

Clostridium difficile by PCR

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CLINICAL APPLICATION

- The BD GeneOhm™ Cdiff PCR assay is for the detection of toxigenic *Clostridium difficile* directly on liquid or soft stool specimens from patients suspected of having *Clostridium difficile*-associated disease.
- *C. difficile* by BD GeneOhm™ assay targets the toxin B gene and is more rapid, more specific and more sensitive, detecting up to 24% more *C. difficile* true positive specimens.
- The rapid turnaround time leads to more timely treatment and infection control management of patients with suspected *C. difficile* colitis.
- Eliminates the need for multiple screening and confirmatory assays.

CLINICAL BACKGROUND

Clostridium difficile-associated diarrhea is an important illness among both hospitalized and non-hospitalized patients that has gained recent notoriety due to the advent of hyper toxin-producing strains. It is the primary cause of hospital-acquired colitis in patients who receive antibiotics, chemotherapeutic agents or other drugs that alter their normal flora. In the United States, the reported rates for *C. difficile* infection increased from 5.7 per million population in 1997 to 23.7 per million in 2004.

C. difficile infection is an independent predictor of increased length of hospital stay and total cost for patients and hospitals. A recent study (Infect Control Hosp Epidemiol 28:1219, 2007) reported the mean *C. difficile* infection-related incremental length of stay as 2.95 days and the mean incremental cost per patient as \$13,675. Complications or severe outcomes have been reported for 22% of patients in a Canadian study (Clin Infect Dis 48:568, 2009). Therefore, pressures are increasing for the laboratory to provide accurate and rapid diagnostic results.

ASSAY INFORMATION

The BD GeneOhm™ assay targets the toxin B gene found in toxigenic *Clostridium difficile* strains. 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.

TEST UPDATE

Quick Facts

- ▶ *Clostridium difficile* is the primary cause of hospital-acquired colitis.
- ▶ PCR testing provides significantly increased sensitivity and specificity over other *C. difficile* testing methods.
- ▶ BD GeneOhm™ PCR assay targets the toxin B gene.
- ▶ Formed stool samples are not appropriate for PCR testing.
- ▶ Order Code is CDTPCR.
- ▶ 24 hour turnaround time (TAT) in most cases.

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In-house validation shows the test to have a sensitivity of 100% and a specificity of 98%. This is in contrast to the cytotoxin assay that demonstrates a sensitivity and specificity of 81% and 100%, respectively. A total of 24% more true positives were detected with the PCR assay compared to the cytotoxin assay.

The PCR test can be performed in less time providing for a more rapid turnaround time. The only caveat is that formed stools, which in general should not be submitted for testing, cannot be tested by the PCR method but will have to be submitted for cytotoxin assay.

TEST INFORMATION

DESCRIPTION *C. Difficile* by PCR

METHOD Real-Time PCR

ORDER CODE CDTPCR

CPT CODE 87798

SPECIMEN REQUIREMENTS 1 gram liquid or soft feces. Transfer liquid or soft stool to a dry sterile container. Store and transport refrigerated.

COMMENTS 1) Min Amt: 0.5 grams feces. 2) Unacceptable conditions: formed or hard stool, urine, toilet paper, water or soap contamination of specimen. 3) Stability: RT - 2 days, Refrigerated - 5 days

RANGES Negative for *Clostridium difficile* Toxin B by PCR

SELECTED REFERENCES

1. Eli N. Perencevich, MD, MS; Kerri A. Thom, MD, MS. Preventing *Clostridium difficile*—Associated Disease: Is It Time to Pay the Piper? *Infect Control Hosp Epidemiol* 28:1219, 2007.
2. Emilio Bouza. *Clostridium difficile* Infection: Same Incidence and Worse Prognosis? *Clinical Infectious Diseases* 2009;48:577–579.
3. Denise Gravel et al. Health Care-Associated *Clostridium difficile* Infection in Adults Admitted to Acute Care Hospitals in Canada: A Canadian Nosocomial Infection Surveillance Program Study. *Clinical Infectious Diseases* 2009;48:568-576.

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