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# TECHNICAL BULLETIN

## *CLOSTRIDIUM DIFFICILE* TOXIN GENE DETECTION BY DNA AMPLIFICATION

James L. Prescott, PhD, HCLD (ABB) Scientific Director, Molecular Diagnostics
Pranil Chandra, DO, Associate Medical Director, Molecular Pathology

### OVERVIEW AND CLINICAL UTILITY:

Because of their low sensitivity, enzyme immunoassay (EIA) tests are no longer recommended for detection of C. difficile toxin in stool specimens.[1] Recent literature indicates that nucleic acid amplification-based assays provide sensitivities and specificities comparable to toxigenic culture, the current "gold standard" and provide significantly shorter turnaround times.[2-4]

### ORDERING:

| | |
|---|---|
| **Test Name** | C. difficile Toxin Gene Detection by DNA Amplification |
| **Test Code** | CDIFF |
| **Method** | DNA Amplification |
| **CPT Code** | 87493 |
| **Changes** | - This assay replaces the *Clostridium difficile* Toxin A+B enzyme immunoassay test.<br>- Formed stool specimens are not acceptable unless ileus is present.<br>- Specimens collected within 7 days of a previous specimen will be rejected. |
| **Specimen** | Raw stool or stool preserved in Cary-Blair-based transport medium.<br>Transport refrigerated (2-8 °C). |
| **Test Schedule** | Monday through Friday |

**Note:** The test code above, CDIFF (Clostridium difficile Toxin Gene by DNA Amplification), replaces test code CDIFB (C. difficile toxin B gene (tcdB), RT-PCR). Where appropriate, it is important that you notify your EMR administrator of this change.

### TEST INFORMATION:

PathGroup will phase-out the enzyme immunoassay (EIA) and will utilize Illumigene's LAMP methodology assay for the detection of toxigenic strains of C. difficile in stool specimens. This test has a much higher sensitivity and specificity, superior turn-around time when compared to 2 and 3 step algorithms and eliminates multiple test orders. This translates to reduced costs for repeat testing, unnecessary isolation and delayed therapy.

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**GENERAL TESTING RECOMMENDATIONS:**

- Only test diarrheal (i.e. unformed) stool (≥3 loose stools/day for 1-2 days).
- Non-diarrheal stool should only be tested with suspected ileus due to C. difficile.
- Testing of asymptomatic patients and test of cure is not clinically useful.
- Repeat testing during the same episode of diarrhea is not recommended.

**RESULT REPORTING:**

Results are reported as: **Detected, Not Detected, or Inhibitory** with recollection recommended.

**REFERENCES:**


1. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA); Infection Control and Hospital Epidemiology May 2010, vol. 31, no. 5
2. Laboratory diagnosis of Clostridium difficile infection can molecular amplification methods move us out of uncertainty?Tenover FC, Baron EJ, Peterson LR, Persing DH. J Mol Diagn. 2011 Nov;13(6):573-82.
3. Rapid and Sensitive Loop-Mediated Isothermal Amplification 1 (LAMP) Test for *Clostridium difficile* Diagnosis Challenges Cytotoxin B Cell Test and Culture as Gold Standard ; Tnorén, * I Alriksson, Josefin Andersson, Thomas Åkerlund, and Magnus Unemo . J. Clin. Microbiol. Vol. 49, No. 2 p. 710-711.
4. Pathology consultation on detection of Clostridium difficile. Svensson AM, LaSala PR; Education Committee of the Academy of Clinical Laboratory Physicians and Scientists. Am J Clin Pathol. 2012 Jan; 137(1):10-5.