BD GeneOhm™ CDiff

Rapid, molecular detection of toxigenic *Clostridium difficile*

BD

Helping all people live healthy lives

Setting the new standard

More sensitive than cytotoxicity with the speed of an EIA

Clostridium difficile infection (CDI) increased length of stay by nearly 3 fold and mortality in the hospital by approximately 4.5 fold.[1] Rates of CDI tripled in US hospitals between 2000 and 2005[2] with attributable costs of approximately $1 billion.[3]

Current diagnostic tests lack a single assay that is sensitive, specific, and rapid.[4]

- Cytotoxicity assays have long turn around times and are labor intense.
- Enzyme immunoassay (EIA) has low sensitivity, leading to duplicate testing and empiric treatment.[4]

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]

1 Elixhauser and Jhung, AHRQ Statistical Brief #50 April 2008
2 McDonald LC, et al. Emerg Infect Dis. 2006;12(3):409-15 and unpublished CDC data, adapted from C. McDonald Webinar, March 20, 2007
3 Dubberke ER, et al. Clin Infect Dis 2008;46:497–504
4 Morelli et al., Clin Gastroenterol Epatol 2004;2:669-674

The BD GeneOhm™ line of products help improve patient outcomes by delivering cost-effective, rapid, molecular solutions for the detection and prevention of Healthcare Associated Infections (HAI).

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The answer you need today from a single test result!

Assay Performance

Sensitivity	94%
Specificity	95%

* BD GeneOhm Cdiff package insert, assay performance compared to cytotoxicity. After discrepant analysis, positive agreement was 95% and negative agreement was 98%.

Assay Features

- Performance comparable to the "gold standard" cytotoxicity assay
- Real-time PCR results in <2 hours for toxigenic *C. difficile*
- Specific detection of the tcdB gene found only in toxigenic *C. difficile*[5]
- One single method that can replace current *C. difficile* testing

Clinical Advantages

- Rapid, sensitive and specific results for patients suspected of having *C. difficile* infection (CDI)
- Earlier accurate diagnosis enables appropriate treatment of infected patients and can help avoid empiric treatment and unnecessary exposure to antibiotics in negative patients[6]
- Facilitates targeted infection control practices to prevent transmission and infection

The **BD GeneOhm™ Cdiff** assay is the first real-time PCR test to detect toxigenic *C. difficile* directly from stool. Rapid, real-time PCR can enable the prompt detection of toxigenic *C. difficile* in patients suspected of CDI, allowing more rapid, appropriate treatment and containment to prevent the spread of *Clostridium difficile*.[7]

5 Cohen et al., Journal of Infectious Disease 2000; 181:659-63
6 Morelli et al., Clinical Gastroenterology and Hepatology 2004;2:669-674
7 Fuller et al., ECCMID 2008 poster number 1756

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