APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

APHL Position Statement

The Need for a Quality Assurance Program for Kits and Devices Used in the Field to Screen for Hazardous Biological and Chemical Warfare Agents

A. Statement of Position

The Association of Public Health Laboratories (APHL) opposes the use of biological and chemical warfare agent screening kits and devices for use in the field in the absence of a federally-approved quality assurance program, which encompasses performance verification, field validation, proficiency testing, training, and annual competency assessment in the application of these kits and devices.

B. Implementation

1. **DESIGNATE THE DEPARTMENT OF HOMELAND SECURITY (DHS) AS THE LEAD FEDERAL AGENCY:** DHS must establish uniform guidelines for the performance standardization and validation of all kits and devices for use in the field by first responders to screen for hazardous biological and chemical warfare agents.
2. **DEVELOP AND IMPLEMENT PERFORMANCE STANDARDS:** Establish guidelines for performance standardization of all kits, assays, and devices for use in the field by first responders to screen for hazardous biological and chemical warfare agents.
3. **VALIDATE FIELD DEVICES (MEASURE WHETHER THE DEVICES DO WHAT THEY SAY THEY DO):** Perform validation studies under variable conditions that may be less than favorable: location (laboratory vs. field), varying levels of experience with such devices and/or laboratory testing by end-users. Engage an independent third party to conduct such evaluations and involve state and local public health LRN member laboratories in validation studies, as appropriate.
4. **DEVELOP AND IMPLEMENT A QUALITY ASSURANCE PROGRAM:** The program should encompass training and certification on the use of all devices and kits that screen for biological and chemical warfare agents and ensure that personnel participate in a proficiency testing program and undergo regular annual competency assessment.
5. **ESTABLISH PROCESS FOR PURCHASE OF APPROVED FIELD KITS AND DEVICES:** Once kits and devices meet the performance standards and have been validated, they should be placed on a federally-approved list. Only items on this list should be approved for purchase with DHS Federal Emergency Management Agency (FEMA) and other federal funds.

C. Background/Data Supporting Position

Commercial industry has stepped forward to develop a variety of field screening kits and devices for use by first responders to determine whether or not hazardous biological or chemical warfare agents are present at the site of an incident.

Results obtained in the field without appropriate device validation, training, and demonstration of proficiency can be dangerously misleading. False positive results may cause unwarranted alarm, public panic, inappropriate action, and ultimately the loss of public trust. False negative results may lead to additional life-threatening exposures, inappropriate action, and again, loss of public trust. Incorrect field test results may actually delay appropriate responses. Additionally, failure to conduct field screening correctly, using standardized protocols prescribed by the validation process, may result in depletion of available sample material with consequential loss of criminal evidence and the ability to conduct the appropriate confirmatory analytical testing essential for implementing effective public safety and public health measures.

While APHL recognizes the potential usefulness of such kits and devices, their use without proper field validation and appropriate training is problematic. At sites where hazardous biological or chemical warfare agents may be present, field screening kits and devices are often used by first responders to make decisions regarding actions necessary to assure public safety. These kits and devices do not have defined performance capabilities and limitations nor have they been validated under field conditions. Validation is essential to assure that kits and devices used in the field are appropriately sensitive and specific to screen for the agents for which they are designed.

Concern regarding the lack of a federally-approved quality assurance program has resulted in a study by the U.S. Government Accountability Office (GAO) recommending the identification of an agency that will develop, certify, and independently test first responders' equipment, including manufacturer's specifications about sensitivity and specificity (1). The following entities support the need for training, certification, and proficiency testing for end-users; sample collection and handling standards; and validated assays: the U.S. Departments of Health and Human Services (HHS) and Homeland Security (DHS), Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the Federal Bureau of Investigation (FBI), APHL, and by state and local public health Laboratory Response Network (LRN) member laboratories (2). This is a critical issue for public safety, public health, and national security.

D. References

1. United States Government Accountability Office (GAO). First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas Is Significantly Limited. June 2008, available at: http://www.gao.gov/new.items/d08180.pdf
2. United States Department of Homeland Security. Framework for a Biothreat Field Response Mission Capability. April 5, 2011, available at: http://www.aoac.org/SPADA/FrameworkforBiothreatFieldResponseMissionCapability%20(Secure).pdf

Recommended by: The Public Health Preparedness and Response Committee, Approved by Board of Directors for Interim Use: January 2013, Approved by Membership: March 2013, Sunset Date: March 2018

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