## DOD PROGRAMS

# Joint Biological Agent Identification and Diagnostic System (JBAIDS)

#### **Executive Summary**

- Based on Follow-on Operational Testing and Evaluation (FOT&E) in April-May 2007, Joint Biological Agent Identification and Diagnostic System (JBAIDS) is operationally effective, but not suitable due to poor reliability. The Joint Project Manager (JPM) took corrective actions to resolve the poor reliability with system software modifications. DOT&E verified that JBAIDS now meets requirements for mission reliability, operational availability, and mean time between operational mission failures following a demonstration at the Air Force Institute for Operational Health Applied Technology Center (AFIOH/ATC) in September 2007.
- The FOT&E followed a full-rate production decision for ground-based medical units, based on Multi-Service Operational Test and Evaluation in April-June 2005, which found the JBAIDS is operationally effective for ground-based units. Timely identification of an agent (3-4 hours versus 24-48 hours from traditional culturing methods) aids in improved situational awareness, isolation of personnel, and reduced exposure to the agent.
- JBAIDS is useful in shipboard operations for situational analyses and implementation of countermeasures and force protection actions.
- When a single JBAIDS is deployed in a medical unit in accordance with Service concepts of operation, and cannot be repaired by the operator, the unit has complete loss of this biological identification capability. This impacts the Air Force, Marine Corps, and Navy, as their medical units are each authorized only one JBAIDS.

#### **System**

- JBAIDS provides biological agent identification and diagnostic capability for fixed-site, mobile (shelter, man portable, and trailer), and shipboard applications.
- The Services intend the JBAIDS to be a reusable, portable, biological agent identification and diagnostic system capable of identifying multiple biological warfare agents (BWAs) simultaneously.
- JBAIDS provides enhanced capabilities to the warfighter to identify conventional infectious organisms that occur naturally in the environment and BWAs.



- 1 Polymerase Chain Reaction (PCR) Thermal Cycler
- 2 Notebook Computer
- 3 Consumables and Support Equipment
- JBAIDS is intended to satisfy a need to rapidly identify these BWAs in environmental samples and in clinical samples after Food and Drug Administration certification.
- It consists of an analytical device, sample preparation kits, reagent kits, laptop computer, and other support equipment weighing up to 1,500 pounds and occupying up to 227 cubic feet.
- JBAIDS is intended to be employed in units such as:
  - Army Area Medical Laboratories
  - Army Combat Support Hospitals
  - Army Veterinary Service Food Analysis Laboratories
  - Navy Environmental Preventive Medical Units, and aboard aircraft carriers, amphibious assault ships, and amphibious command ships
  - Marine Corps Preventive Medicine units
  - Air Force Forward-Deployed or Forward-Positioned Medical Biological Augmentation Teams
  - Air Force Homeland Defense Laboratories

#### Mission

- Units equipped with JBAIDS identify biological agents to support a commander's force protection decisions by providing timely information for determining appropriate treatment, preventive measures, prophylaxis, and operational decisions.
- Units with JBAIDS will be tasked to provide rapid confirmatory identification of specific BWAs detected or identified by other biological detection systems employed in operational environments.

#### Activity

 The Joint Program Executive Officer for Chemical and Biological Defense in March 2006 approved full-rate production of JBAIDS for ground-based units, but did not approve fielding until extraction and inhibition (process quality) controls were developed. JBAIDS production was not approved for shipboard use due to the size of the centrifuge,

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- which was subsequently replaced by an alternate sample preparation protocol.
- Fielding to Air Force units is underway at the request of the Air Force Office of the Surgeon General. Fielding to Army units began upon completion of extraction and inhibition controls testing in March 2007.
- The four Service Operational Test Agencies (OTAs) evaluated revised sample preparation protocols in FOT&E they conducted in two phases in April-May 2007. All four OTAs validated ground unit medical laboratory operations at Brooks City Base, Texas. The Navy OTA conducted a second phase aboard a ship at Norfolk Naval Base, Virginia.
- The AFIOH/ATC conducted seven weeks of reliability testing in July-August 2007 following corrective actions implemented by the JPM after the FOT&E, observed by the Army Evaluation Center.
- The Joint Program Executive Officer for Chemical and Biological Defense will make a full-rate production decision for shipboard JBAIDS in 1QFY08.

#### **Assessment**

- JBAIDS is effective in identifying BWAs in a timely manner (3-4 hours versus 28-48 hours from traditional culturing methods) and aids in improved situational awareness, isolation of personnel, and reduced exposure to the agent.
- JBAIDS is operationally suitable. The JPM is making hardware and software changes to address reliability, availability, and maintainability issues remaining from the August 2007 reliability demonstration. The failure of the JBAIDS during FOT&E Navy shipboard phase prevented mission accomplishment, yet testing continued using a spare

- JBAIDS. Only one JBAIDS is authorized in Air Force, Marine Corps, and Navy medical units, and most Army units.
- The inclusion of extraction and inhibition controls provides greater confidence on the part of operators and reduces false positives and false negative results. The JBAIDS analytical report sent to the laboratory physician did not indicate when the JBAIDS operator applied inhibition controls when preparing samples. Inclusion of this information would improve physician interpretation of the analytical report.
- JBAIDS software can be improved to translate the measured crossing threshold data into estimates of concentration for each BWA against different media (agent/matrix) combinations.
- The revised sample preparation protocols are effective. One of the protocols reduces the footprint and volume of sample required but processing time increases. Additional operator training may improve techniques to limit sample contamination.

#### Recommendations

- Status of Previous Recommendations. All earlier DOT&E recommendations have been resolved.
- FY07 Recommendations.
  - 1. The Services should reassess quantities of JBAIDS in units to provide redundant capability.
  - 2. The product manager should modify the JBAIDS analytical report to indicate use of inhibition controls and associated results.
- 3. The product manager should refine the algorithm that translates the measured crossing threshold data into estimates of concentration for the different BWA/matrix combinations.