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

COMPARISON OF COMMERCIALLY AVAILABLE REAL-TIME PCR TEST SYSTEMS FOR THE DIAGNOSIS OF CLOSTRIDIUM DIFFICILE INFECTIONS

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Objectives:

Comparative evaluation of different molecular real time (RT-) PCR based assays targeting the tcdA and tcdB gene of Clostridium difficile (CD).

Methods:

139 fresh stool samples were used for the comparative evaluation of different methods for the detection of toxigenic C. difficile: the Real-Time-PCR assays RealStar® Clostridium difficile PCR Kit (Altona Diagnostics, Hamburg, Germany) and the IMDx C. difficile (Abbott Molecular, Illionis; USA). 40 of the samples were also tested using the C. difficile ELITe MGB® PCR Kit (ELITech, Berkhamsted, United Kingdom). All samples were also analyzed by the LIAISON® C. difficile GDH chemiluminescent assay (CLIA) (Diasorin, Saluggia, Italy), followed by the LIAISON® C. difficile Toxin A and B CLIA (Diasorin).

Results:

117/139 (84.2%) samples tested positive for GDH chemiluminescent assay. 64 (54.7%) of the 117 GDH-positive samples were positive for C. difficile Toxin A and B CLIA. Of the 139 samples tested 96 (69.1%) and 97 (69.8%) were positive when analyzed either by the RealStar® Clostridium difficile PCR or IMDx C. difficile test systems, indicating a higher specificity of the Real-Time-PCR as a screening test. Of the 64 samples which tested positive with the C. difficile Toxin A and B CLIA 60 (93.8%) and 63 (98.9%) were positive when analyzed by RealStar® Clostridium difficile and the IMDx C. difficile PCR assay respectively. Of the 53 samples which were positive with the GDH but negative with the Toxin A and B CLIA 14 (26.4%) and 15 (28.3%) were positive by the two PCR test systems.

The Real-Time PCR results of all three different suppliers gave a 95% (38/40) concordance.

Conclusions:

Current diagnostic algorithms for the diagnosis of CD infections recommend the combination of the GDH chemiluminescent assay as a screening test and the testing of GDH-positive cases for C. difficile Toxin A and B. Our data challenge this approach and indicate a higher specificity of the PCR-tests to screen for and detect clinically relevant CD-infections. The IMDx C. difficile Kit seemed to be slightly more sensitive in the detection of tcdA then the RealStar® Clostridium difficile PCR Kit. The C. difficile ELITe MGB® PCR Kit needs further testing.