Test Definition: EIACD

Clostridioides difficile Toxin, EIA, Feces

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

Formed stool Fecal ESwabs 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	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