Clinical Evaluation of a New Enzyme Immunoassay (C. DIFF QUIK CHEK COMPLETE®) for the Rapid and Simultaneous Detection of Clostridium Glutamate Dehydrogenase and C. difficile Toxin A/B

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Materials, Specimens, and Procedures

Materials

Specimen Preparation Fecal-Qwik-Prep® specimen preparation devices (Inverness Medical, Princeton, NJ)

Routine EIA: C. DIFF/Qwik-Prep® EIA for detection of toxins A/B (Inverness Medical, Princeton, NJ)

Routine CEN (HEp-2 and MRC-5 cell cultures) (Diagnostic Hybrids, Athens, OH; Viromed Laboratories, Minitok, MN)

New Product: C. DIFF QUIK CHEK COMPLETE® for detection of GDH and toxins A/B (Inverness Medical, Princeton, NJ)

Specimens

218 stool specimens submitted for routine C. difficile testing at a community hospital core laboratory in Cincinnati, Ohio, were examined. All specimens were tested the day of receipt or the next day after being stored at 4°C. RESULTS

The CQD was extremely easy to use and results were easy to read (Figure 1). The total time for the two required incubations was 25 min. Hands-on times were 5 and 25 minutes for one and 10 specimens, respectively.

The results of the 218 CQD-tested specimens are the following:

- Ag+ CdQ Ag-po/pos results (76.1% of the total) were EIA-CTN-pos.
- 41 CQD Ag-po/pos results (11.5%) were EIA-CTN-pos.
- 27 of the specimens (12.4%) were CdQ Ag-po/pos results.

The determined sensitivity, specificity, PPV, and NPV of the separate antigen and toxin EIA components of the CQD are shown in the tables below.

<table>
<thead>
<tr>
<th>Antigen Results</th>
<th>EIA-CTN Results</th>
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<tbody>
<tr>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100%</td>
</tr>
<tr>
<td>Specificity</td>
<td>100%</td>
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<tr>
<td>PPV</td>
<td>100%</td>
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<tr>
<td>NPV</td>
<td>97.9%</td>
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Discussion

The design of the study precluded CQD from statistically outperforming our current EIA and CEN methods because these methods were used as the standard. We were looking for a C. difficile testing method that not only would perform as well as our EIA-CTN but also reduce the turnaround time and labor involved in daily C. difficile testing. The CQD performance was equivalent to that of EIA and CEN routinely used in our laboratory, and the time required to perform the CQD was extremely short.

In practice, the antigen and toxin components of the CQD can be considered a screening test and a confirmation test, respectively. In our laboratory, specimens which yielded either CQD Ag-po or CQD Ag-po/pos results could have been reported as final C. difficile negative and positive, respectively. Specimens which yielded CQD Ag-po/pos-negative results could have contained non-toxigenic strains of C. difficile and/or lower-than-detectable levels of toxin. Such specimens could have been tested by alternative methods.

The high sensitivity and NPV of the CQD antigen and the high specificity and PPV of the CQD toxin component suggest that CQD has potential to facilitate workflow, to provide accurate, rapid results on the same day or during the same shift specimen is received.

Conclusions

The C. DIFF QUIK CHEK COMPLETE® was easy to perform, and results were easy to read. Testing 10 specimens required only 50 minutes of hands-on and incubation time. In our laboratory, the performance of the CQD was equivalent to that of our routinely used EIA and CEN tests for C. difficile toxins A/B. Use of the CQD could allow us to issue final C. difficile results of 97.6% of specimens on the same day or during the same shift specimens are received. Specimens which yield CQD Ag-po/pos-negative results can be tested by alternative methods.