SENTINEL CLINICAL LABORATORIES

PURPOSE OF THIS DOCUMENT:

- Articulate the role of sentinel clinical laboratories in the public health laboratory system
- Articulate the role of sentinel clinical laboratories in the Laboratory Response Network for Biological Threat Preparedness
- Outline the responsibilities of LRN Reference Public Health Laboratories in support of sentinel clinical laboratories

In the broadest sense, all laboratories capable of analyzing or referring specimens or samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites, or radiological agents function as sentinels in the public health laboratory system. This includes environmental, food, veterinary, agriculture, military, public health and clinical laboratories. Because of their routine activities, all of these laboratories have the potential to encounter samples that may contain agents that threaten the public's health. While all of these laboratories are considered to be sentinel laboratories, they may have different roles within the public health laboratory system.

Role of Sentinel Clinical Laboratories in the Public Health Laboratory System

Clinical laboratories testing human and animal samples are often the first interface with patients and the public health system. These laboratories perform a variety of critical tests, providing timely results to impact patient care. Optimally, these laboratories also work with local and state health departments to provide information on nationally notifiable diseases and other threats. While reporting of nationally notifiable diseases to the Centers for Disease Control and Prevention (CDC) is not federally mandated, it is currently required by legislation or regulation at the state or local levels. As such, the list of reportable diseases varies slightly by jurisdiction. Ongoing communications and trainings from public health staff, including laboratorians and epidemiologists, help to assure that clinical laboratories are integrated into the public health laboratory system. This coordination is vital to the surveillance and responses for endemic and emerging pathogens, including identification of novel threats such as pandemic influenza and the development of appropriate countermeasures such as vaccines.

Role of Sentinel Clinical Laboratories in the LRN for Biological Threat Preparedness

In addition to their broad role in the public health laboratory system, clinical laboratories work closely with local and state public health and federal laboratories to recognize potential biological threat agents and other emerging threats to public health. Such laboratories are part of the nation's Laboratory Response Network (LRN) founded by the CDC, the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL). The strength of the LRN lies in its standardized approach and its tiered capability construct—with sentinel clinical laboratories serving at the foundation to quickly recognize, rule-out or refer potential biothreat agents to the LRN Reference Laboratories.

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LRN LABORATORY RESPONSE NETWORK

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

As the LRN continues to evolve, it faces the challenges of diminishing resources and meeting expanding expectations to mitigate the consequences of emerging infectious diseases. Meeting this demand requires enhancing the partnerships between the private and public health communities, with a greater emphasis on reportable diseases at the state and local level. Clinical laboratories have been and continue to be an integral part of the LRN, and their engagement as active partners is the responsibility of each state public health LRN Reference Laboratory in partnership with the CDC. In some large metropolitan areas, the local public health laboratories are LRN Reference Laboratories and have this responsibility of engaging clinical laboratories. Building and maintaining strong relationships in the public health laboratory system is crucial to accomplishing the primary function of the LRN: rapid detection and reporting of biothreat agents. Without the prompt rule-out or referral by an LRN Sentinel Clinical Laboratory to an LRN Reference Laboratory, the rapid identification and response to potential biothreat agents would be jeopardized.

Sentinel Clinical Laboratory Definition

The laboratory is certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare & Medicaid Services (CMS) for the applicable Microbiology specialty or the laboratory is a Department of Defense (DoD) Laboratory certified under the DoD Clinical Laboratory Improvement Program or the laboratory is a veterinary medical diagnostic laboratory that is fully accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). Laboratory in-house testing includes Gram stains and at least one of the following: lower respiratory tract, wound or blood cultures.

Note: If your laboratory does not meet the definition above, please refer to items 1, 2, and 3 in the Responsibilities of the Sentinel Clinical Laboratory section below.

Responsibilities of the Sentinel Clinical Laboratory

1. The laboratory is familiar with reportable disease guidelines in its jurisdiction, and has policies and procedures in place to refer diagnostic specimens or isolates suspected to contain agents of public health significance to the local or state public health laboratory in its jurisdiction.
2. The laboratory ensures personnel have met the applicable federal regulations for packing and shipping of infectious substances.
3. The laboratory has policies and procedures for referral of suspect biothreat agent specimens and/or isolates to the LRN Reference Laboratory in its jurisdiction that reflect the *American Society for Microbiology (*ASM) *Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases* available for download on the ASM website at http://www.asm.org/index.php/policy/sentinel-level-clinical-microbiology-laboratory-guidelines.html.
4. The laboratory maintains the capability to perform testing outlined in the ASM *Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases* and demonstrates annual competency by participation in proficiency testing or exercises, such as the Laboratory Preparedness Exercise or state-developed challenge sets.

5. The laboratory has a Class II or higher Certified Biological Safety Cabinet.
6. The laboratory complies with Biosafety Level II (BSL-2) practices as outlined in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories* guidelines.
7. The laboratory complies with applicable Occupational Safety and Health Administration (OSHA) regulations for a respiratory protection program.
8. The laboratory complies with the rules and regulations of the Select Agent Program.

Responsibilities of the LRN Reference Public Health Laboratory

1. For the sentinel clinical laboratories that meet the above definition, the appropriate LRN Reference Public Health Laboratory will maintain a sentinel clinical laboratory database that includes the elements identified below:

Required List of Common Database Elements

- Laboratory CLIA number
- Laboratory name
- Laboratory mailing address
- Laboratory physical address
- Primary contact information (Name, Title, Email, Phone, Fax)
- Secondary Contact (Name, Title, Email, Phone, Fax)
- 24/7 Emergency contact (Phone/Pager/Answering service)
- List of each method for receiving emergency alerts and communications (e.g., Email, Fax, Phone)

Recommended List of Common Database Elements

- Biosafety precautions:
  - Highest Biosafety Level (BSL-2, BSL-3, Other/Don't Know)
  - Class II Biological Safety Cabinet (Yes, No)
  - Number of Class II Biosafety Cabinets
- Additional Respiratory Protection Information such as N-95 or P-100 fit testing
- Personnel Information:
  - How many personnel are currently competent to collect, refer, ship, and package infectious substances?
  - How many personnel are trained to perform high complexity Microbiology testing?
  - Of these, how many personnel are trained to perform rule-out or refer testing for a suspect biothreat agent as described in the *ASM Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*?
- Participation in a Competency Assessment (CAP/LPX, State Issued Microbiology Challenge Sets, Other)
- Testing Capabilities (e.g., Molecular Biology, Sequencing, Mycobacteriology, Virology)

2. Provides training or assures access to training for sentinel clinical laboratories encouraging them to maintain competent staff knowledgeable in the ASM *Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*. Training must encompass the following subjects: recognition, rule-out testing and referral of potential biothreat agents, packaging and shipping of infectious specimens and isolates following applicable federal regulations, chain of custody, and biosafety and risk assessment.

3. Utilizes real events or develops and implements exercises to assess the functionality of the public health laboratory system, such as the ability of sentinel clinical laboratories in their jurisdiction to correctly refer samples to the local or state public health laboratory.

4. Provides or assures 24/7 availability to the sentinel clinical laboratories for information and technical consultations and necessary confirmatory testing.

5. Ensures a robust electronic system for communication of routine and emergency alerts and critical information to all of the sentinel clinical laboratories within the jurisdiction.

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This document was developed by the Sentinel Laboratory Partnerships and Outreach Subcommittee of the Public Health Preparedness and Response Committee. Members of the subcommittee included representatives from state and local public health laboratories, the Centers for Disease Control and Prevention (CDC), Association of Public Health Laboratories (APHL), American Society for Microbiology (ASM) and the American Society for Clinical Pathology (ASCP).

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