

## Technical Bulletin

*Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests*

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- Test Name: C. difficile (PCR)
  - Test Order Number: 7069
  - CPT code: 87493
  - Department: Microbiology (500)
  - Testing Schedule: Monday-Sunday (once per day)
  - Specimen Requirement: Liquid or (diarrheal) stool only
  - Methodology: Real Time Polymerase Chain Reaction (RT-PCR)
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### **Background Information:**

The C. difficile PCR assay utilizes the BD GeneOhm™ test kit. The assay is a rapid in vitro diagnostic test for the direct, qualitative detection of C. difficile toxin B gene (*tcdB*) in human liquid stool specimens from patients suspected of having *Clostridium difficile*-associated disease (CDAD). The toxin B is responsible for CDAD. The test is performed directly on the specimen, utilizing polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the detection of the amplified DNA.

The assay also includes an internal control (IC) to detect PCR inhibited specimens and to confirm the integrity of assay reagents.

### **Test Information:**

The laboratory will discontinue the enzyme immunoassay (ELISA) and will utilize the polymerase chain reaction (PCR) assay for the detection of toxigenic strains of C. difficile in stool specimens. The PCR test has a much better sensitivity (88-100%) and specificity (94-100%) than the EIA test that has a sensitivity of 43-73% and specificity of 98%-100%. Our validation study showed a 50% increase in the number of true positive specimens detected.

### **Specimen Collection:**

Raw stool specimens should be submitted to the laboratory in a sterile container. Testing will be performed only on liquid stool specimens. **FORMED STOOLS WILL NOT BE TESTED FOR**

**TOXIGENIC C difficile AS RECOMMENDED IN CURRENT LITERATURE GUIDELINES.** Due to the increased sensitivity of the PCR assay, the laboratory will limit testing to one test/patient/week.

Stool specimens received in a preservative or transport medium are not acceptable.

**Laboratory Results:**

Results for the test will be reported as *C. difficile* toxin B gene (*tcdB*) Not Detected, *C. difficile* toxin B gene (*tcdB*) Detected, or Unresolved if the test cannot give a Not Detected or a Detected result.

**Testing Schedule:**

Testing will be performed on Monday through Sunday. Specimens received prior to 1:00 PM will be tested that day with results available by 4:00 PM the same day.

**References:**

1. SHEA/ ISDA Recommendation “ Strategies to Prevent C difficile Infections in Acute Care Hospitals” 2008 Infection Control and Hospital Epidemiology. 29: S81-S92.
2. Terhes G, Urban E, Soki, J et al. 2009. Comparison of a rapid molecular test method, the BD GeneOhm C diff assay to the most frequently used laboratory tests for detection of toxin-producing Clostridium difficile in diarrheal stools. J Clin. Microbiol. 47:78-81.

*Questions?* Call 249-2300 (Client Services) and ask for Microbiology (Edi Hewa, Microbiology Manager (585) 429-2205, or Dr John D’Souza, ACM Medical Director at (585) 429-2246).