

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

Rapid Assay Fielding For Diagnostics And Detection

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A wide range of infectious diseases present challenges to the Warfighter, military readiness, and general public health. Detection of a pathogen in an environmental or clinical context informs responders about isolation requirements, countermeasure needs, and clinical signs to anticipate in an exposed population. Early detection provides the greatest opportunity to limit exposure and spread while maximizing the effectiveness of available countermeasures. While technology is advancing quickly, pathogen-specific assays will still be required in the near future as fully agnostic detection and diagnostic systems come online. Our group has a long history of developing, validating, and fielding assays to detect and diagnose a wide range of viral, bacterial, and parasitic pathogens. Well-designed real-time PCR assays feed into clinical or environmental detection systems following sample collection and processing. Novel extraction methods improve nucleic acid purification efficiencies from clinical and environmental samples while use of open platform instruments such as the portable Biomeme Franklin real-time PCR thermocycler facilitate rapid response capabilities for environmental and clinical applications. Among the lessons learned during the ongoing SARS-CoV-2 pandemic response include supply chain and production limitations as well as initially limited access to the virus itself will impede diagnostics and countermeasure development. Rapidly developing and fielding validated assays was significantly impacted by reagent availability and backlogs at companies supplying critical assay reagents. While the mutation rate of SARS-CoV-2 is relatively modest, emerging sequence variants can result in decreased assay sensitivity or assay failure. Disrupted supply chains could further delay regulatory evaluation of assays updated to detect emerging variants. Utilizing advanced assay design algorithms such as BioAI (Los Alamos National Labs) with current synthetic biology capabilities can rapidly generate real-time PCR assay reagents for genetically divergent or novel pathogen. Coupled to a defined formal validation pipeline, these assays on-demand can quickly provide adaptable and regulatory-grade assays to the field.

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