APHL Position Statement

Field Screening Kits and Devices Must Work

A. Statement of Position

APHL opposes the use of federally unapproved field-screening kits and devices used to detect biological and chemical warfare agents.

B. Background

The 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 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 and negative results may cause unwarranted alarm, public panic, inappropriate action, loss of public trust and additional life-threatening exposures. 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 a quality assurance program, proper field validation and appropriate training is problematic. At sites where 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. Even when using validated screening kits and/or devices, results, whether positive or negative, should not be considered conclusive. It is expected that specimens are still sent to a public health laboratory for confirmatory testing.

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. Department of Health and Human Services (HHS)
- Department of Homeland Security (DHS)
- Centers for Disease Control and Prevention (CDC)
- The Environmental Protection Agency (EPA)
- The Federal Bureau of Investigation (FBI)
- Laboratory Response Network (LRN) member laboratories[2]

This is a critical issue for public safety, public health and national security.

C. APHL's Recommendations

Lead Agency:

1. APHL recommends that the Department of Homeland Security, as the lead federal agency, establish the quality assurance program. This program would provide uniform guidelines for the performance standardization and validation of all kits and devices used by first responders in the field.
2. APHL recommends that state governments designate a lead agency within their state that will be responsible for:
    - Facilitating a dialogue among public health and public safety agencies
    - Coordinating response activities
    - Sharing educational resources on the limitation of various field technologies

Establish Quality Assurance Program for Field Devices:

3. APHL advocates for the quality assurance program to encompass:
    - Training and certification
    - Proficiency testing
    - Regular annual competency assessments
4. APHL proposes that independent third parties to conduct validation studies of field devices under variable conditions
5. Once the kits and devices meet the performance standards and have been validated, APHL recommends 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.

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: https://www.aoac.org/aoac_prod_imis/AOAC_Docs/SPADA/FrameworkforBiothreatFieldResponseMissionCapability.pdf
3. Preliminary Findings on the Evaluation of Hand-Held Immunoassays for Bacillus Anthracis and Yersinia Pestis. January 2003, available at: https://archives.fbi.gov/archives/about-us/lab/forensic-science-communications/fsc/jan2003/fsru.htm
4. Evaluating 6 ricin field detection assays. July 2014, available at: https://www.ncbi.nlm.nih.gov/pubmed/24978020
5. Environmental Technology Verification Report QTL BIOSYSTEMS LLC QTL Biosensor. July 2006, available at: https://nepis.epa.gov/
6. Evaluation of HHA for the detection of Bacillus anthracis, Yersinia pestis and Francisella tularenis. Available at: https://www.labor-spiez.ch/pdf/en/dok/fas/Evaluation_HHAs.pdf
7. Biodetection Technologies for First Responders: 2015 edition. Available at: https://biodetectionresource.pnnl.gov/default.aspx?topic=Publications+and+Presentations
8. Interagency Board: Position Paper: Bioterrorism Preparedness and Response White Paper. Available at: http://www.iaem.com/documents/IAB-Bioterrorism-Preparedness-and-Response-Proposed-Model-18Jan2017.pdf

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