Public Health Emergency Preparedness and Response Capabilities

National Standards for State, Local, Tribal, and Territorial Public Health

Capability 12:
Public Health Laboratory Testing

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For the full 508 compliant document, please visit
https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednessResponseCapabilities_October2018_Final_508.pdf
Capability 12: Public Health Laboratory Testing

**Definition:** Public health laboratory testing is the ability to implement and perform methods to detect, characterize, and confirm public health threats. It also includes the ability to report timely data, provide investigative support, and use partnerships to address actual or potential exposure to threat agents in multiple matrices, including clinical specimens and food, water, and other environmental samples. This capability supports passive and active surveillance when preparing for, responding to, and recovering from biological, chemical, and radiological (if a Radiological Laboratory Response Network is established) public health threats and emergencies.

**Functions:** This capability consists of the ability to perform the functions listed below.

- **Function 1:** Conduct laboratory testing and report results
- **Function 2:** Enhance laboratory communications and coordination
- **Function 3:** Support training and outreach

**Summary of Changes:** The updates align content with new national standards, updated science, and current public health priorities and strategies. Listed below are specific changes made to this capability.

- Updates Laboratory Response Network (LRN) requirements
- Incorporates LRN-chemical requirements
- Prioritizes cooperation, coordination, and information sharing with LRN laboratories, other public laboratories, and jurisdictional sentinel laboratories

**For the purposes of Capability 12, partners and stakeholders may include the following:**

- civil support teams
- clinical laboratories
- emergency management agencies
- environmental health
- epidemiologists
- federal laboratory networks and member laboratories\(^\text{11}\)
- first responders
- food safety
- health care providers
- jurisdictional sentinel laboratories\(^\text{11}\)
- law enforcement
- LRNs
- non-laboratory response health care providers
- non-LRN public health
- poison control centers

\(^\text{11}\) For example, the Food Emergency Response Network, National Animal Health Laboratory Network, and the Environmental Response Laboratory Network
**Function 1: Conduct laboratory testing and report results**

**Function Definition:** Perform or coordinate laboratory testing to detect, characterize, confirm, and report biological, chemical, radiological, and public health threats using established protocols and procedures. Testing may include clinical specimens and food, water, and other environmental samples.

**Tasks**

**Task 1: Check in samples for specimen testing.** Receive, record, and route specimen samples to ensure that the samples are received by the appropriate laboratory for testing and that the specimen information is populated in the laboratory information system.

**Task 2: Conduct specimen sample testing.** Test clinical specimens and food, water, and other environmental samples according to designated laboratory type and level in order to identify biological, chemical, or radiological threat agents.

**Task 3: Report presumptive or confirmed laboratory results.** Notify appropriate public health, public safety, and law enforcement officials of results using electronic messaging in appropriate formats with the ability to notify 24/7.

**Task 4: Maintain plans for surge and continuity of operations.** Establish and maintain the ability to implement continuity of operations (COOP) plans and surge plans for both the short term (days) and long term (weeks to months).

**Preparedness Resource Elements**

**P1: (Priority) LRN for Biological Threats Preparedness (LRN-B) Reference laboratories with proficiency in LRN-B testing methods and the ability to accurately test for agents as defined in the LRN-B Standard Laboratory Checklist.**

**P2: (Priority) LRN for Chemical Threats Preparedness (LRN-C) member laboratories with LRN-C Quality Assurance Program "Qualified" status achieved through the successful participation in proficiency testing challenges. LRN-C core and additional methods are identified on the restricted access LRN website and updated annually.**

**P3: (Priority) LRN for Radiological Threats Preparedness (LRN-R) participating laboratories with LRN-R Quality Assurance Program "Qualified" status achieved through the successful participation in performance testing challenges, if LRN-R is established.**

**P4: Procedures in place for referring suspicious samples, such as samples from sentinel laboratories or first responders, to the laboratory jurisdictionally designated to receive them. Recommended procedures include those to safely package, document, and ship suspicious samples.**

**P5: (Priority) Procedures in place to test and report high-consequence samples from designated areas. If a jurisdiction has a high priority area (HPA), the associated LRN-B Reference laboratory must maintain the ability to ensure testing and results reporting of high-consequence samples from these designated areas within 24 hours of notification that testing is required.**

**P6: Procedures in place to ensure proper security and maintenance of records management systems.**

*(See Capability 6: Information Sharing)*
**P7: (Priority)** Procedures in place for data exchange with law enforcement, public safety, and other agencies with roles in responding to public health threats, as permitted by applicable laws, rules, and regulations. Procedures should address data security and prevent inappropriate or unauthorized disclosure of secure information. Procedures should detail the acceptable data exchange processes and list the order of priority for using each process.  
*(See Capability 6: Information Sharing)*

**P8: (Priority)** Procedures in place for laboratory surge capacity based on best practices and models available through LRN programs. Recommended procedures may include

- Procedures to secure and deploy surge personnel, equipment, and facility resources for short-term (days) and long-term (weeks to months) response efforts
- Procedures for triage and management of surge testing, which may include
  - Referral of samples to other LRN laboratories within or outside the jurisdiction using mechanisms and guidance made available by the LRN
  - Prioritization of testing based upon sample type
  - Prioritization of testing based upon risk or threat assessment
*(See Capability 10: Medical Surge)*

**P9: (Priority)** Procedures in place for a laboratory COOP plan to ensure the ability to conduct ongoing testing on routine and emerging public health threats. COOP plans should include

- Procedures for regular maintenance of redundant testing supplies
- Processes to designate alternate testing facilities for short-term duration in case of localized infrastructure failure
- Agreements with other agencies to take over critical testing, as appropriate
- Procedures to address personnel shortages
- Procedures to address equipment failures
- Procedures to address operational loss of laboratory facilities

**P10:** Notification procedures to detail how laboratory results suggestive of an outbreak or exposure will be reported or messaged to appropriate health investigation partners using secure contact methods per LRN notification policies or laboratory-specific policies. Notification procedures should include appropriate messaging timeframes per LRN data messaging and other laboratory-specific policies.  

**Skills and Training Resource Elements**

**S/T1: (Priority)** LRN-B Standard and Advanced Reference laboratories must meet all requirements of the LRN-B Standard Reference laboratories as listed in the Checklist of Laboratory Requirements for LRN-B Member Standard Level Reference Laboratories located on the restricted access LRN website. In addition, Advanced Reference laboratories must support CDC’s LRN-B program office and the network in activities that may include

- Deployment of new technologies and specialized methods
- Evaluation of new technologies

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12 LRN Notification and Data Messaging Policies are located on the restricted access LRN website.
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- Engagement in multicenter validation studies
- Participation in priority partnership exercises
- Provision of high throughput surge testing capacity
- Assistance with quality initiatives, including network training programs and proficiency testing remediation
- Maintenance of registration with Federal Select Agent Program
- Provision of resources to ship isolates to CDC for further clarification

S/T2: (Priority) All LRN-B, LRN-C, and LRN-R (if LRN-R is established) laboratories able to pass LRN proficiency testing, as required by the respective LRN program.

S/T3: LRN-B Advanced Reference laboratories and other Reference laboratories capable of performing LRN-B approved assays and participate in technical meetings, as necessary.

S/T4: Personnel who perform LRN protocols trained in LRN methods and able to demonstrate proficiency and competency in compliance with applicable regulations, such as Clinical Laboratory Improvement Amendments (CLIA) from regulatory agencies, such as the Centers for Medicare and Medicaid Services (CMS), College of American Pathologists (CAP), or other regulatory equivalent. Documentation should include training date(s) and manner of training delivery, such as formal or “train the trainer.”

S/T5: Personnel from LRN-C laboratories who participate in the LRN-C biannual technical meeting, formerly known as Level 1 surge capacity meeting.

S/T6: Personnel who regularly perform LRN testing, including those identified for surge capacity, trained annually in appropriate safety procedures. Documentation should include training date(s) and manner of delivery, such as formal training or “train the trainer.”

S/T7: Personnel trained on emergency operations and incident management system.

S/T8: (Priority) All laboratories accredited by an appropriate accreditation body, such as CAP, CMS, or the International Organization for Standardization.

Equipment and Technology Resource Elements

E/T1: (Priority) At least one LRN-B approved instrument for rapid nucleic-acid detection and one LRN-B approved instrument for antigen-based detection owned and maintained by each LRN-B Reference laboratory. Instruments are listed in the current equipment list, which is updated annually on the restricted access LRN website. Preventative maintenance and service agreements must be provided for all equipment listed on the LRN-B equipment list.

E/T2: (Priority) Laboratory equipment and instruments serviced, inspected, and certified. The following should be established and maintained in coordination with public health emergency management
- Preventative maintenance contracts and service agreements for equipment and instruments described within applicable LRN protocols, procedures, and methods
- Inspection and certification of equipment and instruments used by the LRN-B and LRN-C according to manufacturers’ specifications
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**E/T3: (Priority)** LRN-C Level 2 laboratories that own and maintain at least one instrument listed on the LRN-C equipment list. LRN-C Level 1 laboratories that own and maintain at least two instruments each listed on the LRN-C equipment list. Preventative maintenance and service agreements must be provided for all equipment listed on the LRN-C equipment list.

**E/T4: (Priority)** Reagent inventory and laboratory supplies maintained to levels adequate to perform routine testing, with plans for obtaining additional reagents or supplies during a surge event, establish priority access rights with suppliers, if possible.

**E/T5: (Priority)** Laboratory Information Management System (LIMS) that is routinely updated and maintained in order to send testing data to CDC according to CDC-defined standards. Procedures and resources needed to use and maintain the LIMS may include

- Protocols, including timelines, to send and receive data from local LIMS to CDC and other partners
- Local codes mapped to federal standards, such as Data Integration Requirements for LRN-B and LRN-C
- Dedicated information technology (IT) support personnel to maintain and update LIMS or contractual agreements with LIMS vendors that are familiar with national standards, such as LIMS integration, Public Health Laboratory Interoperability Project, and industry standards, such as logical observation identities, names, and codes; systematized nomenclature of medicine; Health Level 7 (HL7), to configure the LIMS
- Periodic validation of LIMS functionality and message structure
- Alternate data sharing strategies in the event of a failure in the LIMS or CDC-provided systems for LRN data exchange

**E/T6:** Representative(s) from both the LRN-B and LRN-C laboratories in the jurisdiction with current Secure Access Management Services (SAMS) access to electronic data exchange systems.

**E/T7:** At least one working computer able to access LRN and partner electronic data exchange systems.

**E/T8:** Access to a mechanism (automated, electronic, or paper-based) for messaging results to LRN-B, LRN-C, and LRN-R (if LRN-R is established).

**E/T9:** Access to an operational and biosafety level 3 (BSL-3) laboratory either on site or through a memorandum of understanding (MOU) or other formalized agreement.

**Function 2: Enhance laboratory communications and coordination**

**Function Definition:** Ensure timely laboratory results reporting to stakeholders to support determination of the cause or origin, definitively characterize the threat, and inform deployment of appropriate countermeasures.

**Tasks**

**Task 1: Ensure effective information exchange.** Ensure timely exchange of laboratory information and data with laboratories, laboratory network partners, and other stakeholders. Provide unique identifiers that support linking laboratory data to epidemiologic data.

**Task 2: Coordinate with preparedness partners to support public health investigations.** Use laboratory testing to coordinate public health investigations with preparedness and response partners, as required by the incident.
Task 3: **Provide investigative consultation and technical assistance.** Support jurisdictional public health agencies, first responders, law enforcement, and other health investigation partners with sample collection, management, and safety.

**Preparedness Resource Elements**

**P1: (Priority)** Procedures in place to facilitate cooperation, coordination, and information sharing with and among stakeholders, which may include

- LRN-B, LRN-C, and LRN-R (if LRN-R is established) member laboratories within the jurisdiction, including jurisdictional sentinel laboratories, and non-LRN public health laboratories, such as those identified in COOP planning for example, environmental, agricultural, veterinary, and local public health
- Federal laboratory networks and member laboratories for example, the Food Emergency Response Network, National Animal Health Laboratory Network, and the Environmental Response Laboratory Network
- Poison control centers that can serve as supporting resources for exposure incidents
- Health care providers or clinical laboratories that may be packaging and shipping samples and, subsequently, receiving sample results during a response
- Epidemiologists who interface with hospitals, public health agencies, and laboratories


**P2: (Priority)** Procedures or guidelines in place to coordinate with relevant stakeholders in specific incidents. Procedures may include

- Procedures for communicating with sentinel laboratories in the event of a public health incident
- Policies developed in coordination with jurisdictional stakeholders for handling biological, chemical, radiological, nuclear, and explosive incidents
- Coordination with first responders who may initially identify overt exposure incidents
- Coordination with Civil Support Teams (CSTs) to establish partnerships between CSTs and the public health laboratories with respect to field analysis of unknown samples
- Coordination with local law enforcement and Federal Bureau of Investigation (FBI) field offices for screening and triage procedures for environmental samples, such as biological, chemical, radiological, and explosive materials
- Coordination with emergency management officials and other relevant entities, such as fusion centers supporting an emergency response, including incidents when the Emergency Management Assistance Compact (EMAC) is activated
- Updated contact list for state, local, tribal, and territorial law enforcement and first responder units, such as HazMat and poison control center, who are approved to perform screening and triage procedures on unknown samples

*(See Capability 3: Emergency Operations Coordination and Capability 14: Responder Safety and Health)*

**P3:** Designated individual(s) responsible for coordinating emergency response activities, such as personnel safety, sample collection, methods training, plans, guidance, and outreach to sentinel laboratories and first responder communities.

*(For additional guidance on chain of custody procedures, see the restricted access LRN website)*
P4: Updated contact list for LRN-B laboratories (sentinel and public health laboratories), LRN-C laboratories, and LRN-R laboratories (if LRN-R is established) in the jurisdiction as well as other jurisdictional laboratories that collaborate with the public health agency.

(See Capability 6: Information Sharing)

Skills and Training Resource Elements

S/T1: Personnel with awareness of current national policy and leading practices for biological, chemical, and radiological (if LRN-R is established) threat preparedness attained through regular participation in LRN national meetings, if available.

S/T2: Public health laboratory managers and directors, meaning those responsible for overseeing laboratory activities, who have completed the CDC/FBI Joint Criminal Epidemiology Investigations workshop, as needed. Coordinate with FBI field office to complete this workshop.

Function 3: Support training and outreach

Function Definition: Perform outreach, facilitate access to training, and maintain applicable protocols for sample collection, handling, packaging, processing, shipping, transport, receipt, storage, retrieval, and disposal.

Tasks

Task 1: Facilitate access to training for handling, packaging, and shipping samples. Ensure established International Air Transport Association (IATA), U.S. Department of Transportation (DOT), and other laboratory-specific protocols are followed when managing laboratory samples.

Task 2: Maintain chain of custody procedures. Ensure chain of custody requirements are maintained throughout the sample management process.

Task 3: Support training, exercising, and laboratory participation in preparedness and response operations. Provide or facilitate access to training and exercises for relevant stakeholders.

Preparedness Resource Elements

P1: (Priority) Procedures in place for sample collection, triage, labeling, packaging, shipping, transport, handling, storage, and disposal. Sample collection procedures should include 24/7 contact information and submission criteria in accordance with applicable requirements, such as requirements from the IATA, DOT, and Federal Select Agent Program.

P2: (Priority) Transportation security procedures in place that may include

- Select agent and toxin regulations (if applicable)
- Biosafety or biosecurity plan (applicable even if laboratory is not select agent registered)
- Chemical hygiene plan
- LRN-R: Radiation Safety and Security Plan (if LRN-R is established)
- Other protocols, as needed, to ensure adherence to applicable federal, state, local, tribal, and territorial regulations related to transport of clinical specimens and hazardous and radiological materials
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**P3:** Procedures in place for chain of custody that meet the minimum sample control evidentiary procedures established by federal agencies and partners, such as the FBI, LRN, and Integrated Consortium of Laboratory Networks.

**P4:** A designated biological safety officer or official (BSO) for technical support and guidance regarding internal laboratory activities and technical assistance to strengthen biosafety in sentinel clinical laboratories.

**P5:** Procedures in place to ensure adequate supplies for packaging and shipping are available 24/7, including procedures to rapidly procure additional supplies when needed.

**Skills and Training Resource Elements**

**S/T1:** Ability to provide packaging and shipping training or information on the availability of packaging and shipping training in DOT regulations or IATA guidance for public health laboratory personnel and sentinel laboratories.

**S/T2: (Priority)** Laboratory personnel certified in a shipping and packaging program that meets national and state or territorial requirements.

**S/T3:** Biological, chemical, and radiological (if LRN-R is established) threat laboratory personnel trained annually on chain of custody procedures. Documentation should include training date(s) and manner of delivery, such as formal training or “train the trainer.”

**S/T4:** Laboratory personnel trained annually in safety protocols for handling samples being prepared for shipment. Documentation should include training date and manner of delivery, such as formal training or “train the trainer.”

**S/T5:** Laboratory adherence to appropriate regulatory requirements that may include

- A valid select agent registration number (LRN-B Advanced Reference laboratories only). Standard Reference laboratories are encouraged, but not required, to maintain select agent registration
- Valid shipping permit(s) from the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and Veterinary Services, as necessary
- License(s) from the Nuclear Regulatory Commission or state entities as required (LRN-R laboratories only, if network is established)

**S/T6:** Public health laboratory designee(s) trained, as needed, to advise on proper collection, packaging, labeling, shipping, and chain of custody procedures for shipping samples.

**S/T7: (Priority)** Laboratories trained in partnership with public health emergency management programs to support laboratory preparedness and response operations. Activities may include

- Education, training, and exercising to advance knowledge and skills necessary to perform LRN duties. Trainings may be provided by CDC, the Association of Public Health Laboratories (APHL), or other respected entities with appropriate expertise and may include
  - Rule-out and refer for biological threat agents
  - Packaging and shipping of infectious substances
  - Specimen collection and shipping for chemical and radiological analysis
- Participation in public health exercises and drills, including those required for LRN membership and others necessary for emergency preparedness and response
- Moot court training