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*

ID STOOL		
CTA INTERPRETATION	Positive for to...	❗
C. DIFFICILE GDH A...	Positive	
C. DIFFICILE TOXIN...	Positive	
CLOSTRIDIUM DIFFIC...	📋	

Allina Health
LABORATORY

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...	

Suggests no Active *C. difficile* disease

Comment: C. difficile present but toxin was not de-tected. This could be a non-toxigenic strain, a carrier state, or toxin level too low for detec-tion. The result should be used in conjunction with clinic
al history when deciding on additional testing and/or possible therapy. Consider ID consul-tation.

ID STOOL	
CTA INTERPRETATION	**Suggests no ac... * !**
C. DIFFICILE GDH A...	**Positive**
C. DIFFICILE TOXIN...	**Negative**
CLOSTRIDIUM DIFFIC...	

Invalid

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...			

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CLOST DIFFICILE TOXIN P (Final result)

ID:	19CL-347M0001	Collected:	12/13/2019 1117
Source:	Stool	Verified On:	12/13/2019 1216
Resulting Lab:	ANWLCR		

Component	Value	Ref. Interval
CLOSTRIDIUM DIFFICILE PCR	Positive	
Positive C. difficile PCR results reflexed to EIA testing for confirmation.		
PRESUMPTIVE NAP1 STRAIN	Negative	

Comments:
The NAP1 (O27 or BI) strain is a hypervirulent strain. Detection may be useful for epidemiological purposes.

Toxin Activity (Final result)

ID:	19CL-347M0001	Collected:	12/13/2019 1117
Source:	Stool	Verified On:	12/13/2019 1216
Resulting Lab:	ANWLCR		

Component	Value	Ref. Interval
CTA INTERPRETATION	Suggests no active C. difficile (A) disease	Negative for toxigenic C. difficile

C. difficile present but toxin was not detected. 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 clinical history when deciding on additional testing and/or possible therapy. Consider ID consultation.

| C. DIFFICILE GDH ANTIGEN EIA | Positive | |
| C. DIFFICILE TOXIN A & B EIA | Negative | |

CPT Code for EIA Testing: 87324 and 87449