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THE CORE FUNCTIONS OF PUBLIC HEALTH LABORATORIES

Revised in 2014
The *Core Functions of State Public Health Laboratories* was first adopted and published by APHL in 2000. The original document was revised in 2010 in order to update and standardize the description of each core function and to reflect the changes that had occurred since 2000 with respect to State Public Health (SPH) Laboratory Systems. This 2014 revision of the 2010 document additionally recognizes that the core functions of public health laboratories apply to all public health laboratories (PHLs). Thus, the document has been renamed the *Core Functions of Public Health Laboratories*.

Note: The underlined words in this document can be found in the glossary.

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This publication was supported by Cooperative Agreement # U60HM000803 funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services.

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Coordination Office for Terrorism Preparedness and Emergency Response (CTPER)

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Background

According to the Institute of Medicine (IOM) report, *The Future of Public Health*, published in 1988, “Public health is what we, as a society, do collectively to assure the conditions in which people can be healthy.”1 This definition of public health and its overarching core functions, (i.e. assessment, policy development and assurance), which were identified in that report, have led to further descriptions of the many important components of public health. The authors of the 1988 IOM report felt that only if public health is clearly defined and understood would it be adequately supported. In 1994, Edward L. Baker et al. published the results of a working group that described the 10 essential public health services.2 These services have provided the framework for a National Public Health Performance Standards Program (NPHPSP)3 that measures the extent to which state and local public health agencies provide comprehensive public health services. The NPHPSP, in turn, contributed to the structure of the Laboratory System Improvement Program (L-SIP), introduced in 2006 and described later.

In 2000, the Association of Public Health Laboratories (APHL) developed a white paper titled *Core Functions and Capabilities of State Public Health Laboratories* [hereafter referred to as the Core Functions document]. The 11 core functions of state public health laboratories were subsequently published in *Morbidity and Mortality Weekly Report* in 2002.4 A report by Wilcke et al. in 2007, demonstrated how state public health laboratories (PHLs), through their core functions, support the 10 essential public health services.5 Between 2002 and 2010, building on the concept of a “national laboratory

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system” first advanced by McDade and Hughes, it became clear that broad, inclusive state public health laboratory systems rather than state public health laboratories alone, were more effective in assuring that the core functions are fulfilled. As a result, the Core Functions document was revised in 2010 to acknowledge the role that laboratory systems play in supporting the core functions of state public health laboratories. Over time the concept of these core functions evolved further. The national laboratory system first described by McDade and Hughes encompasses both state and local laboratories. In fact, all of these laboratories in toto help to fulfill the core functions which were first described in 2000. The Core Functions document has been ultimately revised to describe the core functions of all public health laboratories irrespective of their identity as state, regional, county, city or local.

In their role to assure that the 11 core functions are carried out, state and local PHLs engage the entire healthcare community to varying degrees in the State Public Health (SPH) Laboratory System. The SPH Laboratory System, which is scalable to the local, state, and federal level, can be defined as “An alliance of laboratories and other partners within a state that supports the ten essential public health services under the aegis of the state public health laboratory. The system members and stakeholders operate in an interconnected and interdependent way to facilitate the exchange of information, optimize laboratory services, and help control and prevent disease and public health threats.” The state PHL has a leadership role in developing and promoting the public health laboratory system statewide. Similarly local PHLs are leaders in developing the PHL systems in their jurisdictions. The specific makeup of the system varies by jurisdiction, but is comprised of all participants in public health laboratory testing at the state and local level, including those who initiate testing and those who ultimately use the test results. In the

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most general terms, the system includes clinical, environmental, veterinary, and agricultural laboratories as well as other governmental, non-private, or private facilities that perform laboratory testing of public health significance. The laboratory community as a whole benefits from stronger linkages among all stakeholders. Strengthening SPH Laboratory Systems is, therefore, a key component to strengthening the overall national laboratory system structure in support of improved health outcomes and preparedness activities.

The 11 core functions provide a foundation for measurement of a variety of PHL quality systems goals. For example the Core Functions document, along with the 10 essential public health services, provides the basis for L-SIP.9 L-SIP was first implemented in 200610 as a means for all states’ system stakeholders to measure system performance, plan system improvements, implement improvement strategies, and periodically evaluate and reassess while focusing on the goal of continuous quality improvement. Local PHLs have successfully adapted the state L-SIP tool to the local level and some have completed local system assessments.11 Another example of the utility of the Core Functions document is in measuring the re-established Healthy People 2020 Public Health Infrastructure objective 11 (formerly Healthy People 2010, objective 23-13) to “increase the proportion of tribal and state public health agencies that provide or assure comprehensive laboratory services to support essential public health services,” and the newer established objective, Public Health Infrastructure Objective 12, to “increase the proportion of public health laboratory systems (including state, tribal and local) that perform at a high level of quality in support of the 10 essential public health services.” The Comprehensive Laboratory Services Survey (CLSS),12 developed by the Laboratory Systems and Standards Committee of APHL in

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collaboration with the Centers for Disease Control and Prevention (CDC) and distributed biennially to state PHLs, is based on the 11 core functions. The CLSS was originally created to measure the extent to which state PHLs were meeting the Health People 2010 objective and is also used to measure the Healthy People 2020 objective. Finally, the Core Functions document could contribute to the development of standards that may well be used for PHL and agency assessment on state and local levels. For example, the Public Health Accreditation Board (PHAB), which launched national health department accreditation in 2011, accredits state and local health departments that meet required standards of quality and performance. Although PHAB does not evaluate performance in a discipline specific way (e.g. laboratories), “…access to quality PHL services is essential to PHAB accreditation.”

Local PHLs perform many or portions of the same 11 core functions that state PHLs perform. While the scope of testing services depends on the needs of the individual community and the local health department, the local PHL proves to be a critical component of the SPH laboratory system. In 2011, the Local Laboratory Council of APHL developed and conducted a descriptive survey of the core functions of local PHLs. The data analysis was presented at the 2013 APHL Annual Meeting and closely mirrored the 11 core functions of state PHLs. Therefore, as the CLSS has already demonstrated for state PHLs, the 11 core functions provides an appropriate foundation for the measurement of local PHL quality assessment goals in the future.

Just as the onset of Human Immunodeficiency Virus (HIV) epidemic of 1980s highlighted the important role of PHLs in a public health crisis, the anthrax attacks of 2001, the influenza pandemic of 2009, and the Middle

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East Respiratory Syndrome (MERS)-Coronavirus and Ebola outbreaks in 2014,\textsuperscript{18} further accentuated the roles of the PHLs as key players in public health emergencies. The PHLs’ contributions in prevention and emergency response are exemplified by the characterization of numerous foodborne and waterborne outbreaks. Examples include a nationwide listeriosis outbreak associated with cantaloupes in 2011,\textsuperscript{19} a cryptosporidiosis outbreak in Milwaukee, Wisconsin’s North Shore suburbs in 2013,\textsuperscript{20} and a multi-state cyclosporiasis outbreak linked to greens in 2013.\textsuperscript{21} Other examples of PHLs’ ongoing contributions include the expansion of life-saving testing assays in newborn screening, the involvement in environmental and food testing during the response to the Gulf oil spill of 2010\textsuperscript{22} and response to the radiation events associated with Fukushima in 2011.\textsuperscript{23} All are examples of emerging threats requiring a unified response from state and local PHLs in concert with other SPH Laboratory System partners. The PHLs are essential during regional response in assisting health departments in their mission to protect community health. These examples of public health events reinforce the necessity of having an alliance of laboratories and network partners that collectively make up the SPH Laboratory System in each state.

In the second decade of the 21st century, PHLs and the systems in which they operate, face continuing challenges and uncertainties. A prolonged economic downturn led to public health funding shortages at all levels of government. A 2012 IOM report concluded that public health funding is “inadequate, unstable, and unsustainable.”\textsuperscript{24} Yet the 10 essential public


health services and the 11 core functions of PHLs remain unchanged. In the spring of 2011, CDC and APHL launched an initiative designed to provide system-wide tools and resources to help PHL systems continue to provide vital services. Lead by APHL, the initiative was a strategic effort to promote gains in operating and cost efficiencies by the adoption of proven management practices. The goal is to enable the PHL system to meet financial and other challenges, and to sustain capability and quality through laboratory networks.25 One of the other major challenges will be determining the appropriate role of the PHLs in the changing world of health care reform. As the nation transitions to the mandates of the Affordable Care Act (ACA), there will be an as-yet unknown effect on the PHL system.26 In 2013, Hinrichs et al. observed that public health laboratorians are preparing for the impact of improved laboratory reporting associated with the ACA and meaningful use. “This effort is needed to prevent well-intentioned plans from producing the unintended degradation of PHL preparedness and services.”27 The 11 core functions will continue to offer a clear focus as the PHL system navigates the uncertain waters of recession and healthcare reform.

In summary, this revised document emphasizes that SPH Laboratory Systems, including local PHL systems, and not the PHLs alone, are responsible for assuring laboratory services in support of public health. It is acknowledged that SPH Laboratory Systems vary significantly, ranging from small state systems with no local PHLs and relatively few partners to large, complex state and local systems with regional and county PHLs and multiple partners. Regardless of the structure of the individual laboratory system, the local and state PHLs, guided by the 11 core functions, play a central role in providing or assuring with their system partners the full range of laboratory services required in support of public health.

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The Eleven Core Functions of Public Health Laboratories

- Disease Prevention, Control and Surveillance
- Integrated Data Management
- Reference and Specialized Testing
- Environmental Health and Protection
- Food Safety
- Laboratory Improvement and Regulation
- Policy Development
- Public Health Preparedness and Response
- Public Health Related Research
- Training and Education
- Partnerships and Communication

Descriptions of the eleven core functions are following:
Disease Prevention, Control and Surveillance

Provide accurate and precise analytical data in a timely manner in support of the:

- Prevention and control of infectious, communicable, genetic and chronic diseases, and environmental exposure. This may include testing for emerging and re-emerging microbial agents, immune status, antibiotic resistance, screening for inherited neonatal metabolic disorders, environmental toxins, and heavy metals such as blood lead.

- Recognition of outbreaks and other events of public health significance, by the identification and characterization of the causative agents of disease and their origin.

- Population-based surveillance for conditions of public health importance and to guide programmatic decisions.

- Early detection of congenital disorders in newborns leading to timely diagnosis and treatment.

- Monitoring of low incidence and/or high risk diseases, such as antibiotic-resistant tuberculosis, influenza, botulism and rabies.

- Investigation and control of communicable or environmental diseases when testing is not available in the private sector.
**Integrated Data Management**

*Serve as the conduit for scientific data and information in support of public health programs through the:*

- Capturing of laboratory data essential for public health analysis and decision making, including detecting trends and sentinel events.
- Use of standardized data formats.
- Influencing public health policy.
- Participation in statewide disease reporting networks.
- Linkage with CDC and other national and international surveillance databases.
- Collaboration with state and national laboratory systems.
- Continuous improvement of laboratory data systems.
Reference and Specialized Testing

Serve as centers of excellence using their expertise, reference and resources in the areas of biological, chemical and radiologic issues of public health importance to:

- Support the diagnosis of and surveillance for unusual and emerging pathogens.
- Confirm atypical laboratory test results.
- Verify results of other laboratories’ tests.
- Provide reference services to laboratories that may not have the capability to fully identify disease agents of public health importance.
- Provide diagnostic testing for diseases of public health importance directly to providers when testing is not readily available.
- Test for diseases of public health importance that are too rare and unusual for other laboratories to maintain capacity.
Environmental Health and Protection

Collaborate with partners to coordinate and ensure scientific analysis of environmental and human samples to identify, quantify and monitor potential threats to health by:

- Testing for toxic chemical, radiological and microbiological contaminants in air, water, soil and hazardous waste.

- Conducting biomonitoring of human specimens in the assessment of toxic chemical exposure.

- Testing of environmental samples in support of federal and state regulations, aiding in the compliance with those regulations.

- Industrial hygiene/occupational health testing to assist in efforts to protect indoor air quality and worker health, such as routine analysis of asbestos, lead, pesticides and radon.

- Participating in the Chemical Laboratory Response Network (LRN-C) and the Environmental Response Laboratory Network (ERLN).
Food Safety

Collaborate in the detection, monitoring and response to food safety issues by:

- Testing samples from persons, food and beverages implicated in food-borne illness outbreaks to detect and identify potential food-borne pathogens.
- Characterizing isolates and participating in national strain characterization databases, such as PulseNet, to inform epidemiologic investigations.
- Analyzing food specimens to detect, identify and quantify toxic contaminants such as pesticide residues, heavy metals and volatile organic compounds.
- Monitoring for radioactive contamination.
- Participating in the Food Emergency Response Network (FERN).
Laboratory Improvement and Regulation

Provide leadership for laboratory improvement in areas of public health importance by:

- Promoting quality improvement programs for partner laboratories through activities such as training, consultation and proficiency testing.

- Developing and overseeing statewide laboratory improvement programs to ensure the reliability of laboratory data used for environmental monitoring and communicable disease surveillance and control.

- Promoting safe laboratory practice through education, training and consultation.

- Assessing and improving the State Public Health Laboratory System by implementing the Laboratory System Improvement Program (L-SIP).

- Guiding the creation of and supporting enforcement of regulations and laws that contribute to laboratory improvement.
Policy Development

*Play a role in the development of state and federal health policy by:*

- Generating scientific evidence that informs public health practice and law.
- Monitoring the impact of public health laboratory practice on health outcomes.
- Serving as centers of expertise, reference and resources in the areas of biological, chemical and radiologic issues of public health importance.
- Participating in the development and evaluation of standards related to the operation and performance of laboratories involved in public health testing.
- Advocating for the use of sound reasoning in the application of laboratory science and system infrastructure sustainment.
- Engaging in strategic planning at local, state and national levels.
Public Health Preparedness and Response

Fulfill a key partnership role in local, state and national disaster preparedness and response by:

- Functioning as a Laboratory Response Network (LRN) Reference laboratory for biological agents and as an LRN Chemical Laboratory at a level designated by CDC.

- Assuring the triaging of environmental samples for the rapid identification of threat agents (chemical, biological, radiological and nuclear – CBRN); and food samples as a part of the Food Emergency Response Network (FERN).

- Planning for and ensuring that surge capacity is available during a public health emergency.

- Having a Continuity of Operations Plan in the event of a disruption of laboratory services.

- Participating in the Environmental Response Laboratory Network (ERLN).
Public Health Related Research

Engage in research to improve and expand the scientific and policy bases of public health laboratory practice and assure their optimal application in support of the public health system by:

- Developing, evaluating and implementing new technologies and methodologies.
- Partnering with other public health disciplines.
- Collaborating with academic institutions to carry out clinical and translational science.
- Conducting public health systems and service research.
- Working with the private sector to foster scientific innovation.
Training and Education

Facilitate access to training and education by:

- Sponsoring training opportunities to improve scientific and technical skills within the public health laboratory system.
- Supporting management and leadership development opportunities.
- Participating in the training of both domestic and international scientists.
- Partnering with academia to provide experiential learning opportunities.
- Providing continuing education in the area of laboratory practice.
Partnership and Communication

Support their respective state public health laboratory systems by:

• Highlighting the importance of laboratory contributions in support of public health.

• Maintaining a strong communication plan that links all system partners.

• Utilizing information technology for robust connectivity;

• Engaging traditional and non-traditional partners.

• Coordinating activities through the use of a laboratory program advisor, (i.e., laboratory system coordinator).

• Linking the SPH Laboratory System to appropriate national surveillance networks.
Glossary

**Affordable Care Act (ACA):** On March 23, 2010, President Obama signed the Affordable Care Act into law, putting in place comprehensive reforms that improve access to affordable health coverage for everyone and protect consumers from abusive insurance company practices. (http://www.whitehouse.gov/healthreform/healthcare-overview)

**Association of Public Health Laboratories (APHL):** The Association of Public Health Laboratories (APHL) is the national organization representing state and local governmental health laboratories in the United States. Its members, known as “public health laboratories,” monitor and detect health threats to protect the health and safety of Americans. (http://www.aphl.org/AboutAPHL/Pages/aboutaphl.aspx)

**Comprehensive Laboratory Services Survey (CLSS):** The Comprehensive Laboratory Services Survey (CLSS) addresses state public health laboratories and their respective state agencies and serves as a baseline to biannually evaluate the level of improvement in the provision of comprehensive laboratory services over the decade ending 2020. The survey serves as the sole data source for Public Health Infrastructure objective 11: “Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential public health services.” (http://www.aphl.org/aphlprograms/lss/healthy/Pages/OVHFP.aspx)

**Healthy People 2010/2020:** Healthy People provides science-based, 10-year national objectives for improving the health of all Americans. For three decades, Healthy People has established benchmarks and monitored progress over time in order to:

- Encourage collaborations across communities and sectors.
- Empower individuals toward making informed health decisions.
- Measure the impact of prevention activities.
Healthy People 2020 continues in this tradition with the launch on December 2, 2010 of its ambitious, yet achievable, 10-year agenda for improving the nation’s health. Healthy People 2020 is the result of a multiyear process that reflects input from a diverse group of individuals and organizations. (http://www.healthypeople.gov/2020/about/default.aspx)

**Institute of Medicine (IOM):** The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863. Nearly 150 years later, the National Academy of Sciences has expanded into what is collectively known as the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the IOM. (http://www.iom.edu/About-IOM.aspx)

**Laboratory System Improvement Program (L-SIP):** APHL’s Laboratory System Improvement Program (L-SIP) advances the efficacy of state and local public health laboratory systems through a guided process of performance evaluation, system improvements, and periodic evaluation and reassessment. Participating member laboratories receive resources and technical assistance to guide them on their way to system excellence. (http://www.aphl.org/aphlprograms/lss/performance/pages/default.aspx)

**Newborn Screening:** Newborn screening is used for the early identification of infants affected by certain genetic, metabolic, hormonal and/or functional conditions. (http://www.aphl.org/policy/facts/Documents/Hill-Day_Newborn-Screening-2014.pdf)
National Public Health Performance Standards Program (NPHPSP): The National Public Health Performance Standards Program (NPHPSP) is a collaborative effort of seven national partners to enhance the Nation’s public health systems. The stated mission and goals of the NPHPSP are to improve the quality of public health practice and the performance of public health systems by:

- Providing performance standards for public health systems and encouraging their widespread use,
- Engaging and leveraging national, state, and local partnerships to build a stronger foundation for public health preparedness,
- Promoting continuous quality improvement for public health systems, and
- Strengthening the science base for public health

(http://www.cdc.gov/nphpsp/PDF/FactSheet.pdf)

Public Health Laboratory (PHL): Working at the federal, state and local level, public health laboratories monitor and detect health threats ranging from rabies and dengue fever to radiological contaminants, genetic disorders in newborns and terrorist agents. Equipped with sophisticated instrumentation and staffed by highly trained scientists, these unique institutions deliver services that may be unavailable or cost-prohibitive elsewhere. Public health laboratories form the backbone of a national laboratory network on alert 24/7 to respond to novel strains of disease, natural disasters, chemical spills, foodborne outbreaks and other health emergencies.

(http://www.aphl.org/aboutaphl/aboutphls/pages/default.aspx)

State Public Health (SPH) Laboratory System: An alliance of laboratories and other partners within a state that supports the ten essential public health services under the aegis of the state public health laboratory. The system members and stakeholders operate in an interconnected and interdependent way to facilitate the exchange of information, optimize laboratory services,
and help control and prevent disease and public health threats.
(http://www.aphl.org/MRC/Documents/LSS_2010Jun_Deﬁnition-of-a-
State-Public-Health-Laboratory-System.pdf)

**Public Health Accreditation Board (PHAB):** The Public Health Accreditation Board is a nonprofit organization dedicated to advancing the continuous quality improvement of tribal, state, local, and territorial public health departments.
(http://www.phaboard.org/about-phab/)