

UPDATED Guidelines for: *Clostridioides difficile* (*C difficile*)

August 18, 2023

**UPDATED
GUIDELINES**

Effective August 22, 2023, Pacific Diagnostic Laboratories (PDL) will be updating the guidelines for the ***Clostridioides difficile* GDH/TOXIN (EIA) WITH REFLEX TO PCR (LAB10932)** test.

PDL is adjusting the acceptable patient age for this testing to >2 years (previously >1 year).

TEST OVERVIEW

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

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

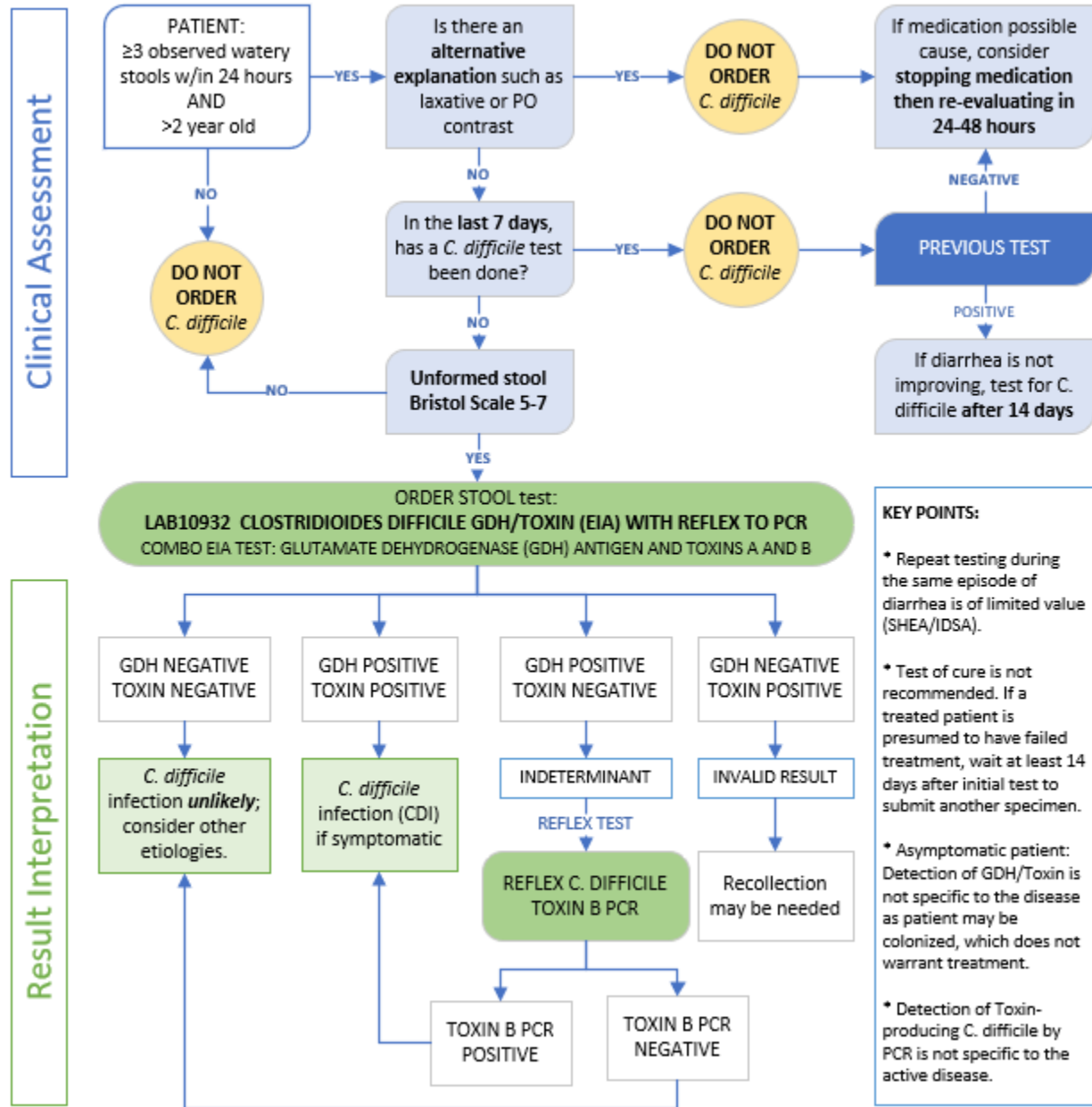
INITIAL TEST	<i>C. difficile</i> Glutamate dehydrogenase (GDH) Antigen and <i>C. difficile</i> Toxin by enzyme immunoassay (EIA)
TEST INFO	GDH is a constitutively expressed enzyme in all <i>C. difficile</i> cells; testing for GDH Antigen provides excellent sensitivity (comparable to PCR assays), however, 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.
REFLEX INFO	<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 test will be reflexed to adjudicate.

GUIDELINES for testing for *Clostridioides difficile* infection (CDI):

TEST SYMPTOMATIC PATIENT IF:	∅ DO NOT TEST PATIENT IF:
<ul style="list-style-type: none"> ▪ Observed watery stools ≥3 w/in 24 hours AND ▪ Age is >2 years AND ▪ No other causes of diarrhea identified: <ul style="list-style-type: none"> ○ Medications (e.g.: laxatives) ○ Travel history ○ Food-related AND ▪ Specimen is unformed stool (Bristol scale 5-7) 	<ul style="list-style-type: none"> ▪ Age is <2 years* ▪ Asymptomatic* ▪ Tested <i>C. difficile</i> NEGATIVE w/in 7 days ▪ Tested <i>C. difficile</i> POSITIVE w/in 14 days ▪ Test of cure† ▪ Specimen is formed stool (Bristol scale 1-4) <p>* <i>C difficile</i> is frequently part of the intestinal commensals. † Test of cure is NOT recommended as test can remain positive for up to 30 days after symptom resolution.</p>

Aligns with the Society for Healthcare Epidemiology of America (SHEA) and Infectious Diseases Society of America (IDSA) guidelines for the diagnosis of *Clostridioides difficile* infection (CDI)

C. difficile Diagnostic Test Algorithm



C. difficile Test Update

SPECIMEN REQUIREMENTS:

Specimen Type	Unformed Stool Bristol scale rating of 5-7	5 = Soft blobs with clear-cut edges 6 = Mushy consistency with ragged edges 7 = Liquid consistency with no solid pieces
Container	Cary-Blair Culture and Sensitivity vial (C&S orange top) or clean container	
Volume	Sufficient stool to raise fluid volume to the red FILL LINE on the C&S vial	
Specimen Handling	<ol style="list-style-type: none"> 1. Collect stool sample in a clean, dry container. Be sure not to mix urine or toilet water in the stool specimen. 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. 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. 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. 5. Label the vial with name, date of birth, time and collection date on each vial. 6. Place vials in the Ziploc biohazard bag provided and keep at room temperature. 7. Deliver to laboratory within 72 hours of collection. 	
Temperature	Stool in C&S vial (preserved): Room Temperature Stool, fresh (unpreserved): Refrigerate	
Rejection Criteria	<ul style="list-style-type: none"> • C&S vial overfilled or underfilled • Formed/solid stool (Bristol scale 1-4) • Previously tested positive within 14 days • Previously tested negative within 7 days • Specimens on patients <2 year old • Stool contaminated with urine or water 	
Turnaround Time	24 hours	

TEST CODE INFORMATION:

Primary Test	Order/Interface Code	Test Code	Order LOINC	Price	
CLOSTRIDIODES DIFFICILE GDH/TOXIN (EIA) WITH REFLEX TO PCR	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	
CLOSTRIDIODES DIFFICILE TOXIN B GENE, PCR	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