REVOLUTIONARY DIAGNOSTICS – NONTRADITIONAL APPROACHES FOR DEVELOPING BREAKTHROUGH CAPABILITIES AGAINST EMERGING THREATS

Unknown Respiratory Pathogen Detector Using Pan-species Signatures

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Military personnel, both at home and during deployment, are vulnerable to respiratory emerging infectious diseases (EIDs) and are often the first to be exposed to threat outbreaks of pre-pandemic strains. Early EID detection in the field will reduce the exploratory phase of outbreak diagnostic development, which currently threatens readiness and increases contagion/death, because critical time is needed to discriminate EIDs from known pathogens.

GeneCapture is developing portable infection diagnostics to support military readiness in austere environments. To date, GeneCapture has demonstrated prototypes for rapid pathogen ID and rapid mixed culture antibiotic susceptibility testing. The subject of this abstract is a novel platform that focuses on the rapid identification of 6 pan-viral families that may be involved in a respiratory EID scenario to quickly determine what approach is needed for treatment and prevention. The design anticipates a field deployable, low-cost, easy-to use, diagnostic system. The platform will detect similarities among the most concerning human or animal respiratory viruses that are found in six viral families (Adenoviridae, Coronaviridae, Orthomyxoviridae, Enteroviruses of family Picornaviridae, Paramyxoviridae, and Pneumoviridae) and report on a universal bacterial signature. Co-author Professor Gregory Gray (UTMB, Galveston, TX) is collaborating on user and performance requirements based on his extensive work in pre-pandemic surveillance as part of One Health.

The platform, named RNA Expression Validated by Enriched Amplicon Levels (REVEAL), has 3 critical requirements. The novel amplicon and detection design must allow for degenerate amplification of any known or emerging pathogen within a viral family with high specificity (95%+). The test must work in a simple temperature controlled step with reagents that are stable for at least 6 months. Lastly, detection must be complete in 20 minutes and produce a meaningful result that can determine on-site action and be shared with a real time, controlled database for global action. The revolutionary aspects of this diagnostic include a new specifically engineered thermostable enzyme, a software program to optimize amplicon design, and innovative design engineering to manage this process with reliable performance in field conditions.

The technology produces and detects single stranded RNA amplicons, which are the product of a one-step (non PCR) isothermal amplification that will take place in a small handheld cartridge. To accomplish the portability and low logistics requirements of a handheld device we have produced the custom thermostable enzyme and identified and begun experiments on two real-time detection techniques that would report the results to a smart phone within 20-30 minutes. Preliminary results using Coronaviridae family targets have shown that degenerate primer sets can be used to amplify RNA from multiple viruses from one viral family in the same reaction. Additionally amplification occurs within 20 minutes and from a starting concentrations as low as 100 copies of the viral genome.

Rapid early detection, especially in austere environments, will provide actionable information for Warfighter protection, allow for quick response and containment of new pathogens, and will have substantial Warfighter, human health, and economic impacts around the globe.

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