Comparison of the CERTEST *Clostridium difficile* GDH+Toxin A+B test with the C. DIFF QUIK CHEK COMPLETE® assay


**INTRODUCTION**

*Clostridium difficile* infection (CDI) has become the leading nosocomial infection in hospitals and nursing homes, and is now associated with community-acquired infections. Many laboratories have replaced or supplemented traditional immunoassays for *C. difficile* detection with molecular methods, usually accompanied by a marked increase in the prevalence rate, sparking a debate as to whether or not this patient population (positive for *C. difficile* by molecular testing but lacking detectable toxin in the faeces) have disease or are merely carriers. Recent studies from the United Kingdom show a correlation between detectable faecal toxin by immunoassay and the presence of *C. difficile* disease. One approach is to use a testing algorithm of an immunoassay for glutamate dehydrogenase (GDH) followed by a second, more sensitive test for toxin. In this study we compared two rapid assays that detect *C. difficile* toxins A and B, and GDH antigen. The performance and utility of a new lateral flow test, the CERTEST *Clostridium difficile* GDH+Toxin A+B (“CERTEST”), and the TECHLAB C. DIFF QUIK CHEK COMPLETE® (“COMPLETE”) rapid membrane enzyme immunoassays were evaluated. Both tests were compared to bacterial culture and a cytotoxicity assay, the recognized gold standards for the detection of *Clostridium difficile* and toxin, respectively, in faecal specimens.

**METHODS**

Both tests were performed according to the Package Insert for testing faecal samples using 158 faecal samples submitted to the clinical laboratory for routine *C. difficile* testing. The presence of *C. difficile* toxin was determined by a cytotoxicity assay (CTA). The presence of *C. difficile* was determined by ethanol shocked culture on cycloserine cefoxitin fructose agar plates (CCFA). Analysis of discrepant samples was performed using a validated in-house qPCR with primer and probe sequences specific for the *C. difficile* toxin B (*tcdB*) gene. For the analytical sensitivity comparisons, serial two-fold dilutions of purified analyte (*Clostridium difficile* GDH, toxin A, or toxin B) were prepared in PBS 2% BSA and tested as a faecal specimen. For culture testing, 72 hr anaerobic BHI cultures were tested as faecal specimens.

**RESULTS**

CCFA culture identified 33 *C. difficile* positive samples - 30 were detected as GDH+ by the COMPLETE (90.9% sensitivity, 96.0% specificity) versus 27 by the CERTEST (81.8% sensitivity, 93.6% specificity). The COMPLETE identified an additional 5 GDH+ samples, 4 of which were positive for the *tcdB* gene by qPCR. The CERTEST identified an additional 8 GDH+ samples, 3 of which were positive by qPCR. Cytotoxicity assay (CTA) identified 18 toxin positive samples - 18 were detected (GDH+ and Toxin+) by the COMPLETE (100% sensitivity, 100% specificity) versus 12 detected by the CERTEST (66.7% sensitivity, 98.6% specificity). The CERTEST gave a false positive antigen result with a broth culture of *Clostridium sporogenes*.

**REFERENCES**


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