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POINT-OF-CARE TESTING FOR THE DETECTION OF *CLOSTRIDIUM DIFFICILE*: DOES SPEED COMPROMISE ANALYTICAL PERFORMANCE?

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Introduction and purpose

Rapid diagnosis of *Clostridium difficile*, which is a frequent cause of nosocomial diarrhoea, is highly desirable.

A new automated, qualitative point-of-care test (POCT), the cobas® Cdiff Nucleic acid test (Roche) for use on the cobas® Liat® System, uses real-time polymerase chain reaction for the detection of the toxin B (*tcdB*) gene of toxigenic *C. difficile*.

The results were compared with those of two Loop mediated isothermal amplification (LAMP) rapid tests (illumigene®-Meridian Bioscience and eazyplex®-Amplex) which can only be performed in a laboratory setting.

Material and Methods (1)

- 17 frozen and 30 fresh unformed stool specimens were analysed following the manufacturer's instructions.
- For the cobas® Cdiff test a swab was taken from the sample and resuspended in FecalSwab™ medium (Copan).
- On all samples a rapid antigen test was performed (C. Diff Quik Chek Complete®-Techlab® Alere).
- To check the reproducibility of the cobas® Liat® system one weak positive sample was analysed during three days.

Fig 1 Workflow:

A) Fecal swab medium is added to the assay tube using the transfer pipette.
B) Assay tube is scanned.
C) Assay tube is placed in the cobas® Liat ® System.

Material and Methods (2)

	 cobas® Liat®	 illumigene® illumipro-10™	 eazyplex® Genie® II
Turnaround time for 1 sample	20 min	55 min	30 min
Turnaround time for 5 samples	100 min	70 min	90 min
Target	*tcdB*	*tcdA, tcdB*	GDH, *tcdA, tcdB,* Binary toxin
Size (L x W x H)	24 x 11 x 19 cm	21 x 29 x 10 cm	30 x 2 1x 20 cm

Results (1)

Comparison of cobas® Cdiff and illumigene®

The total agreement was 88,9%.The positive and negative agreement was 90,9% and 88,2% respectively. The Cohen's Kappa was 72,5% (49,7-95,2%).

	illumigene® positive	illumigene® negative	Total
Liat® positive	10	4	14
Liat® negative	1	30	31
Total	11	34	45*

** Two samples were excluded due to inhibition, no sample was inhibited on the cobas® Liat® System.*

Comparison of cobas® Cdiff and eazyplex®

The total agreement was 84,1%.The positive and negative agreement was 100% and 81,1% respectively. The Cohen's Kappa was 57,7% (29-86,4%).

	eazyplex® positive	eazyplex® negative	Total
Liat® positive	7	7	14
Liat® negative	0	30	30
Total	7	37	44*

** Three samples were excluded due to inhibition, no sample was inhibited on the cobas® Liat® System.*

Results (2)

Sensitivity and specificity

Compared with the gold standard (antigen test combined with culture or minimum two out of three same results for *C. difficile* DNA detection) the sensitivity was 100% and the specificity was 91,4%.

Reproducibility

One weak positive sample gave the same result on all three days.

Conclusions

The agreement between illumigene® and cobas® Cdiff is higher than the agreement between eazyplex® and cobas® Cdiff.

The cobas® Cdiff test is very easy to perform with almost no hands on time (less than 1 minute). The high speed of the results does not compromise the analytical performance.

The cobas® Liat® System can easily be used as a POCT system and is not suitable for a high throughput laboratory as the test is performed one by one. The possibility to perform rapid molecular diagnostics bedside testing will have an improved impact on clinical decision making.

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