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CLOSTRIDIUM DIFFICILE GDH/TOXIN (C. diff)
Test Code 8340

The Pathology Lab has a new algorithm for testing specimens for C. diff as of November 7, 2022

The American Society for Microbiology (ASM) recommends using one of three algorithms for Clostridium difficile testing. The Pathology Lab was using an algorithm that includes only Molecular testing, which is the most sensitive and specific; however, we have recently learned that patients may colonize the bacteria and remain positive for months after a clinical cure when testing with a sensitive method such as PCR or NAAT. In these situations, the patient's symptoms are not caused by C. difficile, and there is a better testing algorithm.

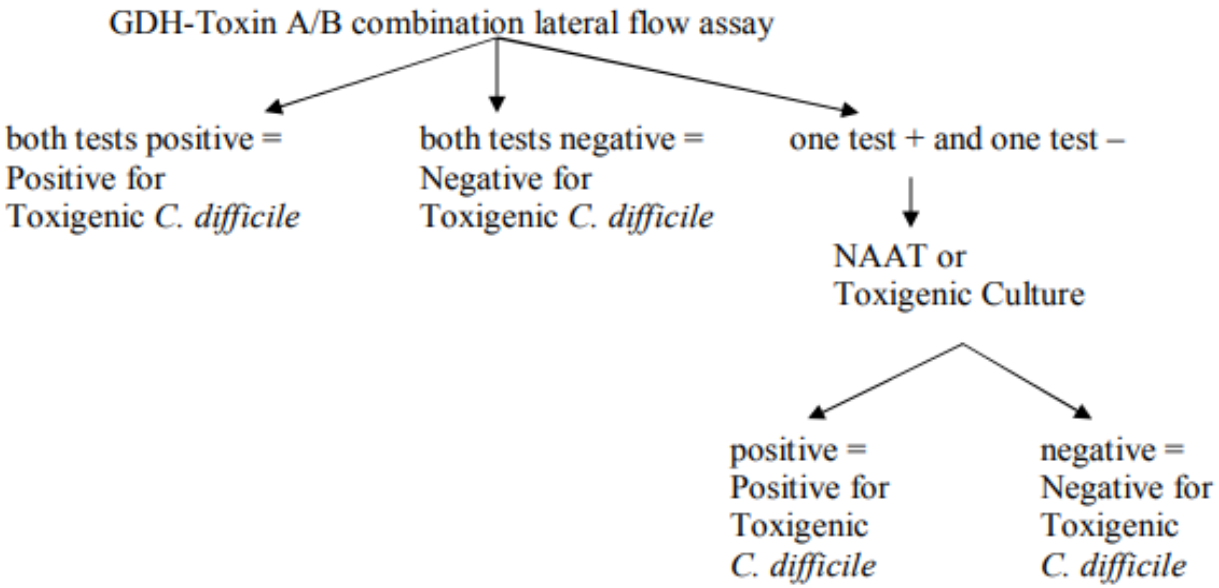
The Pathology Lab began using a new testing algorithm to improve the diagnosis and management of Clostridium difficile infection (CDI) on November 7, 2022. The new algorithm starts with a rapid membrane enzyme immunoassay (EIA) test that detects both GDH antigen (glutamate dehydrogenase), a common antigen found in both toxigenic and non-toxigenic isolates of C. difficile, and toxins A and B. EIA kits are not as sensitive as molecular tests. The toxin may need to be confirmed by a molecular method. Please see **Table 1** below.

Testing for toxigenic C. difficile should be limited to patients with three or more watery, loose, or unformed stools (stools that take the form of the container) per 24-hour period unless ileus (obstruction) is suspected. Any testing of formed stool specimens would need to be communicated to the microbiology department.

Repeat testing following a positive test (test of cure) is not recommended since patients may carry toxigenic C. difficile for months after clinical cure. Repeat testing following a positive test is appropriate if the patient improves with therapy and relapses after completing a treatment regimen (clinical relapse).

Repeat testing following a negative test is not recommended when using the new algorithm because nearly all positive patients will be detected (high sensitivity). Testing a second specimen from a negative patient is more likely to be a false positive.

Table 1 The Pathology Lab Algorithm 11.7.2022



Initial testing will be performed using a rapid membrane enzyme immunoassay to detect Glutamate Dehydrogenase Antigen (GDH) and Toxins A and B. If results are different from one another (i.e. one test is positive and one test is negative), molecular reflex testing (PCR or NAAT) will be performed. The results will be one of the following:

1. **Negative Toxigenic C. diff**
   Disclaimer will report both GDH antigen, and Toxin A&B are negative.
2. **Positive Toxigenic C. diff**
   Disclaimer will report both GDH antigen, and Toxin A&B are positive.
3. **Negative Toxigenic C. diff**
   When GDH or Toxin are different from one another and the PCR or NAAT reflex is negative.
   Disclaimer will report results from Lateral Flow Assay were confirmed by PCR methodology.
4. **Possible positive C. difficile**
   When the lateral flow C. diff GDH Antigen is positive, the toxin is negative, and PCR reflex toxin confirms positive, the following disclaimer will report. The patient has toxigenic C. diff organisms in the bowel, but the toxin was not detected. The patient may be a carrier, or the level of toxin in the sample was below the detection limit. This information should be used in conjunction with the patient's history when deciding on possible therapy.

   *** When the stool is formed, it will not be treated as critical. The client will receive a courtesy call from the lab. When the stool is loose, it will be treated as critical.*

If you have any questions, please contact Sarah Goos at 337.312.1286 or sgoos@thepathlab.com.