P0858
Poster Session III
Molecular diagnosis of gastrointestinal bacterial infections

A MULTICENTER EVALUATION OF THE BD MAX ENTERIC BACTERIAL PANEL FOR THE DETECTION OF SALMONELLA SPP., SHIGELLA SPP., CAMPYLOBACTER SPP., AND SHIGA-TOXIN-PRODUCING ESCHERICHIA COLI

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Objective: According to the World Health Organization, diarrheal disease is the third leading cause of death due to an infectious disease in the world and will cause an estimated 1.5 million deaths in children under the age of 5 this year. Traditional methods for the detection of bacterial enteric pathogens are time-consuming, require bacterial growth and phenotypic expression, and require well-trained technologists. This study evaluated the Enteric Bacterial Panel (EBP), a nucleic acid amplification based assay for the detection of *Salmonella* spp., *Shigella* spp., *Campylobacter* spp. (*C. jejuni* and *C. coli*), and Shiga-like toxin genes (*stx1* and/or *stx2*) in stool specimens. The EBP is run on the BD MAX system, a robotic system designed to automate sample preparation, extraction, amplification and result analysis. Methods: The study included prospective and retrospective (frozen) samples. Samples were evaluated using standard culture methods coupled with a commercial immunoassay (Meridian Bioscience) for shiga-toxins 1 and 2. Alternate target PCR and bi-directional sequencing were used as the confirmatory discrepant method for the prospective samples and to confirm the historical reference results for the retrospective samples. The Positive Percent Agreement (PPA) and Negative Percent Agreements (NPA) were calculated for the EBP compared to conventional methods, with alternate target PCR and bi-directional sequencing, for all samples (prospective and retrospective). Results: A total of 4,242 samples (3,457 prospective, 785 retrospective) were obtained from 13 medical centers, collection centers and reference laboratories (USA, Canada and Mexico). The combined prevalence in the prospective samples as defined by the standard culture methods was: *Salmonella*, 1.2%; *Shigella*, 0.8%; *Campylobacter*, 1.5%; Shiga toxin 0.4%. PPA (n) and NPA (n) for all samples were as follows: *Salmonella*, 99.5% (219), 99.8% (3312); *Shigella*, 99.2% (124), 100% (3340); *Campylobacter*, 98.0% (195), 99.0% (3170); Shiga toxin 100% (83), 99.7% (2439). Conclusion: In this large, multicenter study, the BD MAX EBP showed a very high correlation to the conventional and molecular methods for the detection of *Salmonella* spp., *Shigella* spp., *Campylobacter* spp. and Shiga-toxin-producing *E. coli* in stool specimens of patients with acute bacterial diarrheal disease.