WHAT’S NEW?
Effective Thursday, January 31, 2013, PeaceHealth Laboratories in Vancouver, Washington will transition from the current amplified Polymerase Chain Reaction method to detect toxigenic *C. difficile* to a new, Nucleic Acid Amplification method.

The new test, Toxigenic *C. difficile* DNA Detection, will replace the *C. difficile* toxin B by PCR test. Both tests detect nucleic acid and both tests have improved sensitivity over enzyme immunoassays that detect either *C. difficile* antigen or toxin.¹

BACKGROUND
*Clostridium difficile* infection has become a major cause of sickness and death in hospitalized patients and has recently been recognized as a significant cause of diarrhea in outpatients.

*C. difficile* is responsible for 337,000 infections and 14,000 deaths in the U.S. every year. Death rates are highest in the elderly, however almost half of infections occur in people younger than 65.²

Diagnosis of CDI requires detection of toxigenic *C. difficile* in stool specimens. Accordingly, accurate laboratory testing is of critical importance to ensure optimum diagnosis, treatment and control of CDI.

Recently developed NAA tests have proven to offer improved accuracy for the laboratory diagnosis of CDI.

WHEN TO TEST
- Severe or persistent diarrhea in patients with risk factors (predominantly previous antibiotic use); may also occur several months after antibiotic use.
- Hospitalized patients with >72 hours diarrhea (sooner for clinical indications).

WHY THE CHANGE?
Several test methodologies are used to diagnose CDI. Enzyme immunoassay tests provide rapid results, yet are known to be less sensitive than NAA tests.

Toxigenic culture (growth of the organism from stool cultures and testing for toxin genes by NAA) is the gold standard for CDI testing. However, this method remains technically challenging and has a 3–4 day result turnaround time that is impractical for clinical testing.

Direct detection of *C. difficile* toxin genes in stool specimens using NAA is nearly equivalent in accuracy with toxigenic culture to detect CDI and can be accomplished in a timely manner.

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The upcoming change from PCR to NAA (loop amplification method) will maintain the current test sensitivity while standardizing test methodology throughout the PeaceHealth Laboratories system.

**Loop amplification method**

The loop amplification method is an FDA-cleared NAA method that directly detects *C. difficile* toxin genes in stool specimens. In three recently published studies using toxigenic culture, loop amplification demonstrated 92–95% sensitivity and 99% specificity for the laboratory diagnosis of CDI.\(^1\),\(^3\),\(^4\)

**HOW TO ORDER TESTING**

Keep these points in mind when ordering the Toxigenic *C. difficile* DNA Detection test:

- Only order *C. difficile* testing for your patients with diarrhea defined as three or more soft or liquid stool specimens in a 24-hour period.

- Submit only unformed stool specimens for testing. Formed stool (does not take the shape of the container) will be rejected.

- Submit only one stool specimen per diarrheal illness. Repeat testing is generally not indicated except for recurrent diarrhea after treatment.

- Specimens will be rejected if received within 2 days of a previous negative test or within 7 days of a previous positive test.

- Antibiotic exposure is not required for testing although many patients with CDI have prior antibiotic exposure. Recent studies indicate that up to 30% of CDI patients have no recent antibiotic exposure.

- Pediatric patients may be colonized and otherwise test positive for *C. difficile* when they have no infection. It is important to test only patients with symptoms consistent with CDI.

**QUESTIONS?**

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ORDERING INFORMATION

CDTOX: Toxigenic C. difficile Detection by nucleic acid test
Methodology: Nucleic Acid Amplification
Performed: Testing is done twice daily Monday through Friday
           Testing is done once daily Saturday and Sunday
Released: 24 hours or less from specimen receipt in laboratory
CPT code: 87493

SPECIMEN REQUIREMENTS

Collect: Stool unpreserved, or preserved in a Cary-Blair based medium. Only
         unformed stool specimens are acceptable. Swabs are not
         acceptable.

         Specimens from neonates (<1 month) and young children (<2 years)
         are not accepted as they are often colonized with toxigenic
         C. difficile but do not have the receptor that is necessary to become
         infected.

         Testing should be limited to patient with three or more unformed stool specimens
         in a 24-hour period unless obstruction is suspected.

         Unpreserved stool specimen: Collect 1 ml or 1 gm of specimen in a resealable clean
         container. Store and transport refrigerated (2–8° C) prior to testing. Specimen
         may be held for 24 hours ambient (21–27° C) or five days refrigerated. Sample that
         will not be tested within 24 hours should be frozen immediately upon receipt and
         stored ≤-20° C until tested.

         Preserved stool specimen in Cary-Blair medium should be stored and transported
         refrigerated (2–8° C) prior to testing. If necessary, specimen may be held up to five
         days refrigerated. Sample not tested within this time should be frozen immediately
         upon receipt and may be stored ≤-20° C for seven days prior to testing.

         Submit only one stool specimen per diarrheal illness. Repeat testing is generally not
         indicated except for recurrent diarrhea after treatment.

Stability: Specimen may be frozen and thawed once.
Transport: Refrigerated at 2–8° C prior to testing or frozen on dry ice ≤-20° C.
Rejection Criteria: QNS specimen; formed specimen; colon wash specimen; specimen contaminated
                   with urine, water, soil or Barium; specimen improperly handled: not stored or
                   received per collection criteria; swabs or diapers; second specimen on patient less
                   than 2 days after a previous negative; second specimen on patient less than 7 days
                   after a previous positive.

REFERENCES


