# PROTECTING THE NATION:

## Public Health Laboratories Maintain Preparedness for Emerging Threats

A Report of the 2018 APHL All-Hazards Laboratory Preparedness Survey

**September 2019**


APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

## 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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## ACKNOWLEDGMENTS

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Cover Photo: Courtney Demontigny, from the Emergency Preparedness and Response unit at the Minnesota Department of Health, Public Health Laboratory, extracts an unknown powder sample submitted by FBI and local law enforcement. (Photo: MN Department of Health)

# ABOUT THE ALL-HAZARDS LABORATORY PREPAREDNESS SURVEY

In the fall of 2018, the Association of Public Health Laboratories (APHL) fielded the eleventh-annual All-Hazards Laboratory Preparedness Survey to assess public health laboratories' (PHLs) capability and capacity to respond to biological, chemical, radiological and other threats, such as pandemic influenza. The survey was distributed to 54 PHLs: all 50 state laboratories and the District of Columbia, Puerto Rico, Los Angeles County and New York City PHLs.

APHL received responses from 53 PHLs (for an overall response rate of 98%), capturing key data for Fiscal Year 2017 (FY17) of the US Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) Cooperative Agreement, representing July 1, 2017 to June 30, 2018.


Petri dish art highlighting the Laboratory Response Network (LRN), which celebrates its 20th Anniversary in 2019.
(Photo: MN Department of Health)

# ABOUT PUBLIC HEALTH LABORATORIES

## Public Health Laboratories and Emergency Response

PHLs are a central component in the nation's approach to emergency preparedness, ensuring that the United States is able to prepare for and respond to known all-hazards threats, including biological, chemical and radiological, as well as emerging infectious diseases and natural disasters. During FY17, US PHLs were active in responding to local disease outbreaks, the destructive effects from multiple hurricanes, threat letters and other events that affected the health of individuals nationwide.

The capability of these laboratories to effectively respond relies on maintaining a skilled and ready workforce, up-to-date testing equipment and methods, and forging strong partnerships across a diverse network of partners and laboratories. CDC defines laboratory testing as "the ability to implement and perform methods to detect, characterize, and confirm public health threats. It also includes the ability to report timely data, provide investigative support, and use partnerships to address actual or potential exposure to threat agents in multiple matrices, including clinical specimens, and food, water and other environmental samples. This capability supports passive and active surveillance when preparing for, responding to, and recovering from biological, chemical, and radiological public health threats and emergencies." Because of their diverse capability, PHLs are able to maintain a warm base to respond to emerging threats.

Clinical laboratory scientists participate in a training workshop at the San Antonio Metropolitan Health District Laboratory.
(Photo: San Antonio Metro. Health District Laboratory)

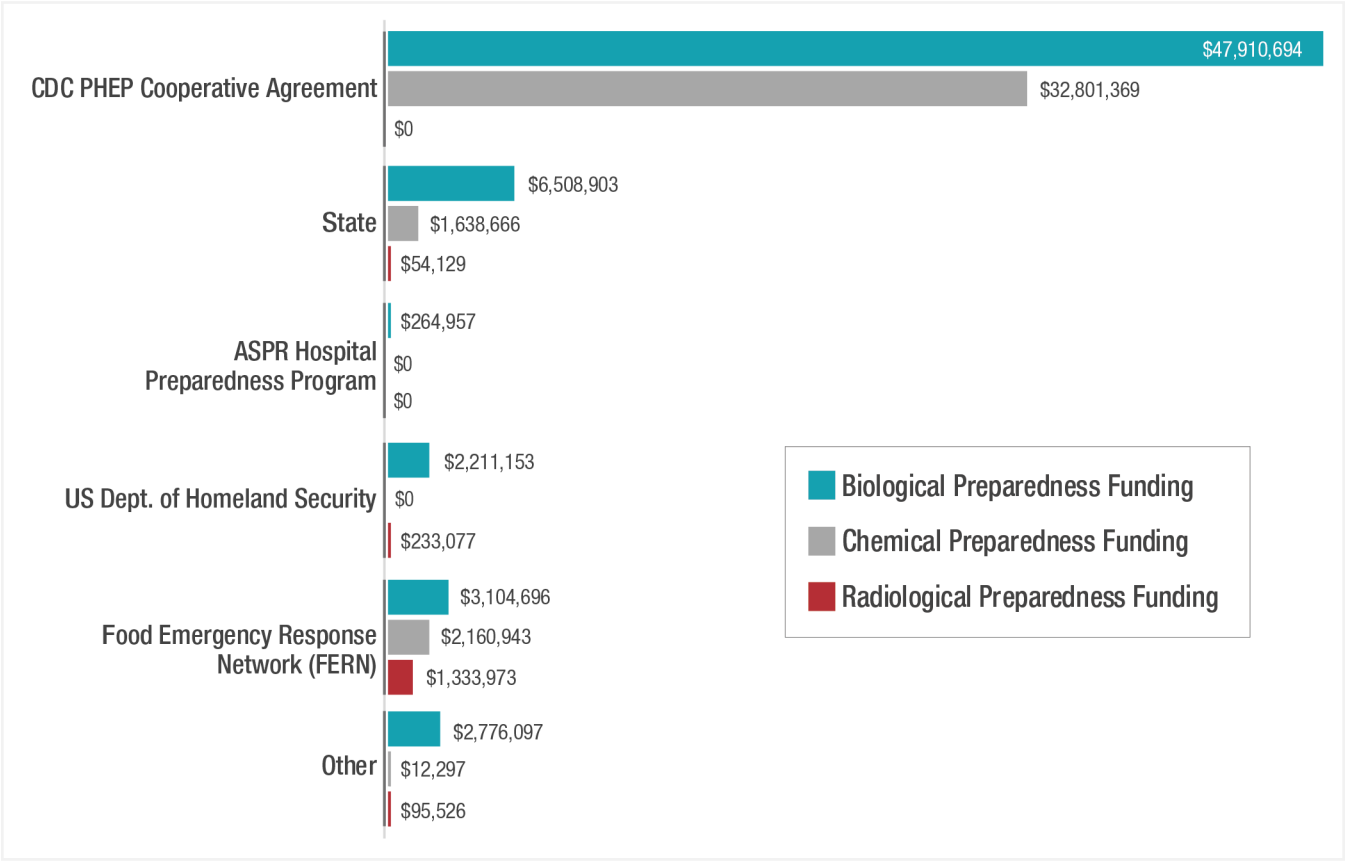
PHLs are also key contributors to emergency responses through their participation in networks such as the Laboratory Response Network (LRN), a system of laboratories operating under a quality umbrella to identify and respond to threats. PHLs make up 70% of the LRN for Biological Threats Preparedness (LRN-B) and 100% of the LRN for Chemical Threats Preparedness (LRN-C). Founded by APHL, CDC and the Federal Bureau of Investigation (FBI) in 1999 to improve US readiness for bioterrorism, the LRN remains a valuable resource for law enforcement and public health officials, while also linking federal, state and local PHLs with sentinel clinical, food, veterinary, environmental and agricultural laboratories across the country.

## Public Health Laboratory Funding

The ability of PHLs to conduct this vital public health and emergency testing is made possible through funding from the US federal government, which works to bolster preparedness across the US public health system. In FY17, 53 PHLs reported receiving a total of $101 million in funds, primarily from federal agencies such as CDC and the US Department of Health and Human Services Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program. In FY17, via the CDC-managed Public Health Emergency Preparedness (PHEP) Cooperative Agreement, CDC provided $612 million to 62 state, local and territorial public health departments to strengthen their abilities to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear and radiological events. The vast majority of PHL preparedness funding—$80.7 million, or 80%—came from the PHEP Cooperative Agreement, demonstrating how much PHLs rely on CDC to resource state and local laboratory preparedness activities (**Figure 1**).

**80%** of PHL preparedness funding came from the **PHEP Cooperative Agreement**

**Figure 1.** FY17 Preparedness Funding for PHLs by Funding Source.



Of this PHEP funding, approximately $47.9 million was dedicated to biological threats preparedness—with the majority of funds dedicated for personnel, the highly skilled staff who ensure laboratories are ready to respond (**Figure 2**)—and $32.8 to chemical threats preparedness (**Figure 3**). In some larger states, funds were further distributed to local PHLs to support preparedness across the jurisdiction.

Although PHEP funding has been relatively stable over the last decade, the FY17 funding level of $80.7 million represents a significant decline from FY04 when PHLs received $143.7 million. The steady decline in funding over the last 10 years has impeded the ability of PHLs to meet the changing demands of public health. Laboratories are expected to maintain preparedness for biological and chemical threats, as well as prepare for and respond to infectious diseases such as Ebola and Zika. As PHLs are called upon to respond to new and complex threats, their ability to maintain equipment, develop new testing procedures and perform outreach to critical partners—such as hospital laboratories and first responder communities—is potentially compromised. The continued decline of CDC PHEP funds further endangers the capability of PHLs to respond to emerging threats.

**Figure 2.** Allocation of FY17 CDC PHEP Funding for Biological Preparedness. (n= $47.9 million)

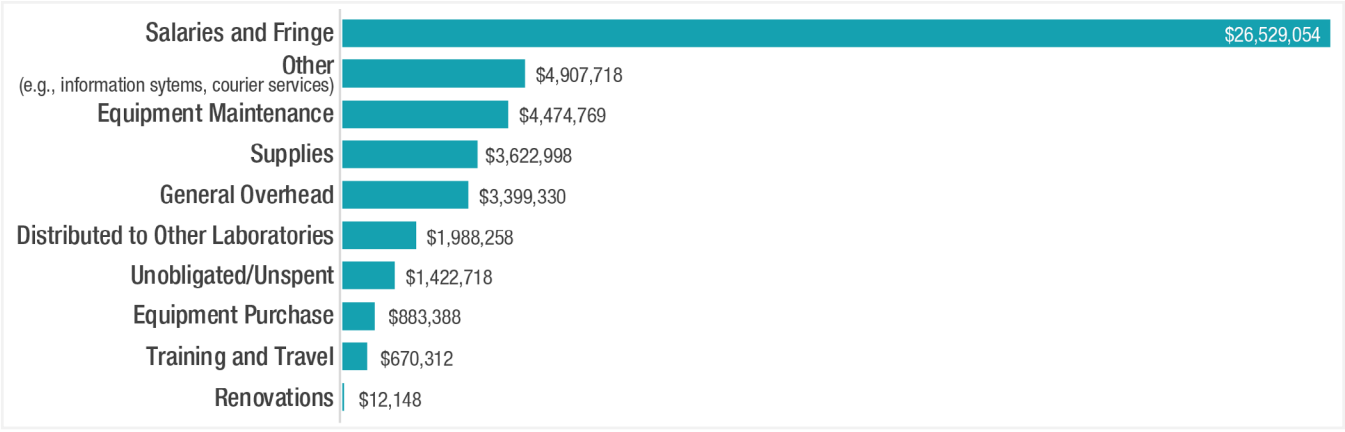
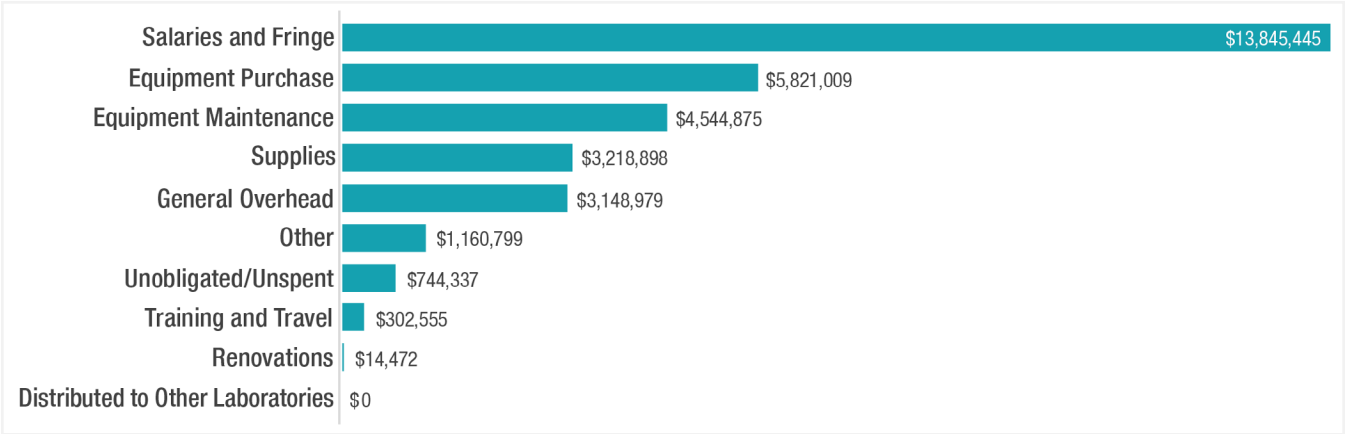



**Figure 3.** Allocation of FY17 CDC PHEP Funding for Chemical Preparedness. (n= $32.8 million)




# METHODS

APHL collected data for the 2018 All-Hazards Laboratory Preparedness Survey in the fall of 2018. The survey covered the 12-month period from July 1, 2017—June 30, 2018, representing FY17 CDC PHEP Cooperative Agreement, Budget Period 1. APHL distributed the survey to every state PHL, as well as PHLs in the District of Columbia, Puerto Rico, New York City and Los Angeles County. Data was collected using Qualtrics®, a web-based survey tool and data repository. Each participant received an email with a unique survey link and a copy of the survey. 53 of 54 PHLs (98%) responded to this survey. The 2018 APHL All-Hazards Laboratory Preparedness Survey Summary Data Report presents aggregate survey assessment results for all questions.

**Figures 4 and 5.**
Sample/Specimen Types Legend

- Environmental
- Clinical (e.g., Zika)

**Figure 4.** Samples Accepted by PHLs, by Sample Type. n=53

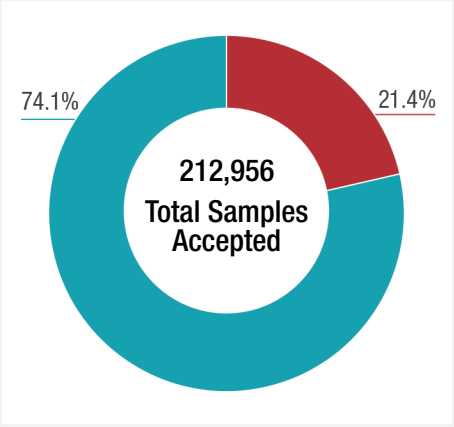
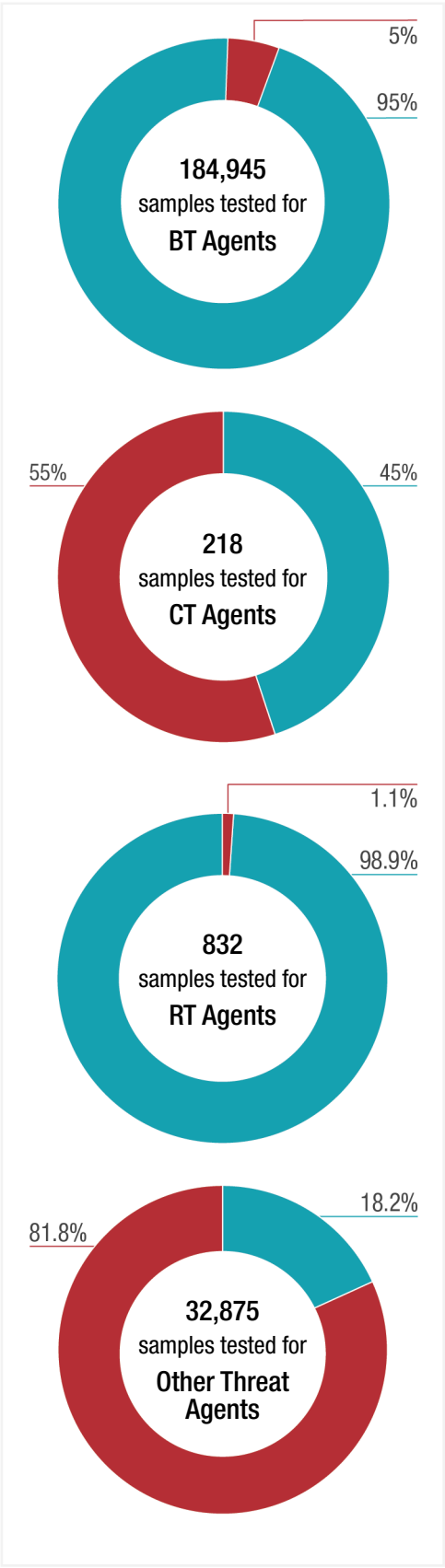



**Figure 5.** Samples Tested by PHLs for Biological (BT), Chemical (CT), Radiological (RT) and Other Threat Agents, by Sample Type. n=53




# KEY FINDINGS

## Sample Receipt and Laboratory Testing Volume

To ensure that samples arrived safely and were tested in a timely manner, 52 PHLs (98%) maintained access to 24-hour transportation throughout the year for specimen pick-up and delivery, while all 53 PHLs (100%) have plans to receive samples from sentinel laboratories during non-business hours.

In FY17, PHLs tested thousands of samples, many of which came from the US Department of Homeland Security (DHS) BioWatch program (included in Figures 4 and 5 as part of the environmental samples). The BioWatch Program was established in 2003 and, according to DHS, the system is capable of providing early warning of a bioterrorist attack in more than 30 major metropolitan areas across the country. By partnering with federal agencies, PHLs help protect both civilians and government workers from various types of nefarious activities, while aiding in criminal investigations.

As the nation addresses the opioid epidemic, PHLs saw a spike in the number of environmental samples received. Many of these samples were tested for fentanyl compounds. PHLs also received over 2,500 food and beverage samples which were tested for threat agents. These laboratories received almost 800 additional packages with unknown powders and tested them for threats such as anthrax and ricin. PHLs continued to support the US Postal Service Biohazard Detection System, testing 14 suspicious samples. In total, 212,956 samples were accepted for testing (**Figure 4**). Some samples were tested for multiple agents (**Figure 5**).

Of note, 832 samples were tested for radiological threats, a 7% increase from the number tested in FY16.

PHLs work tirelessly to ensure testing can continue in light of challenges to laboratory infrastructure, with 50 PHLs (94.3%) having established a continuity of operations plan (COOP) and three PHLs in the process of developing their own COOPs. This approach allows for essential testing services for newborn screening, infectious diseases, environmental health (e.g., water quality and foodborne diseases) and threat agents to continue during a disruption at the laboratory.

## Data Management and Reporting

When responding to potential biological or chemical threats, it is vital that test results are sent to the appropriate recipient as quickly as possible.

Because advanced laboratory equipment can generate enormous amounts of data, most PHLs rely on laboratory information management systems (LIMS) to quickly share results of potentially high consequence samples.

As of FY17, 49 PHLs (92.5%) report having a LIMS in place for data exchange, although only 28 (52.8%) indicate having bidirectional capability to receive and report data from external entities. To ensure they are well-maintained, 35 PHLs (71.4%) have on-site personnel dedicated to supporting their LIMS.

While nearly all PHLs have a LIMS, **only half have bidirectional capability** to electronically receive test orders and report results.

Integration of these systems into the laboratory supports the capability for electronic test ordering and reporting from hospital and clinical laboratories, and provides seamless information exchange while assuring data safeguards. Efficient data exchange can also improve workflows for laboratory scientists, reducing workload burden and error.

Many laboratories have previously reported encountering financial challenges with maintaining up-to-date systems, as well as compliance with data coding standards. As the physical amount of laboratory data continues to expand, many laboratories also struggle with data governance issues. As such, it is critical that PHLs continue to receive financial and programmatic support for maintaining modernized information management systems that function efficiently.

## THE ROLE OF PHLS IN NATIONAL BIODEFENSE STRATEGY

In 2018 the US government released the National Biodefense Strategy, which details programmatic objectives and goals to prevent the harmful effects of both natural and man-made biological threats. PHLs are vital to achieving many of these national goals, namely those targeting information sharing, enhanced preparedness capabilities and advanced biothreat detection methods. Coordinated information-sharing systems are imperative to ensure that results from laboratory detection methods trigger necessary response efforts.

The LRN continues to evaluate and promote the implementation of new detection assays and equipment, initiatives which are captured within the $47.9 million and $32.8 million that laboratories received respectively for biological and chemical preparedness from the CDC PHEP Cooperative Agreement in FY17.

To ensure preparedness for various threats, 53 PHLs (100%) conducted annual site visits to sentinel clinical laboratories, totaling 791 individual locations in FY17. These visits by biological threat preparedness coordinators and biosafety officers provide training of core principles and techniques that protect laboratory scientists from dangerous samples while promoting best practices that ensure public safety. Working together with sentinel clinical laboratories, PHLs help maintain a well-prepared workforce to mitigate risks and promote an effective biodefense enterprise.

## STRENGTHENING SENTINEL CLINICAL LABORATORIES

The North Carolina State Laboratory of Public Health (NCSLPH) Bioterrorism and Emerging Pathogens (BTEP) Unit collaborates with 80 sentinel laboratories throughout the state to prevent exposures when working with samples containing potentially dangerous pathogens. In FY17, sentinel laboratories in North Carolina reported six positive Brucella isolates, with multiple laboratories indicating exposures resulting from working with the isolates. The BTEP staff worked tirelessly to identify common causes of these exposures and develop viable strategies to reduce the risk of exposure for laboratories that encounter suspected Brucella-positive isolates and other gram negative biological threat agents. PHL staff created procedures and scenarios where exposures commonly occurred, and provided this information to sentinel laboratories for awareness. The BTEP Unit took their efforts one step further by validating and launching biochemical speciation testing of Brucella isolates, thereby cutting in half the turnaround time needed to speciate these isolates. These efforts created sample handling awareness for sentinel clinical laboratories along with faster confirmation of pathogen presence, keeping all laboratory scientists safe.

In the photo at right, a NCSLPH laboratory scientist works inside a Class II Biological Safety Cabinet inside a Biosafety Level 3 (BSL-3) Suite. A BSL-3 suite is a contained area that must meet stringent biosafety requirements, including biosafety cabinets, controlled double-door access, and engineering controls, such as negative air pressure relative to surrounding rooms and microfiltration of air.

## Partnerships, Training and Outreach

The strength of the laboratory system to respond to all-hazard threats depends on maintaining strong partnerships with rapid, clear communications and access to comprehensive training for all involved. PHLs often utilize rapid communication methods, such as Health Alert Networks, and email blasts to keep their diverse range of partners informed of urgent health concerns. Last year, 45 PHLs (85%) used various communication methods to inform partners of training events, routine updates and potential outbreaks, such as information on Zika and Influenza outbreaks impacting the state or region.

The core of these partnerships are the thousands of sentinel clinical laboratories that work closely with their local, state or federal (e.g. Department of Defense) governmental laboratories. Sentinel clinical laboratories have the ability to recognize, rule-out and/or refer specimens that may contain microbial agents or biological threats to reference laboratories. To recognize sentinel clinical laboratories, 13 PHLs (24.5%) awarded an LRN Joint Leadership Committee-approved certificate to laboratories in their state, with an additional eight PHLs (15.1%) awarding a state-developed certificate to sentinel clinical laboratories.

The 53 PHLs engaged more that 5,000 sentinel clinical laboratories in preparedness and response outreach activities. With such a large network of sentinel clinical laboratories, outreach and training efforts are continuously in demand. To meet this need, 33 PHLs (62.3%) have staff solely responsible for outreach. Alongside these personnel, biological threat coordinators and biosafety officers also routinely visit sentinel clinical laboratories, with 53 PHLs conducting a total of 791 site visits. Likewise, 49 PHLs (92.5%) sponsored 362 training classes for sentinel clinical laboratories, reaching over 4,700 laboratory scientists. Trainings, such as rule-out testing and packaging and shipping, ensure that sample integrity and laboratory staff safety are constantly on the forefront (**Figure 6**).

Along with numerous trainings, PHLs also evaluated sentinel laboratory testing competencies through external assessment methods, such as proficiency tests and exercises (**Figure 7**). Last year, 48 PHLs (90.6%) evaluated sentinel laboratories using the College of American Pathologists Laboratory Preparedness Exercise (CAP LPX), which is conducted twice per year. These efforts ensure that laboratory scientists are adequately prepared to handle potentially dangerous samples in a manner that protects themselves, their coworkers and the public from a major threat.

**Figure 6.** PHL Training of Sentinel Clinical Laboratories.

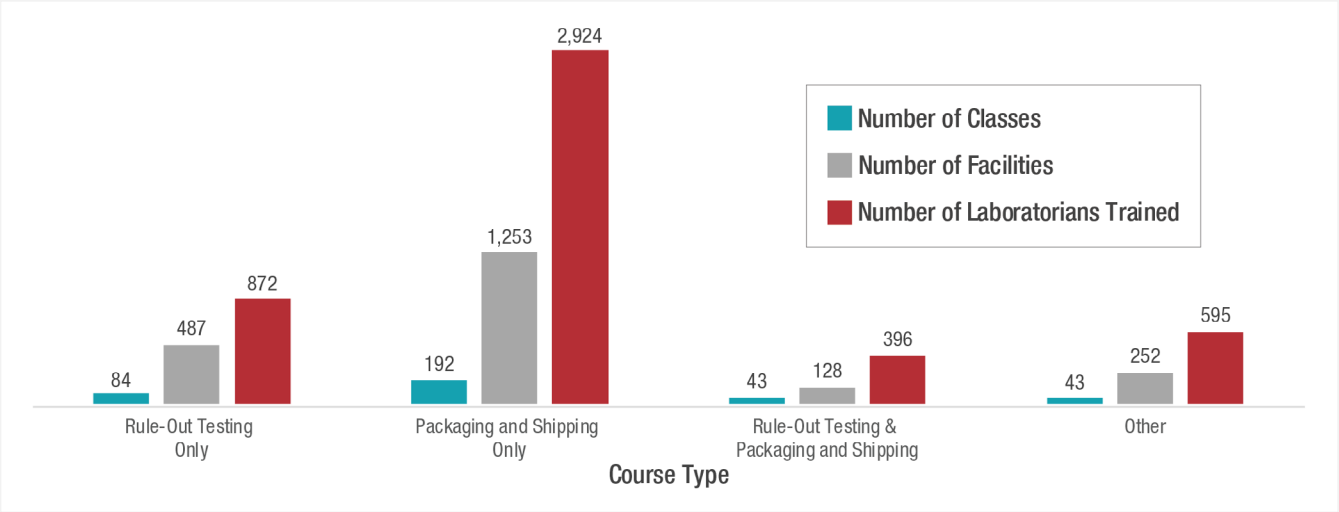
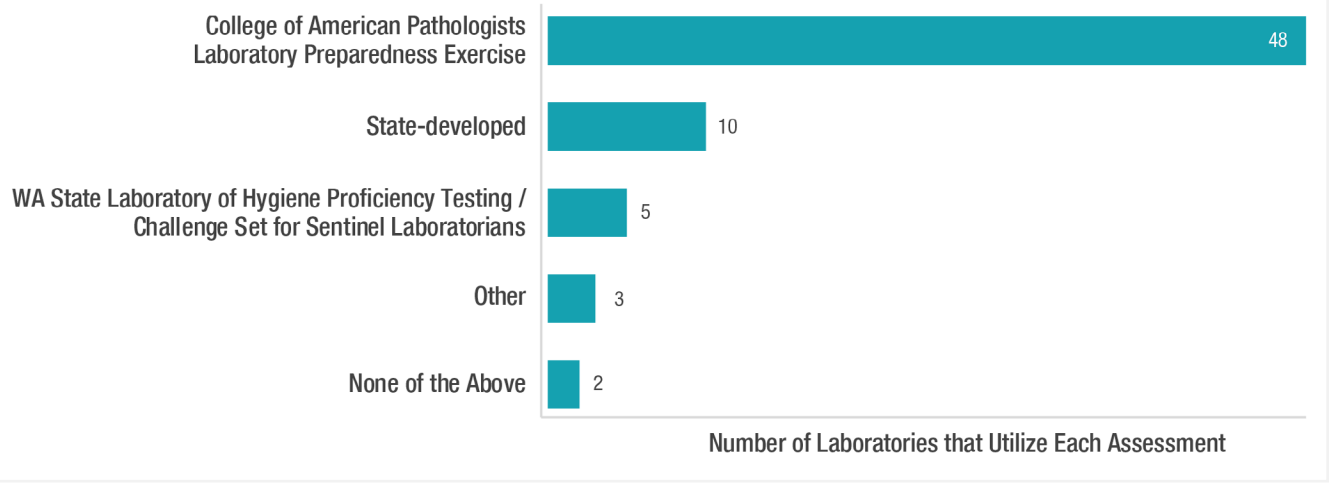


**Figure 7.** Types of Assessments Used to Evaluate the Ability of a Sentinel Clinical Laboratory to Rule-out and Refer Biothreat Agents. n=53




## CONCLUSION

Maintaining preparedness for all-hazard threats is a task that requires collaboration among multiple partners. Laboratories often operate at the center of these efforts, providing a critical function of detecting threats and supporting the ongoing response. To ensure a constant state of readiness, PHLs conduct laboratory testing and report results, facilitate communications and coordination, and support training and outreach. PHLs provide training to numerous partners—namely sentinel clinical laboratories—to ensure they can safely detect, rule-out and refer specimens into the public health system.

Foundational to the ability of PHLs to prepare for and respond to threats, is the CDC PHEP Cooperative Agreement. This funding source enables PHLs to maintain key personnel, purchase and maintain state-of-art equipment, have systems in place for electronic results reporting, train clinical laboratories and others such as first responders, develop and expand partnerships, and attend professional development courses and/or national meetings. If there is a slight decline in PHEP funds, the impact is significant to PHLs. Thus, it is important for the federal government to have stable funding levels for the CDC PHEP Cooperative Agreement. Without it, the nation may not be adequately prepared to act upon the next public health threat.

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