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Physicians Diagnostic Support Service

Kyle Carr, MD Salah Quitiashah, PhD Anne Gore, MT (ASCP)

Beginning July 3, 2017, the Munson Medical Center laboratory will perform *C. difficile* testing using a two-step algorithm. The initial screening test will be a combination glutamate dehydrogenase (GDH) and *C. difficile* toxin antigen assay.

Patients who test GDH positive and toxin negative will be reflexively tested using our current *C. difficile* PCR. Because the GDH assay detects non toxigenic *C. difficile*, the PCR will determine whether a patient is colonized with toxigenic or non toxigenic *C. difficile*. Clinically, a patient with a GDH-positive, toxin-negative result who is PCR-positive for toxigenic *C. difficile* is likely to be colonized but not infected by *C. difficile*, though there is potential for low-level or waxing-and-waning disease (especially under treatment for *C. difficile*, though no test of cure should be performed).

The following are the main reasons for this change.

- 1. There is a high rate of asymptomatic colonization in hospitalized patients<sup>1</sup> that cannot be demonstrated by PCR but can be suggested by the absence of a marker of pathogenesis (*C. difficile* toxin). It has been demonstrated that patients with a negative toxin antigen test, if left untreated for *C. difficile*, do not suffer complications of C. difficile disease<sup>2</sup>.
- 2. This algorithm has been shown to be 100% sensitive and 99.6% specific for the diagnosis of *C. difficile* disease<sup>3</sup>.
- 3. The results for patients who screen negative should be reported more quickly with the GDH/toxin assay.

Key points regarding the new test are as follows:

- Only test diarrheal (i.e., unformed, takes the shape of the container) stool (≥3 loose stools/day for 1 day). Formed stool will be rejected for testing.
- Non toxigenic *C. difficile* does NOT require isolation precautions or treatment.
- Colonizing toxigenic *C. difficile* can cause infection at a later point in time.
- *C. difficile* results for patients under two years of age should be interpreted with caution due to the high rate of asymptomatic carriage in this population.
- Contact precautions will be determined by the Infection prevention department and is mainly based on the presence of diarrhea regardless of the clinical interpretation of the result.

Thus, the algorithm in the appropriate patient will be:

Stool is tested for GDH antigen and Toxin A/B

Both positive=Positive, consistent with C. difficile infection

GDH positive, toxin negative=>PCR for gene for C. difficile:

PCR positive= Discrepant: infection vs. colonization; consider recollection

PCR negative=Negative, testing is not consistent with C. difficile infection (nontoxigenic C. difficile)

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GDH negative, toxin positive: Discrepant: infection vs. colonization; consider recollection

GDH and toxin negative=Negative, testing is not consistent with C. difficile infection

## References:

- 1. F. Alasmari, S. M. Seiler, T. Hink, C.-A. D. Burnham, and E. R. Dubberke, "Prevalence and Risk Factors for Asymptomatic Clostridium difficile Carriage," *Clin. Infect. Dis.*, p. ciu258, Apr. 2014. 2. C. R. Polage, D. L. Chin, J. L. Leslie, J. Tang, S. H. Cohen, and J. V. Solnick, "Outcomes in patients tested for Clostridium difficile toxins," *Diagn. Microbiol. Infect. Dis.*, vol. 74, no. 4, pp. 369–373,Dec.2012.
- 3. S. E. Sharp, L. O. Ruden, J. C. Pohl, P. A. Hatcher, L. M. Jayne, and W. M. Ivie, "Evaluation of the C.Diff Quik Chek Complete Assay, a New Glutamate Dehydrogenase and A/B Toxin Combination Lateral Flow Assay for Use in Rapid, Simple Diagnosis of Clostridium difficile Disease," *J. Clin. Microbiol.*, vol. 48, no. 6, pp. 2082–2086, Jun.