EVALUATION OF A NEW RANDOM-ACCESS ANTIGEN TEST FOR THE DETECTION OF *Clostridium difficile*

Savolainen Roosa[1], Koskinen Juha M.[2], Koskinen Janne O.[2], Kaukoranta Suvi-Sirkku[1]

[1]Department of Clinical Microbiology, Vaasa Central Hospital, Vaasa, Finland
[2]ArcDia International Ltd, Turku, Finland

Background

mariPOC® (ArcDia Int. Ltd, Finland) is an automated IVD CE marked point-of-care compatible platform for rapid multianalyte testing of infectious diseases. The objective of this study was to evaluate the new automated random-access antigen detection test, mariPOC® CDI, for the detection of *Clostridium difficile* GDH and toxins A and B directly from faecal specimens. mariPOC® was prospectively compared with the routinely used PCR method GenomEra® *C. difficile* (Abacus Diagnostica Ltd, Finland) and with the TECHLAB® C. diff Quik Chek Complete™ (Alere Inc., USA) membrane enzyme immunoassay (MEIA).

Methods

The study was performed in Vaasa Central Hospital in Finland during May to September 2017. Leftover native faecal specimens routinely tested for *C. difficile* toxin B gene by PCR were used. In total, 337 specimens were tested with both mariPOC® CDI and PCR. All specimens positive with either the mariPOC® CDI or the toxin PCR test were further tested with the membrane enzyme immunoassay. In addition, 110 randomly selected negative specimens were also tested. True positive was defined as a specimen positive with at least two methods. Cultures on Brazier's CCEY agar plates were made for discrepant specimens stored at -70 °C.

Results

In total, 157 specimens were tested with all of the three methods. The results are summarized in **Table 1.** There were two specimens positive with only PCR that were not confirmed with another method and are not included in the results.

Discussion

Cultures from frozen faecal samples can be unreliable and therefore negative culture results cannot rule out true positivity in our study. However, culture positive result confirmed true positivity.
The two specimens positive with only PCR will be tested with another PCR method.

The similar negative predictive values and identical specificities with the PCR in this study suggest that mariPOC® could also be used as a primary screening tool of toxigenic *C. difficile* from faecal specimens. The random-access analysis of samples and automated result interpretation are advantages compared to other antigen detection methods.

Table 1. The sensitivities, specificities and positive and negative predictive values of the three tests in this study.

	GDH		**Toxin A/B**		**Toxin B gene**
	mariPOC®	MEIA	mariPOC®	MEIA	PCR
Sensitivity	**95.2 %** (40/42)	**100.0 %** (42/42)	**83.8 %** (31/37)	**73.0 %** (27/37)	**97.3 %** (36/37)
Specificity	**95.6 %** (108/113)	**100.0 %** (113/113)	**100.0 %** (298/298)	**99.2 %** (117/118)	**100.0 %** (298/298)
PPV	**88.9 %** (40/45)	**100.0 %** (42/42)	**100.0 %** (31/31)	**96.4 %** (27/28)	**100.0 %** (36/36)
NPV	**98.1 %** (108/110)	**100.0 %** (113/113)	**98.0 %** (298/304)	**92.1 %** (117/127)	**99.7 %** (298/299)