

## INNOVATING CROSS-DOMAIN SOLUTIONS TO DETECT EMERGING BIOLOGICAL THREATS

### Rapid, Affordable, And Scalable Response To Emerging Biological Threats

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Effective response to a new biological threat requires a two phased approach to threat identification. The initial response to such an event is based on threat agnostic technologies which enable sufficient threat characterization to support mission completion. Though threat agnostic technologies provide invaluable insight into the new threat, they often suffer from operational, cost, or throughput challenges. Therefore, a second phase to rapidly deliver target specific solutions (at scale) must be enacted to support long term containment and mitigation.

Chemring Sensors and Electronic Systems (CSES) is addressing these limitations with the development of BIOFASTTM, a point-of-need platform providing sample-to-answer identification of bacteria, viruses, and toxins combining the benefits of both molecular and affinity based assays. The BIOFASTTM molecular assay provides the sensitivity of PCR, the specificity of SNPs, all while remaining rapidly adaptable (at scale) to new biological threats. The BIOFASTTM affinity assay leverages the performance enhancement of Alternating Current Electrokinetics (ACEK) with synthetic bioreceptors (aptamers) to reduce logistical constraints while opening the prospect for custom designed bioreceptors applicable to undefined threats.

BIOFASTTM combines four core technologies in a handheld, battery-operated platform:

Five minute sample preparation (i.e. cell lysis, nucleic acid extraction, and elution) is facilitated using magnetic capture beads transported through process fluids separated by oil valves in a disposable plastic tube.

The hybridized molecular assay provides the specificity and common reagents of Rolling Circle Amplification (RCA), plus the speed of Loop-Mediated Isothermal Amplification (LAMP). Common reagents support low consumable costs, fast assay development, and rapid manufacturing.

The affinity assay identifies biological threats with Aptamer-based binders in under 60 seconds with Alternating Current Electrokinetic (ACEK) enhancement (originally developed at the University of Tennessee). ACEK actively drives threat antigens toward the Aptamer receptors, enhancing both speed and sensitivity over systems that rely on passive diffusion (e.g. ELISA).

The Digital Microfluidic (DMF)-based consumable executes spatially multiplexed assays in which all fluid dispensing, movement, and mixing is completed without moving parts (i.e., pumps or valves), dramatically increasing system reliability, decreasing maintenance, and enhancing sustainability in austere environments.

An initial BIOFASTTM prototype has executed automated assays on-board prototype consumables with all fluid handled via DMF. Initial assay has results show limits of detection comparable to PCR, while the assay architecture enables differentiation of Single Nucleotide Polymorphisms.

The BIOFASTTM sample preparation method has been demonstrated effective with both raw bacterial cultures and whole blood sample matrices.

Testing of field samples from multiple matrices with ACEK-based affinity assays at the University of Tennessee has shown limits of detection similar to Polymerase Chain Reaction with identification times under 30 seconds.

BIOFASTTM will enable warfighters, first responders, and security personnel to rapidly identify both known and emerging biological threats (bacteria, viruses, and toxins) contained within different sample matrices. This broad applicability, combined with reliable and affordable operation, supports rapid and confident understanding of a biological incident as a first critical step toward containment and mitigation.