Evaluation of the Verigene EP IUO Test for the Rapid Detection of Bacterial and Viral Causes of Gastrointestinal Infection

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Abstract

Objectives: We evaluated the performance of the Verigene EP IUO test for the rapid detection of bacterial (Salmonella, Shigella, E. coli O157:H7, and Campylobacter jejuni) and viral (Norovirus, Rotavirus, and Adenovirus) pathogens in stools from patients presenting to a community-based emergency department.

Methods: Prospective clinical specimens were collected from patients presenting to the emergency department at a single academic hospital and tested with and without enrichment. Results were compared with reference tests and evaluated for specificity and sensitivity. Results were also evaluated for discrepant testing and for the presence of false-negative results.

Results: Of 611 prospectively collected clinical specimens, 228 were positive for viral pathogens, 228 were positive for bacterial pathogens, and 155 were negative by both. The Verigene EP IUO test had a sensitivity of 99.8% for viral pathogens and 99.5% for bacterial pathogens.

Conclusions: The Verigene EP IUO test is highly sensitive and specific for the rapid detection of bacterial and viral gastrointestinal pathogens in stools collected from patients presenting to an emergency department.

Background

Acute Gastroenteritis is caused by both bacterial and viral etiologies. According to the CDC website, each year roughly 46 million people get sick, 128,000 are hospitalized, and $1.5 billion of lost productivity. The bacterial etiology of acute gastroenteritis is one of the most common reasons for testing in the clinical microbiology laboratory, with the majority of culture-negative stools. Viral etiologies account for the remaining 30% of cases. The Verigene EP IUO test is a rapid and sensitive method for detecting bacterial and viral pathogens in stools collected from patients presenting to an emergency department.

Methods

Prospective specimens: Specimens were collected from patients presenting to the emergency department at a single academic hospital and tested with and without enrichment. Results were compared with reference tests and evaluated for specificity and sensitivity. Results were also evaluated for discrepant testing and for the presence of false-negative results.

Prospective specimens: Specimens meeting institutional criteria for stool pathogen testing were analyzed by the Verigene EP IUO test and a reference laboratory. Specimens were tested using both the Verigene EP IUO test and a reference laboratory. Reference Laboratories between July 2012 and December 2014. Fresh stool was collected in Cary-Blair transport media (n=404) or collected in stool transport media (n=107) and stored at 4°C in the laboratory. The WHO guidelines for the selection of specimens were followed.

Results

The Verigene EP IUO test had a sensitivity of 99.8% for viral pathogens and 99.5% for bacterial pathogens. The test was able to detect all known viral and bacterial pathogens, and there were no false-negative results.

Conclusions

The Verigene EP IUO test is highly sensitive and specific for the rapid detection of bacterial and viral gastrointestinal pathogens in stools collected from patients presenting to an emergency department.