PUBLIC HEALTH LABORATORY TESTING

Capability Definition

The Public Health Laboratory Testing capability is the ongoing surveillance, rapid detection, confirmatory testing, data reporting, investigative support, and laboratory networking to address potential exposure, or exposure, to all-hazards which include chemical, radiological, and biological agents in all matrices including clinical specimens, food and environmental samples, (e.g., water, air, soil). Such all-hazard threats include those deliberately released with criminal intent, as well as those that may be present as a result of unintentional or natural occurrences.

Outcome

Chemical, radiological, and biological agents causing, or having the potential to cause, widespread illness or death are rapidly detected and accurately identified by the public health laboratory within the jurisdiction or through network collaboration with other appropriate local, State, and Federal laboratories. The public health laboratory, working in close partnership with public health epidemiology, environmental health, law enforcement, agriculture and veterinary officials, hospitals and other appropriate agencies, produces timely and accurate data to support ongoing public health investigations and the implementation of appropriate preventative or curative counter-measures.

Relationship to National Response Plan Emergency Support Function (ESF)/Annex

This capability supports the following Emergency Support Function (ESF)/Annexes:

ESF#8: Public Health and Medical Services
Biological Incident Annex
Terrorism Incident Law Enforcement and Investigation Annex

Preparedness Tasks and Measures/Metrics

Activity: Develop and Maintain Plans, Procedures, Programs and Systems	
Critical Tasks	
Pro.B1e 1.1.1	Identify, establish and maintain working collaboration with all LRN Sentinel and LRN Clinical Chemistry laboratories within the jurisdiction
Pro.B1e 1.1.1.1	Develop and maintain an accurate and current database of contact information and capability for all the LRN Sentinel and LRN Clinical Chemistry laboratories
Pro.B1e 1.1.1.2	Provide all the LRN Sentinel and LRN Clinical Chemistry laboratories with updated LRN Reference laboratory contact information
Pro.B1e 1.1.3	Establish and maintain collaborative linkages with other State laboratories, e.g., environmental, agriculture, veterinary, and university, as well as the jurisdiction's National Guard Civil Support Team (CST) and other first responders

Pro.B1e 1.1.4	Establish and maintain linkages with Federal laboratory networks and member laboratories within the jurisdiction, e.g., the Food Emergency Response Network (FERN), National Animal Health Laboratory Network (NAHLN), and the EPA
Pro.B1e 1.1.5	Establish and maintain a sentinel laboratory advisory committee or equivalent that meets at least annually and includes representatives from clinical microbiology, clinical chemistry, veterinary, food, and environmental laboratories in your jurisdiction
Pro.B1e 1.3.3	Establish and utilize a State and local health alert network that complies with the PHIN Functional Area *Partner Communication and Alerting* for electronic connectivity with all LRN Sentinel laboratories
Pro.B1e 1.3.4	Establish and maintain connectivity with the State Emergency Operations Center (SEOC) and other official components of the State and local emergency response, including the Emergency Management Assistance Compact (EMAC)
Pro.B1e 1.3.5	Establish and maintain communication linkages with local, State, and Federal (e.g., CDC DEOC and LRN) public safety and law enforcement entities, e.g., police, fire, emergency management, and the FBI
Pro.B1e 1.5.1	Hire and/or maintain a biosafety officer for each facility
Pro.B1e 1.5.2	Develop a contingency plan for a breach in biosafety
Pro.B1e 1.6.4	Provide a ready supply of the reagents required for rapid testing of biological threat agents by LRN Reference laboratories
Pro.B1e 1.6.5	Maintain a ready supply of the reagents and materials, not supplied by CDC, required for rapid testing of biological and chemical threat agents at the reference level
Pro.B1e 1.6.6	Maintain an accurate inventory of reagents and supplies in their respective laboratories.
Pro.B1e 1.7.1	Develop and validate, in partnership with LRN Reference and LRN Chemical laboratories, standard laboratory methods to test for chemical and biological threat agents
Pro.B1e 1.7.2	Transfer standardized technology and laboratory methods from the CDC to State and local LRN Reference and LRN Chemical laboratories
Pro.B1e 1.7.3	Develop, in collaboration with CDC, e.g., EPA, FDA, USDA, and DOD, additional standardized and validated methods for testing for chemical and biological agents in non-clinical samples
Pro.B1e 1.7.4	Integrate new advanced biological and chemical rapid identification methods, as they are developed and approved by the LRN, into the current laboratory testing algorithm for human, environmental, animal, or food specimens

Preparedness Measures	**Metrics**
LRN Reference and LRN Chemical laboratories have internal competency training program for LRN methods	Yes/No
LRN Reference laboratory offers training to LRN Sentinel laboratories	Annually
Percent of participating LRN Reference laboratories and Level-1 and Level-2 LRN chemical laboratories that pass their proficiency tests according to CDC criteria	100%
Percent of LRN Sentinel laboratories that participate in State-developed training programs, *i.e., by LRN Reference laboratories* (responsibility aligns with HRSA)	100%
The Public Health Laboratory has or has access to information systems that comply with the PHIN Functional Area *Connecting Laboratory Systems* to send and receive laboratory test	Yes/No

orders and results	
LRN reference laboratory has a system to maintain an inventory of reagents and supplies to support LRN testing	Yes/No
CDC (BPRP) produces and/or acquires sufficient reagents to maintain LRN reference testing of biological threat agents	Yes/No
Percentage of Health Resources & Services Administration (HRSA) funded hospitals that have PHIN compliant IT systems that are interoperable with their jurisdictional public health agency and that transmit clinical and/or hospital utilization data in near real-time to a PHIN-compliant early-event detection information systems. (responsibility aligns with HRSA and interface with Interoperable Communications, Epidemiology and Medical Surge TCLs) *(Reference National Bioterrorism Hospital Preparedness Program FY2005 Continuation Guidance HRSA Announcement number 5-U3R-05-001)*	100%
Tests are conducted of select LRN Sentinel laboratories laboratory to reach a knowledgeable public health laboratory professional at the jurisdictional confirmatory LRN Reference and LRN Chemical laboratories 24/7/365 by landline phone	At least annually
Time to reach public health laboratory professionals by landline phone	Within 15 minutes
Percentage of LRN Sentinel laboratories within the LRN jurisdiction that successfully acknowledge receipt of health alerts. Testing must be at least annually and include at least one priority category (i.e., alert, advisory, update, etc.) *Note: Reference PHIN Preparedness Functional Area Partner Communication and Alerting*	100% (# of successful acknowledgements/# of Sentinel laboratories within jurisdiction)
The laboratory has a primary system that ensures delivery of specimens/samples 24/7/365	Yes/No
The laboratory has a secondary courier (e.g., State patrol helicopter) system that ensures rapid delivery in an emergency situation	Yes/No
At least one operational Biosafety Level Three (BSL-3) facility is available within jurisdiction for testing for biological agents, *or* if not immediately possible, BSL-3 practices, as outlined in the CDC-NIH publication "Biosafety in Microbiological and Biomedical Laboratories, 4th Edition" (BMBL), used (see www.cdc.gov/od/ohs) or formal arrangements (i.e., MOU) established with a neighboring jurisdiction to provide this capability. At least one laboratory exists within jurisdiction for testing of chemical agents or formal arrangements (i.e., MOU) established with a neighboring jurisdiction to provide this capability	Yes/No
Laboratory registration, operations, safety, and security are consistent with both the minimum requirements set forth in Select Agent Regulation (42 CFR 73) and the USA PATRIOT ACT of 2001(P.L. 107-56) and subsequent updates	Yes/No
Public health laboratory website is in place that includes, at a minimum: ▪ Information about protocol updates for rule-out testing ▪ Department of Transportation (DOT) compliant packaging and shipping ▪ Chain-of-custody guidelines ▪ CDC endorsed material on referral of clinical human and Veterinary specimens ▪ Environmental samples ▪ Suspect bioterrorism (BT) isolates ▪ Bacterial and viral food borne pathogens Public health laboratory website is in place that includes, at a minimum:	Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No

▪ Information about protocol updates for rule-out testing ▪ Department of Transportation (DOT) compliant packaging and shipping ▪ Chain-of-custody guidelines ▪ CDC endorsed material on referral of clinical human and veterinary specimens ▪ Environmental samples ▪ Suspect bioterrorism (BT) isolates ▪ Bacterial and viral food borne pathogens	
A ready supply of the reagents, not supplied by CDC, required for rapid testing of biological threat agents at the reference level is maintained by LRN Reference laboratories	Yes/No
Adequate amounts of required test reagents and materials are maintained by and immediately available to LRN Reference and LRN Chemical laboratories during an emergency event	Yes/No
Materials for chemical methods are available through commercial vendors and stocked by chemical laboratories for use in an emergency	Yes/No
Laboratory system is in place to receive and triage specimens and samples	Yes/No
All-hazards team includes: ▪ Chemical terrorism (CT) laboratory coordinator (chemist or medical technologist) ▪ Assistant CT laboratory coordinator ▪ Bioterrorism laboratory coordinator ▪ Biologic sentinel network liaison who is available 24/7/365 to advise public health agencies, hospitals, private laboratories, first responders, HazMat teams, local, State, and Federal law enforcement, the Army National Guard (WMD-CST), and poison control Team is capable of: ▪ Proper triage screening ▪ Collection, packaging, labeling, and shipping of: ▪ Biological/environmental sample ▪ Biological/clinical specimen ▪ Biological/food sample ▪ Chemical/environmental sample ▪ Chemical/clinical specimen ▪ Chemical/food sample ▪ Radiological/environmental sample ▪ Radiological/clinical specimen ▪ Radiological/food sample	Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No

Activity: Develop and Maintain Training and Exercise Programs
Critical Tasks

Pro.B1e 2.1.3	Participate in a CDC-approved proficiency testing program to assure laboratory competency
Pro.B1e 2.1.4	Participate in training provided by other Federal partners for the use of standardized methods to detect and identify chemical and biological agents
Pro.B1e 2.1.5	Provide information and training on the use of appropriate safety and security equipment and procedures
Pro.B1e 2.1.6	Train all LRN Sentinel laboratories in the use of LRN biological agent rule-out protocols, specimen or isolate referral responsibilities and notification algorithms
Pro.B1e 2.1.7	Participate in CDC training to use standardized protocols to detect biological agents
Pro.B1e 2.1.8	Participate in CDC training as required for designated levels of chemical preparedness, e.g., LRN Level-1, 2, or 3
Pro.B1e 2.2.5	Coordinate response planning, drills and exercises for the laboratory with all relevant partners

Preparedness Measures	**Metric**
LRN Reference and LRN Chemical laboratories have internal competency training program for LRN methods	Yes/No
Frequency with which LRN Reference laboratory offers training to LRN Sentinel laboratories	Annually
Percentage of participating LRN Reference laboratories and Level-1 and Level-2 LRN chemical laboratories that pass their proficiency tests according to CDC criteria	100%
Percentage of LRN Sentinel and LRN Clinical Chemistry laboratories that participate in State-developed training programs, *i.e., by LRN Reference laboratories* (responsibility aligns with HRSA)	100%
Percentage of participating LRN Level 1, 2, or 3 chemical laboratories that successfully complete packaging and shipping exercises	100%
Frequency with which tests are conducted of select LRN Sentinel and LRN Clinical Chemistry laboratory to reach a knowledgeable public health laboratory professional at the jurisdictional confirmatory LRN Reference and LRN Chemical laboratories 24/7/365 by landline phone	At least annually
Frequency with which tests are conducted of select LRN sentinel and LRN clinical chemistry laboratory to reach a knowledgeable public health laboratory professional at jurisdictional confirmatory LRN laboratory 24/7/365 by redundant means not dependent on electricity, cellular/landline phone service, internet (e.g., radio/satellite phone)	At least annually
Percentage of LRN Sentinel laboratories within the LRN jurisdiction that successfully acknowledge receipt of health alerts. Testing must be at least annually and include at least one priority category (i.e., alert, advisory, update, etc.) *Note: Reference PHIN Preparedness Functional Area Partner Communication and Alerting*	100%
LRN Sentinel and LRN Clinical Chemistry laboratory staff are trained in the use of standardized procedures for collecting and shipping clinical specimens.	Yes/No
Training includes International Air Transport Association (IATA), and US Department of Transportation (DOT) packaging and shipping of infectious agents regulations	Yes/No

Performance Tasks and Measures/Metrics

Activity: *Direct Public Health Laboratory Testing*	
Definition: Direct and coordinate local, State, and Federal public health, food testing, veterinary diagnostic, and environmental testing laboratory efforts in response to biological and chemical terrorism.	
Critical Tasks	
Pro.B1e 3.1.1	Function as the gatekeeper for the Laboratory Response Network (LRN) within the jurisdiction
Pro.B1e 3.1.2	Function as Laboratory Response Network (LRN) Sentinel laboratories
Pro.B1e 3.1.3	Function as Laboratory Response Network (LRN) Chemical laboratories
Pro.B1e 3.2.2	Work in close partnership with public health epidemiology and environmental health, and poison control to provide timely data to assure implementation of effective prevention, detection, and control measures, including treatment
Pro.B1e 3.2.3	Report surveillance results suggestive of an outbreak immediately to public health epidemiology
Pro.B1e 3.2.4	Report results of CDC chemical or biological testing to submitting LRN Reference and Chemical laboratories through the secure LRN website
Pro.B1e 3.2.5	Notify appropriate public health, public safety, and law enforcement officials immediately (24/7) of presumptive and confirmed laboratory results of a chemical and biological threat agent
Pro.B1e 3.2.6	Report confirmed laboratory results to all submitters in a timely manner using PHIN-compliant Laboratory Information Management Systems (LIMS)

Performance Measures	**Metric**
Percent of calls/inquiries received by the CDC LRN Coordinating Office for which a response is initiated within 2 hours during an emergency	100%
Percent of calls/inquiries received by the CDC LRN Coordinating Office for which a response is initiated within 24 hours on a routine basis	100%
Time from *high-level* threat credibility assessment of suspicious agent to notification of public health department and other State and Federal partners	Within 2 hours
Time from presumptive identification of potential bioterrorism agent or communication that signals a high index of suspicion to sending notification to key Federal , State, and local health partners (e.g. CDC, FBI)	Within 3 hours

Activity: *Sample and Specimen Management*	
Definition: Implement LRN established protocols /procedures for specimen collection, transport, and testing.	
Critical Tasks	
Pro.B1e 4.1	Establish and maintain a jurisdiction-wide transport system to assure timely receipt of samples or specimens for laboratory testing
Pro.B1e 4.2	Perform triage screening on environmental samples per Department of Homeland Security and Environmental Protection Agency protocols

Pro.B1e 4.3	Communicate requirements for all-hazard specimen or sample collection, packaging, and shipping to submitters, e.g., FBI, CST, first responders, HazMat Teams, and LRN Sentinel and Clinical Chemistry Laboratories
Pro.B1e 4.4	Provide consultation to all submitters regarding appropriate collection and shipment of specimens or samples for testing

Performance Measures	**Metric**
Time for designated *State LRN-1 Level 1* Chemical Laboratories to accept clinical specimens to begin analysis	Within 24 hours of receiving the call for assistance from CDC
Time from distribution of health alert by agency epidemiologist, environmental health, or relevant partner via HAN to distribution of laboratory health alert detailing laboratory related information including specimen collection, packaging, and shipping guidelines	Within 12 hours
Time from presumptive identification to 1) shipment to an LRN reference laboratory with relevant confirmatory capabilities 2) confirmatory identification of agent by LRN reference laboratory	Within 2 hours Within 48 hours for laboratories that have appropriate confirmatory capabilities
Percent of LRN reference laboratories that provide technical assistance to submitters on errors within 3 business days of receipt of mislabeled, mis-packaged, and mis-shipped packages	100%

Activity: *Provide Surveillance Support*

Definition: Provide support to agencies in chemical, biological, and radiological agent and public health disease surveillance by testing and analyzing samples.

Critical Tasks	
Pro.B1e 5.3.1	Acquire timely isolates of selected enteric and invasive biological agents from all LRN Sentinel laboratories
Pro.B1e 5.3.2	Analyze quickly the isolates submitted by LRN Sentinel laboratories using advanced technologies to rapidly identify and subtype isolates
Pro.B1e 5.3.3	Provide reference analysis and identification of unusual or emerging biological agents present in communities
Pro.B1e 5.2	Perform analyses for BioWatch 24/7/365
Pro.B1e 5.1.1	Enhance, in coordination with public health epidemiology partners, the capacity to apply standardized molecular methods (e.g., DNA sequencing) in real-time to support surveillance and outbreak investigations as appropriate

Performance Measures	**Metric**

Proportion of isolates for which pulse-field gel electrophoresis (PFGE) testing and analysis of data is completed within 3 working days of receipt in the laboratory (or within 3 working days of organism isolated in pure culture, if lab processes clinical specimen) *E. coli* O157:H7 *Listeria monocytogenes*	100% (# of isolates that have PFGE patterns analyzed within 3 working days of identification/denominator = # of isolates identified in lab) Start time: Date and time isolate identified in lab Stop time: Date and time PFGE sub-typing pattern analysis complete
Proportion of PFGE patterns submitted to the National PulseNet Server (or the PulseNet Database Team at CDC) that are designated with an official PulseNet pattern name within 3 working days of submission. *E. coli* O157:H7 *Listeria monocytogenes*	100% # of isolate patterns in the National PulseNet database that are given an official PulseNet pattern name within 3 working days of submission/# of isolate patterns submitted to the National PulseNet Server/database team Start time: Date and time PFGE isolate pattern submitted to National PulseNet Server/database team Stop time: Date and time official PulseNet name assigned to the submitted isolate pattern
Proportion of PFGE patterns and associated data submitted to the National PulseNet Server (or the PulseNet Database Team at CDC) within one (1) working day of PFGE pattern analysis. *E. coli* O157:H7 *Listeria monocytogenes*	100% (numerator = # of patterns submitted to PulseNet within 1 working day) (denominator = # of isolates PFGE pattern-analyzed) Start time: Date and time PFGE sub-type/pattern analysis complete Stop time: Date and PFGE sub-type/pattern submitted to PulseNet server/team

Activity: *Detection Testing and Analysis* **Definition: Test and analyze initial chemical, biological, and radiological samples to provide presumptive agent identification or diagnosis.**	
Critical Tasks	
Pro.B1e 6.2.5	Evaluate clinical specimens from patients exposed to chemical or radiochemical agents, e.g., tests for blood gases, CBC analysis, and enzyme levels (link with HRSA)
Pro.B1e 6.2.3	Test initial 20-40 clinical specimens to assess human exposure by measuring metabolites of chemical agents (e.g., of nerve agents)
Pro.B1e 6.3	Provide surge capacity for CDC to measure metabolites (e.g., of nerve agents, in clinical specimens)
Pro.B1e 6.2.4	Test environmental samples for toxic industrial chemicals and materials
Pro.B1e 6.4	Contact the nearest LRN Reference laboratory when unable to identify or rule-out emerging infectious agents or possible bioterrorism agents
Pro.B1e 6.2.6	Identify all emerging infectious agents or possible bioterrorism agents using available LRN protocols

Performance Measures	**Metric**
Time from *high-level* threat credibility assessment of suspicious agent to specimen/sample receipt at the public health laboratory	Within 6 hours of identifying a suspicious agent
Time from receiving a specimen/sample in the LRN Reference Laboratory to presumptive identification of agent by rapid biological assays	Within 8 hours of sample receipt
Time for CDC Chemical laboratory to conduct Rapid Toxic Screen on initial 20-40 specimens analyzed for 150 chemical agents (including nerve agents)	Within 36 hours of receipt of specimens (surge)

Activity: *Confirmation Testing* **Definition: Test and analyze chemical, biological, and radiological samples to provide confirmation agent identification or diagnosis.**	
Critical Tasks	
Pro.B1e 7.2.3	Confirm results using CDC clinical chemical detection methods
Pro.B1e 7.1.1	Use standardized, Laboratory Response Network (LRN) protocols to detect emerging infectious agents or possible bioterrorism agents in clinical specimens, food, or environmental samples
Pro.B1e 7.4	Verify reactive BioWatch samples
Pro.B1e 7.4.1	Verify reactive samples from the Biohazard Detection Systems (BDS) located in facilities of the U.S. Postal Service (USPS)

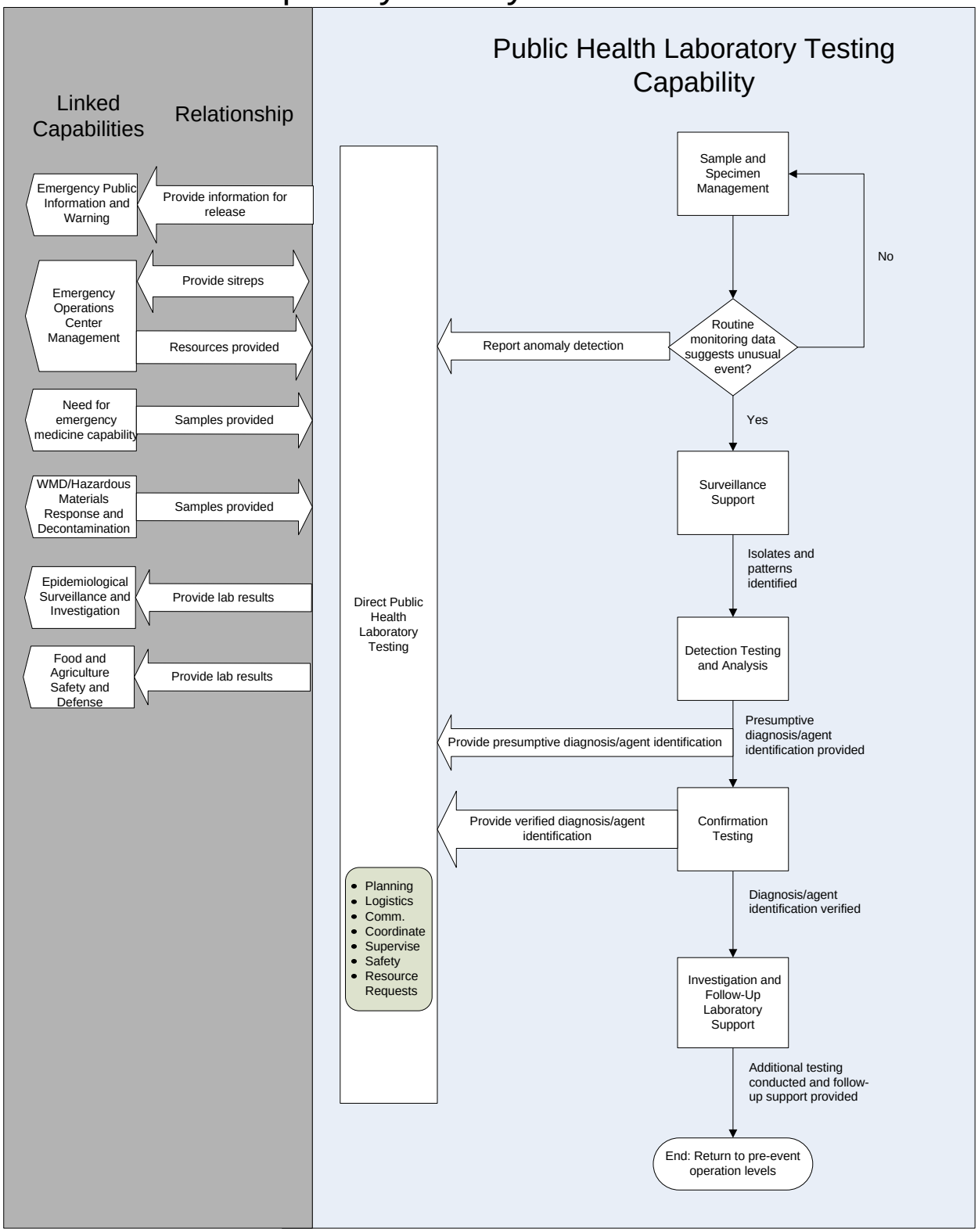
Performance Measures	**Metric**
Time from confirmatory identification (positive or negative) to initiate notification of appropriate Federal, State, and local officials, also including the specimen/sample submitter	Within 1 hour of confirmatory identification

Activity: *Investigation and Follow-Up Laboratory Support*	
Definition: Provide follow-up analytical and investigative support to epidemiologists, law enforcement, and environmental health and/or poison control efforts to test additional specimens, determine cause and origin of an event, definitively characterize an agent, and genotype disease strains through LRN member labs.	
Critical Tasks	
Pro.B1e 3.2.2	Work in close partnership with public health epidemiology and environmental health, and poison control to provide timely data to assure implementation of effective prevention, detection, and control measures, including treatment
Pro.B1e 8.3.2	Collaborate with law enforcement and perform testing of evidentiary samples (link to law enforcement)
Pro.B1e 8.3.3	Test additional clinical specimens by CDC or another qualified select Laboratory Response Network (LRN) Reference lab for retrospective assessment of chemical exposure following an event
Pro.B1e 8.3.4	Coordinate testing of environmental samples for assessment and remediation
Pro.B1e 8.6	Isolate emerging infectious or biological threat agents tested by CDC and qualified select Laboratory Response Network (LRN) reference laboratories using Clinical Laboratory Improvement Act (CLIA) approved methods to determine the agent's susceptibility to antimicrobial drugs used for prevention and control
Pro.B1e 8.5	Use Clinical Laboratory Improvement Act (CLIA) approved methods for antimicrobial susceptibility testing
Pro.B1e 8.7	Determine whether an emerging infectious disease agent or a biological threat agent consists of single or multiple strains
Performance Measures	**Metric**

Linked Capabilities

Linked Capability	Relationship
Emergency Public Information and Warning	Public Health Laboratory Testing provides information for release to Emergency Public Information and Warning.
Emergency Operations Center Management	Public Health Laboratory Testing provides situation reports to Emergency Operations Center Management. Emergency Operations Center Management provides situation reports and resources to Public Health Laboratory Testing.
WMD/Hazardous Materials Response and Decontamination	WMD/Hazardous Materials Response and Decontamination provides samples for testing to Public Health Laboratory Testing.
Epidemiological Surveillance and Investigation	Public Health Laboratory Testing provides lab results to Epidemiological Surveillance and Investigation.
Food and Agriculture Safety and Defense	Public Health Laboratory Testing provides lab results to Food and Agriculture Safety and Defense.

Capability Activity Process Flow



Capability Element Description Details

Capability Elements	Components and Description
Laboratory Response Network (LRN) National Level Laboratories	Laboratories in the Laboratory Response Network (LRN) that have unique resources to handle highly infectious agents and the ability to identify specific agent strains. These include labs at CDC, the US Department of Agriculture, the Food and Drug Administration (FDA), and other facilities run by Federal agencies. National Laboratory at National Center for Environmental Health capable of 24/7 coverage
Centers for Disease Control (CDC) Chemical Laboratory	1. LRN Chemical Laboratory capable of advanced testing located in the National Center for Environmental Health's (NCEH's) Division of Laboratory Sciences.
CDC Biological Laboratory	2. LRN National Level Laboratory at Bioterrorism Preparedness and Response Program (RRAT Lab) capable of 24/7 coverage
State Public Health Laboratory	State laboratory that performs testing and other laboratory services on behalf of the entire jurisdiction, scanning the horizon for anything suspicious.
LRN Reference Level Laboratories	Laboratories that can perform rapid tests to detect and confirm the presence of a threat agent. These labs ensure a timely local response in the event of a terrorist incident or other public health emergencies.
LRN Chemistry Laboratories	Public health laboratories that comprise the chemical component of the LRN; they are designated as Level 3, 2, or 1, with increasing technical expertise. Level 3 laboratories work with hospitals in clinical specimen collection/storage/shipment and also work to help develop a coordinated response plan for their State and/or geographical area. Level 2 laboratory personnel are trained to detect exposure to a limited number of toxic chemical agents in human blood or urine; Level 1 laboratory personnel are trained to detect exposure to an expanded number of chemicals in human blood or urine, including all Level 2 laboratory analyses, plus analyses for mustard agents, nerve agents, and other toxic chemicals.
LRN Sentinel Clinical Labs	Hospital-based laboratories that can perform rule-out or refer testing to LRN Reference Level Laboratory
Courier system for sample transport	System or contract to ensure secure transport of samples
Reagents	A rapidly deployable repository of LRN reagents sufficient to meet current needs and potential emergency surge needs Reagents for biological agent testing and materials for chemical methods
Laboratory equipment and supplies	Sufficient instrumentation and adequate supplies
CDC Directors Emergency Operations Center (DEOC)	
State and Local EOC	
Laboratory equipment	Polymerase chain reaction (PCR) = Smart Cycler, Light Cycler, ABI 7500, or ABI 7000 Time-resolved fluorescence (TRF) = Victor
LRN and biosafety training	TRF Training – 2 day course provided by CDC (Atlanta); Conventional Microbiology train-the-trainer one week course provided by CDC (location varies); PCR Training

Planning Assumptions

- Plans to augment the capacity of public health laboratories should include having or having access to information systems that electronically send and receive test orders and results in compliance with PHIN Functional Area for *Connecting Laboratory Systems*

Scenario-Specific

Public Health Laboratory Testing (Chemical Nerve Agent):

- Assume 10,000 worried well; assume that 2,500 worried well population will require testing. Scenario does not state exact number of worried well. Difficult to determine exactly what proportion of the downwind population would fall in this category but assumed 80 percent for purposes of this effort. Of these, assume 25 percent will require/request testing for exposure to nerve agents.
- 40 analyses per day per instrument.
- 13 instruments within Centers for Disease Control (CDC) and seven instruments within States can perform analysis of nerve agent metabolites.
- CDC stockpiles enough standards/materials to analyze 5,000 samples. Each of seven States stockpiles enough standards/materials to analyze 500 samples. Total for CDC and States are 8,500 samples. Conducting additional analyses requires additional materials/standards.
- Depending on how urgently results are needed, along with involving the States, additional instruments in CDC's laboratory can be ramped up quickly.
- Currently, analytic resources are located at CDC (Atlanta) and 7 State health departments (California, Florida, Michigan, Minnesota, New Mexico, New York and Virginia). Given the nature of the need and this resource, a centralized/regionalized approach is acceptable.

- Public Health Laboratory Testing (Biological)

- Estimates address needs for communities to respond to this emergency once identified. Estimate does not include needs for baseline resources needed for timely initial detection.
- *B. anthracis* spores added directly to product without aerosolization.
- Ground beef was sent San Diego, Seattle, and Phoenix.
- Orange juice was sent to Albuquerque, Las Vegas and Palm Springs.
- Patient presentations involved gastrointestinal, oropharyngeal and cutaneous forms of anthrax.
- Laboratory confirmation by the Laboratory Response Network (LRN) occurred between days 2 and 5 after index case presentation.
- Production facilities and distribution system mechanisms will be contaminated until formally decontaminated.
- Cases will continue sporadically following public health intervention due to consumers and retailers failing to discard/return/destroy contaminated product.
- No simultaneous disasters are occurring during the same time.
- Assume multi-agency coordination is adequately being addressed at Federal (CDC, Food and Drug Administration [FDA], USDA/APHIS [United States Department of Agriculture/Animal and Plan Health Inspection Service, FBI), State, and local levels and the agencies are coordinating as expected. Overall assumptions for LRN testing of specimens/samples: 1. All Reference LRN laboratories in the affected jurisdictions have the testing capability for the agent. 2. For planning purposes, throughput for four types of equipment available in the LRN Reference laboratory was provided. 3. There are a sufficient number of trained personnel to operate the equipment. 4. There is sufficient availability of reagents.

- Factors that could affect the number of specimens/samples calculated assuming laboratorians perform three runs in each shift include time involved to set up the assay, machine capacity, personnel shift duration, condition specimen/sample arrived in, physical working space, individual pace of laboratorian.
- For LRN Sentinel laboratories, the first 1,000 patients are distributed evenly among the six affected cities resulting in an even distribution of laboratory rule-out tests (approximately 167 per city), which would result in approximately 16 tests per Emergency Room. The burden on the LRN Sentinel laboratories for foodborne anthrax is inconsequential.
- Case definition by epidemiologists will be created within the first 10 days resulting in no further rule-out testing at the LRN Sentinel laboratories following the first 1,000 patients.
- Assume a concurrent Law Enforcement Investigation.

Planning Factors from an In-Depth Analysis of a Scenario with Significant Demand for the Capability

Capability Element	Estimated Capacity	Scenario Requirement Values	Quantity of Resources Needed
Public Health Laboratory Testing (Chem Lab)			
Centers for Disease Control (CDC)	Days 1-5: 80 samples/day using 2 instruments (1 instrument can process 40 samples/day) Days 6-10: 320 samples/day using an additional 6 instruments (8 instruments total, so 8*40=320) 520 samples/day using all instruments available (13 instruments total, so 13*40=520)	Testing for 350 injured people (assume testing 2 samples per person) = 700 2500 tests performed for worried well. Total = 3200	1 resource organization (either CDC alone or CDC and affiliated State chemical laboratories) Based on urgency: Approximately 4 weeks if only CDC is involved. With involvement of State public health laboratories, priority analysis of the first 350 samples (one sample from each of the injured people) could be completed in a matter of days
State public health laboratories	40 samples/day/State 5 States currently capable to perform nerve agent analysis = 200 samples/day	See above	Depends on how quickly analyses need to be completed (See above)
Bio Lab: Laboratory Response Network (LRN) National	3 National laboratories (CDC, DOD), 15 CDC laboratorians	CDC would accept specimens/samples for susceptibility testing and genotyping	
LRN reference laboratories	152 Reference laboratories for biological agents (105 public health, 15 military, 9 veterinary, 12 food, 8	LRN reference laboratories in the affected cities would handle test volume (for planning purposes 8235	For this scenario, we assume a 12-hour shift and a 30-day time period If Victor equipment = 14 pieces of

Capability Element	Estimated Capacity	Scenario Requirement Values	Quantity of Resources Needed
	international, 5 other Federal laboratories)	specimens)	equipment needed If ABI 7000 = 3 machines needed If Light Cycler = 11 machines needed If Smart Cycler = 23 instruments needed
LRN Sentinel	4,500 laboratories that can perform rule out or refer testing (majority are in-hospital laboratories)	LRN Sentinel laboratories will perform rule-out or referral tests for all cases LRN Reference laboratories will perform rapid tests and traditional confirmatory tests	Existing Sentinel lab personnel will support the required testing
CDC (e.g., subject matter expert [SME], Scientific Resources Program / Biologics Branch, Coordinating Office for LRN)	Coordinating Office for LRN = 1 LRN Coordinator, 1 Program Manager, 1 Help Desk Support, 1 Technical Officer, 1 Communication Officer (technical writing, interface with CDC Office of Emergency Communication) Scientific Resources Program/Biologics Branch = 6 – production, 2 – shipping, 6 inventory management CDC SMEs = < 1 per agent Bioterrorism Rapid Response and Advanced Technology Laboratory = (Existing) 9 CDC laboratorians for short-term biological response		Coordinating Office for LRN = 1 LRN Coordinator, 3 Program Managers, 4 Help Desk Support on 12-hour shifts, 2 Technical Officers, 1 Communication Officer (technical writing, interface with CDC Office of Emergency Communication) Scientific Resources Program/Biologics Branch = 12 – production, 4 – shipping, 12 inventory management CDC SMEs = 2 per agent Bioterrorism Rapid Response and Advanced Technology Laboratory = 15 CDC laboratorians
LRN Partner Organizations (e.g., APHL, DOD, ASM, FBI, EPA, FDA,	1 APHL Gatekeeper, 1 DOD Gatekeeper, and 1 FDA Gatekeeper All other organization		

Capability Element	Estimated Capacity	Scenario Requirement Values	Quantity of Resources Needed
USDA/APHIS, DHS)	involvement is scenario specific		
Reagents (CDC)	(Food borne/Plague) -- One specimen per suspected case will be sent to the LRN for testing; additional 15% of tests will be conducted for quality control; polymerase chain reaction (PCR) kits can complete 500 tests per kit using smart cycler or light cycler; PCR kits can complete 1,000 tests per kit using ABI 7000 equipment; TRF kits can complete 60 tests per kit using Victor equipment	(Aerosolized Anthrax) Cannot determine lab requirements because scenario involves undetermined environmental exposure which will require extensive sampling for source identification and decontamination efforts (Foodborne) Approximately 7000 suspected cases will result in 7000 specimens and 1235 controls for a total of approximately 8235 tests; does not include food samples that would also be tested at LRN laboratory in response to this event (Plague) Dependent on Epi calculations, not yet complete	(Aerosolized Anthrax) In Anthrax event of 2001, 125,000 environmental samples for less than 10 victims (Pandemic Flu) Cannot determine because assays under development (Foodborne) Assuming all tests are conducted at one LRN, the lab would need 16 PCR kits if at same LRN using smart cycler or light cycler equipment; 9 PCR kits if at same LRN using ABI7000 equipment; 138 TRF kits if at same LRN using TRF equipment; does not include reagents needed for food samples that would also be tested at LRN laboratory in response to this event (Plague) Dependent on Epi calculations, not yet complete
Laboratory equipment	Polymerase chain reaction (PCR) = smart cycler, light cycler, or ABI 7000 Time-resolved fluorometer (TRF) = Victor		
LRN and biosafety training	TRF training – 2 day course provided by CDC (Atlanta) Conventional Microbiology train-the-trainer one week course provided by CDC (location varies)		

Capability Element	Estimated Capacity	Scenario Requirement Values	Quantity of Resources Needed
	PCR training		
LRN lab credentials	Select agent registration and staff security risk assessment approval USDA/APHIS Regulations CLIA (Clinical Laboratory Inspection Standards) Accreditation from AAVLD (American Association Veterinary Laboratorian Diagnosticians)		

Approaches for Large-Scale Events

Pandemic Flu – For all teams, the work force will be diminished by one-third. The need for epidemiologic investigation will be far reduced relative to surveillance needs. Resource needs for pandemic flu are orders of magnitude greater.

National Targets and Assigned Levels

Responsible	Element Resource Unit	Type of Element	Number of Units	Unit Measure (number per x)	Capability Activity supported by Element
Centers for Disease Control (CDC)	Federal Laboratory Response Network (LRN) Chemical Laboratory	Federal Resource Organization	1	Nationally	Provide Surveillance Support Detection and Analysis Confirmation Testing Investigation and Follow-up Laboratory Support
CDC	Federal LRN Biological Laboratory	Federal Resource Organization	1	Nationally	Provide Surveillance Support Detection and Analysis Confirmation Testing Investigation and Follow-up Laboratory Support

Responsible	Element Resource Unit	Type of Element	Number of Units	Unit Measure (number per x)	Capability Activity supported by Element
State/Federal	LRN Reference Level Laboratories	Non-NIMS Resource Organization	1	Minimum per State (152 Nationally)	Provide Surveillance Support Detection and Analysis
Federal	LRN Level 1 Chemistry Laboratories	Non-NIMS Resource Organization	10	Nationally	Provide Surveillance Support Detection and Analysis
State/Local	LRN Level 2 Chemistry Laboratories	Non-NIMS Resource Organization	36	Nationally	Provide Surveillance Support Detection and Analysis
State/Local	LRN Sentinel Clinical Laboratories	Non-NIMS Resource Organization	4,000	Nationally	Sample and Specimen Management
State	Courier system for sample transport	Non-NIMS Resource Organization	1	Per State	Sample and Specimen Management
Federal/State Local	Reagents	Equipment	As needed	Per laboratory	Sample and Specimen Provide Surveillance Support Detection and Analysis Confirmation Testing Investigation and Follow-up Laboratory Support
Federal/State/ Local	Laboratory Equipment and Supplies	Equipment	As needed	Per laboratory	Sample and Specimen Provide Surveillance Support Detection and Analysis Confirmation Testing Investigation and Follow-up Laboratory Support
CDC	CDC Director's Emergency Operations Center (DEOC)	Non-NIMS Resource Organization			Direct Public Health Laboratory Testing
State/Local	State and Local EOC	Resource Organization			Direct Public Health Laboratory Testing

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