

BD GeneOhm™ Cdiff

Definitive Results You Can Trust

Combines Speed, Sensitivity and Specificity in a Single Test

Rapid, molecular detection of *C. difficile* toxin B gene (*tcdB*) direct from stool

Clostridium difficile infection (CDI) increases length of stay by nearly three fold and mortality in the hospital by approximately 4.5 fold.¹

Based on a nationwide survey, 13 out of every 1,000 inpatients were either infected or colonized with *C. difficile* (94.4% infected). This rate is 6.5-20 times higher than previous incidence estimates.² Attributable costs of CDI are approximately \$1 billion.²

Current diagnostic protocols lack a single assay that is sensitive, specific and rapid.³ This leads to:

- Missed CDI cases and delayed diagnosis
- Need for confirmatory or repeat testing and empiric treatment
- Unnecessary use of antibiotics

*“Toxin B gene PCR represents a more sensitive and potentially cost-effective method to diagnose *C. difficile*-associated diarrhea than EIA and should be considered for use as an alternative diagnostic standard.”⁴*

Assay Performance*

Dataset	Sensitivity	Specificity
1†	93.8%	95.5%
2	100.0%	97.7%

* BD GeneOhm™ Cdiff package insert, BD Diagnostics 2008

† Toxigenic culture was positive for 21 out of 34 BD GeneOhm™ Cdiff positives that were negative on direct cytotoxicity

¹ Elixhauser and Jhung, AHRQ Statistical Brief #50 April 2008

² APIC National Prevalence Study of *C. difficile* in Healthcare Facilities. Key Findings released November 11, 2008

³ Dubberke ER, et al., Clin Infect Dis 2008;46:497-504

⁴ Morelli et al., Clin Gastroenterol Hepatol 2004;2:669-674

The BD GeneOhm line of products have been developed to help improve patient outcomes by delivering cost-effective, rapid molecular solutions for the prevention and identification of healthcare-associated infections (HAIs).

BD GeneOhm™ Cdiff

Definitive Results You can Trust

Assay Features

- Combines speed, sensitivity and specificity in a single test
- More sensitive than cytotoxicity with the speed of an EIA
 - Detects 30% more true positives than tissue culture cytotoxicity¹
 - Real-time PCR results in < 2 hours
- Specific detection of the *tcdB* gene found only in toxigenic *C. difficile*²

Clinical Advantages

- Rapid, sensitive and specific results for patients suspected of having *C. difficile* infection (CDI)
- Benefits of sooner definitive diagnosis of CDI
 - Quickly reaching a definitive diagnosis can ensure that CDI patients get the proper treatment without delay³
 - Put CDI-confirmed patients into isolation sooner to reduce transmission and prevent outbreaks of CDI^{3,4}
- Benefits of definitively ruling out CDI
 - Can help avoid empiric treatment and unnecessary exposure to antibiotics in negative patients
 - Physician can focus on other causes of patient symptoms
 - Avoid unnecessary isolation of negative patients

"The BD GeneOhm™ Cdiff assay is more rapid, more sensitive, and as specific as cell culture cytotoxin testing directly from patient samples for the diagnosis of CDAD."⁵



BD Diagnostics

6146 Nancy Ridge Drive
San Diego, California 92121
www.bd.com/geneohm
888-GENEOHM

¹ BD GeneOhm™ Cdiff Assay Package Insert

² Cohen et al., Journal of Infectious Disease 2000; 181:659-63

³ Kuijpers et al., Clin Microbiol Infect 2006;12(Suppl. 6):2-18

⁴ McFarland et al., AJIC 2007;35:237-253

⁵ Stamper et al., Journal of Clinical Microbiology 2008 (in press)