

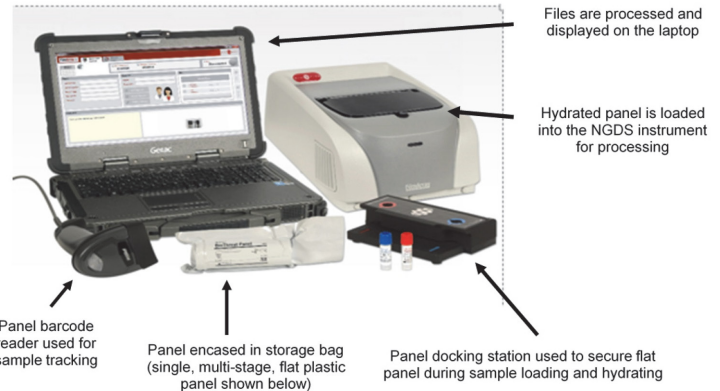
Next Generation Diagnostic System (NGDS) Increment 1

Executive Summary

- The Next Generation Diagnostics System (NGDS) is a polymerase chain reaction analytical instrument to aid in the diagnosis of biological warfare agent (BWA)-related illnesses and environmental sample analysis to identify the presence of BWA in the operational environment.
- The NGDS is operationally effective and suitable for clinical use by deployable medical units to support the diagnosis and treatment of BWA associated illnesses.
- Emerging test results indicate that the NGDS provides a timely, accurate, and reliable capability to identify BWAs in environmental samples to support force protection decisions.

System

- The NGDS Increment 1 is the FilmArray 2.0 commercial off-the-shelf liquid sample polymerase chain reaction analytical instrument with automated sample preparation.
- The NGDS uses the Warrior Panel for BWA identification in clinical samples (e.g., blood, blood culture, and sputum) and the Sentinel Panel for BWA identification in environmental samples (e.g., air, soil, and water).
- 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 in existing microbiology laboratories equipped with common laboratory support equipment such as Class II Biological Safety Cabinet,



refrigerator, freezer, level work surfaces, line power sources, lighting, and appropriately trained laboratory personnel.

Mission

- Commanders intend to employ trained clinical laboratory technicians equipped with the NGDS Increment 1 to identify BWAs and infectious diseases in clinical specimens to support medical provider's clinical diagnosis and treatment decisions.
- Commanders intend to employ trained laboratory technicians equipped with NGDS to 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

- The U.S. Army Medical Research Institute of Infectious Disease at Fort Detrick, Maryland, and Battelle Memorial Institute in Aberdeen, Maryland, conducted combined developmental/operational live agent testing of the NGDS Sentinel Panel and BioFire FilmArray device from April to December 2017.
- The Army Research Laboratory Survivability Lethality Analysis Directorate conducted a cybersecurity Cooperative Vulnerability and Penetration Assessment of the NGDS from July 11-12, 2017, at the Army Medical Department Center and School (AMEDDC&S) in San Antonio, Texas.
- The Army Threat Systems Management Office conducted a cybersecurity Adversarial Assessment of the NGDS from July 31 to August 4, 2017, at the AMEDDC&S.
- The Navy's Operational Test and Evaluation Force conducted IOT&E of the NGDS from August 21 to September 9, 2017, aboard USNS *Comfort* and USS *Gerald R. Ford* and at the

Naval Environmental Preventive Medical Unit, Naval Station Norfolk, Virginia.

- The operational testing was conducted in accordance with DOT&E-approved test plans. DOT&E approved changes to the planned test dates and locations due to unanticipated Navy ship support to Hurricanes Harvey and Irma.

Assessment

- The NGDS is operationally effective in providing deployable medical units with timely clinical sample analysis to aid in the diagnosis of anthrax, plague, tularemia, Q fever, and the hemorrhagic fevers caused by Ebola and Marburg viruses, in response to a suspected or confirmed bioterrorism event or outbreak.
- The NGDS provides increased breadth of diagnostic coverage through compatibility with four FDA-approved commercially

available common infectious diseases panels enabling day-to-day use of the system.

- Emerging results from the combined developmental/operational live agent testing of the NGDS Sentinel Panel indicate the system identifies BWAs present in environmental samples at similar or lower levels than the Joint Biological Agent Diagnostic Systems (JBAIDS), which the Services intend to replace.
- The NGDS is operationally suitable for clinical and environmental sample analysis. It is easy to use, demonstrated 98.6 percent probability of completing analysis of 5 samples without an operational mission failure, and has a smaller operational footprint than the JBAIDS.

Recommendations

- Status of Previous Recommendations. The Services have addressed the previous recommendations.
- FY17 Recommendations.
 1. The Services should develop and implement plans to educate medical providers at units receiving NGDS on the capabilities provided and the diversity of assays available to support medical diagnostics.
 2. The Program Office should provide sample preparation procedures on a single document to improve the logical flow of information.