

NEW TEST ANNOUNCEMENT

NOTIFICATION DATE: April 23, 2013 **EFFECTIVE DATE:** June 4, 2013

CLOSTRIDIUM DIFFICILE TOXIN, MOLECULAR DETECTION, PCR, FECES Test ID: CDFRP

USEFUL FOR: Sensitive, specific, and rapid diagnosis of *Clostridium difficile*-associated diarrhea and pseudomembranous colitis

METHODOLOGY: Real-Time Polymerase Chain Reaction (PCR) Using LightCycler and Fluorescent Resonance Energy Transfer (FRET).

SPECIMEN REQUIREMENTS:

Submit only 1 of the following specimens:

Preferred:

Specimen Type: Preserved Stool

Container/Tube: Commercially available transport system specific for recovery of enteric pathogens from fecal specimens (15 mL of non-nutritive transport medium containing phenol red

as a pH indicator, either Cary-Blair or Para-Pak C and S). **Specimen Volume:** Representative portion of stool

Acceptable:

Specimen Type: Unpreserved Stool

Container/Tube: Stool container (Supply T288)
Specimen Volume: Representative portion of stool

SPECIMEN STABILITY INFORMATION:

| Specimen Type | Temperature | Time |
|---------------|---------------------|--------|
| Fecal | Ambient (preferred) | 7 days |
| | Frozen | 7 days |
| | Refrigerated | 7 days |

CAUTIONS:

- Interfering substances in stool may affect the accuracy of this assay; results should always be interpreted in conjunction with clinical and epidemiological findings.
- The assay must be performed on fresh or fresh-frozen stools or stools in transport medium.
- The assay has not been validated as a test of cure. Since nucleic acid may persist after effective treatment, follow-up testing of a positive result is not recommended.
- Submission of more than 1 specimen for testing is not recommended.
- Testing of colostomy, ileostomy, or colonoscopically-collected specimens has not been validated.
- Patients may asymptomatically carry *Clostridium difficile*; clinical correlation is needed when deciding how to manage patients with a positive test result.

CPT CODE: 87493

DAYS SET UP: Monday through Sunday; Varies ANALYTIC TIME: Same day/1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Brandon DeBoom, MML Laboratory Technologist Resource Coordinator Telephone: 800-533-1710