Infectious Disease Diagnostics and Differentiation of Viral vs. Bacterial Infections for Point of Care Applications Using Novel in vitro CAPTURE™ Diagnostic

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The Warfighter faces threats of endemic infections, multidrug resistant bacteria and biological warfare agents. In order to provide accurate field-forward treatment, a rapid, robust molecular *in vitro* diagnostic (IVD) is needed that will be effective in a "buddy care" or field clinic scenario. GeneCapture's patented ***Confirming Active Pathogens Through Unamplified RNA Expression (CAPTURE ™)*** IVD offers an innovative diagnostic solution for the Department of Defense (DoD) and domestic markets. In about 30 minutes, the CAPTURE ™ IVDwill be effective in differentiating bacterial from viral infections as well as simultaneously identifying the causative agent of a wide range of viral, fungal or bacterial diseases. For many infections, this rapid identification of the infective species is sufficient to inform effective treatment.

The CAPTURE ™ process matches the genetic signature of pathogenic nucleotides in a patient sample with custom DNA "captor" probes in a two-step assay that uses a universal reporter and requires no enzymes or amplification. Since every pathogen contains sequences of genetic material that are unique when compared against the entire genetic databank, these conserved areas can be exploited by the CAPTURE™ assay to specifically identify a pathogen. Conversely, by targeting essential sequences conserved across all bacteria, the same CAPTURE™ assay can monitor for the presence of unspecified bacteria without knowledge of the particular infectious agent. The CAPTURE ™ process targets hundreds of pathogens in a single assay by exploiting the thermodynamics of immobilized, structured DNA captors to distinguish closely related sequences. By targeting several sequences per pathogen and using a cluster analysis of the results, organisms with a mutation in a targeted region remain identifiable by CAPTURE ™ .

The breadboard device currently running the assay, the "CapLab," is on a clear design path to be lightweight and battery-powered. All processes of the innovative CAPTURE ™ assay will occur within a disposable cartridge, and involve: 1) crude sample preparation to concentrate and fragment the nucleic acids present in the patient sample; 2) rapid and specific hybridization of the fragmented nucleic acids to their complementary surface bound captors; 3) hybridization of the labeled universal reporter to any captor/target complexes; 4) detection and analysis of the reporter to give a read-out of yes/no answers for each pathogen on any wireless or wired device. The disposable cartridge has an expected cost of less than $20. With no enzymes required, the assay components have been shown to endure temperature excursions to 40C for 48 hours without suffering a loss of fidelity making the cartridges stable for shipping to remote areas. The matured CapLab device will be fully automated and CLIA-waived.

The CAPTURE ™ assay and CapLab breadboard have accurately verified pathogen ID and distinguished viral and bacterial infections during a CBD Phase I STTR (Solicitation 15C-001) for the identification of pathogens causing undifferentiated febrile illnesses, and the company is currently in contract negotiations for a Phase II continuation of this work. The choice of sample matrix of saliva, urine or blood did not affect the assay, demonstrating the robustness and applicability of the CAPTURE ™ assay for productization and commercialization.

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