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BUREAU OF PUBLIC HEALTH LABORATORIES

The Florida Lab Link

"A Biological and Chemical Preparedness Newsletter"

Recognize, Rule-Out, Refer and Ship Safely

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Florida Department of Health, Bureau of Public Health Laboratories (BPHL), provides a variety of diagnostic and reference laboratory services to all 67 counties in the state. The BPHL also provides biological and chemical threat response testing per standardized protocols of the Laboratory Response Network Biological (LRN-B) and Chemical (LRN-C) programs.[1]

There are three LRN-B reference laboratories in Florida located in Jacksonville, Miami and Tampa. Each laboratory is a biosafety level 3 facility and accepts samples from one of the three geographical areas of testing as shown in Map 1 (see page 2).

Each of these LRN-B reference laboratories have Bioterrorism (BT) defense coordinators specifically trained by the Centers for Disease Control and Prevention (CDC) to use the LRN-B standardized reference protocols for confirmatory testing of anthrax, smallpox and other organisms and toxins that can potentially be used as biological weapons.

Clinical laboratories, also known as sentinel clinical laboratories, are responsible for the early detection of potential biothreat agents. They serve as the foundation for quickly recognizing potential threat agents and for initiating an appropriate response. For this reason, BPHL trains sentinel clinical laboratories to recognize possible BT agents and rule them out as a potential threat using standardized protocols provided by the American Society for Microbiology (ASM).

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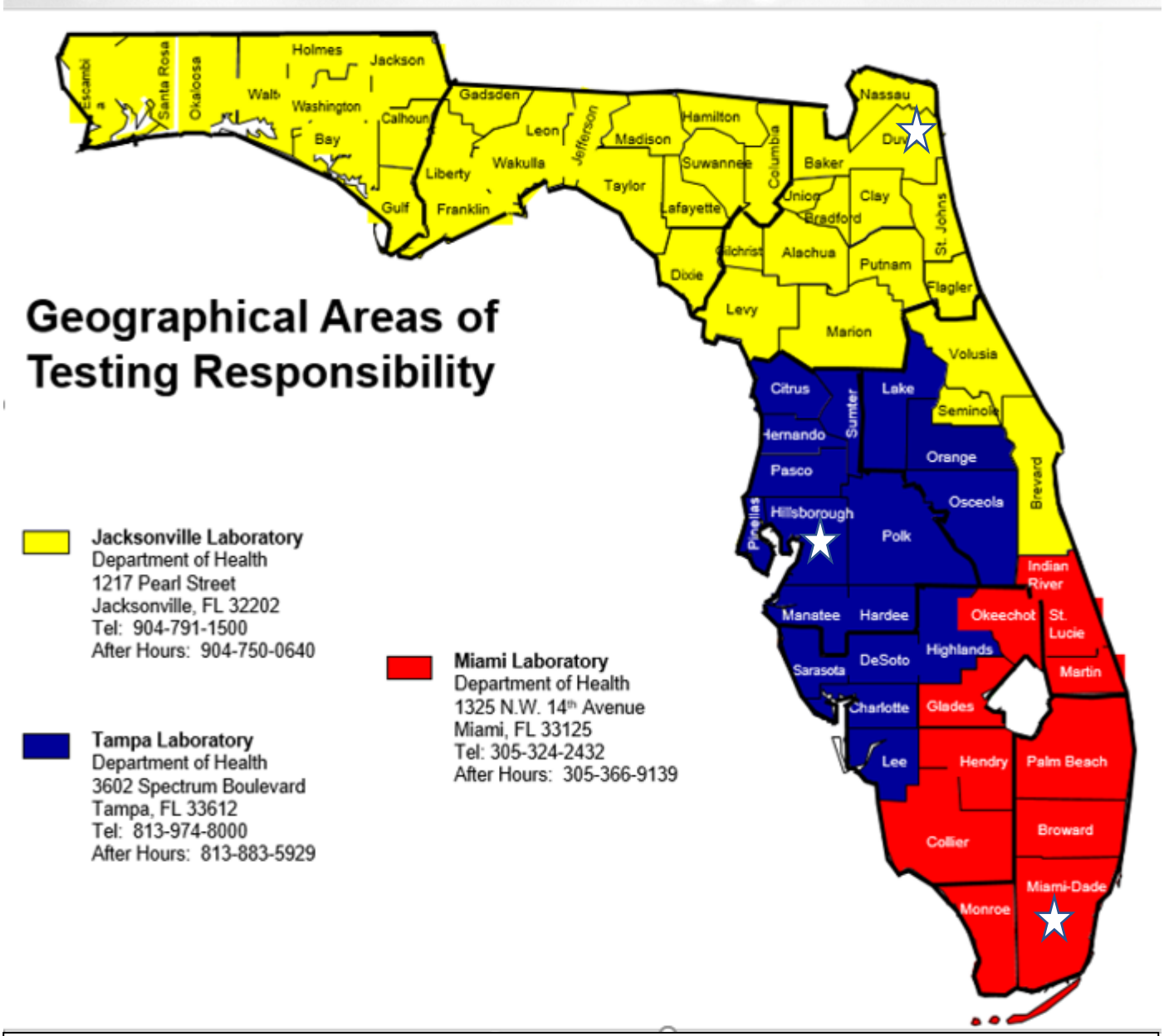
Because of the seriousness of incorrectly shipping possible high consequence agents to the BPHL for rule-out testing, this article will focus on the basic steps involved in recognizing, ruling-out, and referring potential bioterrorism threat agents to the LRN-B reference laboratories with an emphasis on safely shipping these and other specimens to the BPHL.



Map 1. Bioterrorism Defense program areas of testing responsibility by county.

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Recognize: The clinical laboratory will use conventional manual tests such as gram stain, colony morphology and biochemical tests commonly performed in the laboratory to rule-out suspicious organisms in accordance with ASM Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents And Emerging Infectious Diseases (https://www.asm.org/index.php/guidelines/sentinel-guidelines).[2]

Also available for the clinical laboratory to use in conjunction with the ASM protocols, are the Association of Public Health Laboratories (APHL) Biothreat Agent Bench Cards for the Sentinel Laboratory (https://www.aphl.org/aboutAPHL/publications/Documents/2018_BiothreatAgents_SentinelLab_BenchCards_PRINT.pdf).[3]

These bench cards contain checklists and algorithms to aid in rule-out testing. They are a unique resource that can be easily utilized on the bench as a quick reference guide for ruling-out and referring biothreat agents. They were recently revised and now include information on biosafety, biological risk assessments and a gram-negative bacilli/coccobacilli rule-out algorithm to assist the clinical laboratory with the rule-out of these organisms.

If you have a:

Suspect BT Agent

- ☐ Follow rule-out procedures and conduct work in a BSC
- ☐ Initiate/maintain communication with departmental/hospital leadership and infection control
- ☐ Contact BT personnel at designated LRN Reference Level Laboratory
- ☐ Ship isolate to designated LRN Reference Level Laboratory
- ☐ Document courier transfer (e.g., institutional or commercial courier tracking number)
- ☐ Secure all potential biothreat agent(s) and residual samples
- ☐ Document personnel with access to potential biothreat agent(s) (*biosecurity*)
- ☐ Document personnel who have worked with suspect biothreat agent and those present in laboratory if exposure occurred (*biosafety*)

Rule-out: If a suspicious organism cannot be ruled-out using the tests listed in the sentinel level protocols, the clinical laboratory should stop testing.

At this point, no attempt at any further identification using commercial automated or kit identification systems should be made. Further testing could result in erroneous identification and/or exposure to dangerous pathogens. The isolate should be referred to the designated LRN-B laboratory for further testing.

Refer: As soon as the clinical laboratory is unable to rule-out a potential biothreat agent, they should notify, by phone, the designated BT coordinator (see the Bureau of Public Health Laboratories Directory on back page for contact information) for their geographical area as per Map 1. They should inform the BT coordinator they are unable to rule-out the organism and will be referring it to the BPHL for confirmatory testing. Any remaining specimens, isolates and derivatives must be immediately secured until the LRN-B's testing is completed.

Before packaging the specimen, assign it as a UN2814 Category A Infectious Substance or UN3373 Category B Biological Substance as per the Department of

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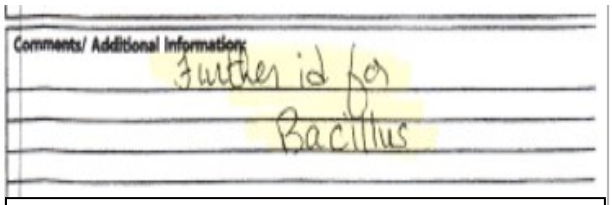

Figure 1. Specimen submitted for rule-out testing without prior notification. Sent to wrong department resulting in possibility of multiple exposures, release of a biothreat agent, a break in chain of custody and a breach in biosecurity involving a select agent.

Transportation and the Dangerous Goods Regulations. If in doubt, obtain assistance from the BT coordinators.

Once again, suspect specimens or cultures submitted to the BPHL for rule-out testing must never be shipped without prior notification, by phone, to the BT Coordinator. The package must be sent using traceable means (i.e. a courier or a commercial carrier with a tracking number) to maintain chain of custody. It is important that the consignee address include the name of the BT coordinator, not only for faster processing once it reaches the BPHL, but also to limit who comes in contact with the package. This maintains chain of custody and reduces the chances for theft, loss or release of a possible select agent. It also indicates to accessions staff that a higher level of containment should be used to open the package to reduce the risk of exposure once the specimen reaches the BPHL.

Ship safely: It is important to remember that most specimens, with very few exceptions, received for testing by the BPHL are suspected of containing a pathogen and therefore, are classified as a Division 6.2 Infectious Substance. Whether assigned as UN2814 Category A Infectious Substance or UN3373 Category B Biological Substance, packages must be prepared and shipped by staff with a current packaging and shipping certification. They must be shipped using a triple packaging system consisting of a leakproof primary receptacle, leakproof secondary packaging and a rigid outer packaging.

These primaries were placed directly in the dry ice inside the outer container. With no secondary container, absorbent or cushioning to secure them as the ice dissipated, they became loose and bounced around.

Suspected pertussis specimen sent in an envelope with no secondary packaging, rigid outer container, or infectious substance markings.

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Improper packaging results in broken primaries causing potential risk of exposure and sharps hazard.

Primary receptacles must be leakproof. If assigned UN2814 Category A Infectious Substance, the primary must be sealed by positive means (skirted stopper, paraffin sealing tape, etc.). If multiple primaries are packed in one secondary packaging, they must be wrapped individually or in such a way that under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging. There must be enough absorbent material to absorb the entire contents of all the primaries.[4,5]

Secondary packaging must be leakproof. It must be secured in a rigid outer packaging and have enough absorbent material that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging. Also, either the primary receptacle or secondary packaging must meet the 95kPA pressure test if there is any chance it may be loaded onto an aircraft. An itemized list of contents must be enclosed between the secondary packaging and the rigid outer packaging.[4,5]

Urine leaked out of primary into secondary container with multiple primaries. No cushioning or absorbent materials were used.

Secondary container over-filled. Improper cushioning of primaries could result in leaks.

The rigid outer package must be of adequate strength for its contents and at least one surface must be 100mm x 100mm. Packaging must be durable and able to withstand the shocks, vibration, temperature and pressure changes associated with normal transport conditions. If assigned UN2814 Category A Infectious Substance, the outer package must meet UN performance testing and packaging specifications.[4,5]

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If wet ice or frozen gel packs are used, the outer package must be leakproof or have a leakproof lining. It must also contain sufficient material to absorb any liquid created as the ice or gel packs melt. If dry ice is used, the package must permit the release of carbon dioxide gas to prevent the buildup of pressure as the dry ice dissipates. The completed package must not be over-filled so that under normal transport conditions there will not be a release of hazardous materials. [4,5]

Frozen gel pack placed directly into a cardboard box with no leakproof lining. As the gel pack thawed, the box absorbed the liquid until it was saturated, compromising the strength of the outer container. Primary was loose inside outer container.

Following the protocols to rule-out or refer specimens and using the procedures and regulations to correctly package and ship all specimens to the BPHL minimizes the risk of laboratory acquired infections for both the laboratorians and the non-laboratory workers who handle these packages.

Reference

1. Bureau of Public Health Laboratories. http://www.floridahealth.gov/programs-and-services/public-health-laboratories/index.html
2. American Society for Microbiology, Washington, DC, 2016. Sentinel Level Clinical Laboratory Protocols For Suspected Biological Threat Agents And Emerging Infectious Diseases. https://www.asm.org/index.php/guidelines/sentinel-guidelines
3. Association of Public Health Laboratories. Biothreat Agent Bench Cards for the Sentinel Laboratory. 2017. https://www.aphl.org/aboutAPHL/publications/Documents/2018_BiothreatAgents_SentinelLab_BenchCards_PRINT.pdf
4. International Air Transport Association (IATA). Dangerous Goods Regulations, 59th Edition. 1 January 2018.
5. Title 49 Transportation. Electronic Code of Federal Regulations Parts 100-185. https://ecfr.io/Title-49/

Updated Resources

APHL Sentinel Laboratory Partnerships and Outreach Subcommittee (SLPOS) of the Public Health Preparedness and Response Committee is pleased to announce the availability of the following updated resources:

1. ***Biothreat Agent Bench Cards for the Sentinel Laboratory:*** These bench cards are a unique resource that can be easily utilized on the bench as a quick reference guide for ruling-out and referring biothreat agents.
    - **a.** Web viewing link
    - **b.** Print link
2. ***Biothreat Agent Poster for the Sentinel Laboratory:*** The poster serves as an abbreviated reference of key biothreat agents.
    - **a.** Web viewing link
    - **b.** Print link
3. ***Definition of Sentinel Clinical Laboratories:*** APHL along with its partners have revised the definition to include language on the use of emerging technologies and the biosafety risks which must be mitigated.
    - **a.** Definition of Sentinel Clinical Laboratories

Both the bench cards and poster are available on www.aphl.org in web and print formats. Please note that the web viewing format is not suitable for printing.

Major changes to the bench cards include:

- Agent specific alignment with current American Society for Microbiology (ASM) sentinel level clinical laboratory protocols for biological threat agents and emerging infectious diseases
- New sections and information for biosafety, biological risk assessments and aerosol generating procedures
- Information on Biosafety Level (BSL)-3 practices in a BSL-2 laboratory, *B. cereus biovar anthracis* and a Gram negative bacilli/coccobacilli rule-out algorithm

Major changes to the Definition of Sentinel Clinical Laboratories include:

- Expanding the definition to be more inclusive of sentinel laboratories that may not fully be meeting the definition (e.g. laboratories not performing full microbiology in-house) while avoiding creation of a two 'tiered' sentinel laboratory system
- Encouraging states that have resources and flexibility to work with their own "non-microbiology" sentinel laboratories for outreach and training
- Addressing moderate complexity testing by including statements about "point of care testing" and "culture independent diagnostic tests"
- Addition of a statement about core/main laboratories having the responsibility to communicate biothreat information with their own satellite laboratories to help disseminate information and share training responsibilities with "non-microbiology" laboratories

Biosafety risk assessment and lab biosafety training

The Bureau of Public Health Laboratories biosafety outreach officer (BOO) is currently offering a course in biosafety risk assessment and laboratory biosafety to clinical laboratory institutions. The training consists of two sessions that are approximately one hour each and offered on-site at no charge to the facility. The first session discusses biosafety risk assessment and the second session focuses on biosafety in the clinical laboratory.

Biosafety risk assessment is a systematic process of evaluating the potential risks involved in a laboratory procedure and determining the measures needed to manage any gaps or risks identified. The BOO has created standard operating procedures and resource documents to assist clinical hospital laboratories in biosafety risk assessment and laboratory biosafety. This session will train clinical laboratory personnel how to use these documents to perform risk assessments in their laboratory.

The second session is for anyone who works in the laboratory or is responsible for a safe working environment. Topics include general laboratory biosafety, the use of biological safety cabinets (BSCs), choosing correct personal protective equipment, proper use and removal of gloves, and spill cleanup. This training awards Florida clinical laboratory and nursing continuing education credits.

For more information or to schedule training, contact Ed Kopp at 813-233-2260 (Edgar.Kopp@flhealth.gov).

New Labels to Identify LPX Specimens

(From APHL's Weekly Newsletter | May 24, 2018)

Association of Public Health Laboratories (APHL), in partnership with Centers for Disease Control and Prevention (CDC) and the College of American Pathologists (CAP), develops and issues the Laboratory Preparedness Exercise (LPX) twice a year to private clinical and public health laboratories. The LPX provides laboratories with a training exercise to help identify live organisms that either exhibit characteristics of bioterrorism agents or demonstrate epidemiologic importance. In recent mailings of the LPX, CAP observed that laboratorians misidentified LPX plates, resulting in potential exposures. In an effort to decrease identification issues, CAP will include brightly colored stickers with the LPX kit to use when plating swabs to media and sub-culturing, alerting readers that the plate contains CAP LPX specimens and to use caution. Please contact Samuel Abrams at samuel.abrams@aphl.org with questions.

Chemical Threat (CT) Preparedness Training

The CT laboratory coordinators continue to reach out to the health and medical community by offering training for CT preparedness at hospitals and county health departments (CHDs). This training covers chemical terrorism awareness and the collection of clinical specimens after a chemical terrorism event. Hospital and CHD staff play an important role in the response to a chemical exposure event when clinical specimens are collected for analysis. For your convenience and to increase participation, this training can be presented at your facility. Each course lasts approximately one hour with one 15-minute break between courses. Florida clinical laboratory and nursing continuing education credits will be offered. Training manuals, "hands-on" exercise materials, and CT preparedness kits will be provided. This training is recommended for physicians, nurses, epidemiologists, emergency department personnel, phlebotomists, hospital and health department laboratory personnel and others who may collect clinical specimens. Contact the CT laboratory coordinators in your region for more information (see the Bureau of Public Health Laboratories Directory for contact information).

Laboratory Response Network (LRN) Training—Biological Defense

The Bureau of Public Health Laboratories is currently offering an LRN sentinel laboratory training course at no cost at your facility. This training follows the American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. Scheduling the training at your facility is a relatively easy process. Determine when you would like to have the training and how many people will be attending. A time will be set up that is convenient for all. The training materials are provided as well as the biodefense reference manuals for your laboratory.

The training syllabus includes: an overview of the LRN; biosafety risk assessment and biosafety for the clinical laboratory; the ASM protocols for ruling out potential bioterrorism agents and how to refer a sample to the state LRN Public Health Reference Laboratory when a bioterrorism agent cannot be ruled out; and an introduction to the CDC Select Agent Program. This class awards Florida clinical laboratory continuing education credits based on five hours of instruction.

Please contact Betty Wheeler at 904-791-1568 (Betty.Wheeler@FLhealth.gov) to schedule a class for your facility.

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