

INTRODUCTION

Clostridium difficile (Cdiff) is one of the most common and deadly hospital-acquired infections (HAIs) affecting nearly 700,000 people in the US annually according to the CDC. With the number of *Clostridium difficile* infections (CDI) on the rise, accurate and rapid diagnosis is imperative to aid in therapy selection, improve patient outcome, prevent disease spread and lessen negative impacts on healthcare systems.

The objective of this study was to establish the performance (sensitivity, specificity, positive and negative predictive values) of the Portrait Toxigenic *C. difficile* Assay, (Great Basin Corp., Salt Lake City, Utah) using stool samples stored up to 24 hours at room temperature. This study was in support of a label change to support the use of stool specimens for up to 24 hours stored at room temperature.

The Portrait Analyzer is a fully automated system that includes the Portrait Analyzer controller laptop PC, and single-use Portrait Toxigenic *C. difficile* Test Cartridges. The Portrait Analyzer is designed to perform automated molecular analysis utilizing isothermal helicase-dependent amplification (tHDA), and chip-based detection with integrated data analysis in approximately ninety minutes. The appropriate specimen for use in the Test Cartridge is a stool specimen of liquid or semi-solid consistency submitted to the clinical laboratory from patients suspected of having CDI.

METHODS

Liquid to soft stool samples from patients suspected of CDI were tested with the Portrait Toxigenic *C. difficile* Assay (using the Portrait Analyzer). Samples were stored at room temperature and tested upon receipt in the laboratory (baseline) according to manufacturer's instructions, and again at 24 hours (+/- 2 hours). Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for the 24 hour samples as compared to baseline



Figure 7

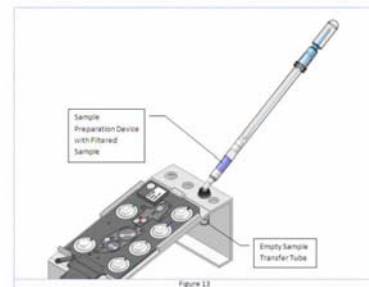


Figure 11

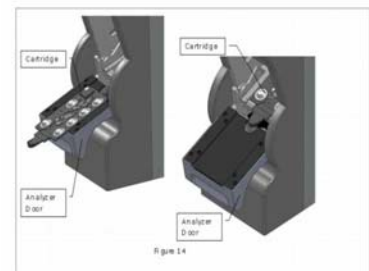


Figure 14

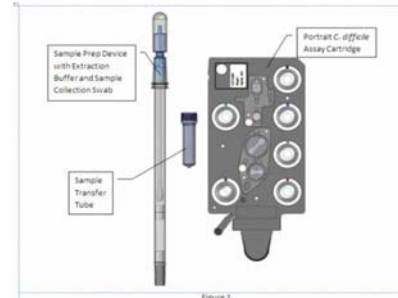


Figure 1

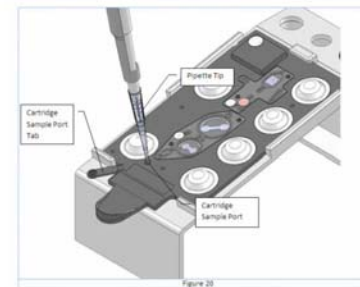


Figure 21



RESULTS

One hundred twenty evaluable samples have been tested (94 negative and 26 positive). All samples showed complete agreement except for two samples that initially tested positive with the Portrait Analyzer at baseline and then repeated negative at 24 hour. The two discrepant stool samples were also tested using the BD GeneOhm™ Cdiff Assay (BD Diagnostics, Sparks, MD) and found to be negative.

The resultant initial performance characteristics for stool samples stored at room temperature for 24 hours were: 92% sensitivity, 100% specificity, 100% Positive Predictive Value (PPV), and 98% Negative Predictive Value (NPV) while the resolved performance characteristics showed complete agreement.

CONCLUSIONS

The Portrait Toxigenic *C. difficile* Assay utilizing the Portrait Analyzer yielded excellent agreement for samples stored at room temperature and tested at baseline and at 24 hours.

The assay is simple to perform, is easily incorporated in to laboratory workflow, and provides results in less than 90 minutes.

ACKNOWLEDGEMENTS

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