

# CHILDLAB

## Guide to Laboratory Services

### 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 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 enterotoxins 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 2 step procedure for the confirmation of CDAD. The first step involves a rapid screening test for the presence of a *C. difficile*-specific associated **antigen** (GDH) in the stool of patients being tested. This antigen test is highly sensitive for the presence of *C. difficile*, but it does not differentiate toxigenic from nontoxigenic stains. Thus if the antigen test is negative, a final report of "**negative for *C. difficile***" can be immediately issued on the same day of testing because there is no evidence of *C. difficile* present in the stool. About 80% of all the stool samples tested are negative in the antigen test. However, if the antigen test is positive, the stool sample is subsequently tested for **toxin B** in a second assay. This is an important second step because it allows for differentiation of antigen positive, toxigenic stains of clinical significance from antigen positive, nontoxigenic, avirulent strains. Only about 1/2 of the antigen positive specimens (10% of all samples submitted for testing) are positive for toxin B. Thus an **antigen positive** stool samples may subsequently be reported as "**negative for *C. difficile* toxin B**" or "**positive for *C. difficile* toxin B**".

### II. SPECIMEN COLLECTION:

- (1) Collect passed stool specimen in a clean container with tight fitting lid. 5 to 10 grams (or 5-10 mL liquid specimen) should be submitted. **A rectal swab specimen or stool transferred to a swab is NOT ACCEPTABLE.**
- (2) Ideally, two specimens should be collected on separate days to improve sensitivity of *C. difficile* toxin detection.
- (3) 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.