



BD MAX™ Cdiff Real-time PCR assay

The need for sensitive Cdiff testing

Clostridioides difficile (Cdiff, formerly *Clostridium difficile*) is an anaerobic, gram-positive bacillus that is proven to be the leading cause of antibiotic-associated diarrhoea and pseudomembranous colitis in healthcare facilities.^{1,2} Incidence of **Clostridioides difficile infection (CDI)** has been increasing and severe cases are becoming more common.^{3,4,5} The most common risk factor is exposure to antibiotics.⁶

ESCMID (European Society of Clinical Microbiology and Infectious Diseases) guidelines recommend a combination of two tests in a diagnostic algorithm to help decrease the possibility of false positive results. **Molecular assays** can be used either **as primary or confirmatory tests** depending on the algorithm.

Discover the assay

The **BD MAX™ Cdiff** is an automated assay including nucleic acid extraction and real-time polymerase chain reaction (PCR) for direct and qualitative detection of the **Cdiff toxin B gene (*tcdB*)** in patients with suspected infection, including infection caused by **strain 027 /NAP1/BI**, although it does not discriminate against it.

The test also includes a sample processing control.

Sample types

Liquid or soft stool

Workflow and time to results



Results obtained in about
2 hours for 24 samples



Less than **1.5 minutes**
of hands-on time
in sample preparation



Compatibility to run alongside
other BD MAX™ assays on
1 to 24 specimens simultaneously
for greater flexibility

Scientific evaluation

Read more about the **BD MAX™ Cdiff** assay from molecular studies and publications.



Camargo et al., *Clostridioides difficile* laboratory diagnostic techniques: a comparative approach of rapid and molecular methods, *Archives of Microbiology* May 2021 Volume 203 Number 4 pages 1683-1690.



Putsathit et al., *Evaluation of the BD MAX™ Cdiff assay for the detection of toxigenic Clostridium difficile* in human stool specimens, *Pathology* February 2015 Volume 47 Number 2 pages 165-168.

Ready-to-use reagents storable at room temperature

REF	Contents	Quantity
442555	BD MAX™ Cdiff Master Mix (A3) Dried PCR Master Mix containing specific molecular probe and primers along with Sample Processing Control and PCR enzyme	24 tests (2 x 12 tubes)
	BD MAX™ Cdiff Strip Unitised reagent strip containing wash buffer, elution buffer, and neutralization buffer reagents, as well as disposable pipette tips necessary for sample processing and DNA extraction	24 strips
	BD MAX™ Cdiff Extraction Tube (A4) Freeze-dried pellet containing DNA magnetic affinity beads, Achromopeptidase and Sample Processing Control	24 tests (2 x 12 tubes)
	BD MAX™ Cdiff Sample Buffer Tube	24 tubes
	Septum Cap	25

Rapid, targeted testing on the BD MAX™ System

The innovation of the BD MAX™ System offers you a **fully integrated, automated real-time PCR platform** with the possibility of running multiple assays simultaneously.* Its automated workflow **reduces manual tasks** to achieve rapid, reliable results and facilitates off-hour testing, helping to **offset molecular testing costs**.** 8,9



Snap

Assemble unitised reagent strips with ready-to-use reagents.



Load

Load Sample Buffer Tubes, Racks and PCR cartridges.



Go

Come back in an average of 2.5 hours for results.***

Discover our full assay portfolio and the BD MAX™ System



advancing-diagnostics.eu



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BD MAX™ Cdiff [IFU 442555], Franklin Lakes, NJ: Becton, Dickinson and Company; 2021.

1. Dubberke ER, Wertheimer AI. Review of current literature on the economic burden of Clostridium difficile infection. Infect Control Hosp Epidemiol 2009; 30:57–66. 2. Poutanen SM, Simor AE. Clostridium difficile-associated diarrhea in adults. Can Med Assoc J 2004;171:51–8. 3. Redelings MD, Sorvillo F, Mascola L. Increase in Clostridium difficile-related mortality rates, United States, 1999–2004. Emerg Infect Dis 2007;13:1417–9. 4. McDonald LC, Owing M, Jernigan DB. Clostridium difficile Infection in Patients Discharged from US Short-Stay hospitals, 1996–2003. Emerging Infectious Diseases, 2006, 12 (3):409–415. 5. Pepin J, Valiquette L, Alary ME. Clostridium difficile-associated diarrhea in a region of Quebec from 1991 to 2003: a changing pattern of disease severity. CMAJ. 2004;171:466–72. 6. Bignardi GE. Risk factors for Clostridium difficile infection. J Hosp Infect 1998; 40:1–15 7. Crobach et al., European Society of Clinical Microbiology and Infectious Diseases; update of the diagnostic guidance document for Clostridium difficile infection, Volume 22, Supplement 4, S63-S81, August 01, 2016 8. Mortensen JE, et al. Comparison of time-motion analysis of conventional stool culture and the BD MAX™ Enteric Bacterial Panel (EBP). BMC Clin Pathol. 2015;15:9. 9. Hirvonen JJ, et al. Comparison of BD Max Cdiff and GenomEra C. difficile molecular assays for detection of toxigenic Clostridium difficile from stools in conventional sample containers and in FecalSwabs. Eur J Clin Microbiol Infect Dis. 2015;34(5):1005-1009.

* BD assays are run & rack compatible – Only MDR-TB and GBS are not run and rack compatible / Vaginal Panel and open systems' assays are only run compatible.

** When compared to culture or immunochromatographic antigen (IA).

*** Time is assay dependent. 4 hours for full results on MDR-TB assay.

The BD MAX™ System and BD MAX™ Cdiff assay are in-vitro diagnostic medical devices bearing a CE-mark.

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