CORPORATE OFFICES
1304 Buckley Road
Syracuse, NY 13212-4302
Tel: 315.453.7200
Fax: 315.461.3030

OPERATIONS CENTER
113 Innovation Lane
Liverpool, NY 13088
Tel: 315.453.7200
Fax: 315.410.7007

LABORATORY ALLIANCE
of Central New York, LLC
www.laboratoryalliance.com

New Rapid PCR Test for the Improved Diagnosis of Clostridium difficile Infection

Effective August 31, 2009, the Microbiology department of Laboratory Alliance of Central New York will be offering a new real-time PCR test for the laboratory diagnosis of Clostridium difficile gastrointestinal disease. This new gene amplification assay offers the best test sensitivity (95%) of any available method for establishing the laboratory diagnosis of this infection.

Clinical Significance:
As you are aware, the laboratory diagnosis of C. difficile diarrheal disease has been problematic as there has been no method that provided for the reliable diagnosis of this infection. Traditionally, culture and cytotoxin assay have been regarded as the "gold standards" for laboratory testing but the sensitivities of even these tests are less than perfect. In addition, these methods are labor intensive and time consuming and, for these reasons, are not offered by most clinical microbiology laboratories. Instead, most laboratories offer EIA tests that screen for toxin B or toxins A and B because they offer convenience with a rapid turn-around time. However, these tests suffer from poor sensitivity.

Based upon comparative scientific studies, the real-time PCR assay, which screens for the toxin B gene, has a 95% sensitivity while the traditional "gold standard" cytotoxin assay has a sensitivity of only 80%. As expected, various EIA methods that screen for toxins A and/or B have the poorest sensitivities ranging from 43 to 55%. Because of this high assay sensitivity, PCR test results may remain positive for many weeks after the completion of treatment. As such, Test of Cure testing is not recommended. Similarly, repeat testing in the face of an initial negative PCR result is of limited value and very costly.

Another important advantage of this assay is that it allows expedited random access testing with results available within two to three hours of specimen receipt. As such, "expedited" testing can be performed on request under special circumstances.

Important Note: During our in-house validation of this assay, we found that 50% of the toxin-positive stool samples were produced by the hypervirulent strain of C. difficile (027/NAP1/B1). This observation is particularly noteworthy because the prevalence of this hypervirulent strain has now reached epidemic proportions in our area since Laboratory Alliance first reported the detection of this strain in our community less than 18 months ago (1).

Test Code:	CDTPCR
Method:	PCR
Specimen Requirements:	Submit **ONE** unformed (soft or loose) stool in a clean container, (at least 5ml or 5 gm). Due to the high sensitivity and specificity of the test, additional specimens submitted within 7 days will be rejected.
Unacceptable Conditions:	Formed stool, swabs, specimens in liquid transport or preservative.
Storage and Transport:	Inpatient; transport at ambient (20-30^{o}C), Outpatient: transport at 2-8^{o} C, Specimen is stable for 5 days at 2-8^{o}C and 24 hours at ambient temperature.
Schedule of Testing:	Daily
CPT Code:	87798
Billing Code:	3010357
Reference Interval:	Negative: Clostridium difficile toxin B gene not detected by PCR.
For more information:	Please do not hesitate to contact Mr. Russell Rawling, Microbiology Manager, at 315-470-7060, or Dr. Paul Granato, Director of Microbiology, at 315-464-7653 if you have any questions or concerns regarding this new service.

References

1. Granato, P.A. 2008. Hypervirulent Clostridium difficile. Vol. 5: p.3.

Cl1445