

## Overview

### Useful For

Diagnosing the presence of toxigenic *Clostridioides difficile*

### Testing Algorithm

For information see [Laboratory Testing for Infectious Causes of Diarrhea](#).

### Special Instructions

- [Laboratory Testing for Infectious Causes of Diarrhea](#)

### Method Name

Enzyme Immunoassay (EIA)

### 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

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) <7 days/Refrigerated <7 days

**Acceptable:**

**Specimen Type:** Unpreserved feces

**Supplies:**

-Stool container, Small (Random), 4 oz (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) <7 days/Frozen <7 days

**Forms**

If not ordering electronically, complete, print, and send an [Microbiology Test Request](#) (T244) with the specimen.

**Specimen Minimum Volume**

See Specimen Required

**Reject Due To**

Formed stool Fecal ESwab Feces in gel transport medium ECOFIX preservative Formalin or polyvinyl acetate (PVA) fixative Preserved feces received frozen	Reject
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Fecal	Varies	7 days	

**Clinical & Interpretive**

**Clinical Information**

In the United States, toxigenic *Clostridioides difficile* (TCD) accounts for 15% to 25% of all episodes of antibiotic-associated diarrhea. TCD is also associated with a spectrum of disease states, ranging from asymptomatic colonization to pseudomembranous colitis, toxic megacolon, sepsis, and death. Pathogenic *C difficile* produces one or

both of 2 toxins, toxin A and toxin B. While toxin A is produced by most disease-causing strains of *C difficile*, it has been shown that some disease-causing strains of *C difficile* produce only toxin B. *C difficile* strains that do not produce toxins A or B are thought to be avirulent.

Toxin A and B enzyme immunoassays (EIA) have low sensitivity and moderate specificity for *C difficile* infection. The suboptimal performance of EIA sparked the development of molecular tests (eg, polymerase chain reaction) that have high sensitivity. EIA may be useful as part of a multi-step algorithm if patients do not meet preanalytic criteria for stool submission (unexplained and new onset diarrhea with at least 3 unformed stools/day and no recent laxative use).

### Reference Values

Negative

### Interpretation

Positive:

*C difficile* toxin detected by enzyme immunoassay (EIA).

Negative:

*C difficile* toxin not detected by enzyme immunoassay (EIA).

### Cautions

Results should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

### Clinical Reference

1. Johnson S, Lavergne V, Skinner AM, et al. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults. Clin Infect Dis. 2021;73(5):e1029-e1044. doi:10.1093/cid/ciab549
2. McDonald LC, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):987-994
3. Miller R, Morillas JA, Brizendine KD, Fraser TG. Predictors of Clostridioides difficile infection -related complications and treatment patterns among nucleic acid amplification test -positive/toxin enzyme immunoassay-negative patients. J Clin Microbiol. 2020;58(3):e01764-19

### Performance

#### Method Description

The C. DIFF QUIK CHEK COMPLETE test uses antibodies specific for toxins A and B of *C difficile*. The device contains a Reaction Window with three vertical lines of immobilized antibodies. The Conjugate consists of antibodies to toxins A and B coupled to horseradish peroxidase. To perform the test, the sample is added to a tube containing a mixture of Diluent and Conjugate. The diluted sample-conjugate mixture is added to the Sample Well and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, any toxins A and B in the sample bind to the antibody-peroxidase conjugates. The antigen-antibody-conjugate complexes migrate through a filter pad to a membrane where they are captured by the immobilized toxins A and B-specific antibodies in the lines. The Reaction Window is subsequently washed with Wash Buffer, followed by the addition of Substrate. This test will detect levels of toxin A at

greater or equal to 0.63 ng/mL and toxin B at greater than or equal to 0.16 ng/mL.(Package insert: C. Diff Quik Chek Complete IFU. RMS 91-525C-03-TL, TechLab; 06/2021)

**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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

**CPT Code Information**

87324

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
EIACD	C. difficile Toxin Antigen, Feces	79177-2

Result ID	Test Result Name	Result LOINC® Value
EIACD	C. difficile Toxin Antigen, Feces	79177-2