TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	7/1/2013
Department:	Micro	**Due Date:**	7/31/2013
		Implementation:	**8/1/2013**

DESCRIPTION OF PROCEDURE

Name of procedure:
Bioterrorism Response Guidelines **GEC / SGAH / WAH QDMI779v2.0A** **Select Agents Receipt, Handling & Transport Guidelines** **GEC / SGAH / WAH QDMI817v1.0A**
Description of change(s):
These are new SOPs to meet CAP requirements. Review the contents to acknowledge you are aware of them. They will be implemented on August 1, 2013

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP **Approved draft for training**

Title	**Bioterrorism Response Guidelines**
Prepared by	William Becker, DO, MPH, and P. Cerwinka, MSc. **Date:** 5/15/2012

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date: 6/04/2012**	
Print Name and Title	**Signature**	**Date**
Paul L. Cerwinka, M.Sc. RM (AAM) **National Director Microbiology**	*On file*	**5/15/2012**
Jay Lieberman, MD **BPT Medical Advisor**	*On file*	**6/1/2012**
Stephen C. Suffin, MD **Chief Laboratory Officer**	*On file*	**6/1/2012**

Retirement Date:	
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. PURPOSE

The purpose of this document is to provide guidance to employees, contractors and other authorized persons at Quest Diagnostics sites who may be presented with a bioterrorism threat (package, letter, call, patient exposure specimens) or an isolated organism of a known "Select Agent".

2. SCOPE

These Guidelines will apply to all employees, contractors and other authorized persons at Quest Diagnostics business units.

3. RESPONSIBILITY

Responsible Party	Task
Managing Director	To provide the resources to support these guidelines and any actions taken in response to an exposure to, containment of, or loss of, a BTA or Select Agent.
Laboratory Director (CLIA license holder)	To provide any support needed to make this SOP operational and to make all appropriate persons aware of its contents. To interface with law enforcement and public heath and to act as a conduit for information between public health and appropriate laboratory personnel. To provide information and consultation regarding need for medical evaluation and follow up, depending on the situation.
Microbiology, Specimen Processing and Referrals Leadership	To provide support and technical information as needed in regards to currently defined suspected or known BTA or Select Agents and any changes that may occur. In addition, to be responsible for the proper packaging and handling of any suspected or known Select Agents they are aware of in their laboratory. To insure all employees are familiar with these guidelines, their location in the department and any actions needed on their part and to cascade information to necessary individuals as appropriate.
EHS Management	Maintenance of this document and to provide bio-safety training to any employees, as needed. EHS will cascade information to necessary individuals as appropriate.

Responsible Party	Task
Other Employees	To be familiar with these procedures and guidelines in relationship to their specific job duties, (e.g. couriers)

4. DEFINITIONS

- **Biological Agents** – Living organisms that can cause disease in humans. These may include viruses, bacteria, or fungi. Category A and B Substances. (See Addendum 1)

- **Bioterrorism** – The deliberate release of a highly lethal biological agent in an unsuspecting civilian population with the intent to spread the organism and cause harm. These agents may include; anthrax, smallpox, Ebola, plague or others.

- **BTA** – Bioterrorism Agent – organism being used as an agent of terrorism. See "*Select Agent*" but may include virulent organisms such as Salmonella, Shigella or M. tuberculosis.

- **BT Event** – Bioterrorism event, which may be either **overt** or **covert**. An **overt** attack would be accompanied by an announcement that a specific agent was released. *Samples for testing would be submitted directly to a public health reference laboratory* (i.e. local or state health laboratory). A **covert** attack involves the release of an organism or toxin without an announcement. Clinical laboratories would almost certainly detect the first cases of disease and raise suspicion of a possible BT Event. *Organisms isolated by the clinical laboratory must be forwarded to the appropriate local or state public health laboratory*.

- **CDC** – Centers for Disease Control and Prevention

- **LRN Reference Laboratory (formerly Level B and C)** – Laboratory Response Network reference Laboratories are local and state public health laboratories, selected academic or university based laboratories, designated specialty laboratories (veterinary, water, food, chemical, military, agricultural) and certain international laboratories that possess the reagents and technology for more specialized testing of organisms, including toxin testing, that specimens are referred to by Sentinel laboratories. In some cases isolates are referred from Reference Laboratories to National Laboratories operated by CDC, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), and the Naval Medical Research Center (NMRC). National Laboratories are responsible for specialized strain characterizations, bioforensics, select agent activity, and handling certain highly infectious biological agents.

- **Select Agent** – Certain biological agents in the form of organisms, virus or toxins, known to have a potential use as an agent of bioterrorism as defined by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and Centers for Disease Control and Prevention (CDC) Select Agent Programs and Federal Bureau of Investigation (FBI). See *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817).
  http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

- **Sentinel Laboratory (formerly Level A)** – Sentinel laboratories are clinical laboratories that follow BSL – 2 guidelines. Their primary responsibility is to recognize and rule out or refer suspicious agents. Even though many sentinel laboratories are capable of providing a "presumptive identification" of some of the BTAs, they must refer isolates to an LRN Reference laboratory or "Registered Entity".

- **Registered Entity** – A laboratory or person who has registered with either the CDC or APHIS (but not both) to posses and work with Select Agents which are all BTA's. They must register using APHIS/CDC form 1. They receive a Unique Identifying Number (UIN) for each person handling Select Agents who is also finger printed and investigated. These labs may be able to provide definitive identifications and other services and may be a LRN lab. Note: Focus Diagnostics is a Registered Entity.

5. PROCEDURE

There are several ways in which the laboratory may come in contact with a BTA or Select Agent; 1) a known or suspected isolate, 2) a clinical specimen suspected of containing a BTA. 3) a substance or item suspected of containing a BTA or, 4) A culture being worked up in Microbiology is grows a presumptive BT or Select Agent. Refer to *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817) for handling and Transport guidelines of Select Agents which are BTA's.

In the event of a bioterrorism threat, please act promptly to diminish the potential harm to you and others. Follow the guidelines below. If at any time you are unable to determine the next step or have questions, contact your supervisor or one of the persons listed at the end of these guidelines.

TEST REQUESTS AND RECEIVING SPECIMENS	
If	**Then take these actions**
You receive a *clinical specimen* and test request from a client containing a possible BTA as the result of an overt BT Event:	• Politely inform the client we **Do Not** accept specimens suspected of containing a BTA, **as the result of an overt BT Event**, for diagnostic testing and or identification. • Ask them to contact their local or state public health laboratory. • Refer them to your manager or director if they still insist that we accept the specimen.
You receive a request for identification of a BT or Select Agent from *a powder or object, or an environmental specimen*:	• In **NO** case can a Sentinel Laboratory accept environmental (powders, letters, packages), animal, food, or water specimens for examination, culture, or transport for BTA. Such **specimens must** be submitted directly to the nearest LRN Reference Laboratory.

TEST REQUESTS AND RECEIVING SPECIMENS	
If	**Then take these actions**
You receive a request for identification of a BT or Select Agent from *a powder or object, or an environmental specimen*: (cont.)	• **Do not** move or shake it • If you have handled the item without gloves , wash your hands thoroughly with soap and water • Wearing gloves, isolate the mail/package and restrict access to the area • Immediately notify your supervisor, manager or director. If unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Do not attempt to clean up the area of receipt unless instructed. • Compile a list of persons who may have had contact with the item or been in the vicinity.
You receive a *clinical specimen* and test request *to rule out Anthrax, Tularemia, Yersinia, or Brucella* from a client in the *absence* of an overt BT Event:	• **Do not** open the package or box. • These requests may processed, **however you must immediately** notify your supervisor, manager or director. • Test order codes are available for each organism. • Accession the specimen and attach labels to the **outside** of the specimen bag. • Wearing gloves, immediately relocate the package to Microbiology where it can be placed in a Class II Biological Safety Cabinet. • If you have handled the item without gloves, wash your hands thoroughly with soap and water.
You receive a request for identification of *an isolate of a suspected or known Select Agent or BTA* from a client as the result of an overt or covert BT Event:	• **Do not** open the package or box. • Wearing gloves, immediately relocate the package to an area where it can be placed in a Class II Biological Safety Cabinet. • If you have handled the item without gloves, wash your hands thoroughly with soap and water. • **Immediately notify your supervisor, manager or director.** If unavailable contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers).

TEST REQUESTS AND RECEIVING SPECIMENS	
If	**Then take these actions**

You receive a request for identification of *an isolate of a suspected or known Select Agent or BTA* from a client as the result of an overt or covert BT Event: (cont.)	• Contain the specimen in a locked, secure area and restrict access.
	• **Important:** Refer to the *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817) for handling and transport instructions of suspected vs. known agents.
	• Compile a list of persons who may have had contact with the item or been in the vicinity and give it to the Laboratory Director.
	• Inform the Quest Diagnostics BT Task Force chairperson of receipt of a known Select Agent:
	Dr. William Becker
	913-577-1703 or
	513-502-5718 (cell) or
	William.J.Becker@QuestDiagnostics.com
	• Call the client and explain that your laboratory is a "Sentinel" Lab and therefore only allowed by law to "rule out and refer" to a Registered Entity or a LRN Reference Laboratory.
	  • Ask the client if they want the isolate sent to a Registered Entity, such as Focus Diagnostics.
	  • If they request the isolate to be sent out, refer to the *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817).
	  • If the client does not request referral to a Registered Entity, destroy the agent by autoclaving or chemical sterilization. Destruction must be documented using CDC form 4A section B within 7 days. For current information, refer to:
	http://www.selectagents.gov/resources/APHIS-CDC_Form_4A_ReferenceLab_SampleProvider-PrintOnly-English.pdf

THREATS AND EXPOSURES	
You receive a phone threat that a BTA has been sent to your lab:	• Immediately complete the Bio-Terrorism Phone Threat Checklist (Addendum 4) and notify your supervisor, manager or director.

If an employee thinks they may have been exposed or a patient presents at a PSC or other Quest Diagnostics site and feels they have been infected with a BTA's:	• Immediately isolate the employee or patient • Restrict access to the area and/or site • Notify the person's doctor. Assist getting them to a medical provider for evaluation and treatment. • Notify EHS, your Laboratory Director and site leadership and if unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Also notify the BT Task force chair or Chief Laboratory Officer listed in Emergency Contact Phone Numbers (Addendum 3). • Once the situation is assessed and the validity of the claim verified, you may need to disinfect the site depending on directions from your management.
If an employee or environmental exposure is <u>confirmed</u>:	• Immediately isolate the employee(s) (as applicable). • Restrict access to the area and/or site. • Notify the employee's doctor. Assist getting the employee to a medical provider for evaluation and treatment. • Notify EHS, your Laboratory Director and site leadership and if unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Notify the BT Task force chair or Chief Laboratory Officer listed in Emergency Contact Phone Numbers (Addendum 3). If unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Complete the **Select Agent or Bioterrorism Agent Exposure Incident Report Form** (Addendum 1) and **Incident, Injury and Illness Report Form** (refer to the EHS Bloodborne Pathogens Exposure Control Plan or EHS intranet webpage). Send them to the EHS Department within 24 hrs. • Disinfect the area, when applicable, according to the *Comprehensive Microbiology Safety* SOP (QDMI726).
If NO Actual BTA Exposure Occurred	• To document that no exposure occurred, complete the Select Agent or Bioterrorism Agent Exposure Incident Report Form (Addendum 1) and send to the EHS Department.

ISOLATION OF AN AGENT IN THE MICROBIOLOGY LABORATORY	
If	**Then take these actions**
A suspected BT or Select Agent is isolated using presumptive methods in the Microbiology department.	• Remember to **ONLY** "Rule out or Refer". • Wearing appropriate PPE, immediately relocate the isolate to a Class II Biological Safety Cabinet and restrict

	access.
	• Follow **ALL** safety precautions as outlined in the *Comprehensive Microbiology Safety* SOP (QDMI726) as well as the *Select Agents Receipt, Handling & Transport Guidelines* (QDMI815).
	• Immediately notify your supervisor, manager or Laboratory Director.
	• If the isolate is one of the following suspect BT agents, refer to the specific BPT SOP for identification and handling instructions:
	  • *Bacillus anthracis Screen* (QDMI725)
	  • *Brucella sp. Screen* (QDMI729)
	  • *Francisella tularensis Screen* (QDMI728)
	  • *Poxvirus Cytopathic Effect (CPE)* (QDMI778)
	  • *Yersinia pestis Screen* (QDMI727)
	• If the isolate is not one of the above suspect BT or Select agents, refer the isolate to a Registered Entity. Follow all applicable procedures as described in *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817).
	• Inform the Quest Diagnostics BT Task Force Chairperson of a suspected BT or Select Agent.
	  Dr. William Becker
	  913-577-1703 or
	  513-502-5718 (cell) or
	  William.J.Becker@QuestDiagnostics.com
	• If the isolate is to be sent to a Registered Entity Lab, it must be packed by qualified persons to meet current standards. Follow guidance from the CDC Select Agent Program. Contact the Quest Diagnostics Registered Entity laboratory (Focus).
	• Complete APHIS/CDC Form 2 to request authorization to transfer a select agent or toxin. It also provides documentation of the transfer. By regulation, an APHIS/CDC Form 2 must be completed for each transfer of select agent(s) or toxin(s) and maintained for three years.

6. RELATED DOCUMENTS

- Quest Diagnostics *Bloodborne Pathogens Exposure Control Plan*
- Quest Diagnostics *Comprehensive Microbiology Safety* (QDMI726).
- Quest Diagnostics *Accessioning, Packing and Shipping of Microbiological Isolates* (QDMI790)
- Quest Diagnostics *Bacillus anthracis Screen* (QDMI725)
- Quest Diagnostics *Brucella Screen* (QDMI729)
- Quest Diagnostics *Clinical Specimens Suspected of Highly Virulence Organisms* (QDMI815)
- Quest Diagnostics Critical and Priority Result Policy and Procedure SOP (QMED704).

- Quest Diagnostics Environmental Health and Safety Manual.
- Quest Diagnostics *Francisella tularensis Screen* (QDMI728)
- Quest Diagnostics *Packing and Receipt of Isolates in the Microbiology Department* (QDMI792)
- Quest Diagnostics Records Management Program for Record Retention Requirements.
- Quest Diagnostics *Select Agents Receipt, Handling & Transport Guidelines* (QDMI817)
- Quest Diagnostics *Transportation of Infectious Specimen Transport Kits* (QDMI791)
- Quest Diagnostics *Yersinia pestis Screen* (QDMI727)
- Quest Diagnostics Mailroom Security Policies. 2001
- Quest Diagnostics *Poxvirus Cytopathic Effect (CPE)* SOP (QDMI778)
- Bioterrorism Response Plan, 35023, Shady Grove Adventist Hospital Safety Management Policy Manual, available on Adventist Healthcare intranet
- Bioterrorism Response Plan, Appendix K, Washington Adventist Hospital Safety Manual, available on Adventist Healthcare intranet

7. REFERENCES

1. CDC website for Emergency Preparedness & Response: http://www.bt.cdc.gov/
2. CDC Guidelines for State Health Departments, October 14, 2001 Revision. U.S Department of Health and Human Services, Washington., DC.
3. CDC and APHIS Select Agent Web sites http://www.selectagents.gov/ and http://www.aphis.usda.gov/programs/ag_selectagent/
4. Federal Register Dept of Health and Human Services CFR parts 73 and 73, http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf

8. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
2.0	6/13/13		Initial adoption of corporate SOP QDMI779 (v2.0) with the following local changes.	L. Barrett	R. Master
2.0	6/13/13	Page 1	Added referral to electronic signature page. Correct SOP title in header	L. Barrett	R. Master
2.0	6/13/13	5	Added Local & State Health Dept. and refer to Addendum 3	L. Barrett	R. Master
2.0	6/13/13	6	Added local hospital policies	L. Barrett	R. Master
2.0	6/13/13	Add. 3	Local BU names and phone numbers added.	L. Barrett	R. Master

9. ADDENDA

Addendum	Title
1	Select Agent or Bioterrorism Agent Exposure Incident Report Form
2	IATA Shipping Regulations for Category A and B Substances by Air
3	Emergency Contact Phone Numbers
4	Bioterrorism Threat by Phone Checklist

Addendum 1

Select Agent or Bio Terrorism Agent Exposure Incident Report

Incident Date: _____
Time:_____ ☐ AM ☐ PM

Person Completing Form
Name:_____
Contact Number:_____

Location of Incident
Name of Site:_____
Address:_____
City, State, Zip_____
Area Code and Number/ext.:_____

Persons Directly Involved in Incident (Attach additional sheets if needed)
Name:_____
Area Code and Number (Work):_____
Area Code and Number (Home):_____

Witness to Incident, If Applicable (Attach additional sheets if needed)
Name:_____
Area Code and Number (Work):_____
Area Code and Number (Home):_____

What Type of Situation Occurred?

☐ Pkg or Mail ☐ Phone Threat ☐ Client Call ☐ Pt/EE Exposure ☐ Isolated Organism

Where at the site did the incident occur?

_____

What Happened? (Describe sequentially and add additional sheets as needed)

_____
_____
_____

What Was Your Response? (Describe sequentially and add additional sheets as needed)

_____
_____
_____
_____

Addendum 2

IATA Shipping Regulations for Category A and B Substances by Air

The international rules for air shipment of Infectious and Noninfectious Substances, known as the ICAO (International Civil Air Organization) Technical Instructions are codified by the International Air Transportation Association (IATA) and affect all air shipment regardless of their origination. IATA describes two categories of infectious material. Category A Infectious Substance and Biological Substances, Category B as well as how such material is defined, classified, packaged, and transported. Requirements for human and animal biological materials that are exempt from the regulations as well as material defined as Regulated Medical Waste are also described.

Infectious substances are materials that are capable of causing disease in humans and/or animals, and include genetically modified microorganisms, biological products, diagnostic specimens, and clinical and medical waste. These substances are known to contain, or reasonably expected to contain, micro-microorganisms including bacteria, viruses, parasites, fungi or recombinant microorganisms (IATA 3.6.2). An infectious substance transported in a form that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans when exposure to it occurs is designated as **a** Category A Infectious Substance. If a material is unlikely to cause human or animal disease (i.e., fixed tissue), it is Exempt from (not subject to) IATA regulations (See iata.org/whatwedo/cargo/dangerous_goods/Pages/infectious_substances.aspx).

Biological Substance, Category B: An infectious substance which does not meet the criteria of an infectious substance, category A is a biological substance, category B for shipping purposes. Substances in this category must be assigned to UN 3373 with a proper shipping name of Biological Substance, Category B. This category includes items formerly shipped as diagnostic specimens.

The most significant provisions in the rules affect air shipment of liquid specimens. Emphasis is on the use of sturdy, leak proof specimen collection containers. Triple packaging (primary container, with absorbent material (if liquid), leak proof secondary container, sturdy outer shipping container) is required for shipping all infectious and noninfectious specimens. When shipping infectious Category A or Category B materials either the primary or secondary container must meet leakage requirements (95kPa pressure test).

Many patient specimens are shipped from collection sites (e.g., physicians' offices, nursing homes, clinics, etc.) to testing laboratories by private or contract couriers in dedicated vehicles. These patient specimens may be classified as either non-infectious (Exempt Human Specimen); or infectious (Category A, UN2814 or Category B, UN3373). Couriers who transport patient specimens are considered to be Hazmat Employees and as such require appropriate training as indicated in the current DOT regulations.

DOT regulations affect all shipments by air or ground transportation within and between the United States, and harmonizes DOT regulations (Title 49 CFR) with the IATA regulations. Refer to the DOT Pipeline and Hazardous Materials Safety See administration website for the current US regulations. www.phmsa.dot.gov.

Addendum 3

Emergency Contact Phone Numbers			
Shady Grove Adventist Hospital Washington Adventist Hospital Germantown Emergency Center			
Title or Department	**Name**	**Office Number**	**Cell Number**
Medical Director	Cacciabeve, Dr. Nicolas	SGAH: 240-826-6096 WAH: 301-891-6620	703-200-9521
Regional Operations Director	Loffredo, Lori	301-891-5627	240-475-9489
Laboratory Director	SanLuis, Rob	240-826-6095	240-6203-413
Chantilly, VA			
Main Laboratory		703-802-6900	
Laboratory Director	Sisco, Dr. Kenneth	703-802-6900 67007	
Technical - Laboratory Operations, Director	Raglin, Ron	703-802-6900 67809	
Environment Health & Safety Director	Mason, Bryan	703-802-6900 66425	301-869-9331
Environment Health & Safety Specialist	Clark, Dr. Richard	703-802-6900 67067	703-330-5952
Director, Hospital Microbiology	Master, Ron	703-802-6900 65206	703-431-2297
Corporate #'s:			
Chief Laboratory Officer	Suffin, Dr. Stephen	973-520- 2081	818-398-6189
Bio-terrorism Task Force Chair	Becker, Dr. William	913-577-1703	513-502-5718
EHS, Director - Corporate	Lewis, Clete	303-779-1597	303-204-3768
Agency #'s:			
CDC Emergency Response		**770-488-7100**	
County Department of Public Safety		911	
County Emergency Dispatch Center, Fire, Police, Ambulance		911	
County Office of Emergency Management	Montgomery County	240-777-2300	
Federal Bureau of Investigation		202-324-3000	
State Public Health Lab (Maryland)		410-925-3121	
Poison Control Center		800-222-1222	

Addendum 4

Bio-Terrorism Phone Threat Checklist

Instructions: LISTEN , do not interrupt the caller.

Name of person receiving the call:_____

Time:_____ Date:_____

Caller's Identity :_____ Sex: M / F Approximate Age: _____

Origin of Call: _____Local _____Long Distance_____Booth_____Internal*

(*within the building?)

Voice Characteristics	Speech	Language	Accent	Manner	Background Noises
□ Loud	□ Fast	□ Excellent	□ Local	□ Calm	□ Office
□ High Pitch	□ Distinct	□ Fair	□ Not Local	□ Rational	□ Factory
□ Raspy	□ Stutter	□ Foul	□ Region	□ Coherent	□ Bedlam
□ Intoxicated	□ Slurred	□ Good	□ Foreign	□ Deliberate	□ Animals
□ Soft	□ Slow	□ Poor	□ Caucasian	□ Righteous	□ Quiet
□ Deep	□ Distorted	□ Other	□ Race	□ Angry	□ Mixed
□ Pleasant	□ Nasal		□ Other	□ Irrational	□ Street Traffic
□ Other	□ Other			□ Incoherent	□ Airplanes
				□ Emotional	□ Party Atmosphere
				□ Laughing	□ Trains
				□ Other	□ Music
					□ Voices
					□ Other

If the caller seems agreeable to further conversation, ask questions like:

Where is the agent/ organism? _____

Where are you now? How do you know so much about this? What is your name and address?

Hold on the line while you notify one or more of the individuals listed below.

- Laboratory Director, (Indicate name and phone# here).
- Laboratory Operations Director (Indicate name and phone# here).
- EHS Director, (Indicate name and phone# here).
- Managing Director, (Indicate name and phone# here).

Did the caller appear familiar with the laboratory or building by his/her description or conversation?_____

Non-Technical SOP **Approved draft for training**

Title	**Select Agents Receipt, Handling & Transport Guidelines**
Prepared by	William Becker, DO, MPH, and the Quest Diagnostics Infectious Agents Team **Date: 5/7/2012**

Laboratory Approval	**Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval	**Corporate Issue Date: 6/4/2012**	
Print Name and Title	**Signature**	**Date**
Maureen Humes and Paul Cerwinka, MSc. National Directors	***On file***	**5/7/2012**
Jay Lieberman, MD Team Medical Advisor	***On file***	**5/11/2012**
Chief Laboratory Officer/Designee		**5/29/12**

Retirement Date:	
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. PURPOSE

The purpose of this document is to provide guidance for handling organisms submitted by clients for local testing, referral or recovered in our own laboratories that are known or suspected Select Agents (see section 4.).

2. SCOPE

These Guidelines will apply to all employees, contractors and other authorized persons at Quest Diagnostics business units.

3. RESPONSIBILITY

Responsible Party	Task
Managing Director	To provide the resources to support these guidelines and any actions taken in response to an exposure to, or loss of, a Select Agent.
Medical Director	To provide any support needed to make this SOP operational and to make all appropriate persons aware of its contents. To interface with public health and to act as a conduit for information between public health and appropriate laboratory personnel. To provide information and consultation regarding need for medical evaluation and follow up, depending on the situation.
Microbiology, Specimen Processing and Referrals Leadership	To provide support and technical information as needed in regards to currently defined suspected or known Select Agents and any changes that may occur. In addition, to be responsible for the proper packaging and handling of any suspected or known Select Agents they are aware of in their laboratory. To insure all employees are familiar with these guidelines, their location in the department and any actions needed on their part and to cascade information to necessary individuals as appropriate.
EHS Management	Maintenance of this document and to provide bio-safety training to any employees, as needed. EHS will cascade information to necessary individuals as appropriate.
Other Employees	To be familiar with these procedures and guidelines in relationship to their specific job duties, (e.g couriers)

4. DEFINITIONS

- ***Biological Agents*** – Living organisms that can cause disease in humans. These may include viruses, bacteria, or fungi. Category A and B Substances. (See Addendum 2)

- ***BTA or BT*** – Bioterrorism Agent – organism being used as an agent of terrorism. See "*Select Agent*" but may include less virulent organisms such as Salmonella, Shigella or M. tuberculosis depending on use.

- ***BU*** – A Quest Diagnostics laboratory performing clinical testing and referred to as a "Business Unit"

- ***CDC*** – Centers for Disease Control and Prevention

- ***LRN Reference Laboratory (formerly Level B and C)*** – Laboratory Response Network (LRN) laboratories are local and state public health laboratories, selected academic or university based laboratories, designated specialty laboratories (veterinary, water, food, chemical, military, agricultural) and certain international laboratories that possess the reagents and technology for more specialized testing of organisms, including toxin testing, that accept specimens from Sentinel laboratories. In some cases, isolates are referred from Reference Laboratories to National Laboratories operated by CDC, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), and the Naval Medical Research Center (NMRC). National Laboratories are responsible for specialized strain characterizations, bioforensics, Select Agent activity, and handling certain highly infectious biological agents.

- ***Registered Entity***- A laboratory or person who has registered with either the CDC or APHIS (but not both) using APHIS/CDC form 1. They receive a Unique Identifying Number (UIN) for each person handling Select Agents who is also finger printed and investigated. These labs may be able to provide definitive identifications and other services and may be a LRN lab. Note: Focus Diagnostics is a Registered Entity.

- ***Select Agent***- Certain biological agents in the form of organisms, virus or toxins, known to have a potential use as an agent of bioterrorism as defined by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and Centers for Disease Control and Prevention (CDC) Select Agent Programs and Federal Bureau of Investigation (FBI). For most current information, copy and paste the following address into your web browser:
  http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html
  - ***Known select agent*** - An organism that has been identified by generally accepted microbiological methods, for example, classical microbiology methods, nucleic acid detection, or antigen detection by immunofluorescence.
  - ***Suspected select agent*** – An organism that has not been completely identified by generally accepted microbiological methods (presumptive), and additional testing may be warranted. For example, a sample that may be Coxiella ELISA positive. A "suspected select agent" is not a "known select agent".

- ***Sentinel Laboratory (formerly Level A)*** – Sentinel laboratories are clinical laboratories that follow BSL – 2 guidelines. Their primary responsibility is to recognize and rule out or refer suspicious agents. Even though many sentinel laboratories are capable of providing a "presumptive identification" of some of the BTAs, they must refer isolates to an LRN Reference laboratory.

5. PROCEDURE

There are basically three scenarios in which the laboratory may come in contact with a Select Agent:

A. **A *known* Select Agent** isolate is submitted for local or referral testing; impacting Specimen Processing and Referrals
B. **A *suspected* isolate** is submitted for local or referral testing; impacting Specimen Processing and Referrals
C. ***An isolate is recovered from routine culture*** or send in for further studies that is not suspected of being a Select Agent, but during work-up, is identified as a possible or known Select Agent. This impacts both Microbiology and Referral depts.

A. KNOWN SELECT AGENT

In the event a client sends an isolate or sample containing *a known Select Agent* as indicated on a requisition or on the packaging or notifies us in some way, and local testing or referral to another laboratory is desired.

Key indicators that this is a known organism are if the client actually indicates the name of the organism on the requisition of if testing such as susceptibility testing is requested. When in doubt ask the Microbiologist on duty

If	Then take these actions
Local Testing is Requested	• Do not open the package or box. Wearing gloves, immediately relocate the package to an area where it can be placed in a Class II Biological Safety Cabinet. A completed APHIS/CDC Form 2 must accompany the isolate. • If you have handled the item without gloves, wash your hands thoroughly with soap and water. • Immediately notify your supervisor, manager or director. If unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Restrict access to the area. • Construct a list of persons who may have had contact with the item or been in the vicinity and give it to the Medical Director. • Inform the Quest Diagnostics BT Task force chair person Dr. William Becker at 913-577-1703 or 513-502-5718 (cell) or William.J.Becker@QuestDiagnostics.com on receipt of a known Select Agent. • Call the client and explain that your laboratory is a "Sentinel" Lab and therefore only allowed by law to "rule out and refer" to a LRN

	Reference laboratory. The remaining options are to destroy the Select Agent or transfer it to a "Registered Entity" (see below in Referrals Testing). If destroyed by autoclaving, destruction must be documented using CDC form 4A section B within 7 days. For current information, see: http://www.selectagents.gov/resources/APHIS-CDC_Form_4A_ReferenceLab_SampleProvider-PrintOnly-English.pdf

If	Then take these actions
Referral Testing is Requested	• Immediately notify your supervisor, manager or director of receipt of the specimen. One of the fundamental elements of the Select Agents Regulations is to keep Select Agents and toxins out of the possession of individuals who might misuse them. Only certain labs or individuals may possess Select Agents and are known as a "Registered Entity" such as Focus Diagnostics. A completed APHIS/CDC Form 2 must accompany the isolate. • Do not open the package or box. Wearing gloves immediately relocate the package to an area where it can be placed in a Class II Biological Safety Cabinet. • If you have handled the item without gloves , wash your hands thoroughly with soap and water • Immediately notify your supervisor, manager or director. • If unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Restrict access to the area. • Construct a list of persons who may have had contact with the item or been in the vicinity. Notify the CDC Select Agent Program as soon as possible at 404-718-2000 or Irsat@cdc.gov • Immediately contact the client and inform them about the inappropriate transfer of a known Select Agent. **If the package is to be sent to a Registered Entity Lab, it may have to be re-packed by qualified persons to meet current standards. Follow guidance from the CDC Select Agent Program. Contact the Registered Entity laboratory (Focus). APHIS/CDC Form 2 must be used to request authorization to transfer a select agent or toxin. It also provides documentation of the transfer. By regulation, an APHIS/CDC Form 2 must be completed for each transfer of select agent(s) or toxin(s) and maintained for three years.**

Note: A select agent or toxin **may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin**. A select agent or toxin may only be transferred under the conditions below and must be authorized by CDC or APHIS, *PRIOR* to the transfer. To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted. For most current information, refer to:
http://www.selectagents.gov/TransferForm.html

BU laboratories that are not Registered Entities should not receive or transfer isolates that are known to be Select Agents/toxins. If a client requests to send a known Select Agent to an unregistered BU laboratory, referral testing should notify Microbiology immediately. In addition, inform the Quest Diagnostics BT Task force chair person Dr. William Becker at 913-577-1703 or 513-502-5718 (cell) or William.J.Becker@QuestDiagnostics.com. The BU will notify the client that they must work directly with a Registered Entity laboratory. If the isolate has already been sent to the BU, then the BU must contact the (intended) Registered Entity, the client and notify the Select Agent Program at CDC. The isolate must be stored securely and following all safety requirements. The BU should also notify the Quest BT Task Force Chair as noted below.

Instructions for Registered Entities receiving known Select Agent isolates:

The recipient must submit a completed APHIS/CDC Form 2 and receive approval from the CDC Select Agent Program *prior* to transfer of a select agent or toxin.
Note – the Select Agent regulations instruct the receiving lab (Registered Entity), not the sending facility/lab, to initiate the completion of Form 2 and receive approval from the CDC SAP prior to the agent transfer. The sending facility must work with the Registered Entity in order to ensure proper completion of Form 2.

The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).
Referrals must comply with all applicable laws concerning packaging and shipping. (See Addendum 2) as well as Quest Diagnostics national SOPs (QDRT730), (QDMI790 & QDMI791 & QDMI792).

A transfer may be authorized if:

The sender:
- Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements.
- Meets the exemption requirements for the particular select agent or toxin to be transferred.

The recipient:
- At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

Reporting Loss, Theft or Release of a Select Agent including Occupational Exposure:

If	Then
In the rare and serious event a known Select Agent is lost in transit, stolen or a person or environment is exposed or contaminated with a known Select Agent.	Upon discovery of the theft, loss, or release of a select agent or toxin, entities must report all incidents as specified below. ▪ First, an individual or entity must immediately notify the lead Agency; i.e., the Animal and Plant Health Inspection Service (APHIS) or the CDC by telephone, fax, or e-mail. (The contact information is provided below.) ▪ If the entity is not registered with either APHIS or CDC (such as an unregistered clinical or diagnostic facility), then it may notify either Agency. ▪ If a responsible official (RO) has a reasonable suspicion that a theft, loss, or release has occurred, the RO should notify APHIS or CDC to make APHIS or CDC aware of a potential incident. This will help the Agency respond quickly if the incident is confirmed. ▪ If the entity is unsure whether a report is required, then it should contact the lead Agency immediately. ▪ The individual or entity must also notify the appropriate Federal, State, or local law enforcement agencies for the theft or loss of a select agent or toxin. For the release of a select agent or toxin, the entity should notify the appropriate local, state, and federal health agencies. ▪ Individuals or entities must report thefts or losses even if the select agent or toxin is subsequently recovered and/or the responsible parties are identified. ▪ The initial report should include as much information as possible about the incident. As required by the regulations, the entity must report the following: o Type of incident o Date and time o Agent and quantity o Summary of events that include the location of the incident and list of other agencies notified. • If a release occurred, the entity must provide the number of individuals potentially exposed, actions taken to respond to the release such as medical intervention and biocontainment, and hazards posed by the release such as estimate of the severity of the event and the proposed impact to public or agricultural health if any.

If	Then
In the rare and serious event a known Select Agent is lost in transit, stolen or a person or environment is exposed or contaminated with a known Select Agent. (cont.)	▪ Information should be submitted as it becomes known, but no later than 24 hours and within seven (7) days, the entity must submit a complete APHIS/CDC Form 3, Report of Theft, Loss or Release to the lead Agency or to either APHIS or CDC if the entity is not registered with either agency. ▪ All appropriate data fields should be completed. Supporting documentation, such as access logs, standard operating procedures, and the follow up investigation, should be provided regarding the reported incident. The form and supporting documentation may be submitted by either fax or mail. ▪ In the event of occupational exposure, Report all accidents and injuries to your supervisor, Medical Director and the Environmental, Health and Safety Manager/Specialist. Document exposure using the form provided in Addendum 1
	Contact information: Agricultural.Select.Agent.Program@aphis.usda.gov APHIS Agricultural Select Agent Program 4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737 Telephone: 301-734-5960 Fax: 301-734-3652 Or CDC Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta, GA 30333 Telephone: 404-718-2000 Fax: 404-718-2096 Irsat@cdc.gov

B. SUSPECTED SELECT AGENT

In the event a client sends an isolate or sample containing a *suspected* Select Agent as indicated on a requisition or on the packaging or otherwise communicated and local testing or referral to another laboratory is requested.

Key words to look for which indicates its suspected status are "rule out" or "R/O", "presumptive", "possible" or "confirm". If the test requested is for bacterial of fungal identification, that can also be another indicator. When in doubt, consult with the Microbiologist on duty.

If	Then take these actions
If Local Testing is Requested	• Do not open the package or box. Wearing gloves immediately relocate the package to an area where it can be placed in a Class II Biological Safety Cabinet. • If you have handled the item, wash your hands thoroughly with soap and water • Immediately notify your supervisor, manager or director. • Restrict access to the area. • Construct a list of persons who may have had contact with the item or been in the vicinity and give it to the Medical Director. • Call the client and explain that your laboratory in a Sentinel Lab and therefore only allowed by law to "rule out and refer" to a LRN Reference laboratory. • *Enter any information such as a suspected organism name into the LIS if further identification is performed locally so that Microbiology is aware of the suspected organism identity.* • If the organism appears to be a presumptive Select Agent, the remaining options are to destroy the Select Agent or transfer it to a "Registered Entity" (see below). If destroyed by autoclaving, destruction must be documented using CDC form 4A section B within 7 days.

If	Then take these actions
Referral Testing is Requested	• Do not open the package. Wearing gloves immediately relocate the package to an area where it can be placed in a Class II Biological Safety Cabinet. • If you have handled the item without gloves, wash your hands thoroughly with soap and water. • Immediately notify your supervisor, manager or director. • Restrict access to the area. • Construct a list of persons who may have had contact with the item or been in the vicinity. • If the package is sent to Focus (a Registered Entity), or Nichols (a Non-Registered Entity) which can perform confirmatory testing on suspected select agents; it may have to be re-packed by qualified persons in Microbiology to meet current standards. See national SOP QDMI790 for current standards and actions to take. For sorting and packing for transport by air carrier, follow guidelines as indicated in National SOPs QDRT730 and Addendum 2 of this SOP.

Note: Anyone may send a suspected or presumptive Select Agent to a Sentinel or Reference laboratory for confirmation without a transfer authorization from APHIS or CDC. However, after identity of the Select Agent or toxin is confirmed, a non-registered entity would be required to either destroy the specimen (a diagnostic sample containing the organism) or any

isolates, and completion of APHIS/CDC Form 4A, OR transfer it to an entity registered for that Select Agent or toxin if additional testing is needed or requested.

That transfer must first be authorized by either APHIS or CDC. To initiate the transfer process, contact a registered entity to arrange for transfer of your sample. *The recipient* must submit a completed APHIS/CDC Form 2 and receive approval from the CDC Select Agent Program prior to transfer of a select agent or toxin. If you need assistance locating a registered entity, contact APHIS (phone: 301-734-5960; fax: 301-734-3652) or CDC (phone: 404-718-2000; fax: 404-718-2096). For further guidance regarding reporting requirements for the identification of a Select Agent or toxin contained in a clinical/diagnostic laboratory specimen, please refer to: www.selectagent.gov/CDForm.html.

C. AN ISOLATE RECOVERED FROM ROUTINE TESTING OR SUBMITTED BY A CLIENT FOR IDENTIFICATION FOR FURTHER TESTING AND DURING WORK-UP IS IDENTIFIED AS A SUSPECTED SELECT AGENT.

First, the reader must be very familiar with national SOP QDMI716 Microbiology Safety, section 5.3 which addresses these general scenarios. Also see national SOP QDMI815 Virulent Organisms. For specific situations indicated below see the national SOP referenced.

Follow the guidelines below. If at any time you are unable to determine the next step or have questions, contact your supervisor or one of the persons listed at the end of these guidelines.

If	Then take these actions
Cultures from Nasal, vesicular fluid, sputum, blood, CSF, pleural fluid, that yield flat, non-hemolytic gray colonies with a ground glass appearance, after 16-24 hours characteristic of *Bacillus sp*. ***B., anthracis*** should be ruled out and referred. Colonies often have comma-shaped projections from the colony edge, producing the "Medusa head" colony. Colonies tend to have a tenacious consistency and when teased with a loop will stand up like beaten egg white. In a class II BSC, Gram stain any isolate suspected to be *Bacillus sp.*; *B. anthracis* is a large "box car" like gram positive rod and is usually encapsulated. The capsule may be best seen using a negative stain such as india ink or nigrosin.	• All plates, tubes, slides and the specimen are to be taken to a Class II BSC for further culture manipulations. • Rule out and refer. See section 8 and 10 of QDMI725 for further steps to take.

If	Then take these actions
Cultures from Blood, Bone marrow, CSF tissue or aspirates yield small, punctate (dimpled) raised, white to cream, non-hemolytic and glistening colonies on 5% sheep blood TSA plate (BAP), or on Thayer-Martin agar that fail to grow on MacConkey agar and average 2-4mm in diameter after 4-5 days of incubation, then ***Brucella sp.*** may be suspected.	• All plates, tubes, slides and the specimen are to be taken to a Class II BSC for further culture manipulations. • Rule out and refer. See section 8 and 10 of QDMI729 for further steps to take.
Cultures from blood, bubo aspirates, respiratory secretions or CSF specimens yield gray-white, translucent, slow growing colonies, usually too small to be seen as individual colonies at 24 hours, ***Yersinia sp;*** should be suspected. *Af*ter incubation for 48 hours, colonies are about 1-2 mm in diameter, grey-white to slightly yellow color, opaque and have a raised, irregular "fried egg" morphology. There is little or no hemolysis on BAP and under 4X magnification, after 48-72 hours colonies have been described as having a "hammered copper," shiny surface when grown at 28°C on BAP. ***Y. pestis*** will appear as small opaque, colorless (non lactose fermenting) colonies on MAC agar by 48 hours.	• All plates, tubes, slides and the specimen are to be taken to a Class II BSC for further culture manipulations. • Rule out and refer. See section 8 and 10 of QDMI727 for further steps to take.
Cultures of ulcer scrapings, lymph node aspirates, CSF, Blood, tissue or from respiratory secretions/washings, pleural fluid, gastric aspirates, or conjunctiva after overnight incubation yield bluish-white to gray, flat and dense colonies on chocolate or Thayer Martin agars from *Do not open plates.* ***F. tularensis*** *must be ruled out and referred.* Colonies are slow growing and may have to be re-incubated for several days. Usually, after incubation for 48 hours, colonies of *F. tularensis* on both media are usually greenish-white, dense, and shiny with an opalescent "sheen".	• All plates, tubes, slides and the specimen are to be taken to a Class II BSC for further culture manipulations. • Rule out and refer. See section 8 and 10 of QDMI728 for further steps to take.

If	Then take these actions
An employee thinks they have been exposed to a Select Agent:	• Immediately isolate the employee • Restrict access to the area and/or site • Notify the employee's doctor • Notify local laboratory leadership or • If unavailable, contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers). • Once the situation is assessed and the validity of the claim verified, you may need to disinfect the site depending on directions from your management.

6. RELATED DOCUMENTS

- Quest Diagnostics Incorporated National SOP Sort, Pack, Label and Document Specimens for Air Transport QDRT730.
- Quest Diagnostics Incorporated National SOPs for Bioterrorism Agents: QDMI725, QDMI727, QDMI728, QDMI729.
- Quest Diagnostics Incorporated Clinical Specimens Suspected of Highly Virulence Organisms SOP QDMI815
- Quest Diagnostics Incorporated Accessioning, Packing and Shipping of Microbiological Isolates SOP, QDMI790
- Quest Diagnostics Incorporated Transportation of Infectious Specimen Transport Kits SOP, QDMI791
- Quest Diagnostics Incorporated Packing and Receipt of Isolates in the Microbiology Department SOP, QDMI792
- Quest Diagnostics Incorporated Comprehensive Microbiology Safety SOP QDMI726.
- Quest Diagnostics Incorporated Corporate Safety Manual.
- Quest Diagnostics Incorporated Critical and Priority Result Policy and Procedure SOP QMED704.
- Quest Diagnostics Incorporated Records Management Program for Record Retention Requirements.
- Bioterrorism Response Plan, 35023, Shady Grove Adventist Hospital Safety Management Policy Manual, available on Adventist Healthcare intranet
- Bioterrorism Response Plan, Appendix K, Washington Adventist Hospital Safety Manual, available on Adventist Healthcare intranet

7. REFERENCES

1. CDC website for Emergency Preparedness & Response: http://www.bt.cdc.gov/
2. CDC Guidelines for State Health Departments, October 14, 2001 Revision. U.S Department of Health and Human Services, Washington., DC.
3. CDC and APHIS Select Agent Web sites http://www.selectagents.gov/ and http://www.aphis.usda.gov/programs/ag_selectagent/
4. Federal Register Dept of Health and Human Services CFR parts 73 and 73, http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf

8. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1.0	6/13/13		Adopting corporate SOP	L. Barrett	R. Master
		Page 1	Added referral to electronic signature page.		
		5	Added "contact the local or state public health laboratory (See Addendum 3 - Emergency Contact Phone Numbers)" in each area as appropriate.		
		6	Added local hospital policies		
		Addendum 3	Local BU names and phone numbers added.		

9. ADDENDA

Addendum	Title
1	Select Agent Exposure Incident Report Form
2	IATA Shipping Regulations for Category A and B Substances by Air
3	Emergency Contact Phone Numbers

Addendum 1. : Select Agent Exposure Incident Report

Incident Date: _____
Time:_____ ☐ AM ☐ PM

Person Completing Form
Name:_____
Contact Number:_____

Location of Incident
Name of Site:_____
Address:_____
City, State, Zip_____
Area Code and Number/ext.:_____

Persons Directly Involved In The Incident (Attach additional sheets if needed)
Name:_____
Area Code and Number (Work):_____
Area Code and Number (Home):_____

Witness To Incident, If Applicable (Attach additional sheets if needed)
Name:_____
Area Code and Number (Work):_____
Area Code and Number (Home):_____

What Type of Situation Occurred?

☐ Pkg or Mail ☐ Phone Threat ☐ Client Call ☐ Pt/EE Exposure ☐ Isolated Organism

Where at the site did the incident occur?:

_____

What Happened? (describe sequentially and add additional sheets as needed)

_____
_____
_____

What Was Your Response? (describe sequentially and add additional sheets as needed)

_____
_____
_____
_____

Addendum_2. IATA Shipping Regulations for Category A and B Substances by Air

The international rules for air shipment of Infectious and Noninfectious Substances, known as the ICAO (International Civil Air Organization) Technical Instructions are codified by the International Air Transportation Association (IATA) and affect all air shipment regardless of their origination. IATA describes two categories of infectious material. Category A Infectious Substance and Biological Substances, Category B as well as how such material is defined, classified, packaged, and transported. Requirements for human and animal biological materials that are exempt from the regulations as well as material defined as Regulated Medical Waste are also described.

Infectious substances are materials that are capable of causing disease in humans and/or animals, and include genetically modified microorganisms, biological products, diagnostic specimens, and clinical and medical waste. These substances are known to contain, or reasonably expected to contain, micro-microorganisms including bacteria, viruses, parasites, fungi or recombinant microorganisms (IATA 3.6.2). An infectious substance transported in a form that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans when exposure to it occurs is designated as a Category A Infectious Substance. If a material is unlikely to cause human or animal disease (i.e., fixed tissue), it is Exempt from (not subject to) IATA regulations. See:
iata.org/whatwedo/cargo/dangerous_goods/Pages/infectious_substances.aspx

Biological Substance, Category B: An infectious substance which does not meet the criteria of an infectious substance, Category A is a biological substance, Category B for shipping purposes. Substances in this category must be assigned to UN 3373 with a proper shipping name of Biological Substance, Category B. This category includes items formerly shipped as diagnostic specimens.

The most significant provisions in the rules affect air shipment of liquid specimens. Emphasis is on the use of sturdy, leakproof specimen collection containers. Triple packaging (primary container, with absorbent material (if liquid), leakproof secondary container, sturdy outer shipping container) is required for shipping all infectious and noninfectious specimens. When shipping infectious Category A or Category B materials either the primary or secondary container must meet leakage requirements (95kPa pressure test).

Many patient specimens are shipped from collection sites (e.g., physicians' offices, nursing homes, clinics, etc.) to testing laboratories by private or contract couriers in dedicated vehicles. These patient specimens may be classified as either non-infectious (Exempt Human Specimen); or infectious (Category A, UN2814 or Category B, UN3373). Couriers who transport patient specimens are considered to be Hazmat Employees and as such require appropriate training as indicated in the current DOT regulations.

DOT regulations affect all shipments, by air or ground transportation within and between the United States, and harmonizes DOT regulations (Title 49 CFR) with the IATA regulations. Refer to the DOT Pipeline and Hazardous Materials Safety See administration website for the current US regulations.
www.phmsa.dot.gov

Addendum 3

Emergency Contact Phone Numbers Shady Grove Adventist Hospital Washington Adventist Hospital Germantown Emergency Center			
Title or Department	**Name**	**Office Number**	**Cell Number**
Medical Director	Cacciabeve, Dr. Nicolas	SGAH: 240-826-6096 WAH: 301-891-6620	703-200-9521
Regional Operations Director	Loffredo, Lori	301-891-5627	240-475-9489
Laboratory Director	SanLuis, Rob	240-826-6095	240-6203-413
Chantilly, VA			
Main Laboratory		703-802-6900	
Laboratory Director	Sisco, Dr. Kenneth	703-802-6900 67007	
Technical - Laboratory Operations, Director	Raglin, Ron	703-802-6900 67809	
Environment Health & Safety Director	Mason, Bryan	703-802-6900 66425	301-869-9331
Environment Health & Safety Specialist	Clark, Dr. Richard	703-802-6900 67067	703-330-5952
Director, Hospital Microbiology	Master, Ron	703-802-6900 65206	703-431-2297
Corporate #'s:			
Chief Laboratory Officer	Suffin, Dr. Stephen	973-520- 2081	818-398-6189
Bio-terrorism Task Force Chair	Becker, Dr. William	913-577-1703	513-502-5718
EHS, Director - Corporate	Lewis, Clete	303-779-1597	303-204-3768
Agency #'s:			
CDC Emergency Response		**770-488-7100**	
County Department of Public Safety		911	
County Emergency Dispatch Center, Fire, Police, Ambulance		911	
County Office of Emergency Management	Montgomery County	240-777-2300	
Federal Bureau of Investigation		202-324-3000	
State Public Health Lab (Maryland)		410-925-3121	
Poison Control Center		800-222-1222	