Joint Biological Agent Identification and Diagnostic System (JBAIDS)

SUMMARY
- The Service Operational Test Agencies conducted an operational assessment August 9-12, 2004, at Eglin Air Force Base, Florida.

SYSTEM DESCRIPTION AND MISSION
The Services intend the Joint Biological Agent Identification and Diagnostic System (JBAIDS) 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. Military clinicians and other trained personnel plan to use JBAIDS to screen for biological agents given such factors as known or suspected threat agents and geographical endemic diseases. The system consists of an identification instrument based on polymerase chain reaction technology, a laptop computer with application software, a storage/shipping case, assay test kits, support equipment, and other laboratory consumables. The Services intend to field JBAIDS to forward-deployable medical treatment facilities, area and theater medical laboratories, laboratories and clinics on ships, and high-threat fixed sites.

The JBAIDS program has three developmental blocks to expedite procurement and fielding while reducing technical risk. Block I uses commercial off-the-shelf technology capable of identifying 10 biological warfare agents within 40 minutes after completion of the test sample extraction process from either a clinical or environmental sample. Since there are already several versions of polymerase chain reaction technology in use by the Services, a Block I goal is to standardize a single system for all Services. Block II will add toxins to its target list of biological warfare agents. Users intend Block III to be a hand-held unit with a capability to identify 50-70 agents with automated sample preparation. It is intended for use by non-medical personnel. Initial fielding of the Block I and II systems is not contingent upon approval from the Food and Drug Administration (FDA). The FDA approval process will be initiated during Block I and will continue throughout the development process for all blocks. Block III should provide an FDA approved diagnostics device. Block III will interface with the Joint Warning and Reporting Network and medical patients’ records/medical surveillance systems.

TEST AND EVALUATION ACTIVITY

TEST AND EVALUATION ASSESSMENT
The Operational Assessment results will be considered in the low-rate initial production decision scheduled for 1QFY05. It will assess progress toward effectiveness and suitability, and readiness for IOT&E scheduled for 3QFY05. The Operational Assessment will assess four areas: operational effectiveness, operational suitability, and operational impacts; programmatic voids; program documentation; and the ability to provide information to support the existing war fighting process. The IOT&E must address all target biological warfare agents in appropriate matrices using inactivated threat representative agents. An objective of the test program is to validate the relevancy of test results using inactivated biological agents. The applicability and timeliness of JBAIDS reporting information must be sufficient to support decision-makers and mission accomplishment.

Scheduling operational assessments or tests in conjunction with training exercises enhances the realism of the test environment and provides a command and control context not otherwise available; but such a strategy is risky. Although the plan called for this assessment to be integrated with an exercise, Eglin Air Force Base cancelled the exercise due to an approaching tropical storm. Earlier in May 2004, Holloman Air Force Base, New Mexico, cancelled an exercise that the Operational Test Agencies had expected to use for this operational assessment. In the case of an operational assessment supporting a low-rate initial production decision, the reduced scope of the test is acceptable. Had this event been the initial operational test and evaluation, the reduction in scope would not be acceptable.