MAYO CLINIC LABORATORIES

Test Definition: CDPCR

Clostridioides difficile Toxin, PCR, Feces

Overview

Useful For

Sensitive, specific, and rapid diagnosis of *Clostridioides* (*Clostridium*) *difficile*-associated diarrhea and pseudomembranous colitis

The test **is not recommended** as a test of cure.

Testing Algorithm

For more information see Laboratory Testing for Infectious Causes of Diarrhea.

Special Instructions

- Laboratory Testing for Infectious Causes of Diarrhea

Method Name

Real-Time Polymerase Chain Reaction (PCR)/Reverse Transcription-(RT) PCR

NY State Available

Yes

Specimen

Specimen Type

Fecal

Ordering Guidance

This test is validated for unformed (liquid or soft) fecal specimens collected from patients suspected of having *Clostridioides difficile* infection.

Specimen Required

The high sensitivity of amplification by polymerase chain reaction requires the specimen to be processed in an environment in which contamination of the specimen by *Clostridioides difficile* toxin DNA is unlikely.

Submit only 1 of the following specimens:

Preferred:
Specimen Type: Preserved feces
Supplies: Culture and Sensitivity Stool Transport Vial (T058)
Container/Tube: Commercially available transport system specific for recovery of enteric pathogens from fecal specimens (15 mL of nonnutritive transport medium containing phenol red as a pH indicator, either Cary-Blair or Para-Pak C and S)

Specimen Volume: Representative portion of feces; 5 mL
Collection Instructions:
1. Collect fresh fecal specimen and submit in container with transport medium.
2. Within 2 hours of collection, place feces in preservative.
Specimen Stability Information: Ambient (preferred) <5 days/Refrigerated <5 days

Acceptable:
Specimen Type: Unpreserved feces
Supplies:
-Stool container, Small (Random), 4 oz Random (T288)
-Stool Collection Kit, Random (T635)
Container/Tube: Fecal container
Specimen Volume: Representative portion of feces
Collection Instructions: Collect fresh fecal specimen and submit representative sample in fecal container.
Specimen Stability Information: Refrigerated (preferred) <5 days/Frozen <5 days

Forms

If not ordering electronically, complete, print, and send 1 of the following with the specimen:
-Microbiology Test Request (T244)
-Gastroenterology and Hepatology Test Request (T728)

Specimen Minimum Volume

See Specimen Required

Reject Due To

Feces in gel transport medium ECOFIX preservative Formalin or polyvinyl acetate (PVA) fixative Preserved feces received frozen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Varies	5 days	

Clinical & Interpretive

Clinical Information

Clostridioides difficile (formerly *Clostridium difficile*) is the cause of *C difficile*-associated diarrhea (CDAD), an antibiotic-associated diarrhea, and pseudomembranous colitis (PMC). In these disorders bacterial overgrowth of *C difficile* develops in the colon, typically as a consequence of antibiotic usage. Clindamycin and broad-spectrum cephalosporins have most frequently been associated with CDAD and PMC, but almost all antimicrobials may be responsible. Disease is related to production of toxin A and B.

Treatment typically involves withdrawal of the associated antimicrobials and, if symptoms persist, orally administered and intraluminally active metronidazole, vancomycin, or fidaxomicin. Intravenous metronidazole may be used if an oral agent cannot be administered. In recent years, a more severe form of CDAD with increased morbidity and mortality has been recognized as being caused by an epidemic toxin-hyperproducing strain of *C difficile* (NAP1 strain). Many toxin-hyperproducing isolates also contain the binary toxin gene and are resistant to quinolones. This test does not differentiate between toxin-hyperproducing and non-toxin-hyperproducing strains.

Traditionally, diagnosis relied upon:
1. Clinical and epidemiologic features
2. Culture, which is labor intensive and time consuming
3. Cytotoxicity assays, which are labor intensive and time consuming
4. Toxin detection immunoassays, which are insensitive

This test utilizes automated real-time polymerase chain reaction to detect toxin B gene sequences. This test is used for rapid diagnosis of CDAD and PMC, enabling prompt treatment that may reduce hospital stays for inpatients with CDAD.

Reference Values

Negative

Interpretation

Positive: Toxin producing *Clostridioides* (*Clostridium*) *difficile* target nucleic acid is detected.

Negative: *Clostridium difficile* target nucleic acid is not detected.

Cautions

The assay must be performed on fresh feces, fresh-frozen feces, or feces in transport medium.

The assay has not been validated as a test of cure. Since nucleic acid may persist after effective treatment, follow-up testing of a positive result is not recommended.

Interfering substances in the feces may affect the accuracy of the assay; results should always be interpreted in conjunction with clinical and epidemiologic findings.

Submission of more than one specimen for testing is not recommended.

Testing has not been validated for colostomy-, ileostomy-, or colonoscopically collected specimens.

Patients may asymptomatically carry *Clostridioides difficile*; clinical correlation is needed when deciding how to manage patients with a positive test result. Because of asymptomatic carriage of toxigenic *C difficile* in infants, treatment for *C*

difficile may not be needed in those 12 months or younger.

Clinical Reference

1. Aichinger E, Schleck CD, Harmsen WS, Nyre LM, Patel R. Nonutility of repeat laboratory testing for detection of *Clostridium difficile* by use of PCR or enzyme immunoassay. J Clin Microbiol. 2008;46(11):3795-3797
2. Sloan LM, Duresko BJ, Gustafson DR, Rosenblatt JE. Comparison of real-time PCR for detection of the *tcdC* gene with four toxin immunoassays and culture in diagnosis of *Clostridium difficile* infection. J Clin Microbiol. 2008;46(6):1996-2001
3. Verdoorn BP, Orenstein R, Rosenblatt JE, et al. High prevalence of *tcdC* deletion-carrying *Clostridium difficile* and lack of association with disease severity. Diagn Microbiol Infect Dis. 2010;66(1):24-28
4. Karre T, Sloan L, Patel R, Mandrekar J, Rosenblatt J. Comparison of two commercial molecular assays to a laboratory-developed molecular assay for diagnosis of *Clostridium difficile* infection. J Clin Microbiol. 2011;49(2):725-727
5. Lawson PA, Citron DM, Tyrrell KL, Finegold SM. Reclassification of Clostridium difficile as Clostridioides difficile (Hall and O'Toole 1935) Prevot 1938. Anaerobe. 2016;40:95-99. doi:10.1016/j.anaerobe.2016.06.008

Performance

Method Description

Test is performed on the Cepheid GeneXpert Dx System, which automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time polymerase chain reaction (PCR) and reverse transcription PCR assays. The system requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is eliminated.

The Cepheid Xpert *C difficile*/Epi Assay is a qualitative in vitro diagnostic test for rapid detection of toxin B gene sequences and for presumptive identification of 027/NAP1/BI strains of toxigenic *Clostridioides* (*Clostridium*) *difficile* from patients suspected of having *C difficile* infection (CDI). Presumptive identification of 027/NAP1/BI strains of *C difficile* is by detection of binary toxin gene sequences and the single base pair deletion at nucleotide 117 in the *tcdC* gene. The *tcdC* gene encodes for a negative regulator in *C difficile* toxin production.

The Xpert *C difficile*/Epi Assay is intended as an aid in the diagnosis of CDI. Detection of 027/NAP1/BI strains of *C difficile* by the Xpert *C difficile*/Epi Assay is presumptive and is solely for epidemiological purposes and is not intended to guide or monitor treatment for *C difficile* infections. Concomitant culture is necessary only if further typing or organism recovery is required.(Package insert: Xpert C difficile /Epi. Cepheid; Rev. J, 04/2020)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87493

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CDPCR	C. difficile Toxin, PCR, F	54067-4

Result ID	Test Result Name	Result LOINC® Value
TCDRR	C. difficile Toxin, PCR	54067-4