Background: Early detection of toxin-producing strains of Clostridium difficile infections is essential for patient management and prevention of nosocomial transmission. The Portrait Toxigenic C. difficile assay from Great Basin Diagnostics (Salt Lake City, UT) is a rapid, automated, qualitative assay performed on the Portrait Dx Analyzer. The assay utilizes thermophilic helicase-dependent amplification (HDA) technology targeting the C. difficile tcdB gene. Toxigenic tcdB-specific C. difficile DNA probes are immobilized on a silicon chip surface to enable detection of the amplified DNA. The objective of this study was to investigate the performance of the Portrait Toxigenic C. difficile assay compared to commercially available BD GenOhm Cdiff PCR assay and the gold standard toxigenic culture.

Methods: In total, 214 liquid and soft stool specimens were prospectively collected and included in the study. The Portrait Toxigenic C. difficile and BD GenOhm Cdiff PCR assays were performed according to the manufacturer’s protocols. Toxigenic bacterial cultures were performed by heat shocking an aliquot of stool, followed by inoculation onto cycloserine cefoxitin fructose agar with horse blood (Anaerobe Systems, Morgan Hill, CA) and prereduced chopped-meat glucose broth (CMG). The C. difficile TOX-B test (TechLab, Blacksburg VA) was used for toxin testing of cultured isolates grown in CMG and inoculated into tissue culture plates containing human foreskin fibroblasts (Diagnostic Hybridis, Athens, OH). Using toxigenic culture as the reference method, the sensitivity, specificity, positive/negative predictive values (PPV/ NPV) of each molecular method was calculated.

Results: The overall prevalence of specimens positive by toxigenic culture and toxin production was 20% (43/214). The sensitivity, specificity, PPV, and NPV were for BD GenOhm Cdiff 97.7%, 98.6%, 95.0%, and 99.4%, for Portrait Toxigenic C. difficile assay 97.6%, 96.4%, 97.2%, and 99.4%. Three samples initially tested by the Portrait as invalid were retested and were found to be negative.

Conclusion: The performance characteristics of the Portrait Toxigenic C. difficile assay in our laboratory compared favorably with the BD GenOhm Cdiff PCR assay and toxigenic culture for the detection of toxigenic C. difficile directly from stool specimens.

INTRODUCTION

Toxigenic C. difficile is a major cause of nosocomial cases of infectious diarrhea and antibiotic-associated colitis. The tcdB gene of C. difficile has increased in both hospital and community-acquired infections. Accurate and rapid diagnosis of Clostridium difficile–associated disease (CDAD) is important for patient management and prevention of nosocomial transmission. A new FDA cleared molecular assay for toxigenic C. difficile (Portrait Toxigenic C. difficile assay; Great Basin Diagnostics, Salt Lake City, UT) was developed for the rapid, qualitative detection of the tcdB gene of C. difficile. The Portrait Dx Analyzer utilizes a novel blocked-primer-mediated helicase-dependent amplification (bHDA) technology which utilizes the isothermal amplification method helicase-dependent amplification (HDA) technology targeting the C. difficile tcdB gene. The Portrait Dx Analyzer is a small, automated bench-top analyzer with low cost and includes in the study. The Portrait Toxigenic C. difficile assay is a rapid and reliable test for the detection of toxigenic C. difficile directly from clinical specimens.