
APHL Position/Policy Statement

Standardized Validation of Screening Kits and Devices for Use in the Field to Identify Hazardous Biological and Chemical Agents

A. Statement of Position

The Association of Public Health Laboratories (APHL) strongly opposes the use of biological and chemical agent detection kits and devices for field testing in the absence of performance standardization, field validation, and certified individuals trained in the application of these kits and devices. It is essential that a standardized validation, approval, and training process for these kits and devices be developed and implemented as soon as possible.

B. Background/Data Supporting Position

Industry has stepped forward to develop a variety of field screening kits and devices for use by first responders to determine quickly whether or not hazardous biological or chemical agents are present at the site of an incident. 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 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. For chemical agents, while such field tests have been available for a number of years, minimum standards for performance have not been established. For biological agents, the kits and devices being developed commercially for this purpose have not been validated under field conditions. Validation is essential to assure that kits and devices used in the field are appropriately sensitive and specific to detect the agents for which they are designed. Analytical results obtained in the field without appropriate device validation and performance training can yield false positive or false negative results. Such data 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 testing 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. In the absence of standardized and validated field kits and devices, public health laboratories must be contacted for confirmatory testing or guidance for such testing.

To reduce the likelihood of erroneous field test results, it is essential that the screening kits and devices that are used on-site be standardized and validated to perform accurately and reliably under field conditions. While these kits and devices are not designed to give definitive results like medical devices, they do need to be reliable in terms of expected sensitivity and specificity. Concern regarding this lack of field standardization and validation has resulted in a statement by the U.S. Department of Health and Human Services (HHS) recommending against the use of field screening kits, such as hand-held assays, to evaluate and respond to incidents involving unknown powders suspected to contain *Bacillus anthracis* (anthrax) or other biological agents (1). This need to standardize and validate field screening kits and devices is supported by the HHS, CDC, FBI, APHL, and by state and local LRN laboratories. It is also supported by public safety officials (2) who must make decisions regarding purchase and use. This is a critical issue for public safety, public health, and homeland security.

C. References

1. Statement by the U.S. Department of Health and Human Services Regarding Hand-held Assays for the Identification of *B. anthracis* Spores, July 2002, available at http://www.gsa.gov/gsa/cm_attachments/GSA_DOCUMENT/Appendix%20E_R2M-y2-t_0Z5RDZ-i34K-pR.doc, accessed October 19, 2006.
2. Lipowicz, Alice and Starks, Tim. "Where Are Standards? Almost Nowhere, Say Rescue Units Struggling to Buy the Right Stuff." CQ Homeland Security – Local Response, Oct. 7, 2003.

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