

TO: Clients of URMCLabs

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RE: Laboratory Detection of *C. difficile* Toxin in Diarrheal Stool

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To increase sensitivity and predictive value of laboratory testing for *Clostridium difficile* toxin in diarrheal stool specimens, we will be changing test format and introducing a new test algorithm. Beginning November 18, 2009, stool specimens will be tested by an enzyme immunoassay (EIA) which simultaneously detects *C. difficile* toxins A&B and glutamate dehydrogenase (GDH), an antigen common to all *C. difficile*. Specimens which are positive for toxin by EIA will not be further tested. Specimens which are negative for toxin but positive for *C. difficile* common antigen (GDH) by EIA will be reflex tested by PCR for presence of the toxin gene. (In an in-house evaluation compared to PCR alone, the simultaneous pairing of tests for detection of *C. difficile* toxin and GDH by EIA had a Sensitivity of 96% and a Negative Predictive Value of 99%.) Compared to our previously used test, these new tests will be performed in a non-batch mode and will have a turn-around-time of approximately 4 hours from the time of specimen receipt in Clinical Microbiology Laboratories.

Important Points to Remember:

- Submit only 1 specimen per patient per diarrheal episode. i.e., routine orders should be written for “stool x 1”.
- Test only at-risk patients having at least 3 stools per day for 1 to 2 days.
- A repeat specimen from patients negative for *C. difficile* toxin, but with persistent diarrhea and no other diagnosis may be submitted ≥ 3 days after the initial negative specimen.
- Repeat specimens from patients positive for *C. difficile* toxin are not tested for at least 7 days.
Note: Re-testing for “test of cure” is unwarranted in patients with resolved or resolving symptoms.
- Due to high colonization rates in babies, specimens from patients <1 year old are not routinely tested.
- Only non-formed stools are accepted for testing.



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For questions or additional information, please contact Sharon Petry, laboratory supervisor, at 275-7801.



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