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Abstract (publication only)

**Comparison of four commercial molecular methods for the diagnosis of Clostridium difficile infection**

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Objectives: Clostridium difficile infection (CDI) is the major cause of health care-associated diarrhoea. Rapid and accurate microbiological diagnosis of CDI is urgently needed. Toxigenic C. difficile detection by the cell culture neutralization assay (CCNA) is considered to be the gold standard. However, this procedure is time and labour intensive. The purpose of the present study was to compare four different commercial molecular methods (Cepheid XpertTM C. difficile assay, Illumigene C. difficile test, RIDA®GENE method and Duplica alpha) using the CCNA as the reference method. Methods: The Cepheid method was tested with 220 faecal samples. The Illumigene with 263, the RIDA®GENE as well as the Duplica alpha with 181 samples each. In all investigations consecutive, non-repetitive fresh unformed stool specimens from patients older than 2 years of age were analysed. All four methods were compared with the standard laboratory diagnosis method i.e. CCNA and culture. Results: In a comparison with the CCNA reference method the sensitivities ranged from 90 to 97% and specificities from 93 to 99%. The methods except Illumigene are based on RT-PCR. The Illumigene uses a Loop-mediated isothermal amplification (LAMP) technology. The major difference between the methods was the pre-analyses time and the reaction time. The fastest method was that from Cepheid. In average it took 65 min from the arrival of the sample until the final result. For the Illumigene method, the corresponding time was 75 min. Both the RIDA®GENE as well as the Duplica alpha methods the overall time was 2.5 h. The tested methods, except Cepheid, were run in batches. The Cepheid method has been run continuously since every sample could be run independently of each other. The Cepheid method targets the genes for the toxin B, the binary toxin as well as the deletion in the regulatory TcdC gene. The Illumigene targets a conservative region in the toxin A gene. The RIDA®GENE targets both the toxin A and toxin B genes and the Duplica alpha targets the toxin B gene. Conclusion: The four methods have high sensitivities and specificities. The methods except the Cepheid XpertTM C. difficile assay, required a separate step of DNA extraction and were run in batches. The Cepheid method has the fastest turn around time of 65 min followed by Illumigene (75 min). With the Cepheid Xpert TM C. difficile assay it is possible to run each sample independently.