

Abstract

The BioSensors Branch within the Edgewood Chemical Biological Center (ECBC) Research and Technology (R&T) Directorate spearheaded a technology down-select to identify surface sampling collection and identification technology candidates to be used with the current DoD Joint Biological Tactical Detection System (JBTDs) selected Chemring Detection Systems' ATHINA platform. A panel of Subject Matter Experts (SME) from across the biodefense community evaluated and down-selected submissions in response to a Request for Information (RFI) for sample surface collection and identification technologies. Ten vendors representing 12 sample collection technologies were evaluated. Each technology was analyzed using an adjustable scoring matrix specific to the needs of the JBTDs program. This scoring matrix was designed to assess time from collection to identification, number of BWA targets, size, JBTDs identifier compatibility, ease of use, maturity, and consumable storage requirements. The JBTDs program placed an emphasis on technologies with both surface collection and integration with an identification device to minimize human interface.

The SME down-selected technologies were then evaluated by two military end user groups (501st technical escort unit, 8th Bioenvironmental Engineers (Kusan Airbase South Korea), and the 20th Support Command). The end users received hands-on training on the BBI Detection BW Integrated Multiplex Assay and Sampling System (IMASS™). These groups also received a user survey to compare the IMASS to the current DoD swab/Handheld Assay (HHA) sampling kit.

Introduction

In May 2015, the Department of Defense (DoD) JBTDs program office selected Chemring Detection Systems' ATHINA platform for its suite of technologies. The suite consists of a modular set of aerosol detector, collector, and identifier components. Prior to award, the JBTDs Program Office engaged its combat developers and recognized a desire, particularly from the Special Operations Command (SOCOM) and the Marine Corps communities, to include sample surface collection requirements and near-real-time presumptive identification capabilities. To help determine how to meet this potential need, an RFI was issued to solicit input from both industry and federal vendors. The RFI titled W911SR-15-ESSRFI was posted 12 March 2015 and closed on 10 April 2015.

This RFI received responses from nine industrial vendors and one government vendor. The responses ranged from technologies for collection- or identification-only, to integrated collection and identification technologies. To evaluate and categorize the submissions, an SME panel consisting of eight members from across the biodefense community and representing a variety of disciplines to include end-user, CBRNE training, and biological and chemical specialists, convened on 12 May 2015 at ECBC. This report summarizes the SME panel assessment of the submitted technologies with regard to their applicability to JBTDs.

The analysis was based both on the RFI responses and SME knowledge and experience. The analysis of each technology has been captured in a criteria table that categorizes and scores a comprehensive list of attributes that include physical characteristics (e.g., size, weight, etc.) and performance characteristics (e.g., ease of use, JBTDs compatibility, etc.). Each technology was analyzed using an adjustable scoring matrix specific to the needs of the JBTDs program. This scoring matrix was designed to assess time from collection to identification, number of BWA targets, size, JBTDs identifier compatibility, ease of use, maturity, and consumable storage requirements. The JBTDs program placed an emphasis on technologies with both surface collection and integration with an identification device to minimize human interface. The customer need was also driven by the need for operation in Mission Oriented Protective Posture (MOPP) IV and compatibility with the JBTDs identifier.

While the panel scored technologies based on their fit into the JBTDs program needs, the criteria table clearly shows how these scores and the weight applied to each specific attribute were obtained. This was important because the requirements of sample collection and rapid biological identification missions are usually unique. By breaking out the scoring weight "attribute weight", it is the panel's hope that this analysis might serve as a foundation for other Federal agencies seeking to advance their capabilities in these areas.

RFI Summary Response Criteria Table

	Collection with Single-Use Identifier		Collection with Multi-Use Identifier				Collection Only					Identifier Only
	BBI BW IMASS	Alexeter RAID 8	ANP NIDS	BioMatrix Innovaprep/Biomeme one 3	MSD Cartridge Reader	SRC Akus Shield	QuickSilver B2C	Innovaprep Rapid Filter Elution Kit	QuickSilver BiSKit	QuickSilver All-In-One	U.S. Army Mano Sampling Kit	Q-linea Aquila 1000
Time from Collection to ID	100	100	100	10	70	10	0	0	0	0	0	10
Number of Targets Per Sample	70	70	70	70	100	100	0	0	0	0	0	100
Size	200	200	110	200	110	200	100	100	100	100	100	10
JBTDs Identifier Compatibility	140	80	170	140	80	170	170	170	170	80	0	0
Ease of Use	400	310	250	160	250	100	250	160	100	250	310	130
Maturity	110	110	110	110	80	80	110	110	170	110	20	80
Consumables	50	50	50	50	35	50	50	50	50	50	50	35
Total Score	1070	920	860	740	725	710	680	590	590	590	480	365



Discussion

The JBTDs program has recognized a desire from its combat developers to improve sample surface collection and presumptive identification technologies available to the warfighter. This RFI was conducted to survey the commercial market place for tactical lightweight biological environmental sampling technologies to satisfy this need. The analysis of the RFI submissions was weighted to emphasize time from collection to ID, number of targets per sample, multiplex capability, size, JBTDs identifier compatibility, ease of use, maturity, and consumable storage requirements. As a result, submissions with both collection and low-cost single-use identifiers ranked highest. Several submissions included collection capability and identification with a multi-use instrument; however, these instruments tended not to meet intended mission requirements, such as ease of use, small size, and low cost. Based on its analysis, the panel concludes that the BBI BW IMASS and the Alexeter RAID 8 should be further evaluated with a more comprehensive third party laboratory analysis that compares these devices to the current DoD Biological Sampling Kit. If the JBTDs program office instead chooses to explore traditional collection-only technologies for surface sampling, the panel recommended further evaluation of the QuickSilver B2C and the Innovaprep Rapid Filter Elution Kit. The Innovaprep collection system is recommended over the QuickSilver All-In-One or QuickSilver BiSKit despite having the same score. The rationale behind this is that the Innovaprep system is already part of the selected JBTDs system, thus if selected, it could reduce the logistical footprint of the system through commonality. As with the integrated collection/identification technologies, a third party laboratory analysis to verify performance of these technologies would be advisable.

ANP TECHNOLOGIES – NIDS

The ANP Technologies, Inc. Nano Intelligent Detection System (NIDS®) Rapid Bio-Threat Detection System detects biological warfare agents in environmental samples. Three five-plexed NIDS assays covering 11 BW targets, along with a handheld reader, are fielded by the U.S. Army SOCOM, as well as DHS/FEMA and National Guards units within fifty States in the US. These targets include B. anthracis spores, vaccinia/smallpox, Botulinum A toxin, Ricin toxin, SEB toxin, Y. pestis, C. burnetii, Brucella, VEE, and V. cholerae. These assays demonstrate true multiplex capability, high sensitivity, low false positive rates, and no hook effect.



BBI DETECTION – BW IMASS

The BBI BW IMASS is handheld, portable, and consists of a set of eight lateral flow immunoassays positioned radially within a cylindrical holder. The device runs eight tests simultaneously from one sample and provides results for all eight bioterror agents (*B. anthracis*, Ricin, *F. tularensis*, *Y. pestis*, *B. mallei*, *Brucella spp.*, Bot Tox A and B, and *S. enterotoxin B*) in 15 minutes. A benefit of the system is that the collection and identification are integrated into one unit. The robust and rugged ergonomic design makes the BW IMASS easy to use, even in MOPP IV gear. The device is easily decontaminated by immersion after sampling, as the sample is fully contained. BBI claims that a technology update of the original BW IMASS, the NG IMASS, is in-development (TRL-6) and will contain 10-12 LFI strips. The version of the IMASS that is currently available used British-developed assays, but BBI claims that the NG IMASS will be compatible with Critical Reagent Program (CRP) LFI strips.



ALEXETER TECHNOLOGIES – RAID 8

The Alexeter RAID 8 BioThreat Detection Kit screens environmental samples for the simultaneous evaluation of eight biological threat agents. The RAID 8 is a multi-channel lateral-flow immunochromatographic device partnered with the Alexeter Collection Swab for sample collection.



Conclusions

- The SME panel assessed that the BW IMASS had a strong potential for utility in a surface collection/identification mission.
- The integrated sampler and identification BW IMASS technology significantly reduces the manipulation efforts needed by the user in MOPP IV.
- One concern that the SME panel expressed was that minimal amounts of fluid sample could be extracted from the system for follow-on analysis with the JBTDs identifier.