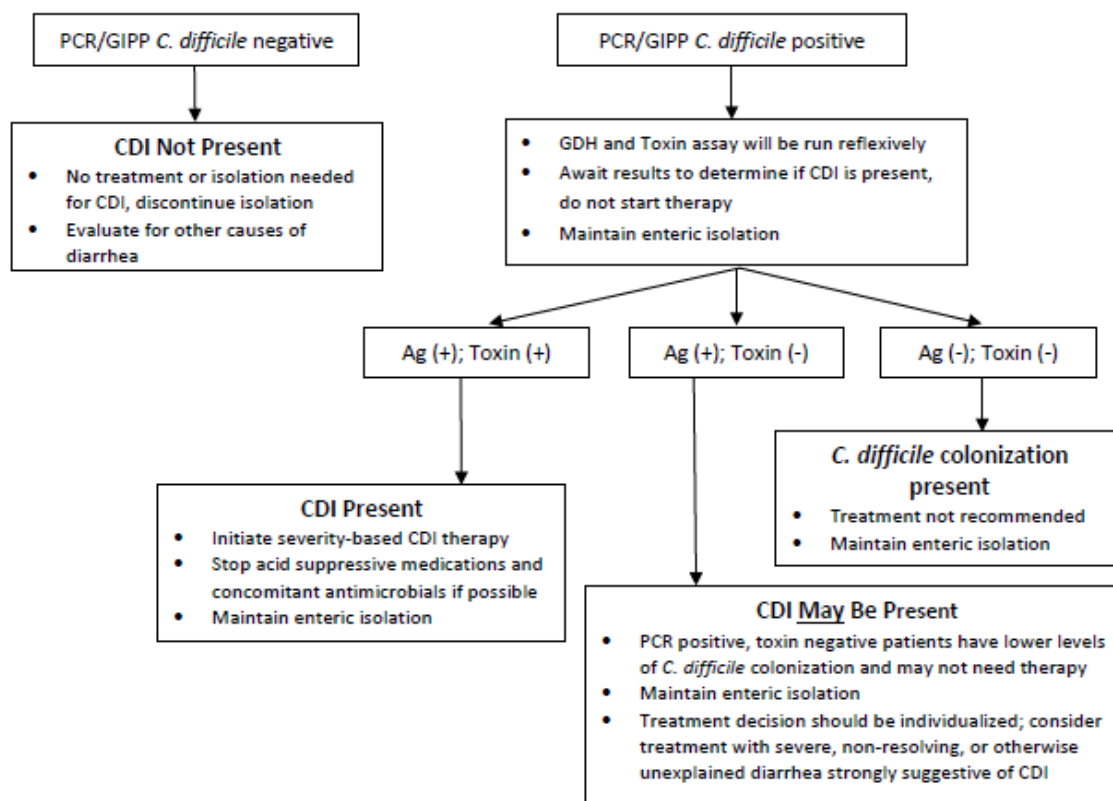


***Clostridium difficile* Testing and Interpretation Algorithm:**

Initial testing for CDI begins with the PCR test (C. Difficile, Amplified PCR [LAB3416]). If negative, CDI is ruled out and no additional testing will occur. If positive the *C. difficile* antigen and toxin (C. DIFFICILE CONFIRM [LAB10172]) will be reflexively processed. Treatment decisions should await the antigen/toxin results.



CDI Test Interpretation

PCR/GIP Result	Antigen Result	Toxin Result	Interpretation	Recommendations
Negative	NA	NA	No <i>C. difficile</i> present	No further action. Repeat testing strongly discouraged.
Positive	Negative	Negative	<i>C. difficile</i> colonization is present. Very low levels of organism present and unlikely to be cause of symptoms	Treatment not indicated but should remain in isolation
Positive	Positive	Positive	Toxigenic <i>C. difficile</i> infection is present	Begin therapy according to management algorithm.
Positive	Positive	Negative	<i>C. difficile</i> infection may be present. Negative toxin due to non-functioning toxin gene, low level of <i>C. difficile</i> , or false negative toxin assay	Determine need for treatment based on risk for CDI and clinical presentation; not all patients need treatment. Consider other causes of diarrhea.
Positive	Negative	Positive	Indeterminate	Repeat test

• ***C. difficile* PCR** = Molecular assays are exceedingly sensitive and the detection of *C. difficile* via PCR alone has not been associated with outcomes different than those who test negative for *C. difficile*. Patients with a positive PCR test for CDI will reflexively be tested for the *C. difficile* antigen and toxin.

- Patients who test negative for both antigen and toxin should be considered to have *C. difficile* colonization without clinically meaningful CDI and should NOT be treated but should be placed in enteric isolation as they may shed *C. difficile* spores into the environment.
- Interpretation of the PCR test should always be made in relation to the antigen and toxin assay (see algorithm above).

• ***C. difficile* antigen** = this test detects vegetative *C. difficile* bacteria but does not detect toxin which is the disease-causing component of CDI. The CDI antigen has a very high negative predictive value (98-99%) for meaningful CDI. A negative antigen test strongly suggests clinically meaningful CDI is absent.

• ***C. difficile* toxin** = Detection of toxin in the stool is associated with worsened outcomes including increased mortality and morbidity compared to molecular tests (PCR/GIPP) and in the setting of diarrhea is strongly suggestive of CDI and the need for treatment.