

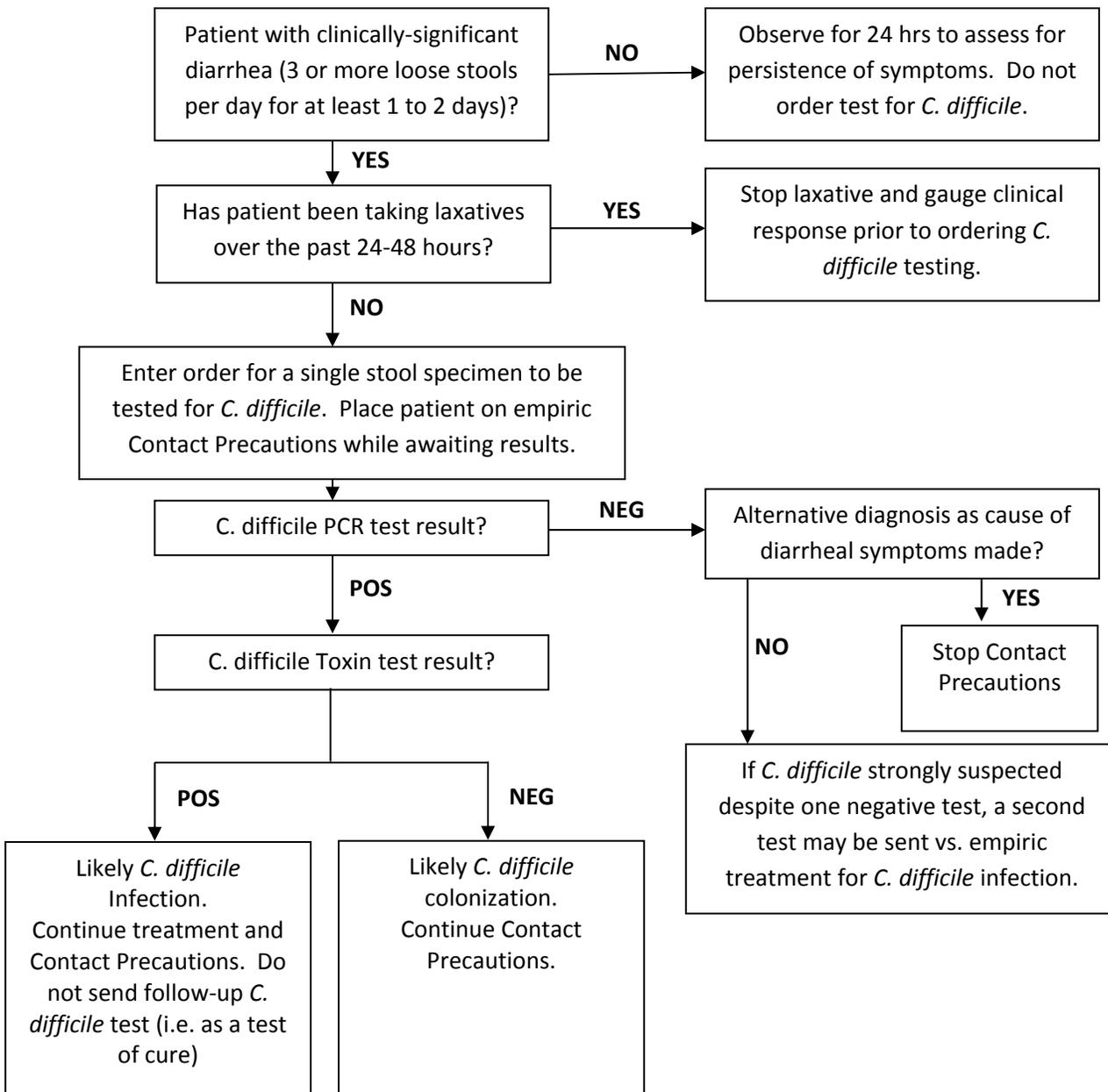
Guidance to Providers: Testing for *C. difficile* Infection

The diagnosis of *Clostridioides difficile* infection (CDI) requires the detection of bacterial toxin and/or antigens in the stool. Due to the need to better assess whether a patient has active CDI vs. stool colonization of a toxin-capable strain, the VUMC lab is migrating to a multistage reflexive test for CD. The previous CD test was a molecular PCR test that only could detect whether the patient had a strain of CD that could produce toxin (which causes clinical disease) NOT whether the toxin was being actively produced. Hence, there was a risk that a patient who was merely colonized with toxin-capable CD strains but had diarrhea due to other causes (e.g. tube feeds, laxatives) would be misdiagnosed as having CD infection and treated as such. **The new test is a multistage test that first looks for the toxin gene by PCR (just like the old test) but then, if the gene is present (“PCR Positive”), the second test looks for active production of the toxin (“PCR and Toxin Positive”).** To facilitate enhanced diagnostic practices, the following recommendations are made:

- 1) Testing for *C. difficile* should be performed on patients with clinically-significant diarrhea, defined as 3 or more loose stools per day for at least 1 to 2 days.^{1,2} Providers should ensure that the patient has not been administered laxatives in the prior 24-48hrs as a possible explanation of diarrheal symptoms.
- 2) Testing is **only performed on loose or watery stool** specimens.^{2,3} The VUMC microbiology lab will reject any formed stools sent for testing. On the rare occasion where an ileus due to *C. difficile* (which occurs in less than 1% of CDI cases) is suspected, the provider must specifically request testing on a formed stool specimen via verbal communication with lab personnel prior to specimen submission.
- 3) **Repeat Testing to Diagnose CDI:** Multiple studies have demonstrated that repeat stool testing is ineffective for the diagnosis of CDI.⁴⁻⁶ **With rare exception, only one test should be ordered to rule in or out CDI**, given the PCR test’s very high negative predictive value. When repeat testing is performed for CDI within a 7-day period, the pre-test probability for the second assay is so low that the ratio of true-positive results to false-positive results becomes very unfavorable; this could result in misdiagnosis for some patients.
- 4) **Do not order multiple tests** for *C. difficile* on a single patient (i.e. “*C. diff* x 3”) but instead wait for the results of a single test to return before considering whether to test again.
- 5) Repeat stool testing for test of cure is **NOT** recommended.^{2,3} *C. difficile* detection may persist despite a clinical response to treatment. In addition, a positive test at the end of a course of therapy does not predict who will develop a recurrence or relapse.
- 6) Patients for whom a *C. difficile* test is ordered are placed on empiric **Contact Precautions**. A negative test is **NOT required** for removal from isolation. Patients placed on **Contact Precautions** for *C. difficile* infection stay on isolation until the following has occurred:
 - a. If **PCR negative** and an alternative diagnosis for the diarrheal symptoms is documented by the patient’s provider, then **Contact Precautions** may be discontinued.
 - b. If **PCR positive and Toxin positive** (e.g. active CD infection), then patients stay on isolation until the following has occurred:

- i. Patient is off of *C. difficile*-specific treatment **AND**
 - ii. Resolution of symptoms for 48 hours **AND**
 - iii. Discharge or transfer from room so that all surfaces in room may be cleaned thoroughly (NOTE: patient must be bathed, placed in a clean gown, and placed in a clean bed if transferred to new room)
- c. If **PCR positive but Toxin negative**, the patient remains on **Contact Precautions** because of the risk of transmission of this strain even though the diarrhea is due to other causes. They patients stay on isolation until the following has occurred:
- i. Resolution of symptoms for 48 hours **AND**
 - ii. Discharge or transfer from room so that all surfaces in room may be cleaned thoroughly (NOTE: patient must be bathed, placed in a clean gown, and placed in a clean bed if transferred to new room)
- 7) **External Transfer of *C. difficile* Infected Patients:** On occasion, accepting facilities (e.g. nursing homes, rehabilitation centers) will request 1 or more negative stool tests for *C. difficile* prior to allowing transfer. As infectivity is guided primarily by the presence of symptoms, and many individuals with carriage of *C. difficile* are not at risk for transmission to other persons, such testing is **not recommended**.² Case managers have been provided with a letter from VUMC leadership outlining our stance on this issue that will be distributed to facility leaders when follow-up *C. difficile* testing is requested. In addition, members of the VUMC Department of Infection Prevention team are available to discuss such requests with the referring facility.

Diagnostic Algorithm for *C. difficile* Infection:



References:

1. Peterson LR, Robicsek A. Does my patient have *Clostridium difficile* infection? *Annals of internal medicine* 2009;151:176-9.
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3. Dubberke ER, Gerding DN, Classen D, et al. Strategies to prevent clostridium difficile infections in acute care hospitals. *Infect Control Hosp Epidemiol* 2008;29 Suppl 1:S81-92.
4. Aichinger E, Schleck CD, Harmsen WS, Nyre LM, Patel R. Nonutility of repeat laboratory testing for detection of *Clostridium difficile* by use of PCR or enzyme immunoassay. *Journal of clinical microbiology* 2008;46:3795-7.
5. Drees M, Snyderman DR, O'Sullivan CE. Repeated enzyme immunoassays have limited utility in diagnosing *Clostridium difficile*. *Eur J Clin Microbiol Infect Dis* 2008;27:397-9.
6. Mohan SS, McDermott BP, Parchuri S, Cunha BA. Lack of value of repeat stool testing for *Clostridium difficile* toxin. *The American journal of medicine* 2006;119:356 e7-8.