Lab Dept:	**Microbiology**
Test Name:	**CLOSTRIDIUM DIFFICILE TOXIN GENE BY PCR**

General Information

Lab Order Codes:	CDTP
Synonyms:	*C. difficile* Toxin PCR; PCR; C. difficile Toxin
CPT Codes:	87493 – Clostridium difficile, toxin gene(s), amplified technique
Test Includes:	Detection of toxigenic *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:	Microbiology, Minneapolis Campus only
Phone Numbers:	MIN Lab: 612-813-7103 STP Lab: 612-813-7103
Test Availability:	Specimens accepted daily, 24 hours
Turnaround Time:	24 hours from receipt in Minneapolis lab
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 Stool ostomy samples are acceptable, if not collected by endoscope or aspirate.
Container:	Plastic, dry, leak-proof 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, leak-proof 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 1 day 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; stool aspirates; 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:

- Non-027/NAP1/BI isolates representing toxinotype XIV will be reported "Toxigenic *C. diff* POSITIVE; 027 PRESUMPTIVE POSITIVE" using the Xpert *C. difficile/Epi* Assay.
- Occasionally, non-027/NAP1/BI isolates representing toxinotypes IV, V and X will be reported "Toxigenic *C. diff* POSITIVE; 027 PRESUMPTIVE POSITIVE" using the Xpert *C. difficile/Epi* Assay.
- The performance of the Xpert *C. difficile/Epi* Assay was validated using the procedures provided in this package insert only.
- Modifications to these procedures may alter the performance of the test.
- Positive results observed with immunocompromised pediatric patients may reflect asymptomatic carriage of *C. difficile/Epi.*
- Detection of *C. difficile* nucleic acid in stools confirms the presence of these organisms in diarrheal patients but may not indicate that *C. difficile* are the etiologic agents of the diarrhea.
- Results from the Xpert *C. difficile/Epi* Assay should be interpreted in

conjunction with other laboratory and clinical data available to the clinician.

● Erroneous test results might occur from improper specimen collection, failure to follow the recommended sample collection, handling and storage procedures, technical error, sample mix-up, or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.

● Because of the dilution factor associated with the retest procedure, it is possible that *C. difficile* positive specimens, very near or at the limit of detection (LoD) of the *C. difficile/Epi* Assay, may result in a false negative result upon retest.

● Inhibition of the Xpert *C. difficile/Epi* Assay has been observed in the presence of the following substances: Zinc oxide paste and Vagisil® cream.

● Outbreaks of CDI may be caused by strains other than 027/NAP1/BI.

● False-negative results may occur when the infecting organism has genomic mutations, insertions, deletions, or rearrangements or when performed very early in the course of illness.

- Performance characteristics were not established for patients <2 years of age.

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

Xpert C. difficile/Epi Package Insert, 200-9680 Rev. F. In: Cepheid; 2016

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. 12/27/2018: Updated method 7/19/2019: Stool aspirated removed as acceptable specimens 8/5/2019: Updated TAT 11/5/2020: Update rejection criteria