P0819
Poster Session III
New developments in molecular diagnosis of C. difficile

PERFORMANCE CHARACTERISTICS THE COBAS® CDIFF TEST, A FULLY-AUTOMATED ASSAY ON THE COBAS® 4800 SYSTEM TO DETECT CLOSTRIDIUM DIFFICILE IN CLINICAL STOOL SPECIMENS

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Objectives: *Clostridium difficile* is an anaerobic, toxin producing microorganism known to cause severe diarrhea following antibiotic therapy. Nucleic acid amplification tests provide sensitive and timely identification of patients with *C. difficile* infection (CDI).This study was conducted to evaluate performance characteristics of the newly developed **cobas®** Cdiff Test using retrospectively collected stool specimens. Performance against Meridian Premier Tox A+B EIA, GDH EIA and toxigenic culture was evaluated.

Methods: Polyester swabs were used to transfer previously evaluated stool specimens into sample vials that were loaded directly on the automated Roche **cobas®** 4800 system for processing, PCR setup, amplification and detection. Specimens were previously tested using Meridian Premier Tox A+B/GDH assays according to the manufacturer's instructions. Toxigenic culture was performed by isolation of *C. difficile* (anaerobic spore culture after alcohol shock on Brazier's Medium / fastidious anaerobe agar) DNA extraction using Chelex®100 and PCR testing to detect the pathogenicity locus (Persson *et al*, 2008. Clin Microbiol Infect 14:1057–1064). All testing was performed in a CPA-UK Accredited laboratory.

Results: The **cobas®** Cdiff Test showed a sensitivity and specificity of 93.9% and 92.7% when compared to toxigenic culture, evaluating 186 total samples. Of the 62 samples determined positive by both Meridian Premier GDH and Tox A+B testing, the **cobas®** Cdiff Test detected 61 samples. Fifty samples were negative by GDH, Toxin A+B, and PCR. Tox A+B testing was negative for 67 specimens that were positive by both Meridian Premier GDH and the **cobas®** Cdiff Test. Two specimens were positive by Toxin A+B EIA alone. One specimen was positive by Toxin A+B EIA and the **cobas®** Cdiff Test.

Conclusion: The **cobas®** Cdiff Test, run on the fully automated cobas® 4800 system, demonstrated excellent performance for detecting toxigenic strains of *C. difficile* in unformed stool specimens when compared to toxigenic culture. Relatively poor performance of Toxin A+B EIA tests makes them unreliable for use as single tests for diagnosis of CDI. Two or three step algorithms incorporating GDH and/or molecular tests are increasingly used to address this problem. A 'PCR first' algorithm using the cobas® Cdiff Test evaluated here would avoid discrepant (GDH-positive, Toxin-negative) results from algorithms using GDH tests.