

## MEMORANDUM #123

**TO:** UNC Hospitals Attending Physicians, Housestaff, Nursing Coordinators,  
Department Heads and Supervisors

**FROM:** Mark Brecher M.D., Director, McLendon Clinical Laboratories  
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**DATE:** August 1, 2007

**SUBJECT:** Change in *Clostridium difficile* testing procedure

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Beginning August 4, 2007, a new two-step testing algorithm for detection of *C. difficile* will be implemented replacing the current EIA test that detects *C. difficile* toxin in fecal specimens.

The initial screening test will be a 30 minute, immunochromatographic test for glutamate dehydrogenase produced by *C. difficile* (GDH test). In a recent study of over 350 clinical specimens in our laboratory, the sensitivity of the GDH test when compared to a tissue culture cytotoxicity test (reference method) was 100% while our current EIA toxin test had a sensitivity of only 60%. Unfortunately the highly sensitive GDH test had a positive predictive value of only 52%. This poor positive predictive value is due in part to the inability of the GDH test to differentiate between toxigenic (disease-causing) and non-toxigenic (non-disease causing) strains of *C. difficile*. The negative predictive value of the GDH test approaches 100%. Therefore a two-step testing algorithm is needed to determine the presence of toxin producing *C. difficile* in feces.

The GDH screening test will be performed 3 times daily. Specimens that are negative in the GDH test will be reported as “negative for *C. difficile*.”

Approximately 20% of fecal specimens will be GDH positive and require confirmation by a tissue culture cytotoxicity, which will determine the presence of *C. difficile* toxin in feces. This test will be performed daily. Specimens positive by the cytotoxicity assay will be reported as “positive for *C. difficile* toxin.” Negative specimens in this assay will be reported as “negative for *C. difficile* toxin.” The turn-around-time of this assay is 48 hours.

For questions, please contact the Clinical Microbiology-Immunology Laboratories at 6-4053.