Comparison of illumigene® C. difficile Assay and Portrait Toxigenic C. difficile Assay for the Detection of Toxigenic Clostridium difficile in Pediatric Patients

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ABSTRACT (Revised)

Background: Clostridium difficile (C. difficile) is the causative agent of a spectrum of clinical manifestations ranging from mild diarrhea to severe diarrhea, colitis, and death. Accurate detection is imperative for disease management and control with molecular detection being well accepted as the diagnostic standard. We sought to compare the performance of two molecular assays, illumigene® C. difficile (Meridian Diagnostics, Cincinnati, OH, USA) and Portrait Toxigenic C. difficile (Great Basin Corporation) for detection of C. difficile in stool samples. In addition, we investigated the workflow capabilities of the two assays in the microbiology laboratory.

Methods: Both molecular assays were performed on 103 liquid or semi-formed stool specimens collected from pediatric patients within 24 hours of receipt. The assay was batched once daily and performed by Clinical Laboratory Scientist (CLS). In contrast, up to two stools were tested at a time using Portrait Toxigenic C. difficile bench top analyzers were available; Clinical Laboratory Technician (CLT) primarily performed all testing for this assay. illumigene® C. difficile was considered the reference method and all discrepant and invalid results were repeated.

Results: When comparing Portrait Toxigenic C. difficile with illumigene® C. difficile, 32 and 29 positives were identified respectively. Both assays correctly identified 28 positives cases; Portrait Toxigenic C. difficile detected 2 more positives and missed 1 positive. Overall sensitivity, specificity, and concordance of Portrait Toxigenic C. difficile were 98.5%, 97.0%, and 96.8%, respectively. The positive predictive value was 98.5% and the negative predictive value was 93.3%.

DISCUSSION

Portraying a significant decline in hospital-acquired infections (CAIs) and death with an annual rate of 5.9% in CAIs, and with the rise in antibiotic resistance, the importance of the tools to detect C. difficile is crucial in order to afford the appropriate therapy. The national rate of CAI per year is 600,000, with up to 30,000 deaths and with the implementation of C. difficile, a 5.9% decline in death is expected to be seen. Our study has demonstrated a 5.9% decline in death, which aligns with previous studies.

RESULTS

Based on illumigene® C. difficile results, a total of 29 positive, 66 negative and 8 indeterminant results were included in the study.

The Portrait Toxigenic® C. difficile assay correctly identified 28/28 positive specimens. An additional 1 true positive was identified but was not detected by illumigene® C. difficile.

In our study, 2 additional positives were detected by Portrait Toxigenic® C. difficile that was reported as negative by illumigene® C. difficile.

2 indeterminant specimens were reported with Portrait Toxigenic® C. difficile. 1 concurred with illumigene® C. difficile and second specimen was called negative by illumigene® C. difficile.

Of the 7 additional specimens that were called indeterminant by illumigene® C. difficile but resolved by Portrait Toxigenic® C. difficile, 3 were negative and 4 were positive (total of 4 new positive cases).

With regards to workflow, illumigene® C. difficile is batched in the CLT, yielding an average turnaround time (TAT) of 15 hours. In contrast, Portrait Toxigenic® C. difficile is semi-automated and tested on arrival by the CLT, significantly decreasing the TAT to about 2.5 hours.

CONCLUSIONS

The performance characteristics of Portrait Toxigenic® C. difficile are comparable to illumigene® C. difficile and is an appropriate option for the diagnosis of C. difficile infection. In addition, a lower number of specimen need to be detected using Portrait Toxigenic® C. difficile, decreasing the need for repeat testing. The semi-automated and sample-in-capacity of Portrait Toxigenic® C. difficile allows the true ‘stat’ testing of C. difficile in the microbiology laboratory, allowing for prompt therapeutic response and infection control.

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METHODS

- A total of 103 liquid or semi-formed clinical stool specimens collected from pediatric patients suspected of having C. difficile were tested by both methods.

- Stools specimens were tested daily by illumigene® C. difficile, as per the manufacturer’s protocol and then stored at 4°C for up to 72 hours or stored immediately at -20°C until additional testing using Portrait Toxigenic C. difficile (Table 1).

- All discrepant results are repeated.

- Sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), concordance are calculated for the Portrait Toxigenic C. difficile using the illumigene® C. difficile as the reference method.

- Figure 1. The Portrait Toxigenic C. difficile Semi-Automated System

- Figure 2. Comparison of C. difficile Detection Methods

- Figure 3. Comparison of Turn-around time based on workflow