



NATIONWIDE CHILDREN'S
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LABORATORY SERVICES IMPORTANT TEST ANNOUNCEMENTS

Positive Clostridium difficile Reflex to Toxin Assay

Beginning **June 19, 2024**, the laboratory at Nationwide Children's Hospital will begin using a new algorithm for the detection of *C. difficile* and *C. difficile* associated disease (CDAD). This algorithm will now include an automatic reflex for *C. difficile* toxin antigen testing on all *C. difficile* positive stool samples identified by molecular methods. The goal of this algorithm is to increase the specificity for the detection of CDAD versus possible *C. difficile* colonization.

Test Codes: **GIIA and CDIFTN**

Live Date: 6/19/2024

- **Methodology:** Molecular with reflex to enzyme immunoassay (EIA)
- **Performed:** 24/7
- **Turnaround Time:** One day
- **Specimen Required:**
 - **Collect:**
 - GIIA: stool in a sterile container or Cary Blair
 - CDIFTN: stool in a sterile container
 - **Specimen Volume:**
 - GIIA: 5 gram or 5 mL stool
 - CDIFTN: 1 gram or 1 mL stool
 - **Specimen Preparation:** Follow guidelines for initial testing
 - **Storage/Transport/Temperature:**
 - Transport to the laboratory as soon as possible
 - GIIA: raw stool must be placed in Cary Blair if not sent to the laboratory within 2 hours
 - CDIFTN: refrigerate if transport is delayed greater than 1 hour
 - **Unacceptable Conditions:** CDIFTN in Cary Blair, any frozen specimen in Cary Blair, rectal swab, unpreserved stool received outside of specified time frame, specimen contaminated with urine, formed or hard stool
 - **Stability:**
 - Stool in sterile container (either test) – 1 to 2 hours at room temp
 - Stool in Cary Blair (GIIA only) – 24 hours room temp
 - Stool in sterile container (CDIFTN only) – Refrigerate for up to 5 days
- **Comments:**
 - All stools testing positive by Gastrointestinal Infection Array (GIIA) or *C. difficile* Toxin Gene by NAAT (CDIFTN) will automatically reflex to testing for the toxin antigen by EIA. Both results will be used for the interpretation of CDAD versus colonization
 - There is no additional charge for this reflex test
 - The same sample used for the molecular testing will be used for toxin testing
 - Samples submitted in Cary Blair transport media (GIIA) may have decreased sensitivity for the toxin antigen test
 - The toxin EIA will be performed and reported **within 2 hours** of the initial molecular testing result
 - Result interpretation will be provided based on the toxin gene and antigen
 - These results must be used in conjunction with clinical signs and symptoms to determine if treatment is appropriate

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If you have any additional questions about testing for **GIIA and CDIFTN** please refer to the Laboratory Test Directory or call Client Services at 614-722-5477