Improved Diagnosis of \textit{Clostridium difficile} Infection (CDI)
by a New Real Time PCR Test

Beginning, November 2\textsuperscript{nd}, 2009 the Infectious Disease Department, Molecular Division, of Metropolitan Medical Laboratory PLC will offer a new real-time PCR (Polymerase Chain Reaction) test for the laboratory diagnosis of \textit{Clostridium difficile} gastrointestinal disease. This new assay provides a diagnostic test that is:

- Highly sensitive
- Can provide same day results, and
- Has a high negative predictive value (true negatives) allowing clinicians to rule out a diagnosis of CDI with confidence from a single test.

\textit{C. difficile} is an anaerobic, spore-forming bacillus that can produce two toxins: toxin A (enterotoxin) and toxin B (cytotoxin). Eighty percent of toxigenic \textit{C. difficile} isolates produce both toxins. Virtually all toxigenic strains of \textit{C. difficile} produce toxin B. The \textbf{BD GeneOhm™ Cdiff PCR} assay targets the toxin B gene (tcdB) which is considered the primary virulence factor responsible for CDI.

The BI/NAP1/027 strain of \textit{C. difficile} has been associated with outbreaks and increased severity of CDI. This strain produces toxins A and B along with a third toxin (binary toxin). The BD GeneOhm™ Cdiff test will detect both outbreak and non-outbreak strains of \textit{C. difficile}, but this test will not distinguish between them.

\textbf{Indications for testing:}

- Only unformed diarrheal stools from patients with clinically significant diarrhea should be tested for \textit{C. difficile}.
- Do not attempt to decolonize asymptomatic patients.

It is important to remember that certain patient population groups have a significant rate of asymptomatic carriage of toxigenic \textit{C. difficile} e.g. infants younger than one year of age. In these infants, detection of \textit{C. difficile} toxin should not be assumed to be a cause of diarrhea.

\textbf{Do not order repeat testing or submit multiple samples for \textit{C. difficile testing}.}

One specimen is sufficient for rule-out or confirmation of a diagnosis of CDI when this highly sensitive assay is used for detection. If a patient has had a stool sample positive for \textit{C. difficile}, retesting is not necessary unless symptoms resolved with treatment and then returned after treatment (i.e. do not perform test of cure on patients successfully treated for CDI).
References:


Specimen Requirements and Testing Information

*C. Difficile* by PCR (10173)

Specimen Required: Only **unformed** diarrheal stools will be accepted. Refrigerate immediately. Transport specimen between 2° and 25°C. Protect against freezing or exposure to excessive heat.

Patient Preparation: None

Days Performed: Daily

Days Reported: Daily

Rejection: Formed stool
Replicate testing

Methodology: Polymerase Chain Reaction

Price: Please contact Marketing at (309)762-8555, ext. 3611.