STATEMENT BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
Regarding Hand-Held Assays for Identification of *B. Anthracis* Spores

Purpose

To provide law enforcement, fire services, emergency managers and other first responders with guidance regarding the purchase and use of hand-held assays used for detecting anthrax spores and other biological agents.

Summary

The U.S. Department of Health and Human Services at this time recommends against use by first responders of hand-held assays to evaluate and respond to an incident involving unknown powders suspected to be anthrax or other biological agents.

Background

In recent months, Federal, State and local first responders have had to evaluate numerous samples of white powdery substances to determine if B. anthracis (anthrax) spores are present. In some cases, field tests showed an apparent "positive" result and this led to the quarantine, isolation or decontamination of people. When these samples were referred to a reference lab in the Laboratory Response Network (LRN), they were found to be negative through microbiological culturing and molecular methods. The devices used for the initial field tests included tickets and strips from at least four vendors. Problems resulted from a variety of factors, such as testing of caustic or harsh chemicals or the performance of tests by inadequately trained personnel.

Discussion

Biological agent field test kits are, at this time, not sufficiently accurate for on-scene decision making in the field. Besides the high number of false positive results, hand-held assays also yield negative results on samples that are truly positive (false negatives). In formal terms, the sensitivity of such assays are in the range of 100,000 spores whereas a culture may detect one spore.

In contrast to situations with chemical exposure where rapid decision making (minutes) can be crucial to the protection and treatment of individuals, there are no examples of biological exposure where decision-making cannot wait for the results of validated laboratory procedures (1-2 days). Any perceived benefit of using currently available hand-held assays fall short of the costs of unnecessary remedial actions and amplified public concern.

No Federal agency certifies or approves these devices. The FBI and CDC have recently evaluated commercially available hand-held assays for the detection of B. anthracis. These studies confirm the low sensitivity of such assays and their potential to produce false-positive results with non-anthrax bacteria and chemicals. The performance of handheld assays for the detection of biological agents other than B. anthracis has not been evaluated and their use is also not recommended at this time.

Conclusions

Until results are obtained that would warrant the use of hand-held assays, DHHS recommends:

(1) hand-held assays systems not be used for the assessment of suspected biological samples;
(2) Whenever a biological agent is suspected, a unified command should assess the credibility of the situation and determine an appropriate response. The unified command should include fire services, public health, the FBI's Weapons of Mass Destruction Coordinator, and law enforcement;
(3) Substances that are found to be a credible public health threat by the unified command should be screened in the field for volatile organic compounds (VOC), pH, explosives, and radiation, and then sent to an appropriate laboratory in the Laboratory Response Network (LRN) for testing. First responders and local public health programs need to establish protocols to provide this support and logistics of the response. Besides testing of samples in an LRN laboratory, the protocol should include a system for identification and follow-up of the potentially exposed population and a joint communication plan for the public and media relations. Since exposure to airborne anthrax spores is potentially life threatening, all credible threats should be handled appropriately in a timely manner.

References:

1. "CDC Health Advisory: Hand-Held Immunoassays for Detection of Bacillus anthracis Spores." October 18, 2001 http://www.bt.cdc.gov/DocumentsApp/Anthrax/10182001HealthAlertPM/10182001HealthAlertPM.asp
2. "Use of Onsite Technologies for Rapidly Assessing Environmental Bacillus anthracis Contamination on Surfaces in Buildings." CDC MMWR Vol 50 Number 48. December 7, 2001. http://www.cdc.gov/mmwr/PDF/wk/mm5048.pdf
3. "Approved Tests for the Detection of Bacillus anthracis in the Laboratory Response Network." http://www.bt.cdc.gov/DocumentsApp/Anthrax/ApprovedLRNTests.asp