EV0825

ePoster Viewing

Molecular bacteriology

"Evaluation of stool specimens with the cobas® Cdiff test for the detection of *Clostridium difficile* toxin B compared with direct toxigenic culture"

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Objectives: Nucleic acid amplification tests have proven to be reliable, sensitive tools for the detection of *Clostridium difficile* from stool samples. *C difficile* is an anaerobic, toxin producing microorganism known to cause severe diarrhea following antibiotic therapy. The objective of this study was to evaluate performance characteristics of the newly developed **cobas**® Cdiff Test using prospectively collected stool specimens from patients representative of the United States as part of a large, multicenter clinical trial.

Methods: Patients suspected of *C. difficile*-associated disease were selected for participation. Specimens were collected at 5 geographically diverse sites across the US. An aliquot of stool from each patient was sent to a reference lab for direct toxigenic culture and one aliquot was evaluated with the **cobas**® Cdiff Test at 1 of 3 designated sites. Stool specimen was transferred with a polyester swab into cobas PCR media, then loaded directly on the automated cobas® 4800 system for processing, PCR setup, amplification and detection. The positive percent agreement (PPA), negative percent agreement (NPA) and overall percent agreement (OPA) values were calculated by comparing **cobas**® Cdiff Test results with direct toxigenic culture. Discrepant analysis was performed on all samples with discordant results, using a second direct toxigenic culture plus enriched toxigenic culture and the Xpert® *C difficile* Epi Test for *C. difficile*.

Results: Specimens were collected from 683 subjects: 306 males (44.8%) and 377 females (55.2%) with a mean age of 56 years (range 3 to 99). Direct toxigenic culture identified 113 positive samples with *C. difficile* . The PPA, NPA and OPA of the **cobas**® Cdiff Test was 97.3% (110/113; 95% CI = 92.5% to 99.1%), 94.9% (541/570; 95% CI = 92.8% to 96.4%) and 95.3% (651/683; 95% CI = 93.5% to 96.7%). The prevalence of *C. difficile* observed in the study population was 16.5%. Of the 3 specimens with false negative **cobas**® Cdiff Test results, 1 was *C. difficile* negative by a second direct toxigenic culture plus enriched toxigenic culture and the Xpert® *C difficile* Epi Test. Of the 29 specimens with false positive **cobas**® Cdiff Test results relative to direct toxigenic culture, 24 were *C. difficile* positive by a second toxigenic culture and/or NAAT (9 by culture only, 12 by culture and NAAT, and 3 by NAAT only).

Conclusion: The results show the **cobas**® Cdiff Test, performed on the automated **cobas**® 4800 system, displayed excellent performance compared to direct toxigenic culture when evaluating 683 clinical specimens for the presence of toxigenic *C. difficile*.