
Lab Dept: Microbiology/Virology

Test Name: CLOSTRIDIUM DIFFICILE TOXIN GENE BY PCR

General Information

Lab Order Codes: CDT

Synonyms: *C. difficile* Toxin PCR; PCR; *C. difficile* Toxin

CPT Codes: 87493 – Clostridium difficile, toxin gene(s), amplified technique

Test Includes: Detection of toxogenic *Clostridium difficile* by PCR directly on liquid or loose stool specimens from patients suspected of having *Clostridium difficile*-associated disease. The assay targets the toxin B gene tcdB.

Logistics

Lab Testing Sections: Molecular Biology, Minneapolis Campus only

Phone Numbers: MIN Lab: 612-813-7103

STP Lab: 612-813-7103

Test Availability: Specimens accepted daily, 24 hours

Turnaround Time: 1 day

Special Instructions: **One specimen per week** will be accepted for testing unless approved by pathology. Requisition must state specific **Specimen site** and **date/time of collection**.

Specimen

Specimen Type: Fresh liquid or soft stool

Container: Plastic, dry, leakproof container

Volume: 2 mL or 2 g (Minimum: 0.5 g) stool

Collection: **Fresh Stool**

1. Collect fresh, diarrheal stool in a clean, dry bedpan or on a newspaper over the toilet. **Do not** contaminate with urine, residual soap or disinfectants.
2. Transfer to a plastic, leakproof container.

Pediatric Patients in Diapers

1. Patients with severe diarrhea may use a U-bag collection system. Place the bag over the anal area in an attempt to retrieve the specimen before it soaks into the diaper.
2. The diaper can be reversed with the plastic side toward the skin to prevent the specimen from soaking into the diaper.
3. Transfer specimen into a plastic, leak proof container.

Transport/Storage:

Transport to the Laboratory at room temperature. If a delay is anticipated, refrigerate specimen at 4 degrees Celsius.

Specimens are stable up to 2 days at room temperature and 5 days at refrigerated temperature.

Sample Rejection:

No diapers accepted. Specimens that are not liquid or loose; specimens exceeding stability requirements; multiple specimens received within 1 week; improperly labeled specimen; specimen contaminated with urine and/or water; leaking container; insufficient volume. If an unacceptable specimen is received, the patient's caregiver will be notified and another specimen will be requested before the specimen is discarded.

Interpretive

Reference Range:

Negative: *C. difficile* Toxin tcdB gene not detected by PCR

Unresolved results due to PCR inhibition are inconclusive. Consider repeat collection if clinically indicated.

Limitations:

- Children less than 2 years may carry asymptotically carry toxigenic strains of *C. difficile* without having the disease. Results need to be interpreted cautiously.
- Inhibitory substances including excessive blood and mucus may give unresolved or negative results. Results should always be interpreted in conjunction with clinical findings.
- Test of cure in patient with *C. difficile* has limited utility since nucleic acid may persist after effective treatment.
- Tums and Maalox liquid may inhibit the *C. diff* assay.
- Testing of colostomy or colonoscopically collected specimens has not been validated.

Methodology:

PCR (Polymerase Chain Reaction)

References:

BD MAX Cdiff Assay, P0137(01) Date:(2013-04), GeneOhm Sciences Canada, Inc. , 2555 Boul. Parc-Technologies, Quebec, Qc, Canada, G1P 4S5

Lyras D. Toxin B is essential for virulence of *Clostridium difficile*, Nature (London) 458L1176 (2009)

Tang P, Roscoe M, Richardson SE. (2005) Limited Clinical utility of *Clostridium difficile* toxin testing in infants in a pediatric hospital. Diagn Microbiology Infect Dis; 52:91-4

Miller, J Michael (1999) A Guide To Specimen Management in Clinical Microbiology, American Society for Microbiology, Washington DC, p 100

Baron, EJ and RB Thompson, Jr (2011) Specimen Collection, Transport, and Processing: Bacteriology IN J. Versalovic, et al., ed), Manual of Clinical Microbiology, 11th ed, American Society for Microbiology, Washington DC, pg 327

Updates:

6/1/2011: Method change, previously listed as Enzyme Immunoassay. CPT change.

11/30/2011: Addition of factors that may cause false negative results under [Limitations](#). Sample storage modified, previously listed as 2-8 degrees C.

6/23/15: Added U-bag collection info for children in diapers and updated Limitations.