of Reference Services located on the web site at http://www.dshs.state.tx.us/lab/prog_desc.htm.
- **Do NOT check a DSHS program as a Payor Source if the patient has Medicaid, Medicare, Medicaid HMO, Medicare HMO, or private insurance.**
- For Title V, check Family Planning, Dysplasia, Child Health, or Prenatal.
- For BIDS (Border & Infectious Disease Surveillance), CLIPP or IDEAS, check the appropriate box. Please check the "Other" box and list the program's name in the space provided if necessary.

HMO / Managed care / Insurance company: Print the name, address, city, state, and zip code of the insurance company to be billed. If all insurance information is not provided on the specimen form, the submitter will be billed. NOTE: The DSHS laboratories are not an in-network CHIP or CHIP Perinate provider. If CHIP or CHIP Perinate is indicated, the submitter will be billed.

Responsible party: Print the Last Name, First Name of the responsible party, the insurance ID number, insurance company's phone number, group name, and group number.

Signature and Date: Have the responsible party sign and date to authorize the release of their information, if DSHS is to bill their insurance or HMO.

Section 11. PARASITOLOGY

Other: If requesting ID on suspected *Naegleria fowleri, Acanthamoeba species, Pneumocystis carinii, Leishmania species, Toxoplasma gondii, Trypanosoma species,* or cultures for amebiasis, mark "Other" and write the name of the organism suspected. Before submitting the specimen, please notify the Laboratory by calling: (888) 963-7111 x7560 or (512) 458-7560.

REFLEX & REFERENCE TESTING:

Please note that additional testing procedures (i.e., reflex testing) will be performed when necessary and clinically indicated by the initial lab test results. Reflex testing will be billed to the appropriate payor in addition to the original test requested. This is particularly applicable to microbiology testing and other laboratory testing requiring confirmation or further diagnostic work.

All reference tests will be billed to the submitter at the prevailing reference laboratory's price with the addition of a handling fee.

For specific test instructions and information about tube types, see the Laboratory Services Section Manual of Reference Services on our web site at **http://www.dshs.state.tx.us/lab/**.

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Appendix H

Shipper's Declaration

Documentation of shipping infectious substances is accomplished by properly completing a *Shipper's Declaration* (a white document with red diagonal stripes along the left and right edges, see below). A *Shipper's Declaration* is not required for diagnostic specimens. 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. The shipper keeps one copy of the Shipper's Declaration, and two originals are given to the carrier with the shipment (NOTE: FedEx requires 3 originals). Only the shipper may complete the document. All corrections in a *Shipper's Declaration* must be neatly "lined out" and the change must be signed (not initialed) by the same person who signed the document. Do not use whiteout. A *Shipper's Declaration* contains the following 20 fields that must be complete and absolutely correct. The numbered fields correspond to those in the sample *Shipper's Declaration* shown at the end of these instructions.

1) *Shipper:* the full name and address of the shipper
2) *Consignee*: the full name and address of the consignee, and the name and telephone number of a responsible person in case of an emergency
3) *Air Waybill Number*: can be entered by the carrier or the shipper
4) *Page __ of __:* number of pages of the *Shipper's Declaration* (usually only one)
5) *Aircraft Limitations:* "mark out" the limitation that does not apply
6) *Airport of Departure*: can be entered by the carrier or the shipper
7) *Airport of Destination:* can be entered by the carrier or the shipper
8) *Shipment Type:* "mark out" the type that does not apply
9) *Quantity of Dangerous Goods and Type of Packaging Used*

These fields are extremely important and must be completed fully and accurately!

a. Proper Shipping Name: proper shipping name 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, please use "G*enus* spp." instead of the specific genus species name. For example: **do not use "Bacillus anthracis", use "Bacillus spp.".**

b. Class or Division: Enter 6.*2* if the substance is an infectious substance. Enter 9 for dry ice or genetically modified microorganisms.

c. 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

d. Packing Group: not applicable to infectious substances, for dry ice use packing group III

e. Subsidiary Risk: not applicable to infectious substances

f. Nature and Quantity of Dangerous Goods

(1) total net quantity of infectious substances
Some carriers require total quantity while others need the quantity broken out. For example, '10 ml' or '2 X 5 ml'. Check with individual carrier for specific requirements.

(2) the number of primary containers (how the substance is divided)

(3) type of material of the outer shipping container

(4) "Overpack Used" if such is the case

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Example: 5 ml x 2 (or 10 ml)
All packed in one fibreboard container (this spelling is required) Overpack used

g. *Packing Instructions Used:* applicable packing instructions
For example:
PI 602 Infectious Substance
PI 904 Dry Ice
PI 913 Genetically Modified Organisms

h. *Authorization:* Enter any special provisions or exceptions used to bypass usual regulations (e.g., A81 and A82 [see Identification section]).

10) *Additional Handling Information:* At least two required notices regarding special responsibilities must be given in this field:
a. 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. Beepers and pagers are not considered "direct access."
b. a statement: "Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made."

11) *Name and Title of Signatory*: name and title of person who signs the document (the shipper)

12) *Place and Date:* place and date of signing

13) *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.

NOTE: Federal Express requires *Shipper's Declarations* to be typed or electronically generated and will not accept handwritten documents. Some carriers may accept handwritten documents. Check with individual carriers to determine their requirements. Federal Express also requires that three (3) originals of the *Shipper's Declaration* accompany the shipment. A *Shipper's Declaration* has many fields, each of which must be completed in an exact way. Entries must be accurate, neat, legible, and correctly spelled and punctuated. Otherwise, the carrier has the right and a duty to reject the shipment. This appendix shows a completed and acceptable *Shipper's Declaration*. If *Shipper's Declaration* is not absolutely, positively 100% correct, it is incorrect and will be rejected by the carrier.

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SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline.)

Shipper Name of Shipper
Company name
Complete address (no P.O. Boxes)
Telephone number (include area code)
Person responsible (name & telephone)

Air Waybill No. 1 1 ← use Air Waybill number of package
Page 1 **of** 1 **Pages** ← REQUIRED
Shipper's Reference Number (optional)

Consignee
Name of Recipient
Company name
Complete address (no P.O. Boxes)
Telephone number
(include area code)

← red markings are REQUIRED ←

Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

Cross-out choice that does NOT apply (if quantity >50 ml, transport must occur on cargo aircraft)

Cross-out choice that does NOT apply (infectious substances are usually non-radioactive)

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT | ~~CARGO AIRCRAFT ONLY~~

Airport of Departure: City, State, Country

Airport of Destination: City, State, Country

Shipment type: *(delete non-applicable)*
NON-RADIOACTIVE | ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification: Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (GENUS SPECIES)	6.2	UN2814			1 FIBREBOARD BOX x _____ ml	602	
Carbon dioxide, solid (Dry ice)	9	UN1845	III		x _____ kg	904	
If parcel contains dry ice, include the following:							
If UN specification markings are not visible because the overpack covers the secondary packaging, include:					OVERPACK USED		

Additional Handling Information
Prior arrangements as required by the ICAO and IATA Dangerous Goods Regulations 1.3.3.1 have been made. ← REQUIRED
24-hr. Emergency Contact Tel. No. _____

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.

Name/Title of Signatory Shipper's name, Title, company name
Place and Date Date shipped, City, State, Country
Signature *(see warning above)* Shipper's signature

Appendix I

TEXAS Department of State Health Service

Specimen Acquisition: (512) 458-7598

G-27 Biothreat Specimen Submission Form (May 2011)
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
Phone: (512) 458-7185 Fax: (512) 458-7431
http://www.dshs.state.tx.us/lab
http://www.dshs.state.tx.us/lab/epr.shtm

For DSHS Use Only
Place DSHS Bar Code Label Here

Please PRINT all FIELDS MUST be FILLED IN-Enter N/A if Appropriate

Has FBI been notified? ☐ YES ☐ NO

NPR assessment ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Section 1. SUBMITTER

Submitting Agency Case #	Submission Date	Submitter #

Agency / Submitter Name				
Address				
City	State	Zip Code	Phone #	Fax #
Email Address	Signature			

Section 2. Reporting Information

Agency/Submitter Name			
Address			
City	State	Zip Code	
Phone #	Fax #		
Email Address			

Section 3. HAZMAT SCREEN

RESULTS OF HAZARDOUS MATERIAL SCREEN DONE BY SUBMITTING AGENCY
(The Laboratory may REJECT Specimens that have not been subject to a Hazard Material Screen)

Explosive ☐ Flammable ☐ Oxidizer ☐

Protein ☐ Radioactive ☐ Corrosive (pH) ☐

Section 4. SAMPLE COLLECTION & SIZE LIMITATION

- At a minimum, all materials submitted for testing must be placed in sealed, triple containers
- Outer packaging must be treated with a disinfectant effective against bacterial spores, e.g., 10% bleach
- Material packaging must not exceed 15"x15"x15"
- If suspect material is a liquid, submit 5ml (5cc)
- Samples can only be returned to the submitter

Section 5. SUBMITTED ITEMS

All Negative Samples will be Destroyed unless otherwise Indicated

Item #	Description	Return to Submitter?
		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO
		☐ YES ☐ NO

FOR LABORATORY USE ONLY: CHAIN OF CUSTODY

Case #_____

Received by: (print/sign)	Date:	Time:
Agency:		
Comment:		
Received by: (print/sign)	Date:	Time:
Agency:		
Comment:		
Received by: (print/sign)	Date:	Time:
Agency:		
Comment:		

Sample Description :

Additional Comments or Instructions:

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Appendix

Document Revision History

Peer Review Requested on 20-Aug-2012 15:48 by Sheri Larson

Peer Review tasks were assigned to the following users: Rahsaan Drumgoole

Tasks were also assigned to the following lists: CT-Chemical Threat (William Edgemond, Sheri Larson).

This review is to be completed by 10-Aug-2013

Document Reviewed on 20-Aug-2012 15:47 by Sheri Larson

Review date set to 10-Aug-2013 - Lab Director approved this document on 8/10/2011. Last review was completed on 8/20/12. Next review scheduled for 8/10/2013.. The following users will be notified when a review is due for this document:

Rahsaan Drumgoole, William Edgemond, Sheri Larson.

This document was originally due for review on 10-Aug-2012.

Review Task Completed on 20-Aug-2012 15:45 by Sheri Larson

Sheri Larson completed task, ""

Review Task Completed on 20-Aug-2012 08:36 by Rahsaan Drumgoole

Rahsaan Drumgoole completed task, ""

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This review is to be completed by 14-Aug-2012

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William Edgemond completed task, ""

Peer Review Requested on 11-Jun-2012 16:00 by Richard Po

Peer Review tasks were assigned to the following lists: BT-BioThreat (Rahsaan Drumgoole, Richard Po), CT-Chemical Threat (William Edgemond, Richard Po, David Klein).

This review is to be completed by 10-Aug-2012

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Authorized on 11-Jun-2012 15:59 by Richard Po

Authorised version 3.0 - Lab Director approved SOP 8/10/11. The following users will be notified when a review is due for this document: Rahsaan Drumgoole, William Edgemond, David Klein, Richard Po

Creation on 11-Jun-2012 10:19 by Cindy Crouch

New SOP created