



**Testimony before the
Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
U.S. House of Representatives**

**Continuing Concerns Over BioWatch and
the Surveillance of Bioterrorism**

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Good morning Chairman Murphy, Ranking Member DeGette, and distinguished Members of the Subcommittee.

Thank you for the opportunity to testify today on the Department of Homeland Security's (DHS) BioWatch program. It is a pleasure to appear before you representing the U.S. Centers for Disease Control and Prevention (CDC), the Nation's leading health protection agency. Throughout its history, CDC and its local, national, and international partners have worked to detect, respond to, and prevent health security threats. CDC works 24-7 to save lives and protect people from threats.

I am Dr. Toby Merlin, Director of CDC's Division of Preparedness and Emerging Infections in the National Center for Emerging Zoonotic and Infectious Diseases. Since the beginning of the BioWatch program, CDC has assisted DHS with several aspects of the program, including in the areas of laboratory testing and public health response. Today, I would like to describe how CDC collaborates with DHS on the BioWatch program, explain the related role that CDC's Laboratory Response Network (LRN) plays in this program, and discuss CDC's broader role in outbreak detection and response. All of these efforts are designed to protect Americans from infectious public health threats, including threats of bioterrorism.

CDC's Role in the BioWatch Program

Since the beginning of the BioWatch program, CDC has provided technical assistance to DHS when requested. In this capacity, CDC currently supplies BioWatch LRN verification reagent panels and also provides technical support for interpretation of laboratory results, process troubleshooting, and an electronic application, Results Messenger, for securely messaging laboratory results to CDC. In some instances, CDC evaluates and validates the best available testing technology for use in the BioWatch program. CDC also provides technical support in quality control testing and assurance of LRN reagents used as verification panels in BioWatch testing.

CDC provides scientific expertise and guidance — especially as it pertains to laboratory methodology and analyses — to DHS and states and localities that participate in the BioWatch program. When DHS initially launched the BioWatch program, CDC helped establish and staff BioWatch laboratories and developed and validated laboratory methods for detection of targeted biological threat agents. Since establishment of the BioWatch program, CDC has provided scientific experts on-call for consultations with BioWatch laboratories and additional laboratory testing at CDC, if requested. CDC coordinates the Federal Government's public health response to the possible detection of a biological threat agent as well.

CDC subject matter experts routinely provide technical advice on preparedness planning documents with DHS and partners to represent the public health perspective.

Ensuring Effective Laboratory Response to Bioterrorism

LRN Overview

The LRN is a CDC-managed network of local, state, and Federal public health and other laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical threats and other public health emergencies. DHS BioWatch laboratories work closely with these LRN laboratories to conduct tests and interpret their results. The LRN became operational in 1999 following the two Presidential Directives, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. CDC, in partnership with the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL), launched the LRN to strengthen the Nation's ability to respond quickly to biological, chemical, and radiological threats and other high priority public health emergencies through rapid testing, timely notification, and secure electronic submission of laboratory results. The network began with just 17 laboratories and, as of May 24, 2013, has expanded to 150 member facilities, including facilities in Australia, Canada, Germany, Japan, Mexico, South Korea, and the United Kingdom. Using 2000 census data, it has been determined that approximately 90 percent of the United States population lives within 100 miles of an LRN member laboratory. The LRN laboratories are not only geographically diverse, but they include public health, military, veterinary, environmental, and food laboratories. These laboratories provide reference testing for agents, such as *Bacillus anthracis* (anthrax), *Francisella tularensis* (tularemia), *Yersinia pestis* (plague), *Variola major* (smallpox) and *Clostridium botulinum* toxins (botulism), as well as cyanide, nerve agents, and other toxic chemicals. The different member laboratories can also identify agents in different types of samples, like clinical, environmental, food, and water samples. The LRN can be used to detect traditional biological threat agents, novel agents, or emerging infections. Just in the past few weeks, CDC developed and deployed through the LRN tests for two new health threats, influenza A H7N9, which has emerged in China, and MERS-CoV from the Middle East.

Participation in the network is voluntary and all member laboratories work under a single operational plan and adhere to strict policies of safety, bio-containment, and security. Laboratories also agree to perform testing using LRN procedures and reagents provided by CDC which allows for rapid testing, reproducible results, and standard reporting. The foundation of the LRN is a unified operational plan and standardization of laboratory testing, where a test result generated from one LRN member laboratory is the same as a result generated from another network laboratory. Some of the other key elements of the LRNs include highly-trained laboratory workers, common laboratory equipment, safe facilities, rapid detection capabilities, and fast and secure notification of results that allow for more efficient medical countermeasure deployment. As I will discuss in more detail later, CDC's investment in epidemiology and laboratory capacity at the Federal, state and local level enables an integrated response to public health threats, whether natural or man-made.

The LRN links state and local public health laboratories with veterinary, agriculture, military, and water- and food-testing laboratories, and the LRN also provides laboratory services to evaluate threat letters containing so-called “white powders.”

LRN and BioWatch

BioWatch laboratories are usually co-located with LRN sites and they use LRN procedures and reagents in the second phase of their serial testing of material collected from air samples to detect biological threat agents. CDC and the LRN provide support to the BioWatch program by participating in their serial testing and review strategy, which is designed to determine when there might be a bioterrorism threat to the public from release of a biological threat agent into the air. The serial testing strategy minimizes the number of false positive laboratory test results that would indicate a bioterrorism threat.

Specifically, the BioWatch serial testing strategy entails at least two separate laboratory tests, the first of which is called the BioWatch screening test. This test is performed by BioWatch laboratories, is a very sensitive test, and can produce preliminary positive results that indicate that the specimen should undergo further testing for confirmation of the presence of material from a biological threat agent. The verification testing utilizes a panel of LRN DNA signatures for each biological agent threat, with an algorithm that has to be met to make a final call decision. The approach of using a sensitive and specific screening assay, coupled with rigorous verification testing, is consistent with Good Laboratory Practices, reduces probability of false positives, and enhances confidence in results. LRN-trained personnel use unified operational plans and standardized laboratory testing approaches to interpret these test results to determine if additional review is needed when there is a positive test result in either of these testing stages.

Outbreak Detection and Response

Laboratory detection and epidemiologic response to disease are the foundation of CDC's activities. In addition to managing the LRN and providing support to DHS' BioWatch program, CDC plays a broader, critical role in the detection of and response to local, state, national, and international outbreaks of infectious diseases caused by naturally occurring or man-made threats.

CDC Laboratories

CDC is home to the country's leading experts and gold-standard laboratories in infectious disease prevention and control. These state-of-the-art laboratories are critical to our Nation's safety and health, and are staffed and equipped to detect, track, and respond to a range of microbes and respond to outbreaks, such as the 2012 fungal meningitis outbreak. They serve as an early warning system to rapidly identify, confirm, and characterize new infectious disease threats. CDC laboratories maintain unique and critical capacities, including evaluating pathogens from outbreaks of infectious disease,

serving as reference laboratories, conducting tests on or identifying pathogens in samples from around the world, developing diagnostic tests to more quickly and easily identify new diseases, and researching a wide range of pathogens to understand better the nature of significant and emerging pathogens.

Federal, state, local, tribal, and territorial public health departments and their laboratories are our Nation's first line of defense against public health threats. These critical partners form a national disease detection tracking network, which is essential to identifying, tracking and responding to disease outbreaks and other health threats as quickly as possible. For this reason, CDC invests in and provides training for state and local laboratories to strengthen detection of and response to infectious diseases, including those caused by influenza, healthcare-associated infections, mosquito-borne diseases (e.g., West Nile virus), foodborne pathogens, and bioterrorism threats. State health department and other laboratories rely on CDC laboratories for further assistance with rare and complex pathogens or when outbreaks are large or widely distributed geographically.

The enormous diversity of microbes—combined with their ability to evolve and adapt to changing populations, environments, practices, and technologies—creates potential threats to health and continually challenges CDC's ability to prevent and control disease. CDC must always be prepared for the unexpected. That means continuing to build state and local public health laboratory capacity throughout the United States and strengthening CDC's core infectious disease laboratories.

Outbreak Response

State and local public health departments are on the front line in detecting and responding to outbreaks, but they rely on CDC to provide laboratory and epidemiologic training and standards, and often CDC funding, to carry out their responsibility at the local level. CDC invests in state and local public health detection and response activities through the Epidemiology and Laboratory Capacity (ELC) mechanism and the Emerging Infections Program (EIP). These platforms bolster state and local capacity to detect and respond to existing and emerging infectious disease threats. Specifically, these investments support state and local public health laboratories, surveillance, outbreak investigations and response, and health tracking systems, and the training to develop the next generation of public health leaders, laboratorians, and disease detectives.

The Public Health Emergency Preparedness cooperative agreement (PHEP) complements the ELC and EIP funding and focuses on all-hazards capability development in 62 state and local public health departments and provides emergency preparedness funding to advance work on 15 key public health preparedness capabilities. These 15 capabilities include public health laboratory testing and public health surveillance and epidemiological investigation, which are tied to the LRN.

The ELC, EIP, and PHEP cooperative agreements allow state and local partners to hire and train staff, buy laboratory equipment and supplies for detecting emerging pathogens, and invest in information technology to improve disease reporting and tracking. These platforms support well over 4,800 full- and part-time positions in the state, territorial, local, and tribal health departments, including epidemiologists, laboratorians, and health information systems experts, to ensure basic capacity at the local level where many infectious diseases are first identified.

CDC often serves as a resource for our state and local partners, when requested, during outbreaks and plays a critical role in identifying disease patterns and linkages across state and local lines. We work in close collaboration with health departments to ensure a rapid and coordinated investigation and response. CDC routinely augments varied state and local capacity by providing scientific guidance to them, assisting with the epidemiologic investigation, and providing laboratory support, when needed. CDC experts also engage in outbreak investigations when the source of infection is very uncommon, new, or complex, or the outbreak occurs in more than one state.

CDC's response to an outbreak does not end once the source of the outbreak has been identified and stopped. CDC uses the information gathered during outbreak investigations to work with health departments, partners, other federal agencies, and policymakers to implement strategies to prevent future outbreaks. CDC's response to outbreaks of infectious disease, along with a thoughtful evaluation of strategies to prevent further outbreaks, continues to improve public health. The crucial laboratory and epidemiological data that CDC and its state and local partners gather allows the public, clinicians, health plans, and policy-makers to make rapid decisions based on objective evidence. CDC's systems help identify our Nation's health priorities, providing hard evidence of what works and what does not work. As a science-based agency, CDC data are used to guide decisions that protect Americans and prevent illness.

Conclusion

CDC works 24 hours a day, 7 days a week protecting Americans from health threats by providing laboratory and outbreak response assistance to federal, state and local partners. CDC helps save lives by preventing, detecting, and controlling the growing risks of infectious disease outbreaks, emerging infectious diseases, drug resistant bacteria, and natural and man-made hazards and disasters.

CDC and LRN laboratories are critical and unique assets to ensuring the Nation's preparedness to detect and respond to biological and chemical terrorism. CDC and LRN laboratories are essential to ensuring rapid detection of these threat agents and other infectious disease that could pose a threat to the public. The BioWatch program, and CDC and state and local public health laboratories that support it, contribute to this effort. CDC will continue to work closely with DHS to support the BioWatch program, as requested, specifically in the areas of laboratory testing and public health response.

I appreciate the opportunity to discuss CDC's collaboration with BioWatch program, describe our LRN program, and our critical role in infectious disease outbreak detection and response.