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TECHNICAL BULLETIN

December, 2022

Clostridioides difficile Test Change

Background: Starting January 17, 2023, the Methodist Health System laboratories will be standardizing the approach to *C. difficile* diagnosis. All laboratories will now utilize a three-step algorithm consisting of a new antigen/toxin screen test (CPT 87324 and 87449) with PCR confirmation (CPT 87798) for antigen/toxin-discrepant specimens.

Specimen Requirements: Fresh liquid stool, unpreserved. Formed stools are unacceptable. The specimen requirements are unchanged from the previous *C. difficile* assay.

Order: Toxigenic *Clostridioides difficile* by EIA with Reflex to PCR

Turn Around Time: Within 24 hours. Unchanged from previous *C. difficile* assay.

Performance:

There is no reliable clinical or laboratory definition for CDI that accurately distinguishes true CDI from non-CDI-related symptoms in all patients. Signs and symptoms of CDI are nonspecific and often overlap with diarrhea due to other causes. Asymptomatic C. difficile colonization is also common, even in patients with risk factors for CDI. Appropriate patient selection for testing including verifying that tested patients have documented diarrheal disease and have not received laxatives prior to testing is essential for diagnostic accuracy.

Reporting/Interpretation:

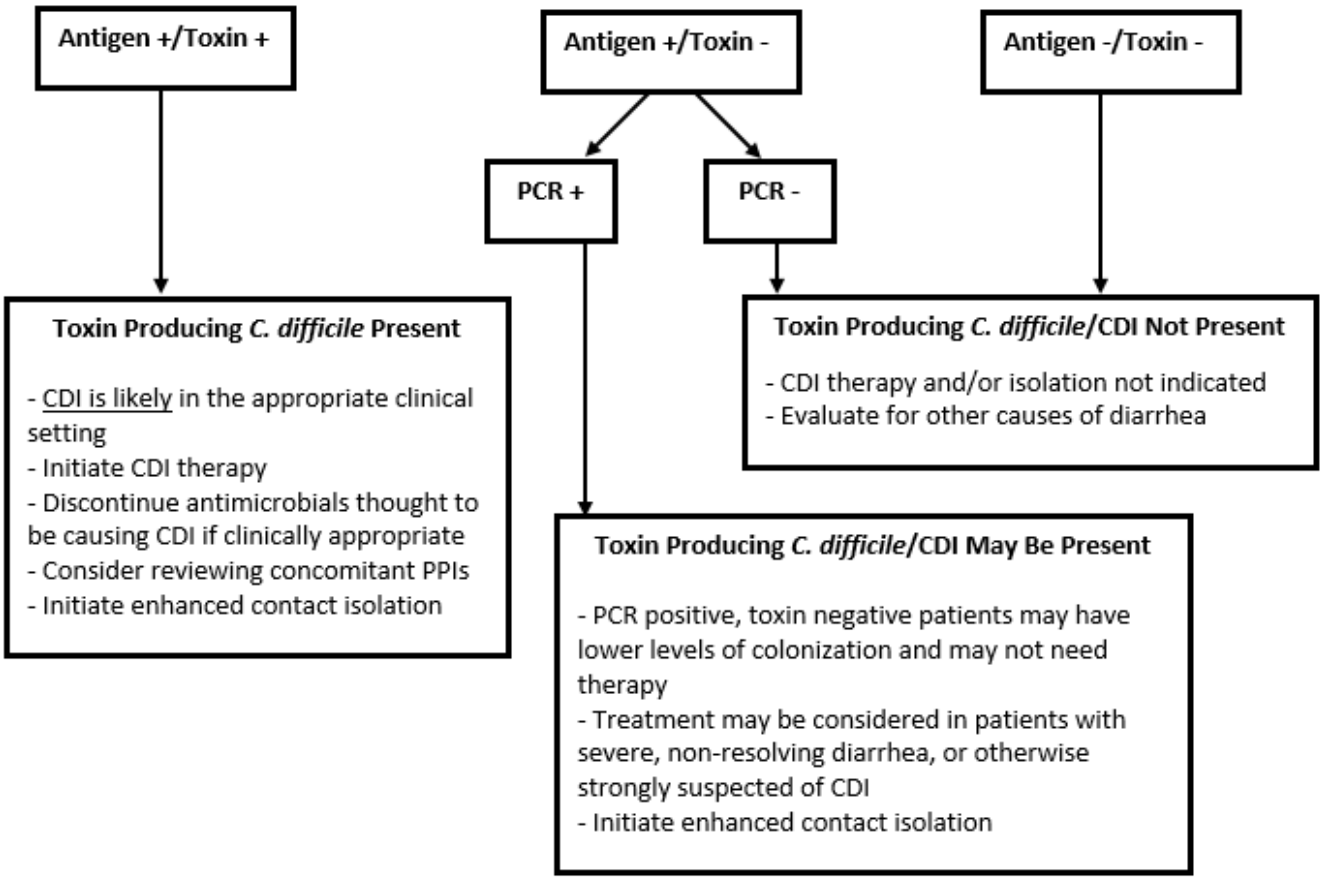
C. difficile antigen: Detects the GDH antigen present in both toxigenic and nontoxigenic strains of C. difficile. A negative result rules out CDI. Reported as Detected/Not Detected.

C. difficile toxin: Detects toxins A and B. Detection of toxin in the setting of diarrhea is strongly suggestive of CDI. Reported as Detected/Not Detected.

C. difficile PCR: Confirmatory test performed only for discordant antigen/toxin results. A negative PCR is interpreted as absence of toxigenic C. difficile. Positive tests for both the antigen and PCR may represent meaningful CDI or may represent low-level colonization. These patients should be placed in isolation regardless of whether treatment is initiated, as they may shed C. difficile spores which could contaminate the environment. If performed, reported as Detected/Not Detected.

Interpret results according to below flowchart.

C. difficile Assay Interpretive Algorithm



Please direct any questions to Dr. Karre, Director of Microbiology, at 402-354-7842 or LaNett Whisler, Microbiology Service Leader at 4-4586.