INTRODUCTION

Clostridium difficile is the causative agent of hospital-acquired antibiotic-associated diarrhea (AAD) and colitis. The two toxins of C. difficile are responsible for approximately 35-45% of AAD and many 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 stool specimens. C. difficile assay using cultured cells and specific neutralization antiserum (tissue culture assay) is considered by many to be the gold standard for detecting toxins A and B, and requires cell culture equipment. A sensitive rapid test to complete and requires cell culture equipment. A sensitive rapid test will reduce the labor and turnaround 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®, and compared its performance with the tissue culture assay.

METHODS

• A total of 769 AAD fecal specimens, submitted for routine C. difficile toxin testing from AAD patients, were collected for analysis. The specimens included solid, semi-solid and liquid samples. The test results were not linked to the diagnosis of C. difficile disease.

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

RESULTS

- Compared to the tissue culture assay, the gold standard, the sensitivity and specificity of the TOX A/B QUIK CHEK® were 93.1% and 99.3%, respectively. The positive and negative predictive values were 99.4% and 97.8%, respectively, and the correlation was 97.9%. The performance characteristics of the TOX A/B QUIK CHEK® and the TOX A/B IT® were similar when compared to tissue culture assay.

DISCUSSION

- The TOX A/B QUIK CHEK® was comparable or slightly better than commercial A/B ELISAs when compared to the tissue culture assay, considered to be the gold standard. The sensitivity and specificity of the test was 93.1% and 99.3%, respectively, with a correlation of 97.9% with tissue culture. Of the 14 specimens that were tissue culture positive, TOX A/B QUIK CHEK® negative, 12 were negative by an A/B ELISA. Of the 2 specimens that were tissue culture positive, TOX A/B QUIK CHEK® positive, 1 was positive by an A/B ELISA.

- The TOX A/B QUIK CHEK® did not exhibit any cross-reactivity with members of the normal intestinal flora or with enteric pathogens including bacteria, viruses, and parasites.

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

- The high sensitivity and high negative predictive value, 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 tissue culture assay and commercial A/B ELISAs.

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A variety of normal intestinal bacteria and intestinal pathogens, including bacteria, viruses, and parasites, were checked for cross-reactivity in the TOX A/B QUIK CHEK™. Only toxigenic C. sordelli, which produces toxins EET (hemorrhagic toxin) and LT (lethal toxin) that are immunologically related to toxin A and B, reacted in the test.