RAPID RESPONSE

QUICK, ACCURATE IDENTIFICATION OF BIOLOGICAL PATHOGENS

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The Department of Defense operates worldwide, including in remote and austere environments without access to modern medical facilities. The task of diagnosing and caring for sick and injured soldiers on the battlefield, especially in isolated regions, remains a challenge. The austere environment, coupled with the potential to contract local diseases, creates a need for rapid diagnostics and treatment. Developing in-field detection of pathogens, disease and biological warfare agents allows warfighters to request necessary medical evacuation or quarantine for sick or contagious troops; thus mitigating the risk of exposure to other personnel.

Soon, taking clinical and environmental samples to a laboratory for high quality, highly reliable molecular diagnostics tests will be outdated. The era of point of care and point of need diagnostics tests is here and the applications for these diagnostic tests are broad, diverse and limited only by the imagination. But, ensuring the sensitivity, specificity, robustness and reliability of performance of point of care and point of need molecular diagnostics is essential.

This means the platform or device running the test, as well as the assays, or the test itself, must be thoughtfully and rigorously designed, and have proven performance. Investment in this type of product represents a significant opportunity for DoD to improve the survivability rate for its soldiers and maximize the potential of field medics to treat as many ill and wounded as possible.

Researchers with the PositiveID Corporation designed Firefly Dx, a hand-held, battery powered, cartridge-based, rapid, multiplex, real-time polymerase chain reaction diagnostic device for point of care and point of need, lab-quality detection of pathogenic organisms, biomarkers and single nucleotide polymorphism identity assays.

The device will allow detection and identification of Influenza at the point of need with lab-grade results in 15 to 30 minutes. This is simply not possible with existing systems, which require lab-based equipment, technical personnel, and can take hours or even days to provide results. The ability to rapidly test and diagnose a contagious or deadly illness will allow medics to administer appropriate treatment for the correct illness instead of providing general care while they wait for lab results. In remote locations, the option to send for a laboratory test is not feasible. The use of the Firefly Dx would allow for testing and identification of an infectious disease when previously there was no option.

The Firefly Dx is a two-part device consisting of a portable hand-held instrument and disposable single-use cartridges. The cartridges will contain all of the reagents necessary for sample lysis, purification and PCR analysis of the extracted DNA or RNA. Firefly Dx will be able to process a variety of sample types, including whole blood, buccal and nasopharyngeal swabs, urine and environmental field samples. PositiveID Corporation is teaming up with GenArraytion, Inc., to provide high quality, rapidly developed, proven assays.

Key attributes of the Firefly Dx system design include:

- Portable and battery powered
- Low cost and fully automated
- Single-use disposable cartridges
- Ease of use (one-button operation)
- Sample-to-results in 30 minutes
- RFID tracking of cartridges
- Public Health trusted real-time PCR chemistry and interpretable results

GenArraytion brings its highly successful approach to assay development to bear on development of Influenza assays. GenArraytion's MultiFLEX™ Bioassays for infectious disease agents provide a significant advance in multiplexing flexibility, with more than 20 DNA and/or RNA targets in a single assay panel that can be mixed and matched to suit various platforms and operational scenarios.

The multiplex PCR assays are readily configurable, highly specific and ready for use in real-time and bead-based, end-point platforms. The assays are available for clinical pathogens and veterinary disease agents as well as food or waterborne pathogens and biological threats. Recently the company developed panels for both tick and mosquito-borne pathogens including Aedes aegypti (yellow fever mosquito) associated viruses.

GenArraytion's approach to molecular infectious disease diagnostic assay devel-

Broad Range of Applications

First Responders

- Biothreat agent detection and confirmation (such as Anthrax) from environmental samples and powders
- Rad/Nuc incident true exposure determination of casualties
- Agricultural
- True "Pen-side" diagnostic ability for high-priority and routine animal diseases (such as Porcine Reproductive and Respiratory Syndrome) for veterinarians and animal health technicians
- Rapid and accurate diagnostics on-site for Foreign Animal Disease outbreaks (such as Foot and Mouth Disease Virus)
- Field diagnostic capability for high-consequence invasive crop diseases

Human Infectious Diseases

- Biothreat agent detection and diagnosis in multiplex test
- True "Bed-side" diagnostic capability for example, respiratory differential diagnostic panels
- Diarrheal differential diagnostic panels
- Antibiotic resistance detection panels (such as MRSA)
- Seasonal and Pandemic Influenza panels
- Other emerging and re-emerging concerns such as Dengue Fever Virus, Chikungunya, Nipah, Zika, etc. in resource constrained environments
- Human Clinical (non-infectious disease)
- Radiation exposure biodosimetry panel post-Rad/Nuc incident and for manned space missions (such as the International Space Station)
- Cancer detection and diagnostics panels

opment leverages available genetic sequence information by mining the data for highly informative genetic targets that are optimized and validated using a robust iterative laboratory assay development process. The company demonstrated the ability to rapidly develop high fidelity molecular infectious disease tests and various real-time PCR platforms, as well as more highly multiplexed assays, including planar microarrays and bead-based assays.

Figure 1 shows a graph of real-time PCR raw data generated in the Firefly Flu Dx integrated breadboard following RNA extraction and sequence specific reverse transcription, using GenArraytion Influenza assays. GenArraytion has performed a bioinformatics analysis of flu strains published in GenBank and we have designed a screening array containing over 15,000 sequences representing unique regions of various Influenza isolates. Assay targets were selected based on the specificity of more than 20 Influenza isolates.

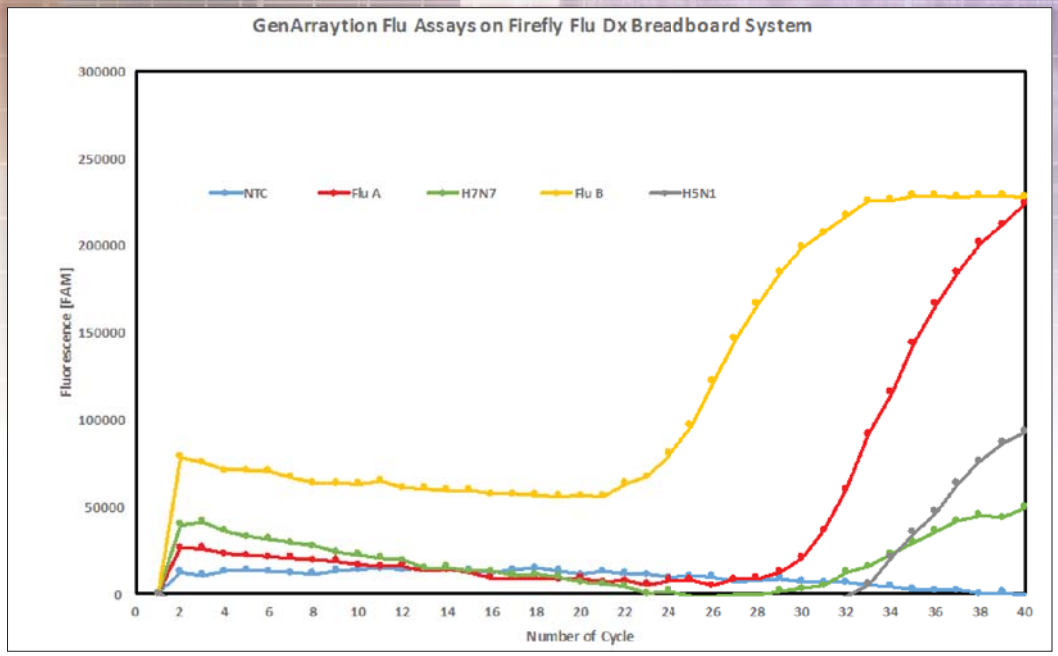

Figure 1. Real-time PCR raw data generated by the Firefly Flu Dx breadboard system following RNA extraction and sequence specific reverse transcription using GenArraytion Influenza assays. Target amounts were all 500 pg. (Released)

Dr. Kimothy Smith is the chief technology advisor on the Board of Advisors for PositiveID Corporation. Dr. Smith has served as a professor of advanced analytics and most recently the senior director for the Applied Innovation Center for Advanced Analytics at the Desert Research Institute. Dr. Smith is a co-founder of McCarthy & Smith Consulting, LLC, where he provides professional consulting services in the areas of biosurveillance, bioforensics, biodefense, biosecurity, molecular genetics and diagnostics, and food safety, defense and security. Dr. Smith was named the first Chief Veterinarian for the Department of Homeland Security in 2005. PositiveID Corporation™ (OTCQB: PSID) is a life sciences tools and diagnostics company specializing in biological detection and molecular diagnostic systems for America's homeland defense and the global healthcare market. PositiveID specializes in the development of microfluidic systems in order to detect biological threats and outbreaks, whether airborne, in a healthcare setting, or at the point of need. PositiveID is also a leader in the mobile technology vehicle market.