

PathoGenetix Protocol Enables Bacterial Identification from Clinical Samples

A new protocol from PathoGenetix, Inc. enables identification and strain typing of bacteria directly from clinical stool samples in five hours, without the need for a cultured isolate. The protocol has important applications in both public health and microbiome research, and is currently being evaluated by public health laboratories to assess utility.

WOBURN, MASS (May 16, 2014) – PathoGenetix, Inc. has developed and validated a protocol for the identification and subtyping of bacteria directly from human clinical stool samples without prior cultural isolation. The protocol, which runs on the RESOLUTION™ System, enables public health and microbiome research laboratories to determine serotype and strain type information for multiple bacteria directly from an enriched stool sample, in just five hours.

The new protocol also demonstrates the potential use of the System for follow-up identification to the culture independent diagnostic tests (CIDTs) used by hospital and clinical laboratories in diagnosing foodborne diseases. CIDTs screen for multiple pathogens in stool samples without obtaining a pure culture isolate. But identification methods currently used in public health laboratories to determine if the disease-causing organism is part of a larger foodborne outbreak require a cultured isolate. The PathoGenetix protocol has the potential to enable the public health system to do its important work even when CIDTs are employed and no culture is available.

PathoGenetix's RESOLUTION™ Microbial Genotyping System is based on proprietary Genome Sequence Scanning™ (GSS™) technology, which provides bacterial serotype identification and strain typing in five hours directly from complex mixtures. The level of discrimination between bacterial strain types provided by the System is comparable to pulsed field gel electrophoresis (PFGE), the current gold standard for pathogen typing in foodborne illness outbreak investigation and response. Because the System is culture independent, and fully automated from sample preparation to final report, it has the potential to greatly reduce the time, complexity and skill-level required to identify foodborne pathogens in public health labs monitoring foodborne outbreaks.

The fully automated RESOLUTION System, including instrument, bioinformatics software and database, and pathogen-specific assays, will be commercially available by early 2015 for use in both food industry testing and public health foodborne illness outbreak investigations.

About PathoGenetix™, Inc.

PathoGenetix, Inc., is a commercial-stage developer of an automated system for rapid bacterial identification from complex samples. PathoGenetix is a venture-backed company that has also received more than \$50 million in technology development funding from the Department of Homeland Security. The company's core Genome Sequence Scanning™ (GSS™) technology isolates and analyzes DNA directly from an enriched biological sample, without the need for a cultured isolate, and provides results in just five hours, days faster than current methods. GSS has broad applicability in food safety, industrial microbiology, and clinical diagnostics and research. The first commercial GSS system, the RESOLUTION™ Microbial Genotyping System, will be available by early 2015 for use in food safety testing and foodborne illness outbreak investigations. Learn more at www.pathogenetix.com.