<u>Guanine</u> CTX-M Guanine-Amplified Immunoassay for POC

Extended spectrum β -lactamases (ESBL)-producing *Enterobacteriaceae* (EPE) pose a serious threat to public health. These organisms cause infections that are associated with high mortality rates, have the potential to spread widely, and are resistant to multiple antimicrobial agents leaving few treatment options for infected patients. Unfortunately, the laboratory detection of ESBLs can be complex and, at times, misleading. Antibacterial choice is often complicated by multi-resistance. This has resulted in healthcare-associated outbreaks which extend hospital stays and greatly increase healthcare costs, particularly for immunocompromised patients. Much of the increase in EPE has been due to the spread of *E. coli* producing CTX-M type in the urinary tract, blood stream and central nervous system. The proposed in vitro diagnostics is an extremely sensitive POC immunoassay that quantifies low levels of CTX-M enzymes. Not only will the test confirm that a particular EPE is present, viable and resistant to a cefotaxime by producing CTX-M enzymes, it will also provide a quantitative CTX-M concentration. This concentration will provide medical professionals with unique insight to treatment options using a more simple and useful clinical breakpoint that is applicable to localized treatment decisions.