Ovagene

Ovagene's in vitro Diagnostic Multiple Drug Resistant (MDR) Device

Antimicrobial Resistance (AMR) has become a global healthcare crisis. Urinary tract infections (UTIs) have contributed significantly to the problem with the frequent empiric prescribing of broad-spectrum antibiotics that are often ineffective or incorrectly selected on the basis of clinical bias. Over 150 million UTIs are thought to occur globally each year and about 8 million UTIs occur in the US yearly, of which an estimated 10% or 800,000 are antibiotic resistant. Many of these arise in clinical 1 settings deemed "complicated" such as in elderly and immunosuppressed patients or those having co-morbid conditions such as indwelling catheters, anatomic abnormalities, diabetes or neurogenic bladders. Such complicated UTIs are often polymicrobial and a potential source of sepsis with increased morbidity and mortality. New Molecular Point of Care test devices will provide guidance to Antimicrobial Stewardship programs to improve therapy selection, patient outcomes and cost efficiency, especially UTIs involving antibiotic resistant bacteria recognized by the CDC as urgent and serious antibiotic-resistant threats.2 OvaGene's objective is to expand our in vitro diagnostic platform menu to include the detection of nucleic acids from antimicrobial resistant bacteria that cause health-care associated and community-acquired urinary tract infections. That entails clinical validation of identified markers, FDA authorization, and commercialization of our rapid diagnostic and CLIA waivable tests. The intended use of our in vitro diagnostic Multiple Drug Resistant (MDR) device is to diagnose urinary tract antimicrobial resistance at the point of need in less that 30 minutes.