Introduction

Clostridium difficile is the leading cause of hospital-acquired antibiotic-associated diarrhea (AAD) and colitis. The two toxins of C. difficile are responsible for about 25% of AAD and most cases of pseudomembranous colitis. The diagnosis of C. difficile disease is based on clinical history such as antibiotic treatment, symptoms, and the presence of C. difficile toxin in fecal specimens. ELISAs for the detection of toxins A and B in fecal specimens are commonly used as in vitro diagnostic aids for C. difficile disease. However, there is a need for more rapid tests for these toxins. A sensitive rapid test would reduce the labor and turn-around time for detecting the presence of toxin in fecal specimens. In this study we evaluated a new rapid test, the TOX A/B QUIK CHEK™ test, and compared its performance with commercial A+B ELISAs.

Methods

Fecal specimens that were submitted for routine fecal testing were collected from the West Virginia University Hospital (Morgantown, WV) and the Carillon Medical Center (Roanoke, VA). The specimens included solid, semi-solid, and liquid samples. Stool specimens from babies (6 months to 2 years) were included in these studies because only the presence of C. difficile and its toxins were tested. Test results were not linked to the diagnosis of C. difficile disease. The following tests were used in the evaluation:

TOX A/B QUIK CHEK™ — This test is a new rapid test from TECHLAB®, Inc. Fecal specimens were prepared by a simple dilution. No filtering of specimens was required.

Commercial A+B ELISAs — C. DIFFICILE TOX A/B IT™ (TECHLAB®, Inc.) and another commercial A+B Test.

Results

Comparison of the C. difficile TOX A/B QUIK CHEK™ test to the C. DIFFICILE TOX A/B IT™ ELISA

<table>
<thead>
<tr>
<th>Test</th>
<th>N=465</th>
<th>TOX A/B IT™ positive</th>
<th>TOX A/B IT™ negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOX A/B QUIK CHEK™ positive</td>
<td>72</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>TOX A/B QUIK CHEK™ negative</td>
<td>2</td>
<td>391</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity 97.3% (99.0 to 99.5%)
Specificity 99.7% (98.4 to 99.9%)
Predictive Pos Value 96.8% (91.6 to 99.9%)
Predictive Neg Value 99.5% (98.0 to 99.9%)
Correlation 99.4% (98.3 to 99.9%)

Comparison of the C. difficile TOX A/B QUIK CHEK™ test to another commercial A+B ELISA

<table>
<thead>
<tr>
<th>Test</th>
<th>N=256</th>
<th>A+B ELISA positive</th>
<th>A+B ELISA negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOX A/B QUIK CHEK™ positive</td>
<td>50</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>TOX A/B QUIK CHEK™ negative</td>
<td>1</td>
<td>203</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity 90.0% (88.2 to 90.9%)
Specificity 99.0% (96.1 to 99.8%)
Predictive Pos Value 96.2% (85.7 to 99.3%)
Predictive Neg Value 99.5% (96.9 to 99.9%)
Correlation 98.4% (96.5 to 99.7%)

Discussion

The TOX A/B QUIK CHEK™ was comparable in its performance to two commercial A+B ELISAs. In both studies, the sensitivity and specificity were >97% and 99.0% or higher, respectively. The correlation in both studies was >98%.

The TOX A/B QUIK CHEK™ does not require any filtration of the fecal sample, simplifying the preparation of the specimen. In addition, the test does not require the washing steps used with the micowell ELISAs. Thus, the procedure is easier to perform and more rapid than the ELISAs.

The TOX A/B QUIK CHEK™ can be performed as soon as the samples reach the lab. This eliminates the waiting time for batch testing, which is routine in some labs using ELISA.

The high sensitivity and high predictive values, along with a rapid turnaround time demonstrate that the TOX A/B QUIK CHEK™ test is a suitable in vitro diagnostic test for the detection of toxins A and B in fecal specimens.

Conclusions

The TOX A/B QUIK CHEK™ test is a new rapid test for the detection of toxins A and B in fecal specimens. The test offers clinical laboratories a suitable alternative assay that correlates well with commercial A+B ELISAs.

References