

Affected Test:

- CLOSTRIDIUM DIFFICILE TOXIN DETECTION (LAB253)

Explanation:

On 17 October 2022, the Microbiology Laboratory at Ruby Memorial Hospital will update its testing algorithm for *Clostridium (Clostridioides) difficile* infection (CDI). This change will have no impact on diagnostic test performance (sensitivity/specificity) or test turnaround time. The updated “reverse” algorithm will include:

1. Toxin gene (*tcdB*) PCR (Cepheid GeneXpert) performed on ALL samples.
2. Toxin A/B immunoassay (Alere Quik-Chek Complete) ONLY on PCR positive specimens.

Test results are reported as before (“Positive”, “Negative”, “Indeterminate”), however, individual test values will be displayed differently to reflect both the change in testing sequence and the elimination of GDH common antigen. Example reports are illustrated in the Appendix.

These changes are made to optimize required institutional reporting for CDI to the National Healthcare Safety Network.

QUESTIONS ABOUT THIS TESTING

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Appendix

Ruby Memorial Hospital *C. difficile* Laboratory Test Reporting Format

New Reporting Format:

Positive

🚫 CLOSTRIDIUM DIFFICILE TOXIN DETECTION

Order: 449719

Status: Final result Visible to patient: No (blocked) Next appt: None

Specimen Information: Stool; Other

0 Result Notes

Component	10/4/22 1238
Ref Range & Units	
C. DIFFICILE INTERPRETATION	Positive !
Negative	
C. DIFFICILE TOXIN GENE, PCR	Positive
C. difficile toxin	Positive

Narrative

Presence of toxin-producing *C. difficile* confirmed.

This test algorithm incorporates two FDA-cleared assays: (1) toxin gene PCR using Cepheid GeneXpert *C. difficile* assay, and (2) immunoassay for toxins A/B using TechLab Quik Chek Complete.

Indeterminate

🚫 CLOSTRIDIUM DIFFICILE TOXIN DETECTION

Order: 443283

Status: Final result Visible to patient: No (blocked) Next appt: None

Specimen Information: Stool; Other

0 Result Notes

Component	10/4/22 0817
Ref Range & Units	
C. DIFFICILE INTERPRETATION	Indeterminate !
Negative	
C. DIFFICILE TOXIN GENE, PCR	Positive
C. difficile toxin	Negative

Narrative

Presence of *C. difficile* detected by PCR without evidence of toxin production. Findings may represent toxin level below assay limit of detection or colonization by a toxigenic strain. Alternative etiologies of diarrhea and thorough clinical assessment should be considered before ascribing symptoms to *C. difficile* infection.

This test algorithm incorporates two FDA-cleared assays: (1) toxin gene PCR using Cepheid GeneXpert *C. difficile* assay, and (2) immunoassay for toxins A/B using TechLab Quik Chek Complete.

Negative

CLOSTRIDIUM DIFFICILE TOXIN DETECTION

Order: 449699

Status: Final result Visible to patient: No (blocked) Next appt: None

Specimen Information: Stool; Other

0 Result Notes

Component	10/4/22 0822
Ref Range & Units	
C. DIFFICILE INTERPRETATION	Negative
Negative	
C. DIFFICILE TOXIN GENE, PCR	Negative
C. difficile toxin	Not Performed

Narrative

No evidence of toxigenic *C. difficile* detected.

This test algorithm incorporates two FDA-cleared assays: (1) toxin gene PCR using Cepheid GeneXpert *C. difficile* assay, and (2) immunoassay for toxins A/B using TechLab Quik Chek Complete.