



Creighton
MEDICAL LABORATORIES

MOLECULAR PCR TEST REPLACING CLOSTRIDIUM DIFFICILE TOXIN EIA

Clostridium difficile is the major cause of antibiotic-associated diarrhea and can progress to pseudomembranous colitis. Disruption of the normal intestinal flora by antibiotic therapy can result in the loss of "colonization resistance" against *C. difficile*, predisposing the patient to infection. The virulence mechanisms of *C. difficile* are related to the production of two toxins, toxin A and toxin B. The recent increased incidence and severity of *C. difficile* disease may be due to expanded use of antibiotics, especially of the quinolone class. These increases have prompted the JCAHO to include reduction of *C. difficile* infections in their national patient safety goals for 2009.

Past laboratory testing for *C. difficile* was largely based on a toxin A/B EIA. This test is rapid, technically simple to perform, and comes in a variety of formats. However, it has been recently demonstrated that this test has very poor sensitivity (40-60%), and suboptimal positive predictive value (70-90%). Other tests such as culture and cell cytotoxicity are more accurate, but are labor intensive and have unacceptably long turnaround times (2-7 days). The "common antigen" EIA has promise as a screening test but because of its poor specificity, positive results require confirmation.

Creighton Medical Laboratories is pleased to begin offering a new test to detect *C. difficile* toxin from stool specimens using state-of-the-art molecular amplification methodology (PCR) as a replacement for the *C. difficile* EIA, which will be discontinued. This new PCR test has a much higher overall accuracy ($\geq 95\%$) with superior sensitivity and specificity relative to EIA. The turnaround time for PCR will be similar to that of the EIA test. Specimens received by early afternoon on a weekday will generally be tested and resulted that same afternoon.

Any request for *C. difficile* toxin EIA test will automatically be changed to the PCR test unless specifically requested otherwise by stating "DO NOT DO PCR" on the requisition. In this case the specimen will be sent to our reference laboratory for toxin EIA (expect results in 2-3 days).

Effective Date: August 10, 2009

Specimen and Transport Requirements: Same as for *Clostridium difficile* toxin A/B EIA. Stool specimens should be submitted in clean, sealed container.

Test Order: *Clostridium difficile* Toxin PCR

Availability: Performed on weekdays with results available in the afternoon if specimen received before 2PM.

Creighton Medical Laboratories is proud to be your partner in providing effective and timely health care.

AUG/2009