The Core Functions of Public Health Laboratories

This document, originally named *Core Functions of State Public Health Laboratories,* was first adopted and published by the Association of Public Health Laboratories (APHL) in 2000. The second edition was published in 2010 to update and standardize the description of each core function and to reflect the changes with the evolving State Public Health (SPH) Laboratory Systems. In 2014, the document was once again revised in recognition that the core functions apply to all public health laboratories including city, county, local, state, tribal, regional and territorial jurisdictions; thus, the third edition was renamed, *Core Functions of Public Health Laboratories*. The core functions have been reviewed, updated as required, and reaffirmed in this newest edition: Version 4.0. This version reflects the complementary and supportive roles that public health laboratories play with federal public health agencies, the national laboratory system and the other sectors (animal health and environmental health) found within a "One Health" approach.[1]

The 11 Core Functions

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

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

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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Core Functions of Public Health Laboratories

Disease Prevention, Control and Surveillance

Provide accurate and precise analytical data in a timely manner by:

- Preventing and controlling infectious, communicable (infectious) and non-communicable diseases (genetic and chronic illness, and exposure to environmental agents). This may include testing for emerging and re-emerging infectious agents, immune status, antimicrobial resistance, environmental toxins, heavy metals (such as blood lead), biological, radiological and chemical agents of terrorism.
- Recognizing outbreaks and other surveillance activities of public health significance, by the identification and characterization of the causative agents of disease and its epidemiology using robust advanced molecular detection methods for timely response.
- Participating in population-based public health surveillance to guide and evaluate programmatic decisions with the recognition and inclusion of socio-economic and ecological factors.
- Detecting inherited neonatal metabolic and congenital disorders in newborns early, leading to timely diagnosis and treatment.
- Monitoring low-incidence and/or high-risk diseases in humans and animals, such as antimicrobial resistance threats, tuberculosis, botulism and rabies.

Integrated Data Management

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

- Capturing essential laboratory data for public health decision-making, including trend detection and sentinel event identification.
- Using standardized data formats and electronic data exchanges, allowing more accurate and efficient communication and reporting.
- Modernizing surveillance systems and processes in collaboration with partners to receive notifiable disease data.
- Facilitating partner participation in reporting networks using standardized messaging systems to improve data quality, accessibility and accuracy.

Reference and Specialized Testing

Serve as a technical resource using their expertise in the areas of biological, environmental, chemical and radiologic issues of public health importance by:

- Supporting the detection and surveillance of unusual and emerging pathogens.
- Identifying and confirming unusual biological, chemical and radiological agents.
- Fully characterizing agents using multiple technologies including advanced molecular detection methods, such as next generation sequencing.
- Collaborating and providing guidance to system partners and member laboratories on best practices to implement and support robust quality management systems.
- Providing necessary information to key partners for targeted disease surveillance, quicker response to disease outbreaks, and population-based data to develop new guidelines or policies.

Environmental Health and Protection

Provide accurate and precise analytical data to inform and evaluate environmental and public health policy and practice by:

- Monitoring air, water, soil and wastewater for toxins, chemical compounds, radiological nuclides and microbiological contaminants.
- Assessing human chemical exposures by testing clinical specimens to identify trends or emerging concerns, or to conduct community investigations.
- Identifying emerging chemical, radiological and biological threats through participation in various laboratory networks such as the Laboratory Response Network for Chemical Threats (LRN-C), National Wastewater Surveillance System, Food Emergency Response Network and Environmental Response Laboratory Network.
- Promoting the health and safety of individuals through compliance with federal, state and local regulations by:
  - Performing routine surveillance testing
  - Collaborating with system partners
  - Notifying state and federal agencies on potential environmental threats
- Informing industrial hygiene/occupational health to assure indoor air quality and protect worker health.

Food Safety

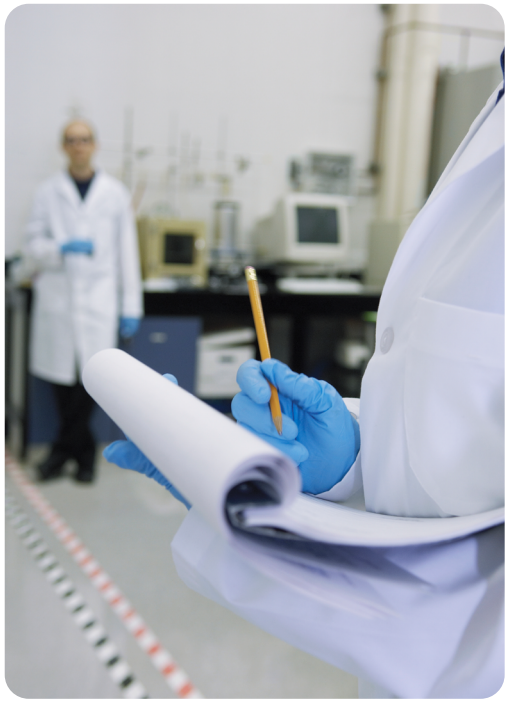
Provide accurate and precise analytical data in a timely response supporting food safety activities by:

- Testing samples from persons, food and beverages implicated in foodborne illness outbreaks to detect and identify potential:
  - Foodborne, parasitic, bacterial and viral pathogens
  - Chemical contamination, such as pesticides and heavy metals
  - Radiochemical contamination, such as Gamma-emitting radionuclides.
- Informing epidemiologic investigations through activities, such as characterizing isolates and participating in national molecular subtyping networks, such as PulseNet and CaliciNet.
- Promoting the health and safety of individuals and animals through compliance with federal, state and local regulations by:
  - Performing surveillance testing
  - Collaborating with system partners
  - Notifying state and federal agencies on potential food and feed recalls.
- Collaborating with various food safety networks, such as the Food Emergency Response Network (FERN) and National Animal Health Network.

Laboratory Improvement and Regulation

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

- Sharing, promoting and guiding quality improvement best practices to ensure reliable laboratory data.
- Promoting safe laboratory practice through education, training and consultation.
- Assessing and improving the public health laboratory system (e.g., through APHL's Laboratory System Improvement Program (L-SIP)).
- Influencing the creation of and supporting enforcement of regulations and laws.



Policy Development

Supporting the development of federal, state, tribal and local health policy by:

- Generating scientific evidence that informs public health practice and law.
- Monitoring the impact of public health laboratory action on health outcomes.
- Serving as centers of excellence, reference laboratories 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 public health laboratories.
- Advocating for the use of sound reasoning in the application of laboratory science.
- Assuring maintenance of the public health laboratory system infrastructure.
- Engaging in strategic planning at all levels.

Public Health Preparedness and Response

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

- Maintaining continuity of operation plans to ensure core laboratory testing is available during a disruption of laboratory operations.
- Promoting public health laboratory preparedness and response through the implementation of global health security initiatives in laboratory systems, biosafety, biosecurity and emergency operations.
- Functioning within the Laboratory Response Network (LRN) for biological (LRN-B) and chemical (LRN-C) agents, FERN for food samples and ERLN for environmental samples.
- Supporting enhancement of laboratory capability and capacity response to threats using new and emerging technologies to ensure surge capacity testing.

- Collaborating with federal partners to strengthen public health laboratory emergency preparedness.
- Strengthening and promoting partnerships with state and local public health laboratories, law enforcement agencies and first responders.
- Promoting preparedness and response by providing training and knowledge sharing with sentinel hospital laboratories.

Public Health Related Research

Engage in applied public health research to improve and expand the foundations for laboratory practice and policy by:

- Developing, validating, verifying and implementing new technologies and methodologies of public health need and importance.
- Conducting analysis of surveillance testing data for public health action.
- Collaborating with academic, private, and government institutions to conduct clinical, agricultural and environmental testing to foster scientific innovation.

Training and Education

Facilitate access to training, education and knowledge retention by:

- Partnering with academia, government, and industry for training and mentoring opportunities to improve laboratory scientific and technical skills.
- Supporting workforce development through fellowships and internships.
- Fostering professional development through management and leadership training opportunities.
- Participating in the training of both domestic and international scientists by engaging global health partners.
- Utilizing knowledge retention tools to capture institutional knowledge.
- Providing continuing education in laboratory practice and management.

Partnerships and Communication

Support public health laboratory systems by:

- Sustaining a strong communication plan linking all system partners through robust information technology.
- Highlighting the importance of laboratory contributions in support of public health.
- Engaging and continually building diverse partnerships to strengthen infrastructure.
- Coordinating laboratory system improvement initiatives.
- Connecting laboratory system partners to national public health networks for enhanced surveillance and preparedness.

About the Core Functions

The Role of Laboratory Systems in Public Health

According to the **Institute of Medicine (IOM)** (now the **National Academy of Medicine**) 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."[2] 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 subsequent descriptions of the many important components of public health, including laboratory systems. The authors of the 1988 IOM report felt that only if public health and its various critical components were clearly defined and understood would they be adequately supported.

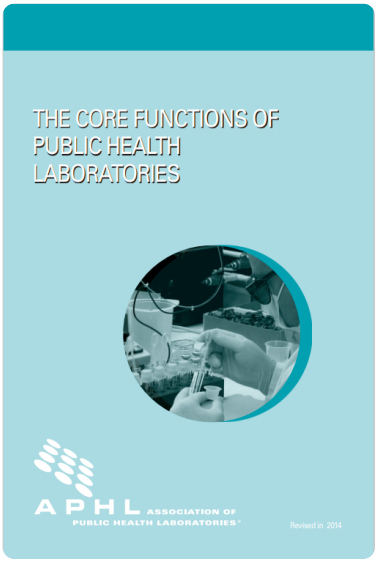
In 2002, a subsequent IOM publication, *The Future of the Public's Health in the 21st Century,* (released after the national anthrax bioterrorism event of 2001), stated that "Public health laboratories are a critical component of the disease surveillance resources of the public health infrastructure" and further "that federal, state, and local public health agencies should have access to a strong, state-of-the-art public health laboratory system."[3]

On the international front, the World Health Organization's (WHO) International Health Regulations (IHR)—which were adopted in 2005 and implemented in 2007—specifically identified laboratory systems and services as a critical component in the progress towards complying with the new IHR. The core capacities for national laboratory systems outlined within the IHR closely mirror the "Core Functions of Public Health Laboratories," and progress has been made in implementing these requirements within certain WHO regions.[4]

Now—over 35 years since the publication of the seminal 1988 IOM report—with the global trends and challenges with pandemics, the need for clearly laying out, reaffirming and supporting the core functions of public health laboratories is more important than ever.

Defining Essential Services and Core Functions

Six years after the original IOM report, in 1994, Baker *et al.* published the results of a working group that described the 10 Essential Public Health Services (EPHS).[5] These services have provided the framework for the **National Public Health Performance Standards Program (NPHPSP)**, which is coordinated by the US Centers of Disease Control and Prevention (CDC) and measures the extent to which state and local public health agencies provide comprehensive public health services as defined in the 10 EPHS. Recently, the EPHS have been updated to establish equity across assessment, policy development and assurance by the Public Health National Center for Innovations.[6]



The NPHPSP, in turn, contributed to the creation of the **Laboratory System Improvement Program (L-SIP)**. L-SIP was introduced in 2006 and establishes measurable public health laboratory system services that are linked to the EPHS.

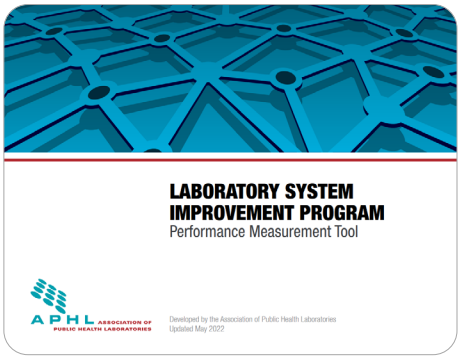
In 2000, the **APHL** developed a white paper titled *Core Functions and Capabilities of State Public Health Laboratories* [hereafter referred to as the Core Functions document]. The 11 core functions of state public health laboratories were subsequently published in *Morbidity and Mortality Weekly Report* in 2002.[7] A report by Wilcke *et al*. in 2007, demonstrated how state **public health laboratories**, through their core functions, support the 10 EPHS.[8] Between 2002 and 2010, building on the concept of a "national laboratory system" first advanced by McDade and Hughes in 1998,[9] it became clear that broad,

inclusive state public health laboratory systems rather than state public health laboratories alone, were necessary in order to assure that the core functions were being fulfilled.[10] As a result, the Core Functions document was revised in 2010 to acknowledge the role that laboratory systems play in supporting the core functions. Over time the concept of these core functions evolved. The national laboratory system first described by McDade and Hughes encompasses both state and local laboratories. In fact, public health laboratories including city, county, local, state, tribal, regional, or territorial contribute to fulfilling the core functions which were first described in 2000. The Core Functions document was ultimately revised in 2014 to describe the core functions of all public health laboratories which collectively support and complement the federal public health agencies that make up national laboratory system.

The Core Functions in Action

In their role to ensure that the 11 core functions are carried out, state and local public health laboratories engage multiple partners from within and beyond their respective communities. In each state, these unique partnerships comprise 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 10 essential public health services under the aegis of the state public health laboratory. The system members and partners 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."[11] The state public health laboratory has a leadership role in developing and promoting the public health laboratory system statewide; local public health laboratories are leaders in developing the public health laboratory systems within their jurisdictions. The specific makeup of the system varies by jurisdiction, but is comprised of all participants who conduct public health laboratory testing at the state and local level, including those who initiate testing, those who perform the testing and those who ultimately use the information generated. In the most general terms, the system includes clinical, environmental, veterinary, food and agricultural laboratories as well as other governmental or private-sector facilities that perform laboratory testing of public health significance. The laboratory community benefits from stronger linkages among all its members. 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 the measurement of a variety of public health laboratory quality systems goals. For example, the Core Functions document, along with the 10 EPHS, provides the basis for L-SIP.[12] L-SIP was first implemented in 2006[13] 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 public health laboratories have successfully adapted the state L-SIP tool to the local level and several have completed local system assessments.[14] L-SIP has recently undergone its own revision to align with the most recent version of the 10 EPHS.[6, 15]



Another example of the utility of the Core Functions document relates to the **Healthy People** plans. During the last two Healthy People plans, 2010 and 2020, the Core Functions document was used as the basis for measuring progress under the two objectives that called for increasing "the proportion of tribal and state public health agencies that provide or assure comprehensive laboratory services to support essential public health services," and increasing "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."

Finally, the Core Functions document has provided the necessary framework to measure "...access to quality public health laboratory services is essential to [**Public Health Accreditation Board**] accreditation,"[16] a condition which needs to be met in order for state, local and tribal public health agencies to be accredited by the Public Health Accreditation Board.

Local public health laboratories perform many or portions of the 11 core functions. While the scope of testing services depends on the needs of the individual community and the local health department, the local public health laboratory proves to be a critical component of the SPH Laboratory System.[17] In 2011, the Local Laboratory Council of APHL developed and conducted a descriptive survey of the core functions of local public health laboratories. The data analysis was presented at the 2013 APHL Annual Meeting and closely mirrored the 11 core functions of state public health laboratories.[18] Thus, the 11 core functions are instrumental for assessing core public health laboratory functions at both the state and local levels.

We know that the onset of the Human Immunodeficiency Virus (HIV) epidemic of the 1980s demonstrated the important contributions of public health laboratories in a public health crisis. The critical role of public health laboratories has been revealed numerous times since then. A few examples include 2001 anthrax attacks,[19] 2009 influenza pandemic[20] and the repeated Ebola outbreaks over the last decade.[21] More recently, the COVID-19 pandemic[22] and the increased transmission of mpox on a global level[23] have further accentuated the roles of the public health laboratories as key players in public health emergencies. The combined efforts of public health epidemiologists and laboratory scientists monitored the COVID-19 pandemic within the school-aged population and beyond.[24]

The contributions of public health laboratories to prevention and emergency response are also exemplified by their role in the detection of foodborne and waterborne outbreaks. Examples include a nationwide listeriosis outbreak associated with cantaloupes in 2011,[25] a cryptosporidiosis outbreak in Milwaukee, Wisconsin's North Shore suburbs in 2013,[26] and multiple cyclosporiasis outbreaks involving several different food sources in 2018.[27]

Other examples of ongoing public health laboratory contributions include the expansion of life-saving testing assays in **newborn screening**[28] and the response to the radiation events associated with the Fukushima nuclear accident in 2011.[29] All are examples of emerging threats requiring a unified response from state and local public health laboratories in concert with other SPH Laboratory System partners. Public health laboratories are essential during regional response in assisting health departments in their mission to protect the community. 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, county and district level.

In 2011, CDC and APHL launched an initiative designed to provide system-wide tools and resources to help public health laboratory 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, with the goal of enabling the public health laboratory system to meet financial and other challenges, and to sustain capacity, capability and quality through laboratory networks.[30]

In the third decade of the 21st century, public health laboratories—and the systems in which they operate—face continuing challenges and uncertainties. Even before the COVID-19 pandemic, an IOM report concluded that public health funding is "inadequate, unstable, and unsustainable."[31] Despite these challenges, the 10 EPHS and the 11 core functions remain as foundational underpinnings for the SPH Laboratory System. This fourth edition of the Core Functions document reaffirms and emphasizes that laboratory systems—not the public health laboratories alone—are responsible for assuring quality laboratory services in support of public health. Regardless of the structure of the individual laboratory system, public health laboratories, 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.

Glossary

Association of Public Health Laboratories (APHL)

APHL works to strengthen laboratory systems serving the public's health in the United States and globally. APHL represents state and local governmental health laboratories in the United States; this includes public health, agricultural, environmental and other related laboratories. Its members, known collectively as "public health laboratories," monitor, detect and respond to health threats.

Healthy People

Sets data-driven national objectives to improve health and well-being over the next decade.

Institute of Medicine (IOM)/National Academy of Medicine (NAM)

Founded in 1970 as the IOM, the NAM is one of three academies that make up the National Academies of Sciences, Engineering, and Medicine (the National Academies) in the United States. Operating under the 1863 Congressional charter of the National Academy of Sciences, the National Academies are private, nonprofit institutions that work outside of government to provide objective advice on matters of science, technology and health.

Laboratory System Improvement Program (L-SIP)

APHL's L-SIP program 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.

National Public Health Performance Standards Program (NPHPSP)

The 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.

Newborn Screening

Newborn screening is used for the early identification of infants affected by certain genetic, metabolic, hormonal and/or functional conditions.

Public Health Accreditation Board

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.

Public Health Laboratory

Working at the federal, state and local levels, 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 infectious diseases, natural disasters, chemical spills, foodborne outbreaks and other health emergencies.

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.

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