

## Joint Biological Agent Identification and Diagnosis System (JBAIDS)

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) is intended to be a reusable, portable, modifiable, biological agent identification and diagnostic system capable of identifying multiple biological agents of operational concern and other pathogens of clinical significance in clinical specimens and environmental samples. JBAIDS is intended to be used by military clinicians and other trained personnel to screen for biological agents given such factors as known or suspected threat agents and geographical endemic diseases. The system will consist of an identification instrument based on polymerase chain reaction technology, a laptop computer with software, a storage/shipping case, assay test kits, support equipment, and other laboratory consumables. JBAIDS will be used at forward deployable medical treatment facilities, area and theater medical laboratories, laboratories and clinics on ships, and at high threat fixed sites.

The JBAIDS program is divided into three developmental blocks in order to expedite procurement and fielding while reducing technical risk. Block I will use commercial-off-the-shelf technology capable of identifying 10-20 biological warfare agents within 40 minutes after completion of the test sample extraction process from either a clinical or environmental sample. Initial fielding of the Block I and II systems is not contingent upon approval from the Food and Drug Administration (FDA). Therefore, prior to FDA approval, clinical results must be confirmed using established diagnostic methods. The FDA approval process will be initiated during Block I and will continue throughout the development process for all blocks. There are already several versions of polymerase chain reaction technology in use by the Services. A Block I goal is to standardize on a single system for all Services. Block II will add toxins to its target list of warfare agents. Block III will involve a newly developed hand-held unit with a capability to identify 50-70 agents with automated sample preparation and be able to be used by non-medical personnel. Block III is intended to be an FDA approved diagnostics device. Block III will interface with the Joint Warning and Reporting Network and medical patients' records/medical surveillance systems.

JBAIDS is an Acquisition Category III program. The Operational Requirements Document (ORD) was approved on May 3, 2003. A Milestone B decision occurred on September 25, 2003, and a contract award for production of the Block I system on September 29, 2003.

### TEST & EVALUATION ACTIVITY

During August 2002, the West Desert Test Center (WDTC) at U.S. Army Dugway Proving Grounds, Utah, conducted a competitive test of candidates for the JBAIDS system. Seven systems were challenged to exhibit their ability to identify inactivated agents of biological origin. Two inactivated agents of biological origin, diluted in defibrinated sheep blood, were used: *Bacillus anthracis* (Ames Strain) and vaccinia virus. The program manager evaluated three areas: system performance, physical characteristics (e.g., size, weight) and other subjective factors such as reliability, ease of operation, and expandability.

The Test and Evaluation Master Plan was approved by DOT&E on September 26, 2003. The IOT&E is currently planned for FY04.



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# DOD PROGRAMS

## **TEST & EVALUATION ASSESSMENT**

The results of the competitive test indicate that technology exists to meet the sensitivity and specificity goals of detecting biological agents of interest. Two of the systems passed the defined criteria and were taken into source selection.

IOT&E must address all target biological agents in appropriate matrices using inactivated threat representative agents. Assay performance will be assessed using assumptions that performance levels are independent of sample matrices. The applicability and timeliness of JBAIDS reporting information must be sufficient to support decision-makers and mission performance