

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 for the analysis of environmental samples to confirm the presence of BWAs to support force protection and situational awareness.
- The NGDS is operationally effective for analysis of clinical samples to support the diagnosis and treatment of symptomatic patients.
- The NGDS is operationally suitable. The system exceeds reliability and availability requirements, is easy to use, and has a smaller logistics footprint than the system it replaces.
- The NGDS is survivable against cyber threats.

System

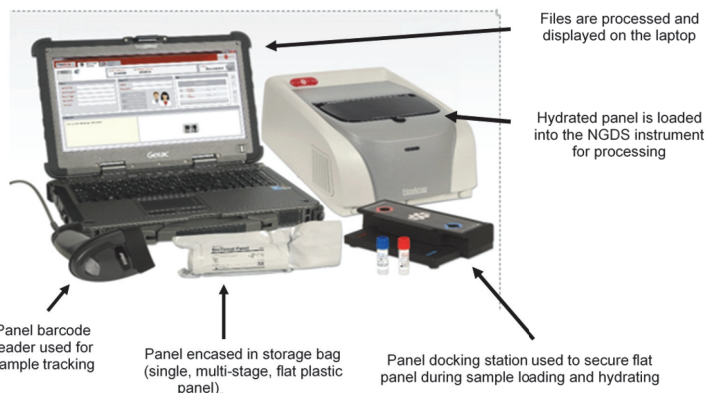
- The NGDS is a U.S. Food and Drug Administration (FDA) cleared commercial off-the-shelf diagnostic device manufactured by BioFire Defense, LLC.
- Two consumable panels are available for use with the NGDS: the Warrior Panel to identify the presence of BWA in clinical samples and the Sentinel Panel to identify the presence of BWA in environmental samples.

Activity

- The U.S. Army Medical Research Institute of Infectious Disease at Fort Detrick, Maryland, and the Battelle Eastern Science and Technology Center, Aberdeen, Maryland, conducted combined developmental/operational testing of the Sentinel Panel and BioFire FilmArray device from April 2017 to February 2018.
- The combined developmental/operational testing was conducted in accordance with DOT&E-approved test plans.
- DOT&E submitted the NGDS Operational Test and Evaluation Report to Congress in May 2018.

Assessment

- The NGDS is operationally effective for deployable medical units to analyze clinical samples to aid in the diagnosis of anthrax, plague, tularemia, Q fever, and the hemorrhagic



Mission

Army, Navy, and Air Force units equipped with the NGDS analyze clinical and environmental samples to identify the presence of BWAs and infectious diseases to aid in medical diagnosis and provide situational awareness to support force protection decisions.

Major Contractor

BioFire Defense, LLC – Salt Lake City, Utah

- fevers caused by Ebola and Marburg, in response to a suspected or confirmed bioterrorism events or outbreak.
- The NGDS is operationally effective for the analysis of environmental samples to confirm the presence of BWAs to provide timely and accurate information to improve situational awareness and support force protection decisions.
- The NGDS is operationally suitable. It exceeds mission reliability and operational availability requirements, requires less support equipment thus reducing the operational footprint from the system it replaces. The NGDS is easy to operate and requires minimal operator hands-on time.
- The NGDS is survivable against cyber threats.

Recommendations

None.

FY18 DOD PROGRAMS