**Lab Dept:** Microbiology/Virology

**Test Name:** CLOSTRIDIUM DIFFICILE TOXIN GENE BY PCR

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**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.

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**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.

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**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


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.