

# UPDATED *Clostridioides difficile* TEST (formerly *Clostridium difficile*)

February 28, 2022

**NEW TEST**

Effective March 7, 2023, Pacific Diagnostic Laboratories (PDL) will be introducing a new test ***Clostridioides difficile* GDH/TOXIN (EIA) WITH REFLEX TO PCR (LAB10932)**. This test is:

1. The Primary test to use for confirmation of the presence of toxigenic *C. difficile* strains causing diarrhea
2. Replacing *C. difficile* Toxins A and B (EIA) LAB257; on March 7, 2023, orders submitted for LAB257 will be re-ordered as LAB10932 unless otherwise indicated

This test and reflex algorithm for diagnosis of *Clostridioides difficile* infection (CDI) aligns with The Society for Healthcare Epidemiology of America (SHEA) and Infectious Diseases Society of America (IDSA) guidelines.

## TEST OVERVIEW

Toxigenic *Clostridioides difficile* (*C. difficile*) strains produce enterotoxin (toxin A) and cytotoxin (B), causing approximately 0.2% of community-acquired diarrhea and <10% of hospital-associated diarrhea.

When assessing for diagnosis of *Clostridioides difficile* infection (CDI) consider the following:

- Asymptomatic and patients <1 year of age should not be tested for *C. difficile* as it can be part of intestinal commensals
- Symptomatic patients should be checked for other causes of diarrhea (e.g., medication, travel history, food-related)
- Test of cure is not recommended as tests can remain positive for as long as 30 days after symptoms have resolved

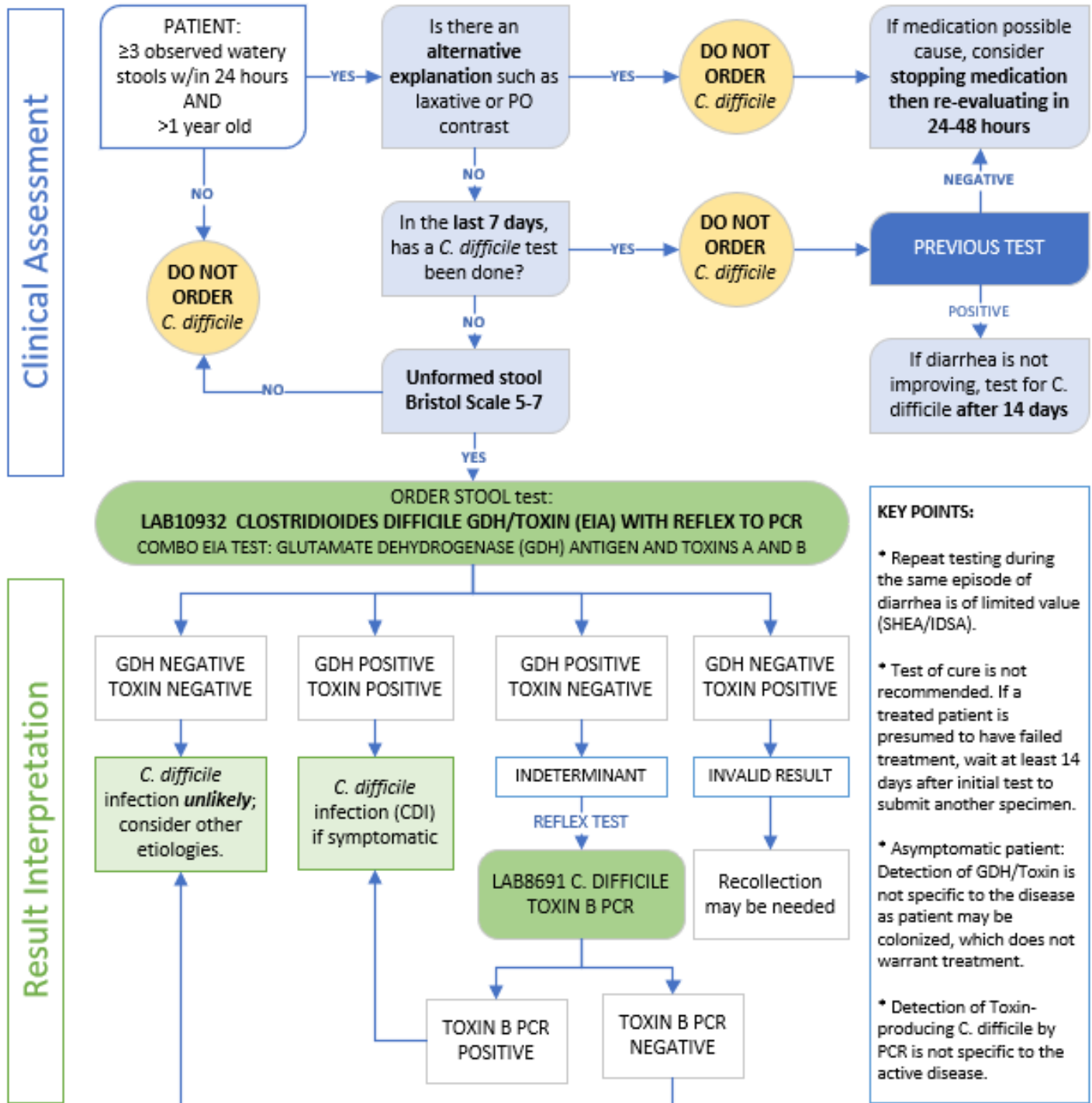
**DIAGNOSTIC CDI TEST ALGORITHM** (flowchart is included on [page 2](#)):

<b>INITIAL TEST</b>	<b><i>C. difficile</i> Glutamate dehydrogenase (GDH) Antigen and <i>C. difficile</i> Toxin by enzyme immunoassay (EIA)</b>
<b>TEST INFO</b>	GDH is a constitutively expressed enzyme in all <i>C. difficile</i> cells; testing for GDH Antigen provides excellent sensitivity (comparable to PCR assays), however, GDH detection cannot distinguish between toxigenic and nontoxigenic strains. Toxins A and B are produced by most <i>C. difficile</i> strains. Testing for both toxins by EIA provides the greatest specificity.
<b>REFLEX INFO</b>	<u>NO REFLEX:</u> If the GDH and Toxin A and B EIA results match, testing is complete and reported as either negative or positive for toxigenic <i>C. difficile</i> <u>REFLEX TO TOXIN B PCR:</u> If the GDH and Toxin A and B EIA results do not match, then a <i>C. difficile</i> Toxin B Gene PCR will be reflexed and performed to resolve the discrepancy

*Why test first with the combination GDH/Toxin EIA versus the C. difficile Toxin B PCR?* *C. difficile* PCR tests have been found to be over-sensitive to *C. difficile* toxin detection and are not specific to CDI, which can lead to antibiotic overuse and antibiotic-associated colitis. Additionally, PCR testing is more costly than EIA and has a longer turnaround time to obtain the result.

*Why do stool specimens submitted for C. difficile testing sometimes get rejected?* The stool specimen must be unformed stool (Bristol scale 5-7) on patients >1 year old. Stools not meeting this criterion will be rejected as testing formed stool or infants <1 year old may detect colonized, not infected, cases. Since all positives must be reported to the CDC National Healthcare Safety Network (NHSN), this can lead to over-reporting CDI.

### C. difficile Diagnostic Test Algorithm



## C. difficile Test Update

### SPECIMEN REQUIREMENTS:

<b>Specimen Type</b>	<b>Unformed Stool with Bristol scale rating:</b> <b>5 = Soft blobs with clear-cut edges</b> <b>6 = Mushy consistency with ragged edges</b> <b>7 = Liquid consistency with no solid pieces</b>
<b>Container</b>	Cary-Blair Culture and Sensitivity vial (C&S orange top) or clean container
<b>Volume</b>	Sufficient stool to raise fluid volume to the red FILL LINE on the C&S vial
<b>Specimen Handling</b>	<ol style="list-style-type: none"> <li>1. Collect stool sample in a clean, dry container. Be sure not to mix urine or toilet water in the stool specimen.</li> <li>2. Unscrew the cap of the vial. Be careful to keep upright (vial may contain fluid). A plastic scoop is attached to the vial lid.</li> <li>3. Using the scoop, select stool from areas which appear bloody, slimy or watery and place 1-4 scoops of stool into the vial (total volume of stool needed is approximately the size of a walnut). DO NOT FILL the vial above the FILL LINE or underfill the vial.</li> <li>4. Mix the contents with the scoop and screw the vial cap back on ensuring it is tight. Shake the vial to guarantee all contents are mixed.</li> <li>5. Label the vial with name, date of birth, time and collection date on each vial.</li> <li>6. Place vials in the Ziploc biohazard bag provided and keep at room temperature.</li> <li>7. Deliver to laboratory within 72 hours of collection.</li> </ol>
<b>Temperature</b>	Stool in C&S vial (preserved): Room Temperature Stool, fresh (unpreserved): Refrigerate
<b>Rejection Criteria</b>	<ul style="list-style-type: none"> <li>• Formed/solid stool (Bristol scale 1-4); stool contaminated with urine or water</li> <li>• C&amp;S vial overfilled or underfilled</li> <li>• Specimens on patients &lt;1 year old</li> <li>• Previously tested positive within 14 days; previously tested negative within 7 days</li> </ul>
<b>Turnaround Time</b>	24 hours

### TEST CODE INFORMATION:

Primary Test	Order/Interface Code	Test Code	Order LOINC	Price	
<b>CLOSTRIDIODES DIFFICILE GDH/TOXIN (EIA) WITH REFLEX TO PCR</b>	LAB10932	1230119183	79177-2	GDH \$54.88	Toxin \$54.88
<i>Result name</i>		<i>Result Code</i>	<i>Result LOINC</i>	<i>CPT</i>	<i>CDM</i>
C. difficile GDH Antigen		1230018921	83087-7	87449	30101368
C. difficile Toxin		1230018922	34468-9	87324	30600028
Reflex Test	Order/Interface Code	Test Code	Order LOINC	Price	
<b>CLOSTRIDIODES DIFFICILE TOXIN B GENE, PCR</b>	LAB8691	123010007	54067-4	\$160.65	
<i>Result name</i>		<i>Result Code</i>	<i>Result LOINC</i>	<i>CPT</i>	<i>CDM</i>
C. difficile (C. difficile.) Toxin, by PCR			54067-4	87493	30600029

### DEACTIVATE:

Test to Deactivate	Order/Interface Code	Test Code	Order LOINC	Price
<b>C. DIFFICILE TOXINS A AND B (EIA)</b>	LAB257	1230100162	8251-1	\$54.90