Next Generation Diagnostic System (NGDS) Increment 1

Executive Summary
- The Next Generation Diagnostic System (NGDS) is a polymerase chain reaction analytical instrument. The Services intend NGDS to provide clinical diagnostic capability to diagnose biological warfare agent (BWA)-related illness and environment sample analysis to identify the presence of BWA in the operational environment.
- BioFire Defense, Limited Liability Corporation (LLC), the major contractor, is conducting Food and Drug Administration (FDA)-approved clinical trials on the NGDS hardware, software, the consumable assay, and analytical methods for BWA-related diseases to support FDA clearance of NGDS for clinical use.
- The Army Test and Evaluation Command conducted an operational assessment of the NGDS May 18 – 27, 2016, at Camp Bullis, Texas.
- Based on an analysis of operational assessment data, deployable medical units equipped with NGDS can analyze clinical specimens and provide timely and accurate information to support medical diagnosis, treatment, and force health protection decisions.
- The NGDS demonstrated 98 percent mission reliability and 98 percent operational availability during the operational assessment.

System
- The NGDS Increment 1 Deployable Component is the FilmArray 2.0 commercial off-the-shelf liquid sample polymerase chain reaction analytical instrument with automated sample preparation.
- The NGDS and the Warrior Panel for biological warfare agent identification will be FDA-cleared for diagnostics use on clinical specimen types.
- The system includes a ruggedized computer, software, ruggedized transport case, optical handheld barcode scanner, optical mouse, power and communication cables, pouch loading module, consumable assays. and an operator's manual with sample protocols.
- The Services intend to use the NGDS Increment 1 Deployable Component in existing microbiology laboratories equipped with common laboratory support equipment such as Class II Bio Safety Cabinet, refrigerator, freezer, level work surfaces, line power sources, lighting, and appropriately trained laboratory personnel and units.

1 - Laptop running NGDS software
2 - NGDS PCR (Polymerase Chain Reaction) instrument
3 - Barcode reader
4 - Assay Panel (in bag)
5 - Assay Panel Docking Station
6 - Hydrating Solutions

Mission
- Trained clinical laboratory personnel equipped with the NGDS Increment 1 Deployable Component will identify BWAs and infectious diseases in clinical specimens (e.g., blood, sputum, nasopharyngeal swabs) to support medical provider's clinical diagnosis and treatment decisions.
- Trained laboratory personnel equipped with NGDS will identify BWAs in environmental samples to confirm a potential BWA incident and support Force Health Protection decision making.

Major Contractor
BioFire Defense, LLC – Salt Lake City, Utah

Activity
- BioFire Defense conducted FDA-approved pre-clinical trial testing of the NGDS during FY15. It is currently conducting FDA-approved clinical trials on the NGDS hardware, software, the consumable assay, and analytical methods for BWA-related diseases. The FDA will use clinical trial data to determine if the system should be cleared for diagnostic use.
- The NGDS program conducted the following developmental and logistics testing between July 2015 and August 2016:
  - Electromagnetic compatibility testing and Military Standard 810 environmental testing from July to August 2015

  - Synthetic DNA material testing to validate its use as a stimulant for operational testing from February to March 2016
  - Cooperative Vulnerability and Penetration Assessment cybersecurity testing in April 2016
  - Logistics Demonstration in May 2016
  - Military Standard 810 follow-on testing in May 2016
- DOT&E approved the NGDS Increment 1 Deployable Component operational assessment plan on May 9, 2016.
- The Army Test and Evaluation Command conducted the operational assessment May 18 – 27, 2016, at Camp Bullis, Texas, in accordance with the DOT&E-approved Test and Evaluation Master Plan and operational test plan.

Assessment

- Based on an analysis of operational assessment data, deployable medical units equipped with NGDS can analyze clinical specimens and provide timely and accurate information to support medical diagnosis, treatment, and force health protection decisions.
- Clinical laboratory personnel are able to prepare and analyze a clinical sample in an average of 68 minutes and correctly report diagnostic results for multiple agents at the same time.
- The NGDS automated sample preparation and analysis process reduces operator sample preparation tasks and minimizes the opportunity for error.
- The NGDS infectious disease diagnostic capability will enable laboratory personnel to maintain proficiency that can be applied should a BWA incident occur.
- The NGDS demonstrated 98 percent mission reliability and 98 percent operational availability during the operational assessment.
- NGDS has cybersecurity vulnerabilities that need to be corrected and re-tested prior to fielding.
- FDA clearance for medical use must be obtained for the NGDS and Warrior Panel prior to fielding.

Recommendations

- Status of Previous Recommendations. There are no previous recommendations for this program.
- FY16 Recommendation.
  1. The program manager should correct cybersecurity vulnerabilities prior to the IOT&E and fielding.