Legacy Laboratory Services

C difficile Detection Update

November 2012

For the detection of *C difficile* toxin, Legacy utilizes a two-step algorithm (ordered as **C Diff Toxin).** Our algorithm begins with a glutamate dehydrogenase (GDH) EIA assay performed on unformed stool, to detect the presence or absence of *C. difficile,* regardless of its toxigenic capability. If GDH-positive, the specimen proceeds to a confirmatory *C difficile* toxin test utilizing the Xpert *C. difficile* PCR assay. Because the PCR is completed within a matter of hours, most C Diff Toxin orders are now turned around within 24 hours. Screening for GDH before confirmation of positives by PCR is cheaper than screening all specimens by PCR and is an effective method for routine use [4]. The Xpert C. diff PCR assay may be ordered as a stand-alone test (**C diff toxin by PCR**), bypassing the GDH EIA [1].

C *difficile* testing update.

According to the IDSA/SHEA guidelines [3], testing for *C. difficile* or its toxins should only be performed on diarrheal (unformed) stools, unless ileus is suspected. A single specimen at the onset of a symptomatic episode is usually sufficient and routine testing of multiple specimens is NOT supported. Testing on asymptomatic patients is not clinically useful, including use as a test of cure. Specimens that are formed or hard and rectal swabs and fluid obtained at colonoscopy will be rejected. The following statement will be attached to all orders “Testing on formed stools (unless ileus is suspected), asymptomatic patients, and test of cure is not helpful. Due to the sensitivity of the testing method, repeat testing during the same episode of diarrhea is of limited value. Tests sent on formed stools or repeat testing within five days of the original test will be rejected. Exceptions will be made on a case by case basis, by contacting the Microbiology laboratory at 503-413-4084. Testing on asymptomatic patients and for proof of cure is discouraged."

NOTE - The PCR test is only approved for patients over 2 years of age. Children less than 2 years will have the two step algorithm performed, with the second step being cell culture cytotoxicity neutralization assay (CCCN) instead of PCR.

References:

1) Haihui Huang, et al, “Comparison of a Commercial Multiplex Real-Time PCR to the Cell Cytotoxicity Neutralization Assay for Diagnosis of *Clostridium difficile* Infections.” Journal of Clinical Microbiology, November 2009, 47:3729-3731.
2) Nolte, Fredrick “Molecular Testing for *C difficile* at Medical University of South Carolina: Validation, Implementation, and Realized Benefits.” BD Inform Educational Seminar, March 2010.
3) SHEA-IDSA Guideline: Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). March 2010.
4) Goldenberg SD et al, “Two-Step Glutamate Dehydrogenase Antigen Real-Time Polymerase Chain Reaction Assay for Detection of Toxigenic *Clostridium difficile*.” J Hosp Infect. Jan 2010; 74(1): 48-54.

For technical information, contact:

Claudia Atherton
System Manager Microbiology
Legacy Laboratory Services
503-413-2828

Mitchell Ryan MD
Medical Director Microbiology
Legacy Laboratory Services
503-413-7636

LEGACY HEALTH

Collection Guidelines

Description	**Clostridium difficile toxin by PCR**
Order Code	87493
Collect	Fresh unformed stool (soft or liquid) in a leak proof container or Enteric Transport
Handling	
Preferred Volume	5 ml
Minimum Volume	2 ml
Transport	Refrigerated
Rejection Criteria	Specimens past stability or stool in any preservative including SAF, PVA, or formalin. Formed stool, rectal swabs or colonoscopy fluid, unless approved by Microbiology. Duplicate testing unless approved by Microbiology.
Performed	Sunday – Saturday, 0700-1500
Turn-around Time	24 hours
Stability	24 hours room temperature, up to 3 days refrigerated (2-8 degrees C).
Reference Ranges	Negative for toxigenic C difficile
Method	Real-time reverse transcription PCR

Description	***C difficile* toxin detection**
Order Code	87449 and 87493
Collect	Fresh unformed stool (soft or liquid) in a leak proof container or Enteric Transport. DO NOT FREEZE.
Handling	
Preferred Volume	
Minimum Volume	2 ml
Transport	Refrigerated
Rejection Criteria	Specimens past stability or stool in any preservative including SAF, PVA, or formalin. Formed stool, rectal swabs or colonoscopy fluid, unless approved by Microbiology. Duplicate testing unless approved by Microbiology.
Performed	Sunday – Saturday 0700-1500
Turn-around Time	24 hours
Stability	24 hours room temperature, up to 3 days refrigerated (2-8 degrees C).
Reference Ranges	Negative for toxigenic C difficile
Method	EIA or GDH, followed by PCR if GDH positive

For technical information, contact:

Claudia Atherton
System Manager Microbiology
Legacy Laboratory Services
503-413-2828

Mitchell Ryan MD
Medical Director Microbiology
Legacy Laboratory Services
503-413-7636