PATHOGENOMIX
› INFECTION INTELLIGENCE

Pathogenomix granted FDA Breakthrough Device Designation

Patho-Seq uses NGS to rapidly identify bacteria from human samples during dangerous and life-threatening infections

Santa Cruz, CA: January 19th 2022– Pathogenomix Inc., a Next Generation Sequencing, pathogen diagnostic company, announced that the US Food and Drug Administration (FDA) has granted it a Breakthrough Device Designation for its Patho-Seq assay.

Patho-Seq is designed for the rapid detection and identification of hundreds of clinically relevant bacteria for a broad list of clinical conditions and sample types, including sepsis from whole blood samples and bacterial meningitis from CSF. The FDA has granted Patho-Seq a Breakthrough Device Designation due to its significant advantages compared to current FDA-approved methods for the diagnosis of pathogenic bacteria in cases where infection may threaten life or long-term health.

"Perhaps the most important advantage of using Next Generation Sequencing for bacterial ID is its ability to rapidly detect any of hundreds of infectious bacteria from a single test run, without requiring a specific hypothesis from the clinician about what might be causing the infection. In the other diagnostics, in order to select the correct growth medium or NAAT, the clinician must have a strong hypothesis about which one of hundreds of potential pathogens may be infecting their patient. The same breadth also allows multiple bacterial ID's from polymicrobial samples in cases where more than one species may be contributing to the infection. In addition, if a sample is taken after the patient has been treated with antimicrobials then traditional culture for ID often delivers a false negative. Patho-Seq can identify all bacteria even if the sample was taken after the patient was treated," said Chris Risley, Executive Chairman of Pathogenomix, Inc.

Pathogenomix, Inc. collaborated with Mayo Clinic on the development of the techniques and data which supported the application for this FDA Breakthrough Device Designation.

The Patho-Seq test has the potential to significantly advance infectious disease treatment through its targeted 16S sequencing approach. 13.9% of all hospital admissions in 2018 were for infections with a likely bacterial organism.[i] A review of the leading cause of infectious disease admissions, sepsis, found that of the 2.5 million cases studied, the causative organism was never identified in over 70% of the cases[ii]. Sepsis alone was the cause for over 2 million hospital admissions and 200,000 deaths in 2018[iii], with a mean medical cost ranging from $16,324 - $38,298 per patient[iv].

Patients can develop systemic infections, like sepsis, from uncontrolled infections at many sites in the body, representing a massive variety in potentially causative organisms. Current FDA-approved methods don't address such a breadth of causes with a single test. Patho-Seq's approach answers this broad spectrum problem. As a rapid, hypothesis-free diagnostic that can detect any of hundreds of bacteria, Patho-Seq addresses the critical weaknesses of current FDA-approved methods for the diagnosis of inpatient bacterial infections. For many infectious organisms, the Patho-Seq test can return results more than 48 hours faster than the currently approved Standard of Care tests. Patho-Seq was granted Breakthrough Device Designation for the identification of infectious bacteria from sepsis and bacteremia, bacterial meningitis, joint and implant infections, and tick-borne bacterial infections. Pathogenomix's customers in research institutions use it for a much broader range of sample source sites in the body and for a much broader range of pathogen ID's.

Through the Breakthrough Device Program, FDA will provide Pathogenomix with continued guidance and accelerated review for its subsequent *De Novo* FDA approval process. When approved, FDA Breakthrough Designated Devices will also be eligible for new Center for Medicare and Medicaid Services (CMS) rules to incent the rapid adoption of Breakthrough-Designated Technologies at U.S. Hospitals.

Mayo Clinic has a financial interest in the technology referenced in this release. Mayo Clinic will use any revenue it receives to support its not-for-profit mission in patient care, education and research.

About Pathogenomix, Inc.:

Founded in 2016, Pathogenomix is a privately-held company providing SaaS online software tools and lab protocols for the rapid identification of pathogens via DNA/RNA sequencing of the pathogen's genome. Bringing a new approach to Pathogen ID,

Patho-Seq's technology incorporates the advantages of FDA-approved/cleared pathogen diagnostics, while bypassing their key limitations. Patho-Seq provides:

- More complete results than Traditional Culture and more complete results than Traditional Culture followed by LC/MS
- Results at least 48 hours faster for the many difficult to culture bacteria
- The ability to identify polymicrobial infections and to identify pathogens in the frequent case where the patient has already been treated by antimicrobials
- A broad hypothesis-free diagnostic which can identify any of thousands of pathogens from a single test. Clinicians using other pathogen diagnostics need a strong hypothesis in order to select the correct growth medium or NAAT to confirm that pathogen is in the sample.

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[i] 2018, Healthcare Cost and Utilization Survey

[ii] Paoli CJ, Reynolds MA, Sinha M, Gitlin M, Crouser E. Epidemiology and Costs of Sepsis in the United States-An Analysis Based on Timing of Diagnosis and Severity Level. *Crit Care Med*. 2018;46(12):1889-1897. doi:10.1097/CCM.0000000000003342

[iii] 2018, Healthcare Cost and Utilization Survey

[iv] Paoli CJ, Reynolds MA, Sinha M, Gitlin M, Crouser E. Epidemiology and Costs of Sepsis in the United States-An Analysis Based on Timing of Diagnosis and Severity Level. *Crit Care Med*. 2018;46(12):1889-1897. doi:10.1097/CCM.0000000000003342