

PathoGenetix Delivers Bacterial Identification System to FDA for Evaluation

FDA has leased PathoGenetix's RESOLUTION Microbial Genotyping System to assess the effectiveness of the proprietary bacterial strain typing system in identifying pathogens involved in foodborne illness outbreaks, and in shortening decision and response time in public health investigations.

WOBURN, Mass. (February 6, 2014) – PathoGenetix, Inc., developer of an automated system for bacterial strain typing, announced today that it has delivered an early commercial version of the RESOLUTION™ Microbial Genotyping System to the U.S. Food and Drug Administration (FDA). The FDA is leasing the RESOLUTION System as part of a three-year collaborative agreement to evaluate the rapid bacterial identification technology for use in FDA foodborne illness outbreak investigation and response.

The RESOLUTION System, based on PathoGenetix's proprietary Genome Sequence Scanning™ (GSS™) technology, enables pathogen serotype identification and strain typing in just five hours, directly from complex mixtures such as enriched food and clinical samples. The bacterial strain information provided by the RESOLUTION System is comparable to pulsed field gel electrophoresis (PFGE), the current gold standard for pathogen typing in foodborne illness outbreak investigation and response.

Identifying the pathogen strain that is causing a foodborne illness outbreak is a critical step in defining the extent of the outbreak, determining the food involved, finding the original source of the contamination and defining the scope of a product recall. The ability of the RESOLUTION System to derive useful pathogen strain and serotype information directly from a complex mixture, and to shorten the time for pathogen typing to just five hours, could allow for quicker decisions affecting public health.

Current microbial identification techniques such as PFGE and whole genome sequencing (WGS) require a cultured isolate as input, and advanced, time-consuming laboratory processes for preparation and processing of food samples. Analysis of the patterns created by PFGE, or the extensive data generated by WGS, can be complex and add significantly to the time required to identify the pathogen strain and serotype. Because the PathoGenetix 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 hospital and public health labs monitoring foodborne outbreaks.

Under a research plan outlined in the collaboration agreement, the FDA will evaluate the RESOLUTION instrument, reagents and database on a variety of food samples typically collected by the agency during routine food safety audits or foodborne disease outbreak investigations. The FDA will review and provide feedback to PathoGenetix on capabilities of the technology, including:

- Extraction and purification of high quality, high molecular weight bacterial DNA from complex mixtures such as enriched broths from food samples
- Subtyping of bacteria from complex samples without prior cultural isolation and preliminary characterization
- Processing of samples in 5 hours.

The research agreement also provides for FDA bacterial strains of public health interest, such as *Salmonella*, *E. coli* and *Listeria*, to be added to the RESOLUTION System database of pathogen "fingerprints." Integrated bioinformatics software in the RESOLUTION System generates and compares GSS fingerprints from the input sample to an onboard database of fingerprints of known pathogen strains.

The fully automated RESOLUTION Microbial Genotyping System, including instrument, bioinformatics software and database, and pathogen-specific assays, will be commercially available in Q4 2014 for use in both food industry testing and public health foodborne illness outbreak investigations. This month PathoGenetix also shipped a RESOLUTION System to Marshfield Food Safety, LLC, under an agreement with the Wisconsin-based microbiology- and chemistry-testing laboratory to conduct independent testing and feedback on use of the RESOLUTION System for pathogen confirmation and identification in food industry applications.

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 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 in 2014 for use in food safety testing and foodborne illness outbreak investigations. Learn more at www.pathogenetix.com.