Genefluidics

Rapid, Evidence-based pathogen ID and AST Directly from Patient's Specimens

The emergence and rapid spread of resistant bacteria has become a serious public health concern worldwide. Delayed antimicrobial therapy significantly increases mortality in high-risk infections with a particularly strong association with septic shock. Therefore, antimicrobial agents are often injudiciously used without any evidence-based microbiological confirmation. Antibiotic consumption is strongly linked to the emergence and dissemination of antibiotic-resistant bacteria strains in several epidemiological studies. According to CDC's recent publication, an estimated 30% of outpatient oral antibiotic prescriptions may have been inappropriate, and up to 70% of the "appropriate" prescriptions still require improvements in selection, dosage and duration to delay the development of antibiotic-resistant bacteria. The vast majority of antibiotic prescriptions are made by physicians outside the hospital setting without the use of a sophisticated diagnostic device. *A compact and rapid pathogen identification (ID) and antimicrobial susceptibility testing (AST) can address both the unnecessary use and overuse of antibiotics, and therefore effectively reduce antibiotic microbial resistance.* Our overall goal is to deliver a molecular diagnostic platform that is *capable of* ***rapid diagnosis of common bacterial infections in as short as 30 minutes*** *and profiling their* ***antibiotic resistance in as short as 90 minutes***. Our product will lead to more rational use of antibiotics and will reduce the development and spread of multidrug-resistant pathogens. Our goal is to obtain the first FDA clearance of UtiMax, a rapid urinary tract infection ID/AST test currently in the pilot production stage, through a FDA *de novo* submission. A follow-up product line, BsiMax (with additional feature of lysis centrifugation), can process whole blood samples for bloodstream infections with a ***limit of detection (LOD) < 10 CFU/mL***. Both UtiMax and BsiMax can be performed by Proteus, our robotic liquid handling system, with appropriate reagent kits and sensor chips.