



TECHNICAL NOTICE

SOUTH BEND MEDICAL FOUNDATION

Clostridium difficile in Feces – New Guidelines for Testing

Effective Date: April 1, 2011

Performing Department: Microbiology

Overview:

Based on current recommendation for the diagnosis of *Clostridium difficile* infections, the South Bend Medical Foundation will offer two options (1) ***Clostridium difficile* Toxin B Gene, by PCR, Feces** and (2) ***Clostridium difficile* GDH Antigen and Toxins A & B, by EIA, with *C. difficile* Toxin B Gene, by PCR, if Indicated, Feces.**

Direct PCR testing (option 1) provides a higher sensitivity than antigen testing, is rapid, and specific. Performing antigen and toxin testing alone has poor sensitivity, is no longer recommended, and will not be offered. Physicians can expect 12% of patients will be reflexed to PCR if they order antigen and toxin testing with PCR if indicated (option 2 above).

Use:

The tests for *Clostridium difficile* are useful for the diagnosis of infection. Only diarrhea stools, not well formed stools should be submitted. Testing should be limited to one stool per week unless there is clinical or laboratory documentation of changes (leukocytosis, decreased albumin, increased serum lactate, increased bowel movements). These tests are not indicated for establishing a cure after treatment.

Reference Range:

- Negative for *C. difficile* Glutamate Dehydrogenase (GDH) Antigen by EIA
- Negative for *C. difficile* Toxins A & B by EIA
- Negative for *C. difficile* Toxin B Gene by PCR.

Specimen Requirements and Collection:

Preferred Specimen: Feces, liquid (preferred), in sterile plastic container with tightly fitting lid

Alternate Specimen: Feces, unformed (semi-solid), in sterile plastic container with tightly fitting lid

Requested Volume: 1.0 mL liquid feces

Minimum Volume: 0.25 mL liquid feces -or- 2.0g unformed feces

Processing: Maintain refrigerated during storage and transport: if refrigeration is not available, place in ice slush

Stability: 3 days (72 hours) refrigerated (2-8°C) • Greater than 72 hours, freeze (-20°C)

Storage/Transport: Refrigerated (72 hours) or, if greater than 72 hours, freeze

Rejection Criteria: Sample not refrigerated • Sample refrigerated, but greater than 72 hours and not frozen • Formed stool

Specimen Remarks: *C. difficile* toxin is heat labile (toxin degrades without refrigeration)

Testing Schedule: Daily • Results are available within 24 hours

Order:

• *Clostridium difficile* Toxin B Gene, by PCR, Feces Test #: **21137** CPT: • 87493

• *Clostridium difficile* GDH Antigen and Toxins A & B, by EIA, with *C. difficile* Toxin B Gene, by PCR, if Indicated, Feces Test #: **21142** CPT: • 87324 • 87449

If indicated by EIA testing for GDH Antigen and Toxins A & B, add: • 87493

For additional information contact C. Kurtis Kim, M.D., Mary G. Stepney, Microbiology Specialist, or Nan Boston, Microbiology Manager, South Bend Medical Foundation , (574) 234-4176 or (800) 544-0925.

SOUTH BEND MEDICAL FOUNDATION

530 N. Lafayette Boulevard • South Bend, IN 46601 • (574) 234-4176

Elkhart (574) 293-8441 • (800) 544-0925

Robert J. Tomec, M.D. • *Medical Director*