



CAPABILITY 12: Public Health Laboratory Testing



Public health laboratory testing is the ability to conduct rapid and conventional detection, characterization, confirmatory testing, data reporting, investigative support, and laboratory networking to address actual or potential exposure to all-hazards.²⁶⁰ Hazards include chemical, radiological, and biological agents in multiple matrices that may include clinical samples,²⁶¹ food, and environmental samples (e.g., water, air, and soil). This capability supports routine surveillance, including pre-event²⁶² or pre-incident²⁶³ and post-exposure activities.

This capability consists of the ability to perform the following functions:

- Function 1:** Manage laboratory activities
- Function 2:** Perform sample management
- Function 3:** Conduct testing and analysis for routine and surge capacity
- Function 4:** Support public health investigations
- Function 5:** Report results

Function 1: Manage laboratory activities

Manage and coordinate communications and resource sharing with the jurisdiction's network of human, food, veterinary, and environmental testing laboratory efforts in order to respond to chemical, biological, radiological, nuclear, explosive, and other public health threats.

Tasks

This function consists of the ability to perform the following task:

Task 1: Exchange information and data with laboratories and laboratory networks within the jurisdiction. *(For additional or supporting detail, see Capability 6: Information Sharing)*

Performance Measure(s)

This function is associated with the following CDC-defined performance measures:

- Measure 1:** Time for sentinel clinical laboratories to acknowledge receipt of an urgent message from the CDC Public Health Emergency Preparedness (PHEP)-funded Laboratory Response Network biological (LRN-B) laboratory
- Start time: Time CDC PHEP-funded laboratory sends urgent message to first sentinel clinical laboratory
 - Intermediate stop time: Time at least 50% of sentinel clinical laboratories acknowledged receipt of urgent message
 - Intermediate stop time: Time at least 90% of sentinel clinical laboratories acknowledged receipt of urgent message
 - Stop time: Time last sentinel clinical laboratory acknowledged receipt of urgent message
- Measure 2:** Time for initial laboratorian to report for duty at the CDC PHEP-funded laboratory
- Start time: Date and time that a public health designated official began notifying on-call laboratorian(s) to report for duty at the CDC PHEP-funded laboratory
 - Stop time: Date and time that the initial laboratorian reported for duty at the CDC PHEP-funded laboratory

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

PLANNING (P)

- P1: (Priority)** Written plans must include at a minimum the identification of laboratories and laboratory networks within the jurisdiction^{264,265} as well as procedures for interaction with the following laboratories and groups:
- LRN-B reference laboratories within the jurisdiction
 - Support and ensure LRN-B reference laboratory communication with all LRN-B sentinel and all other LRN-B reference laboratories within the jurisdiction
 - CDC's LRN chemical (LRN-C) laboratories within the jurisdiction
 - CDC's LRN radiological (LRN-R) laboratories within the jurisdiction (if program funds become available)

Function 1: Manage laboratory activities

Resource Elements *(continued)*

PLANNING (P)	<ul style="list-style-type: none"> - Other state laboratories within the jurisdiction <ul style="list-style-type: none"> □ e.g., non-LRN public health, environmental, agricultural, veterinary, and university laboratories - Federal laboratory networks and member laboratories within the jurisdiction <ul style="list-style-type: none"> □ e.g., the Food Emergency Response Network, National Animal Health Laboratory Network, and the Environmental Response Laboratory Network - Poison control centers for chemical or radiological exposure incidents, such as food poisoning <p>P2: (Priority) Written plans must include the following elements:</p> <ul style="list-style-type: none"> - Documented procedures for contacting sentinel laboratories in the event of a public health incident ²⁶⁶ - Coordination of jurisdiction-wide stakeholders involved in chemical, biological, radiological, nuclear, and explosive response and their standard response guidelines <ul style="list-style-type: none"> □ e.g., American Society for Testing and Material, Operational Guidelines for Initial Response to a Suspected BioThreat Agent <p>P3: Written plans should include processes and protocols for continuity of operations (e.g., Continuity of Operations Plan or Annex) for chemical laboratory, radiological laboratory, biological laboratory and select agents consistent with federal guidelines, which are updated on an annual basis.²⁶⁷ Continuity of Operations should include not only the ability to conduct testing on unknown and unusual agents but also routine testing such as the assurance of newborn screening.²⁶⁸ Plans should address, but are not limited to the following elements:</p> <ul style="list-style-type: none"> - Laboratory maintenance of redundant utilities supplies for testing and support areas for short-term duration (i.e., 72 hours) in case of localized infrastructure failure - Formal or informal agreements in place with other agencies to take over critical testing - Staff illness - Equipment failure <p>Suggested resource</p> <ul style="list-style-type: none"> - Association of Public Health Laboratories, Guidelines for the Public Health Laboratory Continuity of Operations Plan: http://www.aphl.org/aphlprograms/phpr/Documents/PHL_COOP_Guidelines.pdf
SKILLS AND TRAINING (S)	<p>S1: Laboratory staff should be aware of current national policy and practice. Maintaining this understanding can be accomplished through sending one chemistry representative, one radiological representative, and one biological representative from the jurisdiction to the LRN national meeting. Also, it is recommended if possible, but not required, that each LRN Laboratory Director also attend LRN national meetings.</p> <p>S2: At least one individual on staff should be capable of coordinating personnel safety and methods trainings, plans, and guidance, and outreach to sentinel and first responder communities throughout the jurisdiction. These staff should coordinate biological, chemical, and radiological activities. Depending on the jurisdiction, these positions may be filled by one or more individuals with the appropriate experience and training to perform the duties.</p>
EQUIPMENT AND TECHNOLOGY (E)	<p>E1: Have or have access to a database of current contact information for identified LRN-B advanced sentinel laboratories, LRN-B reference laboratories, LRN-R laboratories (if program funds become available), and LRN-C laboratories in the jurisdiction, as well as laboratories both inside and outside the jurisdiction that work with the jurisdictional public health agency.²⁶⁹</p>



CAPABILITY 12: Public Health Laboratory Testing

Function 2: Perform sample management

Implement LRN-established protocols and procedures where available and applicable [and other mandatory protocols such as those for the International Air Transport Association (IATA) and the U.S. Department of Transportation (DOT)] for sample collection, handling, packaging, processing, transport, receipt, storage, retrieval, and disposal.

Tasks

This function consists of the ability to perform the following tasks:

Task 1: Handle, package, and transport samples following established IATA/DOT and laboratory-specific protocols.

Task 2: Maintain forensic chain-of-custody throughout the sample-management process.

Performance Measure(s)

This function is associated with the following CDC-defined performance measures:

Measure 1: Percentage of LRN clinical specimens without any adverse quality assurance events received at the CDC PHEP-funded LRN-B laboratory for confirmation or rule-out testing from sentinel clinical laboratories

- Numerator: Number of LRN clinical specimens without any adverse quality assurance events received at CDC-PHEP-funded laboratory for confirmation or rule-out testing from sentinel clinical laboratories
- Denominator: Total number of LRN clinical specimens received at CDC PHEP-funded laboratory for confirmation or rule-out testing from sentinel clinical laboratories

Measure 2: Percentage of LRN non-clinical samples without any adverse quality assurance events received at the CDC PHEP-funded LRN-B laboratory for confirmation or rule-out testing from first responders

- Numerator: Number of LRN non-clinical samples without any adverse quality assurance events received at CDC PHEP-funded laboratory for confirmation or rule-out testing from first responders
- Denominator: Total number of LRN non-clinical samples received at CDC PHEP-funded laboratory for confirmation or rule-out testing from first responders

Measure 3: Ability of the CDC PHEP-funded LRN-C laboratories to collect relevant samples for clinical chemical analysis, packaging, and shipping those samples

- Sample Collection, Packing and Shipping Exercise Results (Pass/Did not pass)

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

PLANNING (P)

P1: Written plans should include procedures and protocols for sample collection, triage, packaging, shipping, transport, handling, storage and disposal. Sample collection procedure should address 24/7 contact information and submission criteria.

P2: Written plans should address transportation security and, at a minimum:²⁷⁰

- LRN-B: Select Agent and Toxin Regulations
- LRN-C: Chemical Hygiene Plan
- LRN-R: Radiation Safety and Security Plan, if program funds become available

P3: Written plans should include a protocol for chain of custody. Forensic chain of custody procedures must meet the minimum evidentiary control procedure requirements established by federal partners such as the Federal Bureau of Investigation (e.g., LRN, Integrated Consortium of Laboratory Network).²⁷¹

P4: Written plans should include procedures in place to maintain sampling and/or shipping supplies stock, or demonstrate ability to procure or have access to supplies 24/7.²⁷²



CAPABILITY 12: Public Health Laboratory Testing

Function 2: Perform sample management

Resource Elements *(continued)*

SKILLS AND TRAINING (S)

- S1: (Priority)** Laboratory staff responsible for sample management must maintain certification of laboratory personnel in a shipping and packaging program that meets national and state requirements (e.g., Sample Collection, Packing and Shipping; ShipPack).
- S2:** Document forensic chain of custody procedures training, with documentation updated a minimum of once per year, for laboratory and sample submission personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training examples: CDC courses and CD or DVD-based courses, with completion verified by a formal demonstration.
- S3:** Ensure the ability to provide packaging and shipping training or information on the availability of packaging and shipping training in DOT/IATA regulations to LRN laboratorians utilizing commercial carriers.
- Suggested resources
- Association of Public Health Laboratories 902-11 SS Preparing Category B Infectious Substances for Transport: <https://www.aphlnet.org/eweb/DynamicPage.aspx?Site=aphl&WebKey=6d83bd79-2883-4c00-b426-0ffa422658b>
 - World Health Organization Infectious Substances Shipping Training http://www.who.int/ihr/i_s_shipping_training/en/index.html
 - Saf-T-Pak (<http://www.saftpak.com/>),
 - IATA (<http://www.eduwhere.com>)
- S4:** Document training on practices for personnel safety while managing samples, with documentation updated a minimum of once per year, for laboratory personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training examples: CDC courses and CD or DVD-based courses, with completion verified by a formal demonstration.
- S5:** Maintain appropriate regulatory requirements, including the following elements:
- A valid Select Agent Registration Number (LRN-B labs only)
 - A valid U.S. Department of Agriculture/Animal and Plant Health Inspection Service/Veterinary Services shipping permit (LRN-B labs only)
 - Nuclear Regulatory Commission or state licensing requirements (LRN-R labs only, if program funds become available)
- S6:** State public health laboratory coordinator or designee should be able to advise on proper collection, packaging, labeling, shipping, and chain of custody procedures for samples.

EQUIPMENT AND TECHNOLOGY (E)

- E1:** Have or have access to sampling and/or shipping supplies stock, along with contingency agreements to procure supplies 24/7.



CAPABILITY 12: Public Health Laboratory Testing

Function 3: Conduct testing and analysis for routine and surge capacity

Perform, or coordinate with the applicable lead agency, testing of chemical, biological, radiological, nuclear, and explosive samples, utilizing CDC-established protocols and procedures (e.g., LRN), where available and applicable, to provide detection, characterization and confirmatory testing to identify public health incidents. This testing may include clinical, food, and environmental samples.

Tasks

This function consists of the ability to perform the following tasks:

Task 1: Provide LRN-B reference-level testing in clinical, food, and environmental samples for both rapid and conventional methods.

Task 2: Conduct chemical laboratory testing following LRN-C testing methods.

Task 3: Conduct radiological and nuclear laboratory testing following LRN-R (if program funds become available) testing methods.

Performance Measure(s)

This function is associated with the following CDC-defined performance measures:

Measure 1: Proportion of LRN-C proficiency tests (core methods) successfully passed by CDC PHEP-funded laboratories

- Numerator: Number of LRN-C core methods successfully proficiency tested by the CDC PHEP-funded laboratory
- Denominator: Total number of LRN-C core methods for which the CDC PHEP-funded laboratory is qualified to test

Measure 2: Proportion of LRN-C proficiency tests (additional methods) successfully passed by CDC PHEP-funded laboratories

- Numerator: Number of LRN-C additional methods successfully proficiency tested by the CDC PHEP-funded laboratory
- Denominator: Total number of LRN-C additional methods for which the CDC PHEP-funded laboratory is trained to test

Measure 3: Proportion of LRN-B proficiency tests successfully passed by CDC PHEP-funded laboratories

- Numerator: Number of LRN-B proficiency tests successfully passed by CDC PHEP-funded laboratory(s)
- Denominator: Total number of LRN-B proficiency tests participated in by CDC PHEP-funded laboratory(s)

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

PLANNING (P)

P1: (Priority) Written plans should include the following considerations for surge capacity:

- Options to optimize procedures based on regular and surge personnel, equipment, and facility resources for short-term (e.g., days) and long-term (e.g., weeks to months) response efforts. Options should also be based on best practices and models available on the LRN website or other sources.
- Triage policies that address how the laboratory will manage surge testing, that may include:
 - Referral of samples to other jurisdictional laboratories
 - Prioritization of testing based upon sample type
 - Prioritization of testing based upon risk or threat assessment
 - Contingencies to assure newborn screening in a surge situation. Newborn screening can be assured by memoranda of agreement or contracts with commercial vendors²⁷³
- Ensuring that laboratory testing and reporting can be performed for extended shifts based on need for Level 1 and Level 2 LRN-C laboratories. *(Not applicable for territories)*
- Ensuring that laboratory testing, quality assurance and control review, and reporting can be performed for extended shifts based on need for LRN-R laboratories, if program funds become available



CAPABILITY 12: Public Health Laboratory Testing

Function 3: Conduct testing and analysis for routine and surge capacity

Resource Elements *(continued)*

PLANNING (P)

- P2: (Priority)** Written plans should include preventative maintenance contracts and service agreements in place for equipment and instruments utilized in LRN protocols, procedures, and methods – at a minimum. Plans should also include protocols to ensure that equipment and instruments utilized in LRN protocols, procedures, and methods have been inspected and/or certified according to manufacturer’s specifications.
- P3:** Written plans should include a process that provides guidance for referring suspicious samples (e.g., from sentinel labs or first responders) to an LRN reference laboratory.
- P4:** Written plans should include considerations for supply accessibility, including identifying multiple vendors for critical commercially available reagents/supplies.
- P5:** Written plans should include processes and procedures to operate at expanded laboratory capacity for surge events and incidents.

SKILLS AND TRAINING (S)

- S1: (Priority)** Laboratories participating in radiological or nuclear testing must attain LRN-R (if program funds become available) Proficiency Testing Program Qualified status for all analysis methods transferred by LRN-R through the following:
- Attending LRN-R training, if program funds become available
 - Completing the associated laboratory validation exercise, demonstrating performance and precision according to the minimum standards for each analytical method
- S2: (Priority)** LRN-B reference laboratories must attain competency for LRN-B testing methods by having the ability to test for all agents/sample types/tests listed in the high risk environmental sample testing algorithm posted on the secure LRN website.
- S3: (Priority)** All LRN Laboratories (excluding LRN-B sentinel laboratories) must maintain the competency to pass LRN proficiency tests.
- S4: (Priority)** Laboratories participating in chemical testing must attain LRN-C Proficiency Testing Program Qualified status, through the ability to perform the following:
- Core LRN-C methods testing, for all Level 1 (surge capacity laboratories only) and Level 2 analysis methods transferred by CDC. Core LRN-C methods are identified on the LRN website and updated at least annually.
 - Validation and qualification of at least one new analysis method per year is required.
- S5:** Document LRN methods training, with documentation updated a minimum of once per year, for personnel that regularly perform LRN methods, as well as staff identified as surge-capacity personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training: CDC courses and CD or DVD-based courses, with completion verified by a formal demonstration.
- S6:** If possible, (but not required) send one chemical, one radiological, and one biological laboratory representative to meetings focused on technical competencies.
- S7:** Send at least one chemistry representative from each LRN-C Level 1 surge laboratory to participate in the bi-annual LRN-C Level 1 surge capacity meeting.
- S8:** Document safety training, with documentation updated a minimum of once per year, for personnel that regularly perform LRN testing, as well as staff identified as surge-capacity personnel. Documentation should include training date and manner of delivery (e.g., formal training or “train the trainer”). Formal training: CDC courses and CD or DVD-based courses, with completion verified by a formal demonstration.
- S9:** Attain accreditation for LRN-C clinical testing, at a minimum, via an appropriate accreditation body [e.g., at a minimum, Clinical Laboratory Improvement Amendments (CLIA) or College of American pathologists (CAP)]



CAPABILITY 12: Public Health Laboratory Testing

Function 3: Conduct testing and analysis for routine and surge capacity

Resource Elements *(continued)*

SKILLS AND TRAINING (S)

- S10:** Attain accreditation for LRN-B clinical testing, at a minimum, via an appropriate accreditation body (e.g., at a minimum, CLIA or CAP)
- S11:** Attain accreditation for LRN-R clinical testing, at a minimum, via an appropriate accreditation body, if program funds become available (e.g., at a minimum, CLIA or CAP)

EQUIPMENT AND TECHNOLOGY (E)

- E1:** Have or have access to a biosafety level 3 laboratory.
- E2:** Laboratory owns and maintains at least one instrument each for rapid nucleic-acid detection and antigen-based detection and instruments are listed in the current equipment list (which is updated annually on the secure LRN website).
- E3:** Level 2 laboratories own and maintain equipment for at least one instrument each for detection of LRN-C agents, that are listed in the current equipment list (which is updated annually on the secure LRN website), to demonstrate qualified status for the listed Level 1 (surge capacity laboratories only) and Level 2 methods.
- E4:** Level 1 laboratories must obtain and maintain additional support equipment and supplies listed in each method.
- E5:** LRN-R laboratories (if program funds become available) own and maintain equipment and maintain staff for at least one instrument each for detection of LRN-R agents that are listed in the LRN-R Equipment List (which is updated annually on the secure LRN website).
- E6:** Maintain inventory or reliable sources of testing material that includes CDC/LRN provided analyte-specific test kits, ancillary reagents, control strains, calibration standards, and laboratory supplies required to run LRN analytical methods.
- E7:** Have or have access to equipment necessary for performing LRN assays.

Function 4: Support public health investigations

Provide analytical and investigative support to epidemiologists, healthcare providers, law enforcement, environmental health, food safety, and poison control efforts to help determine cause and origin of, and definitively characterize, a public health incident.

Tasks

This function consists of the ability to perform the following tasks:

- Task 1:** Establish and maintain the ability to provide analytical support for investigations with first responders and other health investigation community partners. *(For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation)*
- Task 2:** Provide investigative consultation and technical assistance to jurisdictional health departments, first responders, and other health investigation community partners regarding sample collection, management, and safety. *(For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation)*

Function 4: Support public health investigations

Performance Measure(s)

This function is associated with the following CDC-defined performance measures:

Measure 1: Time to complete notification between CDC, on-call laboratorian, and on-call epidemiologist

- **Start time:** Date and time that CDC Department of Emergency Operations official began notification of on-call laboratorian
- **Stop time:** Date and time on-call epidemiologist (after receiving notification from on-call laboratorian) notifies CDC Department of Emergency Operations that notification drill is complete

Measure 2: Time to complete notification between CDC, on-call epidemiologist, and on-call laboratorian

- **Start time:** Date and time that CDC Department of Emergency Operations official began notification of on-call epidemiologist
- **Stop time:** Date and time on-call laboratorian (after receiving notification from on-call epidemiologist) notifies CDC Department of Emergency Operations that notification drill is complete

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

PLANNING (P)

P1: Written plans should include processes to coordinate activities, gain assistance from, and/or share data with the following group:

- Poison control centers that can act as resources for chemical exposure incidents, such as food poisoning (*For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation*)
- First responders (e.g., police, fire, and hazardous materials teams) who can be initial resources for identifying overt chemical, radiological, or biological exposure incidents (*For additional or supporting detail, see Capability 14: Responder Safety and Health*)
- Civil Support Teams (CSTs), to establish a technical link between CSTs and the public health biological, radiological, and chemical laboratories with respect to field analysis of unknown samples
- Healthcare providers who may be packaging and shipping samples and subsequently receiving sample results during a response (*For additional or supporting detail, see Capability 7: Mass Care and Capability 10: Medical Surge*)
- Epidemiologists who are at the interface between clinicians/hospitals, health departments, and the laboratory (*For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation*)
- Veterinary diagnostic or food safety laboratories, if applicable, which serve animal populations and investigate food products (*For additional or supporting detail, see Capability 13: Public Health Surveillance and Epidemiological Investigation*)
- Local law enforcement and Federal Bureau of Investigation regional offices for screening and triage procedures of mixed environmental samples (to include chemical, biological, radiological and explosive materials) (*For additional or supporting detail, see Capability 3: Emergency Operations Coordination*)
- State emergency operations center and other official components of the state and local emergency response, including the Emergency Management Assistance Compact^{274,275} (*For additional or supporting detail, see Capability 3: Emergency Operations Coordination*)

P2: Written plans should include processes to disseminate and receive information to/from select partner agencies as applicable to the situation.

SKILLS AND TRAINING (S)

S1: Public health lab managers and directors should be trained on the CDC Public Health Law Program 101, Forensic Epidemiology 3.0 curriculum (<http://www.cdc.gov/phlp>).

Function 5: Report Results

Provide notification of laboratory results and send laboratory data to public health officials, healthcare providers, and other institutions, agencies, or persons as permitted by all applicable laws, rules, and regulations.

Tasks

This function consists of the ability to perform the following tasks:

Task 1: Notify appropriate public health, public safety, and law enforcement officials (24/7) of presumptive and/or confirmed laboratory results from clinical, food, or environmental samples that involve a chemical, radiological, or biological threat agent. *(For additional or supporting detail, see Capability 6: Information Sharing)*

Task 2: Send presumptive and confirmed chemical, radiological, or biological laboratory results to CDC and all submitters. *(For additional or supporting detail, see Capability 6: Information Sharing)*

Performance Measure(s)

At present this function is associated with the following CDC-defined performance measures:

Measure 1: Time for CDC PHEP-funded laboratory to notify public health partners of significant²⁷⁶ laboratory results

- Start time: Time CDC PHEP-funded laboratory obtains a significant laboratory result
- Stop time: Time CDC PHEP-funded laboratory completes notification of public health partners of significant laboratory results (i.e., time when last public health partner was notified, if partners were not notified simultaneously)

Resource Elements

*Note: Jurisdictions must have or have access to the resource elements designated as **Priority**.*

PLANNING (P)

P1: Written plans should include processes and protocols to ensure proper security and maintenance of records management system.^{277,278} *(For additional or supporting detail, see Capability 6: Information Sharing)*

P2: Written plans should include data-exchange processes, as permitted by all applicable laws, rules and regulations, with law enforcement, public safety, and other agencies with roles in responding to public health threats. These processes should address data security and inappropriate disclosure of information.^{279,280,281} *(For additional or supporting detail, see Capability 6: Information Sharing)*

P3: Written plans should include notification procedures that detail the process of reporting results that are suggestive of an outbreak or exposure to appropriate health investigation partners utilizing secure contact methods per the LRN-B, LRN-C, or LRN-R (if program funds become available) Notification Policy and/or laboratory-specific policies.²⁸² *(For additional or supporting detail, see Capability 3: Emergency Operations Coordination and Capability 6: Information Sharing)*

P4: Written plans should include protocols to ensure messaging follows the LRN data messaging and laboratory-specific policies for determining specific time frames for sending data.

EQUIPMENT AND TECHNOLOGY (E)

E1: (Priority) Each LRN laboratory will build or acquire and configure a jurisdictional Laboratory Information Management System (LIMS) with the ability to send testing data to CDC according to CDC-defined standards. (This will reduce the duplicate entry into multiple data exchange systems, i.e., having to put data into results messenger or other data exchange systems to be able to send to CDC, public health partners, and other submitters).^{283,284} Configuring the LIMS includes the following elements:

- Developing project plans with deliverables and a timeline to achieve ability to send and receive data from local Laboratory Information Management Solution (LIMS) to CDC and other partners
- Mapping local codes to federal standards (e.g., LRN-B Test Configuration and Vocabulary Requirements, LRN-B Laboratory Results Message Guide)
- Working with IT support staff or developing contractual agreements with LIMS vendors that are familiar with federal (e.g., LIMS integration, Public Health Laboratory Interoperability Project) and industry (e.g., logical observation identities, names, and codes; systematized nomenclature of medicine; HL 7) standards to configure the LIMS



Function 5: Report results

Resource Elements *(continued)*

EQUIPMENT AND TECHNOLOGY (E)

- Validating function of LIMS and structure of message by being able to send a test message to CDC
- Ensuring health information infrastructure and surveillance systems are able to accept, process, and analyze standards-based electronic messages from sending electronic health records (EHRs) as defined by Centers for Medicare & Medicaid Services (42 Code of Federal Regulations Parts 412, 413, 422 et al.) Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule (published on July 28, 2010 in the Federal Register at <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>) and the Office of the National Coordinator for Health Information Technology (45 Code of Federal Regulations Part 170) Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule (published on July 28, 2010 in the Federal Register at <http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf> and http://healthit.hhs.gov/portal/server.pt/community/onc_regulations_faqs/3163/faq_3/20765)

E2: Ensure at least one member of each laboratory area represented in the jurisdiction (LRN-B, LRN-C, LRN-R, if program funds become available) has a working digital certificate for access to electronic results-reporting systems.

E3: Have or have access to at least one working computer for access to LRN and partner electronic reporting systems.

E4: Have or have access to a mechanism (e.g., automated or electronic) for reporting results to LRN-B, LRN-C and LRN-R (if program funds become available), at a minimum, as appropriate.²⁸⁵