

Memorandum

TO: All DUHS and PDC providers and nursing staff

FROM: Christopher R. Polage, MD, MAS
Medical Director, DUHS Clinical Microbiology Laboratory

DATE: March 10, 2020

SUBJECT: Change to *C. difficile* Testing

Brief Description:

On March 17, 2020, the DUHS Clinical Laboratory will switch to a two-step method for *Clostridioides difficile* infection (CDI) testing and the test name will change to **C. difficile PCR w/ reflex to Toxin EIA**. There will be a new result format with interpretive comments to guide treatment and clinical decision-making. The ordering workflow will not change. **A one page summary of the new result format and expected clinical response is attached for reference and review.** Any questions can be directed to the DUHS Microbiology Laboratory (919) 684-2089 or Microbiology Laboratory Medical Director, Christopher Polage, MD (christopher.polage@duke.edu).

Additional Information:

Most hospital-onset diarrhea is caused by underlying illness, medications, or treatment, not *C. difficile*. Similarly, *C. difficile* colonization is more common than disease. However, the current DUHS polymerase chain reaction (PCR) test only detects *C. difficile* DNA and cannot distinguish active infection from colonization with another cause of symptoms. **With the change to two-step testing, a positive PCR will be followed by a stool toxin enzyme immunoassay (EIA), to detect the presence of free fecal toxins (protein) and improve clinical diagnostic accuracy.** Two-step testing will help clinicians distinguish active infection from colonization. Treatment is not indicated for toxin-negative patients without signs of severe disease but all PCR-positive patients require special enteric contact isolation.

Summary:

- Two-step approach to *C. difficile* testing begins on March 17th
 - PCR followed by a toxin EIA – will distinguish colonization from an active infection
- New test name - C. difficile PCR w/ reflex to Toxin EIA
- Interpretive comments will help guide treatment
- Colonized patients, as well as those with an active infection require enteric contact isolation



Summary – How to Interpret 2-step *C. difficile* Results

If this	Means this	Do this
 C difficile PCR Negative for <i>C. difficile</i> DNA (Toxin EIA not performed)	• <i>C. difficile</i> NOT detected • High NPV for CDI • CDI ruled out unless prior treatment or sample error	• Treatment for CDI NOT indicated • Isolation for <i>C. difficile</i> NOT indicated • No retest ≤7 days without major clinical change & Micro approve
 C difficile PCR See toxin result !  C difficile Toxin EIA Positive for toxins (see comment) !	• <i>C. difficile</i> DNA <u>AND</u> toxins detected • CDI likely, if clinical symptoms c/w CDI	• Treatment for CDI indicated • Isolation for <i>C. difficile</i> indicated • No retest ≤14 days without Micro approve (Test of cure not rec'd)
 C difficile PCR See toxin result !  C difficile Toxin EIA Negative for toxins (see comment)	• <i>C. difficile</i> DNA present but toxins <u>NOT</u> detected • Moderately high NPV for active CDI • Occasional CDI cases can be toxin- but should be uncommon / few	• Evaluate patient • Treatment NOT indicated unless severe/fulminant CDI disease (e.g., Unexpl. leukemoid rxn, megacolon) • Isolation for <i>C. difficile</i> indicated • No retest ≤7 days unless high clinical suspicion / major clinical change