RML
REGIONAL MEDICAL LABORATORY

M E M O

To: All Regional Medical Laboratory (RML) Clients

From: Gerald Miller, Ph.D., Chief of Microbiology and Immunology
Linda Strycker MT(ASCP), Manager of Microbiology

Date: April 19, 2011

Subject: **Clostridium difficile by Molecular Method**

RML is now offering a new molecular diagnostic test *for Clostridium difficile*. We now offer Meridian Bioscience's Inc, illumigene *C. difficile* assay. This is a qualitative, in vitro, diagnostic molecular amplification test that detects the pathogenicity locus by targeting the tcdA region which is found in all A+B+ and A-B+ toxinotypes.

The assay method utilizes loop mediated isothermal amplification (LAMP) to detect toxin gene sequences associated with toxin producing *C. difficile*. The assay provides a sensitivity of 95.2% and a specificity of 95.3% respectively when compared to gold standard of toxigenic culture. The currently used EIA assay for *C. difficile* has been reported to have much lower sensitivity (33-97%) and specificity (83-100%). The illumigene *C. difficle* assay is also the only commercially available assay that is **FDA cleared for pediatric testing in patients under the age of 2.**

The specimen requirements are: **Liquid or soft stools (i.e. takes the shape of container) only.** Note that formed or hard specimens will be rejected for molecular testing and the client notified. This is because patients may be colonized with toxin-producing *C. difficile* strains which are not causing active disease; therefore it is not recommended that formed stool be tested or that positive results on formed stool be treated.

Another advantage of the assay is **the elimination of the need for duplicate or multiple sample testing**. Because the molecular assay is more sensitive than EIA, duplicate testing is not necessary. However because *C. difficile* can emerge within a few days of starting antibiotics, one specimen every 4 days will be acceptable. Requests for additional testing within 4 days will be canceled and the client notified.

Test name:	Clostridium difficile Molecular
Order Mnemonic:	**C DIFF MOL**
Test number:	6001200
Methodology:	LAMP for detection of toxin gene sequences
Reference Range:	Negative for toxigenic Clostridium difficle
Specimen required:	Raw diarrheal stool transported within 24hours (at 2 -8^{o}C) or stool preserved in ETM or Cary-Blair transport (at 2-8^{o}C)
CPT code:	87493

If you have questions, please contact Gerald C. Miller, Ph.D., Chief of Microbiology and Immunology or Linda Strycker, MT(ASCP), Microbiology Manager at 918-744-2553 or 800-722-8077.