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Poster Session III

New developments in molecular diagnosis of *C. difficile*

TOXIGENIC CLOSTRIDIUM DIFFICILE DETECTION WITH THE COBAS® CDIFF TEST ON THE COBAS® 4800 SYSTEM FROM STOOL SPECIMENS OF PATIENTS FROM HVIDOVRE DENMARK AND REGENSBURG GERMANY

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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 representative of patients from Hvidovre and Regensburg.

Methods: Patients suspected of *Clostridium difficile* associated disease were selected for participation in the study. Stool specimens were transferred with a polyester swabs into sample vials that were loaded directly on the automated **cobas**® 4800 system for processing, PCR setup, amplification and detection. An aliquot of the fresh stool specimen was evaluated by a comparator molecular method, the Xpert® *C. difficile* Test and direct culture for *C. difficile*.

Results: The **cobas**® Cdiff Test showed a sensitivity and specificity of 92.3% and 95.2% when compared to direct culture, evaluating 226 total samples from Hvidovre and Regensburg. The sensitivity and specificity of the Xpert® *C. difficile* Test compared to direct culture was 89.7% and 95.7%. Comparison between the two molecular methods showed a positive and negative percent agreement of 90.7% and 96.7%, respectively. The frequency of samples requiring repeat testing (invalid, error, no result, failed) was 3.5 fold lower with **cobas**® Cdiff Test than the Xpert® *C. difficile* Test (0.76% compared to 2.65%).

Conclusion: The **cobas**® Cdiff Test, run on the automated **cobas**® 4800 system, displayed excellent performance when compared with a direct culture for *C. difficile* and a comparator molecular method.