Title:	Evaluation of the Verigene® EP IUO test for the rapid detection of bacterial and toxin causes of gastrointestinal infection
Speaker:	Susan Novak-Weekley
Author(s):	Novak-Weekley S.; Marlowe E.M.
Affiliation(s):	Microbiology, Kaiser Permanente (North Hollywood (CA), USA)
Date	Sunday - May 11, 2014 13:30

Objectives:

Gastroenteritis can be caused by a number of different bacteria, viruses, and parasites. Gastroenteritis is typically mild in presentation with symptoms that are self-resolving in immunocompetent individuals. While these infections are rarely the cause of severe morbidity and mortality in developed countries, severe infections requiring treatment can occur in the very young, the elderly, and the immunocompromised. Conventional diagnostics for gastrointestinal pathogens include culture, ova and parasite exams, and antigen detection tests. These methods, however, are associated with long turnaround times, require extensive hands-on time, and may have poor sensitivity. With upwards of 95% of stool specimens negative for any gastrointestinal pathogen, these conventional diagnostic tests are not an ideal use of technologist time in the laboratory. New molecular-based methods for the detection of the bacterial causes of gastroenteritis can provide timely and accurate diagnosis of gastroenteritis, minimizing the medical technologist time required in the workup of both positive and negative stool specimens. We evaluated the performance of the sample-to-result Verigene Enteric Pathogens Nucleic Acid (EP) IUO Test for the detection of common bacterial (Salmonella spp., Shigella spp., Campylobacter, Vibrio spp., Yersinia enterocolitica) and toxin (stx1, stx2) causes of gastroenteritis directly from stool preserved in Cary-Blair media.

Methods:

A total of 725 stool specimens were analyzed using the Verigene EP Test. This included 541 prospectively collected clinical specimens and 184 contrived specimens. Results of the Verigene EP Test were compared to the gold standard method, which consisted of selective media culture and Vitek2 and/or Phoenix for bacterial identification. Prospective clinical specimens were preserved in Cary-Blair media within 4 hours of collection and were tested on the Verigene EP Test within 48 hours of collection and with bacterial culture within 60 hours of collection.

Results:

Total agreement between the Verigene EP Test and culture for each of the bacterial analytes and Shiga toxin genetic virulence markers was greater than 98.5%. The initial call rate for the Verigene EP Test was 95.7%. Upon repeat testing, the final call rate was 98.5%. The Verigene EP Test had an error rate (inability to process assay to completion) of 1.3%. Results of the Verigene EP Test were available within 2.0 hours of test initiation.

Conclusions:

Appropriate management of gastroenteritis is complicated by the increasing number of resistant bacterial isolates and the risk of worsened illness (STEC). Rapid diagnostic tests that accurately detect the bacterial and toxin-related cause of gastroenteritis can potentially improve patient management decisions to avoid unnecessary or inappropriate treatment. These tests can also optimize technologist time by reducing the time required to work up both negative and positive stool specimens. The Verigene EP Test is a viable diagnostic test with these capabilities.

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