CLOSTRIDIUM DIFFICILE-ASSOCIATED DISEASE (CDAD) TOXIN GENE TEST

I. GENERAL CONSIDERATIONS:

Clostridium difficile is an anaerobic, Gram-positive bacterium associated with a spectrum of GI disease including antibiotic-associated diarrhea, non-specific colitis and pseudomembranous colitis, mainly in patients who have previously received antimicrobial therapy. Clinical presentation may include mild to severe diarrhea, dehydration, fever, leukocytosis, abdominal pain, and GI bleeding.

The mechanism of pathogenesis of the organism relates largely to the production of a number of toxins with toxin: enterotoxin TcdA and cytotoxin TcdB found on the pathogenicity locus (PaLoc), with toxin B believed to be the major virulence factor. However not all *C. difficile* isolates carry the toxin genes and thus some strains are avirulent. In addition, toxigenic strains may be recovered from a small percentage of healthy adults and from a much larger percentage of healthy neonates and infants. It has been suggested that infants, particularly those < 1yr of age, lack receptors for the toxins in the colon. Thus, although toxin detection is a necessary criterion for laboratory diagnosis of CDAD, a positive laboratory test for *C. difficile* toxin must be interpreted cautiously, particularly in the neonate/infant age group.

Our laboratory currently uses a molecular assay based on loop-mediated amplification technology which uses specifically designed primers to detect the PaLoc pathogenicity locus.

II. SPECIMEN COLLECTION:

(1) Collect passed stool specimen in a clean container with tight fitting lid. A minimum of one (1) gram (or 1 mL liquid specimen) should be submitted. **A rectal swab specimen or stool transferred to a swab is NOT ACCEPTABLE. Formed stool is NOT accepted for testing.**

(2) **A positive toxin test must be interpreted in light of the patient's age and clinical symptoms because neonates may harbor toxin-producing *C. difficile* in the absence of disease.**