

Initiative Yields Effective Methods for Anthrax Detection; RAMP and MIDI, Inc., Methods Approved

AOAC INTERNATIONAL, and its subsidiary AOAC Research Institute, announced the approval of two biodefense methods for the detection of *Bacillus anthracis* (commonly known as anthrax). One method, commonly referred to as MIDI, is for the confirmatory identification of pure cultures of *B. anthracis*. The second method, a hand-held assay (HHA), is intended for the presumptive detection of *B. anthracis* spores. Soon, scientists will begin field-testing to confirm the effectiveness of the approved HHA method for use by “first responders,” such as trained HazMat technicians, who may be called upon to respond to an emergency situation.

The comprehensive initiative conducted by AOAC INTERNATIONAL and funded by the Department of Homeland Security (DHS) and Department of Defense began in June 2003. Its purpose was to identify reliable analytical methods to enable security, defense, and other federal agencies to make science-based decisions in the event of biological attacks. Additionally, first responders, public health agencies, defense, and security needed validated field-usable methods for detecting agents.

“AOAC has taken the lead in the evaluation and validation of detection methods for biological and chemical

threat agents,” said James Bradford, executive director of AOAC INTERNATIONAL.

The DHS-sponsored project has established an infrastructure to support the development of standards and evaluation of biological and/or chemical threat agent detectors. AOAC INTERNATIONAL and DHS are working jointly to determine which detectors and methods for other chemical and biological agents should be evaluated next.

“The cooperation of many federal agencies, the biodetector industry, the academic and the first responder communities—all working in concert with AOAC—was critical in executing this project,” said Bradford.

At this stage, AOAC has just awarded *Official Methods*SM status to two methods for use in the laboratory—RAMP Anthrax Test Cartridge by the Response Biomedical Corp. of Canada and MIDI Sherlock Microbial Identification System of Newark, Delaware, USA.

Previously, in February 2004, AOAC had granted *Official Methods of Analysis*SM status to a confirmation procedure used by the Centers for Disease Control and Prevention (CDC) and the Laboratory Response Network (LRN).

RAMP Anthrax Test Cartridge

The RAMP test was one of five HHAs that underwent an exhaustive AOAC collaborative study in 12 different laboratories. As a rapid screening method, the RAMP test was found to be reliable in detecting anthrax spores at levels of 1 million or more in visible powders. Field-testing studies, still in the planning stage, will determine if any operational parameters related to the use of the RAMP Anthrax Test Cartridge in the field would affect the analytical performance of the assay.

In studies designed by AOAC scientists and implemented at U.S. Army Dugway Proving Grounds in Utah, the RAMP was demonstrated to

reliably detect *Bacillus anthracis* isolates representing a wide variety of geographic sources and physical variants. The specificity of the RAMP was also demonstrated in evaluations to confirm that it would not cross react with non-*Bacillus anthracis* bacteria. To judge the accuracy of the data generated, AOAC organized 12 laboratories nationwide to assess the RAMP's performance using identical samples. The RAMP test performed well in the collaborative study, and little variation was seen in the data produced by the 12 laboratories.

MIDI Sherlock Microbial Identification System

The second method approved in November by AOAC is a laboratory-only method, commonly referred to as MIDI Sherlock Microbial Identification System, which includes the MIDI BIOTER database version 2.0. The MIDI method was subjected to exhaustive testing of many strains of *B. anthracis* and of related strains to determine its ability to differentiate among them. The 11 laboratories involved in the study reported an acceptable overall sensitivity for *B. anthracis* identification of 96.3%. ■

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—James Bradford, AOAC's Executive Director

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