BACKGROUND

Clostridium difficile is a commensal bacterium of the human intestine present in 2-5% of the population over the age of 2 years, with a higher prevalence in children under 2 years of age, with a higher prevalence in children under 2. Treatment with certain antibiotics or anti-neoplastic agents can disrupt the normal flora and allow C. difficile to become the predominant bacteria in the colon. When toxigenic strains overgrow, C. difficile infection (CDI) results, and can lead to debilitating diarrhea and occasionally death. C. difficile typically produces two toxins: Toxin A (tcdA), an enterotoxin, and Toxin B (tcdB) a cytotoxin. Detection of C. difficile toxin A or B can be used to make the diagnosis of CDI. Prompt diagnosis, especially in a pediatric setting, allows for appropriate patient care.

Great Basin Corporation’s Portrait Toxigenic C. difficile Assay™ is a DNA amplification test for the rapid qualitative detection of the C. difficile tcdB gene in human fecal samples collected from patients suspected of having CDI. The Portrait Dx Analyzer is a fully automated system that includes the analyzer, controller laptop PC, and single use assay cartridge and the Sample Port Tab is locked to prevent leakage. (see figures 1-6) The assay cartridge is then placed in the instrument and the analyzer door is closed. (see figures 7-9) Pertinent patient and cartridge information is entered into the Portrait Dx Analyzer Interface and the run is started. (see figures 10-11) Upon completion of the Portrait Toxigenic C. difficile Assay™, the User Interface screen will indicate the test is completed and the blue light will flash on the Portrait Analyzer front panel. Open the door and remove the test cartridge.

RESULTS

As can be seen by the tables, both the Portrait and the illumigene® had higher positivity which shows increased assay sensitivity over the toxigenic Bacterial Culture. This is a common theme with molecular assays versus cultured results.

CONCLUSIONS

• The Portrait Toxigenic C. difficile Assay is a straightforward and easy to use.
• The Portrait Dx Analyzer is fully automated once the assay cartridge is placed into the analyzer.
• The cartridge is self-contained for all reagents, sample and waste.
• The Assay takes less time from setup to result than traditional PCR.

96 stool specimens from children 2 years of age who were suspected of having CDI were tested using both Portrait Toxigenic C. difficile Assay™ and TCB. The Portrait Toxigenic C. difficile Assay™ procedure is as follows:

• The Portrait Toxigenic C. difficile Assay™ kit (pouch) is brought to room temperature.
• An aliquot of stool is mixed in sample diluents and passed through a filter. 180 µl of filtered stool specimen is then pipetted into the Portrait Toxigenic C. difficile Assay™ cartridge and the Sample Port Tab is locked to prevent leakage. (see figures 1-6)
• The assay cartridge is then placed in the instrument and the analyzer door is closed. (see figures 7-9)
• Pertinent patient and cartridge information is entered into the Portrait Dx Analyzer Interface and the run is started. (see figures 10-11)
• Upon completion of the Portrait Toxigenic C. difficile Assay™, the User Interface screen will indicate the test is completed and the blue light will flash on the Portrait Analyzer front panel. Open the door and remove the test cartridge.
• Discard the used test cartridge into the biohazard trash in accordance with your laboratory’s established biohazard disposal procedures.
• Once a test is completed, the “End Session” button is highlighted. Click the “End Session” button to begin another test.

All 96 specimens were tested using toxigenic Bacterial Culture as the “Gold Standard” and the illumigene® as an alternate PCR method.