

Clostridium difficile toxin B gene (*tcdB*) by PCR

FOR DETECTION OF TOXIGENIC CLOSTRIDIUM DIFFICILE IN STOOL

Test Highlights

- FDA-approved assay detects the toxin B gene (*tcdB*) of *Clostridium difficile* by real-time PCR.
- Higher sensitivity than enzyme immunoassay or cytotoxin neutralization assay.
- Rapid turnaround time.

Clinical Background

- *Clostridium difficile* is a gram-positive anaerobic bacillus recognized as an important nosocomial pathogen.
- *C. difficile* causes ~25 percent of antibiotic-associated diarrhea in hospitalized patients.
- *C. difficile* can also cause serious disease such as pseudomembranous colitis and toxic megacolon.
- Risk factors for disease include use of antibiotics, extended hospital stay, and age > 65 years.
- Disease is caused by toxin production (toxins A and B). Toxin B is believed to be essential to virulence.

Epidemiology

- *C. difficile* is estimated to cost >\$1 billion per year in the United States alone.
- Incidence and severity of disease has increased over the past decade.
- The epidemic strain (NAP1, BI, or ribotype 027) has been associated with worse disease severity.

Indications for Ordering

- *C. difficile* toxin testing in stool can help establish a diagnosis of *C. difficile*-associated diarrhea in hospitalized patients.
- Testing should target patients with clinically significant diarrhea (three or more loose stools over 1–2 days) and risk factors for disease.
- Only loose stools (defined as stools that conform to the shape of the specimen container) will be accepted for testing.

Interpretation

- *Clostridium difficile* toxin B gene (*tcdB*) by PCR is a qualitative assay.
- Presence of the *tcdB* gene correlates highly with toxigenicity in *C. difficile*.

- Other causes of diarrhea should be considered in the case of a negative PCR result.
- If *C. difficile* is still strongly suspected, utilization of another test (e.g., *C. difficile* culture with reflex to toxin testing or *C. difficile* cytotoxin cell assay) may be necessary to establish the diagnosis.
- Up to 70 percent of healthy neonates are colonized with toxigenic *C. difficile*. Testing in this population is controversial and results should be interpreted with caution.

Limitations

- Inhibitory substances may interfere with testing in a small subset of patient specimens.
- Because hospitalized patients may be asymptotically colonized with toxigenic *C. difficile*, use of a sensitive test such as PCR should be limited only to patients with appropriate signs and symptoms of *C. difficile*-associated disease.
- In rare cases, the *tcdB* gene target is not detected by PCR although toxin production is demonstrable by cytotoxin cell assay.
- Test of cure in a patient with *C. difficile* infection has limited utility and is not recommended.

Methodology

- Real-time polymerase chain reaction (PCR).

Related Tests

- [Clostridium difficile Cytotoxin Cell Assay \(0060851\)](#)
- [Clostridium difficile Culture with Reflex to Cytotoxin Cell Assay \(0060140\)](#)
- [Clostridium difficile Toxins \(A & B\) by EIA \(0065146\)](#)

References

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3. Kvach EJ. Comparison of BD GeneOhm Cdiff real-time PCR assay with a two-step algorithm and a toxin A/B ELISA for diagnosis of toxigenic *Clostridium difficile* infection. *J Clin Microbiol* 2010;48(1):109–114.
4. Peterson LR. Detection of toxigenic *Clostridium difficile* in stool samples by real-time polymerase chain reaction for the diagnosis of *C. difficile*-associated diarrhea. *Clin Infect Dis* 2007;45:1152–60.
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Test Information

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For specific collection, transport, and testing information, refer to the ARUP website at www.aruplab.com.

For information on test selection, ordering, and interpretation, refer to ARUP Consult® at www.arupconsult.com.