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INTRODUCTION

Clostridium difficile (Cdiff) is one of the most common and deadly hospital-acquired infections (HAIs) affecting nearly 700,000 people in the US annually according to the CDC. Cdiff diagnosis has traditionally been done by labor intensive culture procedures, followed by cell cytotoxicity testing of the isolates (still considered to be the primary reference method). With the number of Clostridium difficile infections (CDI) on the rise, accurate and rapid diagnosis is imperative to aid in therapy selection, improve patient outcome, prevent disease spread and lessen negative impacts on healthcare systems. This evaluation compared the Portrait Toxigenic C. difficile Assay (PTcdA) performed on the Portrait Analyzer (Great Basin Corp., Salt Lake City, Utah) and the BD GeneOhm™ Cdiff Assay (BDCA) (BD Diagnostics, Sparks MD) for the rapid detection of Cdiff toxin B gene (tcdB) in fecal specimens. During the course of this study, an additional assay was added to this evaluation (Cepheid Xpert® C.difficile Assay (Cepheid, Sunnyvale, CA) and compared to PTcdA. The PTcdA is a qualitative in vitro diagnostic test for the detection of toxigenic Cdiff utilizing automated blocked primer enabled helicase-dependent amplification (bpHDA) to detect toxin gene sequences associated with toxin producing Cdiff. The BDCA is a rapid in vitro diagnostic test for the direct, qualitative detection of Cdiff toxin B gene (tcdB) utilizing polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The Cepheid Xpert Cdiff Assay (Xpert), performed on the Cepheid Xpert® Dx System, is a qualitative in vitro diagnostic test for the rapid detection of toxin B sequences utilizing real-time PCR.

Table 1. Comparison of the Portrait Toxigenic C. difficile Assay to other molecular methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Total Tested</th>
<th>Portrait (+) Comparator (+)</th>
<th>Portrait (+) Comparator (-)</th>
<th>Portrait (-) Comparator (+)</th>
<th>Portrait (-) Comparator (-)</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>GeneOhm</td>
<td>165</td>
<td>72</td>
<td>4 1*</td>
<td>2 2*</td>
<td>87</td>
<td>96.4%</td>
</tr>
<tr>
<td>Xpert</td>
<td>42</td>
<td>14</td>
<td>1 1*</td>
<td>0 2</td>
<td>27</td>
<td>97.6%</td>
</tr>
<tr>
<td>Total</td>
<td>207</td>
<td>86</td>
<td>5 2</td>
<td>2 114</td>
<td>96.6%</td>
<td></td>
</tr>
</tbody>
</table>

* 2 samples tested positive with Xpert, 2 tested negative with Xpert
  1 sample tested negative with Xpert, 1 sample tested positive with Xpert
  1 sample tested negative with BD GeneOhm

METHODS

Surplus, de-identified, liquid to soft stool samples from patients suspected of CDI were tested with PTcdA, and BDCA or the Xpert assay. Each stool was collected, processed, and tested according to the institution’s standard of care and each assay was performed according to manufacturer’s package insert instructions. Discordant results were resolved by either BDCA or the Xpert and results were used for sensitivity and specificity calculations.

CONCLUSIONS

The Portrait Toxigenic C. difficile Assay (utilizing the Portrait analyzer for detection of toxigenic Cdiff) exhibited excellent sensitivity and specificity for detection of toxigenic Cdiff in clinical samples when compared to other FDA-cleared molecular assays. The PTcdA is easy to perform with no more than two or three hands – on steps, fits easily into laboratory workflow and provides a rapid turn-around-time.

REFERENCES

2. BD GeneOhm™ Cdiff Assay Package Insert.

ACKNOWLEDGEMENTS

Great Basin Corporation supplied the Portrait analyzer and Portrait Toxigenic C.difficile Assay kits for this study.