

# Definition of 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 (LRN) for Biological Threats Preparedness.
- Outline the responsibilities of the LRN Reference Laboratories in support of sentinel clinical laboratories.

## Role of Sentinel Clinical Laboratories in the Public Health Laboratory System

In the broadest sense, all laboratories capable of analyzing or referring samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites, or radiological agents of public health significance 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.

Clinical laboratories testing human and animal samples are often the first interface between patients and animal owners/keepers and the public health system. These laboratories perform a variety of critical tests, providing timely results that impact patient and pet/livestock care. Optimally, these laboratories also work with local and state health departments to receive and provide information on nationally notifiable diseases and other threats. While reporting of nationally notifiable diseases to the US 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 can vary by jurisdiction. Ongoing communication and training from public health staff, including laboratorians and epidemiologists, helps to assure that clinical laboratories are integrated into the public health laboratory system. This coordination is vital for the surveillance and response to endemic and emerging pathogens, including detection of emerging threats such as novel influenza virus and the development of appropriate countermeasures such as vaccines.

## 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 specialty of Microbiology, or the laboratory is a Department of Defense (DoD) Laboratory certified under the DoD Clinical Laboratory Improvement Program (CLIP), 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 the laboratory does not fully meet the definition above, all clinical laboratories should still act in accordance to the full list of items in the Responsibilities of the Sentinel Clinical Laboratory section below, as it applies to their facility.*

## 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 LRN founded by 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. Sentinel clinical laboratories serve as the foundation for quickly recognizing potential threat agents and for initiating an appropriate response. Critically, sentinel clinical laboratories should never test environmental (e.g. powders, letters, packages), animal, food, or water samples for examination, culture, or transport for biological threat associated agents which have not been approved by the public health laboratory. If a biological threat agent is suspected, such samples should be immediately directed to the nearest LRN Reference Laboratory.

As the LRN continues to evolve, it faces the challenges of diminishing resources, meeting expanding expectations to mitigate the consequences of emerging infectious diseases, and adapting to evolving or emerging clinical diagnostic technologies, including the use of culture independent diagnostic tests (CIDTs) and other tests that may be performed in point of service settings. 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 continued engagement as active partners is the responsibility of each state public health LRN Reference Laboratory in partnership with CDC. In some large metropolitan areas, the local public health laboratories are also LRN Reference Laboratories and therefore have this responsibility of engaging clinical laboratories. Building and maintaining strong relationships with the public health laboratory system is crucial to accomplishing the primary function of the LRN: rapid detection and reporting of biothreat agents and other emerging threats. 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 or other emerging threats would be jeopardized.

## Responsibilities of the Sentinel Clinical Laboratory

1. Clinical core/central laboratories are responsible for providing their satellite facilities with written directions and training as needed for appropriate sample collection and handling. Core/central laboratories should also provide satellite facilities with procedures for the recognition of the agents of bioterrorism and assure training at a level commensurate with the complexity of services offered at that facility.
2. The laboratory maintains the capability to perform the testing outlined in the American Society of Microbiology (ASM) *Sentinel Level Clinical Microbiology Laboratory Protocols and Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*<sup>1</sup> and must demonstrate annual competency by participation in proficiency testing or exercises, such as the APHL, CDC and College of American Pathologists (CAP) Laboratory Preparedness Exercise (LPX), State-developed proficiency/challenge sets, or other equivalent assessment.
3. The laboratory is familiar with reportable disease guidelines in its jurisdiction, and has policies and procedures in place to refer clinical and diagnostic samples or isolates suspected to contain agents of public health significance to the appropriate local or state public health laboratory.
4. The laboratory ensures a sufficient number of personnel have met the applicable **federal regulations for packaging and shipping of Category A and B infectious substances**.<sup>2</sup>
5. The laboratory has policies and procedures for the collection and referral of suspect biothreat agents or other emerging threat samples and/or isolates to the appropriate LRN Reference Laboratory consistent with the ASM *Sentinel Level Clinical Microbiology Laboratory Protocols and Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*.<sup>1</sup>
6. The laboratory complies with the practices as outlined in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) guidelines<sup>3</sup> and those detailed in the *Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories*.<sup>4</sup>

7. The laboratory has a biosafety and biosecurity risk assessment policy and ensures that such risk assessments are routinely performed as part of their quality management program.
8. Based on the laboratory's risk assessment, the laboratory has and utilizes a Class II or higher currently certified Biological Safety Cabinet (BSC) when there is a risk of aerosol production or when working with a biological threat agent or an emerging threat organism is suspected.
9. The laboratory complies with applicable Occupational Safety and Health Administration (OSHA) [regulations for bloodborne pathogens](#)<sup>5</sup> and has a respiratory protection program.
10. The laboratory complies with the applicable rules and regulations of the [Federal Select Agent Program](#).<sup>6</sup>
  - a. The laboratory has policies and procedures for secure storage of any remaining suspect biothreat or other emerging threat agent material retained within its facilities until it is transferred or destroyed.
  - b. The laboratory has policies and procedures for final decontamination/destruction of any remaining suspect biothreat or other emerging threat agent material within the required time-frame (e.g., primary samples or subcultures retained within its facilities).

## Responsibilities of the LRN Reference Laboratory

1. For the Sentinel Clinical Laboratories that meet the aforementioned criteria, the appropriate LRN Reference Laboratory will maintain a Sentinel Clinical Laboratory Database that includes the elements identified below:

### Required List of Database Elements

- Laboratory CLIA (or CLIP for DoD laboratories) number
- Laboratory name
- Laboratory mailing address
- Laboratory physical address
- Primary contact information (name, title, email, phone, fax)
- Secondary contact information (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 Database Elements

- Biosafety Precautions:
  - ◆ Highest Biosafety Level (BSL-2, BSL-3)
  - ◆ Certified Class II Biological Safety Cabinet (Yes/No)
  - ◆ Number of Class II Biosafety Cabinets
  - ◆ Additional respiratory protection information such as whether powered air purifying respirators (PAPRs), N-95 or P-100 are available (Yes/No) and whether the applicable fit testing was performed (Yes/No)
  - ◆ Established policy and procedures for conducting laboratory risk assessments (Yes/No)
- Personnel Information:
  - ◆ Number of personnel trained to perform moderate or high complexity Microbiology testing: Bacteriology? Virology? Other subspecialty (specify)?
  - ◆ Of these, how many personnel are trained to perform testing to rule-out or refer suspect biothreat agents according to the methods described in the ASM [Sentinel Level Clinical Microbiology Laboratory Protocols and Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases](#)?<sup>1</sup>
- Participation in a laboratory biothreat proficiency test or exercise such as the APHL, CDC and CAP LPX, State-developed proficiency/challenge sets, or other equivalent assessment (Yes/No)
- Testing Capabilities (e.g., Bacteriology, Molecular Biology, Sequencing, Mycobacteriology, Virology, Mass Spectrometry/MALDI-TOF)

- Packaging and Shipping Capabilities:
    - ◆ Does the laboratory maintain a sufficient number of staff that are currently certified in safe and proper packaging and shipping of Division 6.2 Category A and B infectious substances? (Yes/No)
  - Decontamination Capabilities:
    - ◆ Established decontamination and destruction plan and procedures such as chemical inactivation procedures for any remaining biothreat agent testing materials (Yes/No)
    - ◆ Onsite autoclave (Yes/No)
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 Protocols and Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases*.<sup>1</sup> Training must encompass the following subjects: recognition, rule-out testing and referral of potential biothreat agents, packaging and shipping of Category A and B infectious samples and isolates following applicable federal regulations, chain of custody awareness, developing biosafety plans, and performing biosafety and biosecurity laboratory risk assessments.
  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.

## REFERENCES

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**Approved By:** The Laboratory Response Network Joint Leadership Committee

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## Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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