UR MEDICINE | Labs

Change to C. difficile Testing Algorithm

Date: January 3rd, 2022

Effective Date: January 5th, 2022

Our current testing algorithm for laboratory diagnosis of C. difficile disease utilizes an Enzyme Immunoassay (EIA) for detection of Toxin and GDH (a non-specific marker for C. difficile) followed by PCR assay for detection of Toxin gene if Tox-GDH+ by EIA. This testing approach is geared toward providing maximum sensitivity for detection of Toxin or Toxin gene while accepting reduced specificity. More recent experience and data indicate, however, that the reduced specificity of the current testing approach can detect colonization with C. difficile in the absence of toxin production and lead to over diagnosis of disease and unnecessary treatment. After discussions with Infection Prevention, Infection Diseases, medical leadership of URMC and its affiliates, and representation from residential facilities, we will implement a new testing approach which will first test for Toxin gene by PCR followed by EIA for Toxin if the PCR assay is positive. This new testing approach will be implemented January 5, 2022. Ordering in EPIC (inpatient and outpatients) and affiliate computer systems has been adjusted to reflect this new testing approach. Example test results with interpretation are shown below.

1. **C. difficile PCR**: Positive
   C. difficile Toxin: Positive
   Interpretation: Suggests C. difficile disease. Test results should be interpreted in clinical context.

2. **C. difficile PCR:** Positive
   C. difficile Toxin: Negative
   Interpretation: Suggests C. difficile colonization; occasional patients with C. difficile disease may have negative toxin. Test results should be interpreted in clinical context.

3. **C. difficile PCR:** Negative
   C. difficile Toxin: Not Done
   Interpretation: Negative. PCR has a negative predictive value of >99%.

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