

Massachusetts General Hospital

Point-of-care Diagnostic System for Healthcare Associated Infection (HAI) Control

Healthcare-associated infections (HAIs) and drug-resistant pathogens have become a major healthcare issue with millions of reported cases every year and a cost of \$150 Billion/year in the U.S. Advanced diagnostics would allow clinicians to more quickly determine the most effective treatment, reduce the speculative use of broad-spectrum antimicrobials, and facilitate targeted antibiotic treatment. We have recently demonstrated a new detection technology, PAD (polarization anisotropy diagnostics), for rapid bacterial detection. The PAD utilizes changes of fluorescence anisotropy when detection probes recognize target bacterial nucleic acids. The technology is inherently robust against environmental noise, and economically scalable for parallel measurements. Our pilot study demonstrated PAD's potential: the assay was fast (<2 hour) and performed on-site in a single tube format. Building upon these results, the goal of this proposal is to fully advance the PAD technology from the proof-of-concept to clinical use. We specifically focus on two objectives in Step 2. First, we will implement an integrated system for the PAD assay, combining nucleic acid amplification and detection. This new system is expected to further shorten the total assay time (<1 hour), minimize contamination risk, and render the PAD assay user-friendly. Second, we will expand our HAI detection panel to include antibiotic resistant bacteria, and rigorously test the PAD technology according to FDA guidelines for *invitro* diagnostics. Completing these objectives will allow us to deliver the second generation PAD system ready for clinical testing, and significantly enhance PAD's value proposition as a point-of-care HAI-screening technology for further product development.