



Continuation Guidance – Budget Year Five Attachment C Focus Area C: Laboratory Capacity—Biologic Agents

CRITICAL CAPACITY #8: To develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.

RECIPIENT ACTIVITIES:

1. Develop and maintain the capability of Level A (sentinel) laboratories to (a) perform rule-out testing on critical BT agents, (b) safely package and handle specimens, and (c) refer to LRN Level B/C (reference/confirmatory) laboratories for further testing. **(LINK WITH FOCUS AREAS D AND G AND HRSA PRIORITY AREA #4)**
2. **CRITICAL BENCHMARK #12:** (HRSA/CDC Cross-cutting Activity) Based on a jurisdiction-wide inventory of all analytical laboratories, complete and implement an integrated response plan that directs how public health, hospital-based, food testing, veterinary, and environmental testing laboratories will respond to a bioterrorism incident, including: (a) roles and responsibilities; (b) inter- and intra-jurisdictional surge capacity; (c) how the plan integrates with other department-wide emergency response efforts; (d) protocols for safe transport of specimens by air and ground; and (e) how lab results will be reported and shared with local public health and law enforcement agencies, ideally through electronic means. **(LINK WITH FOCUS AREAS A, B, D, E AND F.)**
3. Address the identified needs for testing food specimens for critical BT pathogens. This may be done by contracting for services with laboratories that possess the requisite capabilities, by sponsoring such capability development within collaborating organizations (such as food regulatory laboratories), and/or by developing the requisite capabilities directly within public health department laboratories. Technical assistance with respect to selection of analytic methods is available through the Food and Drug Administration (FDA), in consultation with CDC.
4. Establish and maintain operational relationships with local members of HazMat teams, first responders, local law enforcement and FBI to provide laboratory support for their response to bioterrorism, including environmental testing for exposure assessment and chain-of-custody procedures. Examples of enhanced relationships include designated points of contact, cross-training in each discipline, and/or joint sponsorship of conferences. **(LINK WITH FOCUS AREA D)**
5. Enhance relationships with hospital-based laboratory practitioners, university laboratorians, and infectious disease physicians through participation in infectious disease rounds and conferences. **(LINK WITH FOCUS AREA D)**



6. Appoint a liaison from the state or local LRN-member laboratory to participate in meetings and conference calls with smallpox steering committee, stakeholders, and any other activities relevant to LRN operations and smallpox activities.

CRITICAL CAPACITY #9: As a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.

RECIPIENT ACTIVITIES:

1. Continue to develop or enhance operational plans and protocols that include: (a) specimen/samples transport and handling; (b) worker safety; (c) appropriate Biosafety Level (BSL) working conditions for each threat agent; (d) staffing and training of personnel; (e) quality control and assurance; (f) adherence to laboratory methods and protocols; (g) proficiency testing to include routine practicing of LRN validated assays as well as participation in the LRN's proficiency testing program electronically through the LRN website; (h) threat assessment in collaboration with local law enforcement and Federal Bureau of Investigations (FBI) to include screening for radiological, explosive and chemical risk of specimens; (i) intake and testing prioritization; (j) secure storage of critical agents; and (k) appropriate levels of supplies and equipment needed to respond to bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident. **(LINK WITH FOCUS AREA D)**
2. **CRITICAL BENCHMARK #13:** Ensure capacity exists for LRN validated testing for all Category A agents and other Level B/C protocols as they are approved.
3. Ensure at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed real-time polymerase chain reaction (PCR) and time-resolved fluorescence (TRF) rapid assays. Integrate new advanced rapid identification methods approved by the LRN into the current laboratory-testing algorithm for human, environmental, animal or food specimens. Contact CDC technical support staff for further information on approved equipment as necessary. **(LINK WITH FOCUS AREA B)**
4. **CRITICAL BENCHMARK #14:** Conduct at least one simulation exercise per year, involving at least one threat agent in Category A, that specifically tests laboratory readiness and capability to perform from specimen threat assessment, intake prioritization, testing, confirmation, and results reporting using the LRN website. **(MAY LINK WITH ALL FOCUS AREAS)**
5. Ensure the availability of at least one operational Biosafety Level 3 (BSL-3) facility in your jurisdiction. If not immediately possible, BSL-3 practices, as outlined in the CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories, 4th Edition" (BMBL), should be used (see www.cdc.gov/od/ohs) or formal arrangements (i.e., MOU)



should be established with a neighboring jurisdiction to provide this capacity.

6. Ensure that laboratory registration, operations, safety, and security are consistent with both the minimum requirements set forth in Select Agent Regulation (42 CFR 73) “Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule” and the USA PATRIOT Act of 2001, P.L. 107-56, as well as incorporate subsequent updates detailed in www.cdc.gov/od/sap and www.aphis.usda.gov/vs/ncie/bta.html. **(LINK WITH FOCUS AREA D)**
7. Enhance electronic communications and LRN electronic laboratory reporting, at the bench level, to enable integration with CDC’s LRN capacity monitoring efforts, online results reporting, sentinel surveillance, proficiency testing, multi-center validation studies, and support for future LRN site enhancements. Laboratories should participate in reporting results of LRN proficiency testing electronically, as they would in an actual event. Laboratories should have appropriate computer equipment, firewall and high-speed Internet connectivity to access the LRN’s protocols, reagents, and lab user applications. Laboratories should continue the adoption and implementation of LOINC as the laboratory data standard. **(LINK WITH FOCUS AREA D, E, AND CROSS-CUTTING ACTIVITIES.)**
8. Identify the laboratories that have the capacity for LRN-validated testing and reporting of *Variola major*, *Vaccinia* and *Varicella* through human and environmental samples. Each state should have at least one laboratory that can meet CDC biosafety and security requirements for variola-specific testing.