# Test changes

Test name: Clostridium difficile toxin PCR

Test #: 8288/LAB8288

Notification date: December 20, 2019

Effective date: January 14, 2020

#### **EXPLANATION**

On January 14, 2020, Allina Health Laboratory will implement a multi-step algorithm for *C. difficile* testing

#### **DETAILS**

Effective January 14, 2020 Allina Health Laboratory will be instituting a multi-step algorithm for testing and reporting *C. difficile* results. Positive *C. difficile* toxin PCR tests will reflex additional testing, at an additional charge, to confirm that the patient has existing *C. difficile* disease as opposed to being colonized or a carrier.

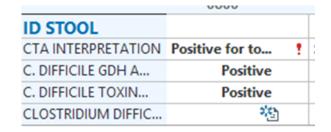
The PCR test detects the gene encoding for *C. difficile* toxin but does not indicate whether the toxins are actively being produced. The reflexed EIA (enzyme immunoassay) test will detect GDH antigen, indicating the presence of the organism. In addition, it will detect the presence of the Toxin A/B.

By using a testing algorithm that utilizes PCR as the first layer of testing the lab is able to screen out most of the negative samples. If a sample is PCR positive it is reflexed to a less sensitive EIA test to screen out possible carriers, a positive EIA with antigen and toxin detected are considered a true *C. difficile* infection.

Note: Questions regarding interpretation of this algorithm should be directed to Infection Prevention or an Infectious Disease practitioner. The lab cannot interpret patient specific result for this algorithm.

The testing results will be accompanied by an interpretation and comment when indicated:

#### Positive for toxigenic C. difficile





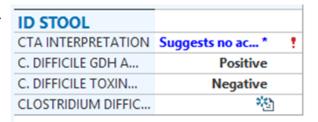
#### Negative for toxigenic C. difficile

	12/12/2019
	1427
ID STOOL	
CTA INTERPRETATION	Negative for to
C. DIFFICILE GDH A	Negative
C. DIFFICILE TOXIN	Negative
CLOSTRIDIUM DIFFIC	*(5)

### Suggests no Active C. difficile disease

Comment: C. difficile present but toxin was not tected. This could be a non-toxigenic strain, a carrier state, or toxin level too low for detection. The result should be used in conjunction with clinic

al history when deciding on additional testing and/or possible therapy. Consider ID consultation.



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## <u>Invalid</u>

Comment: Invalid result. Consider recollection if clinical suspicion of infection still exists.

ID STOOL	
CTA INTERPRETATION	Invalid * !
C. DIFFICILE GDH A	
C. DIFFICILE TOXIN	
CLOSTRIDIUM DIFFIC	*(5)

### **Printed report**

ID:	19CL-347M0001	Collected:	12/13/2019 1	117
Source:	Stool	Verified On:	12/13/2019 1:	216
Resulting Lab:	ANWLCR			
Component		V	alue	Ref. Interval
CLOSTRIDIUM DI Positive C.		Pos eflexed to EIA testing for	sitive confirmation.	
PRESUMPTIVE N	AP1 STRAIN	Nega	Negative	
	19CL-347M0001	Collected	12/13/2019 1	117
ID:		Collected: Verified On:	12/13/2019 1 12/13/2019 1:	
ID: Source:	19CL-347M0001			
ID: Source: Resulting Lab:	19CL-347M0001 Stool	Verified On:		
ID: Source: Resulting Lab: Component CTA INTERPRETA	19CL-347M0001 Stool ANWLCR	Verified On: Vo Suggests no active C. diffi	12/13/2019 1: alue icile (A)	216  Ref. Interval  Negative for toxigenic C. difficile
ID: Source: Resulting Lab: Component CTA INTERPRETA  C. difficile carrier stat.	19CL-347M0001 Stool ANWLCR  ATION  present but toxin was re, or toxin level too lo	Verified On: Volume Verified On: Verified On: Verified On: Verified On:	12/13/2019 1: alue icile (A) ase be a non-toxige ilt should be i	Ref. Interval  Regative for toxigenic C. difficile enic strain, a used in conjunction
carrier state with clinica	19CL-347M0001 Stool ANWLCR  ATION  present but toxin was re, or toxin level too lo lo history when deciding	Verified On:  Vi  Suggests no active C. diffied dise not detected. This could be low for detection. The resu on additional testing and/	12/13/2019 1: alue icile (A) ase be a non-toxige ilt should be i	Ref. Interval  Regative for toxigenic C. difficile enic strain, a used in conjunction

CPT Code for EIA Testing: 87324 and 87449