C-026 Comparison of the *C. difficile TOX A/B QUIK CHEK*™ with commercial *C. difficile* A+ B ELISAs

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INTRODUCTION

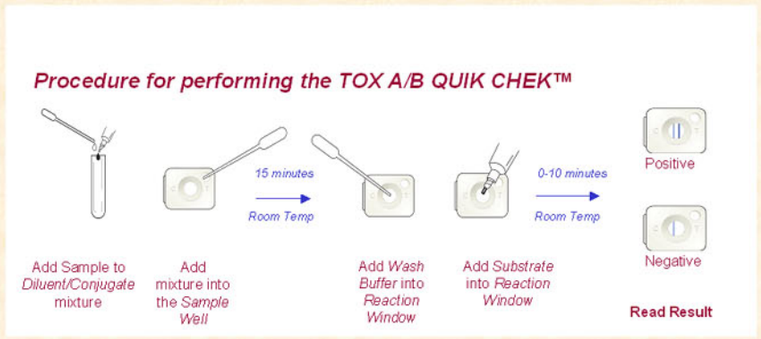
Clostridium difficile is the leading cause of hospital-acquired antibiotic-associated diarrhea (AAD) and colitis. The two toxins of *C. difficile* are responsible for about 25% of AAD and most cases of pseudomembranous colitis. The diagnosis of *C. difficile* disease is based on clinical history such 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 will 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 Carilion Medical Center (Roanoke, VA). The specimens included solid, semi-solid, and liquid samples. Stool specimens from babies (8-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 II*™ (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 II*™ ELISA

N=466	TOX A/B II™ positive	TOX A/B II™ negative
TOX A/B QUIK CHEK™ positive	72	1
TOX A/B QUIK CHEK™ negative	2	391

Sensitivity	97.3% (89.7 to 99.5%)
Specificity	99.7% (98.4 to 99.9%)
Predictive Pos Value	98.6% (91.6 to 99.9%)
Predictive Neg Value	99.5% (98.0 to 99.9%)
Correlation	99.4% (99.3 to 99.4%)

95% Confidence Intervals are in parentheses

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

N=256	A+B ELISA positive	A+B ELISA negative
TOX A/B QUIK CHEK™ positive	50	2
TOX A/B QUIK CHEK™ negative	1	203

Sensitivity	98.0% (88.2 to 99.9%)
Specificity	99.0% (96.1 to 99.8%)
Predictive Positive Value	96.2% (85.7 to 99.3%)
Predictive Negative Value	99.5% (96.9 to 99.9%)
Correlation	98.4% (98.0 to 98.7%)

95% Confidence Intervals are in parentheses

RESULTS

In the first study, a total of 466 specimens were analyzed. There were 72 specimens that were positive in both the *TOX A/B QUIK CHEK*™ and the *C. DIFFICILE TOX A/B II*™ ELISA. There were 391 specimens negative in both tests. The positivity rate was 15.5%. The sensitivity and specificity were 97.3% and 99.7%, respectively, and the correlation was 99.4%.

In the second study, a total of 256 specimens were analyzed. There were 50 specimens positive in the *TOX A/B QUIK CHEK*™ and the other A+B ELISA. There were 203 specimens negative in both tests. The positivity rate was 19.5%. The sensitivity and specificity were 98.0% and 99.0%, respectively, and the correlation was 98.4%.

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 specimen, simplifying the preparation of the specimen. In addition, the test does not require the washing steps used with the microwell 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 labs. 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

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