

PathoGenetix and FDA to Evaluate Bacterial Identification System for Use in FDA Public Health and Food Safety Efforts

Collaborative research will assess the effectiveness of Genome Sequence Scanning™ (GSS™) technology in identifying pathogens involved in foodborne illness outbreaks, and shortening decision and response time in public health investigations.

WOBURN, MA (April 25, 2013) – PathoGenetix, Inc. has signed a collaborative agreement with the U.S. Food and Drug Administration (FDA) to evaluate the company’s proprietary bacterial identification technology for use in FDA foodborne illness outbreak investigation and response. The Genome Sequence Scanning™ (GSS™) system provides pathogen serotyping and strain typing, directly from complex mixtures such as enriched food and clinical samples, in just five hours.

Identifying the specific pathogen causing a foodborne illness outbreak is a critical step in defining the extent of the outbreak, determining the food involved, finding the source of the contamination and defining the scope of a product recall. The ability of GSS™ to derive useful data directly from a complex mixture and to shorten the time for pathogen subtyping, may allow for quicker decisions affecting public health.

“We are very pleased to collaborate with FDA to demonstrate the value of GSS™ in FDA efforts to ensure safe food and improve public health,” said PathoGenetix CEO Ann Merrifield. “Reducing the time involved in foodborne outbreak investigations means quicker response time, and that means fewer illnesses and deaths from contaminated food.”

The bacterial strain information provided by GSS™ is comparable to pulsed field gel electrophoresis (PFGE), the current gold standard for pathogen typing in foodborne illness outbreak investigation and response.

The increased automation in preparation, measurement and analysis in the GSS™ system has the potential to reduce the need for advanced laboratory and analysis skills in hospital and public health labs monitoring foodborne outbreaks, and in food industry labs conducting ongoing food safety testing and source tracking.

Other microbial identification systems like PFGE, and even new approaches such as whole genome sequencing (WGS), require a cultured isolate as input. Selecting and culturing a bacterial isolate is a complex and time-consuming process that requires experienced microbiology skills, expensive supplies, and multiple days to complete. The cultural independence of GSS™ eliminates the selection bias inherent in other molecular epidemiology tools. It also makes GSS™ compatible with newer pathogen detection methods increasingly used in clinical and food industry laboratories.

The collaboration will evaluate the GSS™ instrument, reagents and database on a variety of food samples typically collected by FDA during routine food safety audits or foodborne disease outbreak investigations. As a part of the collaboration, FDA bacterial strains of public health interest such as *Salmonella*, *E. coli* and *Listeria* will be added to the GSS™ pathogen database.

“The FDA is pleased to have the opportunity to evaluate this technology and its ability to complement our existing pathogen identification systems,” said Dr. Donald Zink, Senior Science Advisor at FDA’s Center for Food Safety and Applied Nutrition.

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