

## Lab Testing Update New Molecular Test

### Clostridium Difficile Toxin DNA Assay

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#### Attention: Medical Staff

Effective March 15, 2011, the SEH Laboratory will replace the longstanding enzyme immunoassay (EIA) test for *C. difficile* toxin with direct PCR (polymerase chain reaction) testing on all appropriately submitted specimens using the BD-GeneOhm™ *C. diff* real time PCR assay. The test will be performed in the Molecular Department at Edgewood. This test detects the toxin B gene, not the toxin itself, and represents an order of magnitude higher sensitivity and specificity (85-96% and 98-99.7%) compared to EIA. Because of its superiority to EIA, duplicate testing is neither necessary nor recommended.

Only patients with a high pre-test probability of clinical infection should be tested. This means testing only patients who meet the clinical criteria for *C. difficile* illness, which includes true diarrhea, defined as 3 or more loose stools that take the shape of the container in a 24-hour period.

Please note the following changes:

- Stool specimens that are not liquid or soft (do not take the shape of the container) will be rejected
- Testing will be restricted to one specimen in 7 days. Duplicate specimens submitted within 7 days or “tests for cure” will be canceled (special approval will be required in those rare instances when a second specimen is required).
- Specimens will be tested twice daily Monday thru Friday and once daily on weekends.
- The laboratory will no longer call the results
- The PCR assay detects the toxin B gene; reports will read “Positive” or “Negative” for the toxin B gene

Collection is liquid or soft stool in a clean container. Avoid mixing toilet paper, water, urine, or soap with the sample. Specimens should be kept between 2°C and 25°C for up to 48 hours during transport. Avoid freezing and excessive heat. **Ice is no longer needed** during transport.

Please contact Vicki Stegner in the Molecular Lab (859-301-9360) or Dr. Eisenstein at 859-301-5405 for any questions.