

PHHS BLOCK GRANT SUCCESS STORY 2016

MICROBIAL DISEASES LABORATORY BRANCH/SELECT AGENT AND BIOSAFETY

LABORATORY PROTECTS CALIFORNIA AGAINST BIOLOGICAL THREATS.

Issue: The September 11, 2001, terrorist attacks and anthrax mailings that same month prompted federal investments in the biosecurity and response infrastructure by the Centers for Disease Control and Prevention (CDC). CDC's Laboratory Response Network for Biologicals (LRN B), comprised of national, reference, and sentinel LRN B laboratories, was established to respond to biological threats to public health.

The Microbial Diseases Laboratory (MDL) at the California Department of Public Health (CDPH) serves as a reference laboratory for the select agent program regulated by the Federal Select Agent Program and CDC's Division of Select Agents and Toxins, as enacted in the Code of Federal Regulations (42 CFR Part 73 and 9 CFR Part 121).

- MDL serves as an LRN B reference laboratory and must continually support the over 2,000 hospital based LRN B sentinel laboratories across the state, providing conclusive results for biological threat agents, and aiding local authorities in for the emergency response.
- MDL is the only public health entity registered for Tier 1 status in California. Tier 1 select agents include the causative agents of anthrax, botulism, tularemia, and plague. These agents pose the greatest risk of deliberate misuse, mass casualties, devastating effects to the economy, critical infrastructure, and/or public confidence.²
- MDL Tier 1 status required additional regulatory and resource commitments. The full implementation of the federal requirements led to a more secure laboratory facility and better screened workforce.

Intervention: With PHHSBG funds, MDL (1) upgraded facilities and staffing for the highly regulated Tier 1 Select Agents Program, and (2) hired a full time Public Health Microbiologist Specialist to serve as the designated Alternate Responsible Official (ARO) and as a liaison with the Federal Select Agents Program.

Impact: The Alternate Responsible Official (ARO) managed Tier 1 compliance and performed outreach to California local public health, sentinel laboratories, and external partners to strengthen emergency preparedness.

- The ARO surveyed all 14 California LRN B reference laboratories for biothreat preparedness and provided training and consult to over 20 local public health and sentinel laboratories.
- The ARO performed 3 CDPH Tier 1 laboratory inspections and compliance audits.
- The ARO served as liaison during a Federal Select Agents Program renewal inspection of CDPH in August 2016.

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In 2016, MDL provided confirmatory testing of select agents for over 18 LRN B laboratories, local public health laboratories, and surveillance programs.

- MDL activated surge testing capacity for potential biothreat events and emergency response during Super Bowl 50.
- MDL tested 40 cases of suspected Clostridium botulinum neurotoxin and/or C. botulinum organism in human and environmental (food) samples. This included confirmation of foodborne botulism from a commercial product.
- MDL tested 16 human samples for other Tier 1 select agents including Bacillus anthracis (anthrax), Burkholderia, and Yersinia pestis, and identified Brucella (brucellosis) and Francisella tularensis (tularemia).
- MDL tested 12 mammal carcasses for Yersinia pestis and Francisella tularensis as part of the ongoing vector borne plague and tularemia surveillance in California.