

Rapid Diagnostics for Category B Enteropathogens

Abstract

This program is based on a unique decade-long University – Industry partnership in the development and production of stool diagnostic tests for enteric pathogens. Our goal is to produce rapid, sensitive, specific and cost-effective diagnostics appropriate for public health laboratories and point-of-care use for the highest priority Category B enteropathogens. *Our hypothesis is that real-time multiplex PCR is the future of enteropathogen diagnostic tests for public health laboratories and that dipstick-formatted antigen detection tests are ideally suited for point-of care use.* Preliminary studies by the Program Investigators have resulted in FDA 510k-approved stool antigen detection tests for Category B agents *Entamoeba*, *Giardia* and *Cryptosporidia*. Project investigators have also pioneered methodology for DNA extraction from stool and PCR-based stool tests for the identification and DNA fingerprinting of *Entamoeba*. The Project Investigators therefore have the immediate capability to develop improved and cost-effective diagnostic tests for all 3 of the major biodefense Category B enteric protozoa threat agents. Three projects will work together towards the goal of producing an effective vaccine based on the GalNAc lectin. Project 1 will develop stool antigen detection dip stick tests for point-of-care diagnosis of Biodefense Category B Enteric Protozoa and Shiga toxin. Project 2 will develop real-time multiplex PCR using molecular beacons, FRET and/or Taqman™ probes for public health laboratory diagnosis of Biodefense Category B Enteropathogens. Project 3 will field validate the diagnostic tests produced by Projects 1 and 2 and will correlate protozoal genotype with virulence. The Laboratory Core will provide reagents, testing, and be the clearinghouse for obtaining, culturing and distributing Category B enteric parasites and bacteria for Projects 1-3. The Administrative Core will coordinate activities of the three projects, and facilitate scientific exchange and interactions of investigators. It will also provide administrative oversight and financial accountability.