Press release: GeneFluidics Announces CE-IVD Marking of UtiMax™ uropathogen identification (ID) and antimicrobial susceptibility testing (AST)

GeneFluidics, a molecular diagnostics company based in California and specializing in the development of diagnostics solutions for infectious diseases, today announced CE marking for UtiMax™ under the Directive 98/79/EC on *in vitro* diagnostic medical devices. The company's new urine-to-result test has successfully completed a multicenter validation study and clinical testing. UtiMax™ utilizes well-established electrochemical technology for rapid detection of species-specific 16S rRNA directly from viable causative pathogens in urine with a robotic lab automation system. In contrast to current routine practices, UtiMax™ does not require clinical isolates from urine cultures, enabling a streamlined ID-AST analysis directly from urine in one system, as well as a rapid ID reporting in as short as 30 minutes and AST in 120 minutes for a positive ID result. **Note**

A compact platform capable of rapid pathogen ID and AST directly from patients' samples can provide clinicians and healthcare providers with evidenced-based information to start patient-specific antimicrobial treatment only when necessary. UtiMax™ has been validated with clinical patient samples and thousands of spiked samples in a multicenter validation study and clinical testing. The study was performed at the Clinical Microbiology Laboratory of Children's Hospital Los Angeles in Los Angeles, California, and GeneFluidics' GLP laboratory. The results showed an overall sensitivity of 100.0% and specificity of 98.2%, and 100% AST categorical agreement (CA). "With this CE marking, GeneFluidics will scale up the clinical testing for our first of a pipeline of FDA 510(k) submissions." stated Vincent Gau, Ph.D., GeneFluidics's President. "We also would like to acknowledge the strong support from the National Institute of Allergy and Infectious Diseases (NIAID) at National Institute of Health (NIH), which made the successful implementation of this innovative platform technology possible."

About pathogen ID and AST

The absence of definitive microbiological diagnosis at point of care has largely driven excess and misuse of antibiotics. Standard culture-based diagnosis of bacterial infections, including pathogen identification (ID) and antimicrobial susceptibility testing (AST), requires two to three days from clinical sample acquisition to result reporting. Standard automated platforms are time consuming, due to the need of a priori isolation of the pathogens from the samples prior to AST with overnight culture.

About UtiMax™ Lab Automation System

The UtiMax Lab Automation System is a fully automated rapid diagnostic system for the identification of uropathogens directly from urine samples. Identification (ID) and antimicrobial susceptibility testing (AST) are performed by the UtiMax™ Lab Automation System with the reagent kit and disposable sensor array chip. UtiMax ID/AST is an electrochemical-based sandwich hybridization test to quantify species-specific ribosomal 16S ribosomal RNA (rRNA). Each sample is lysed chemically prior to hybridization at high stringency. A built-in multi-channel potentiostat reads the electrical current from the steady-state enzymatic cycling amplification: signal is proportional to the bound 16S rRNA content from lysate and reported in ranges of colony forming units (CFU) per milliliter through an established calibration curve.

About GeneFluidics

GeneFluidics was incorporated in 2000 to develop a fast, accurate, and simple testing system for improving worldwide healthcare. By integrating novel molecular analysis and lab automation technologies, the company's revolutionary platform enables complex tests that are normally performed only by skilled technicians in a laboratory to be performed by anyone, anywhere. GeneFluidics is committed to improving the quality of human life with advanced engineering and molecular analysis technologies.

Note: Total assay time for ID assay with a limit of detection (LOD) of 1E5 CFU/mL is 30 minutes, and for the LOD of 1E4 CFU/mL is 45 minutes.