ROCHESTER REGIONAL HEALTH Laboratories

Molecular Amplification of Bacterial Enteric Pathogens

September 2018: *Rochester Regional Health Laboratories now offers a molecular alternative to Stool Culture for enteric bacterial pathogens. The test offered will be the BD MAX™ Enteric Panel and will replace Stool Culture and the Shiga Toxin Enzyme Immunoassay. The BD MAX™ Enteric Panel is a multiplex PCR method that detects Salmonella, Shigella, Campylobacter (coli and jejuni) and the genes for Shiga Toxin (STX-1 and STX-2). This PCR method provides increased sensitivity for the detection of these pathogens and will provide a much faster turnaround time compared with traditional Stool Culture and Shiga Toxin EIA testing.*

Background:

Bacteria that cause enteric diseases represent a significant cause of morbidity and mortality worldwide. The CDC estimates there are 48 million cases of foodborne illness in the United States each year resulting in 128,000 hospitalization and 3,000 deaths. Although the most common gram-negative enteric bacteria may be grown in the laboratory, with the additional detection of Shiga Toxin performed using enzyme immunoassays, this approach lacks sensitivity and is time consuming. A laboratory diagnosis may take several days, which places patients at risk for an untreated infection and may facilitate the spread of the infection to others. Alternatively, empirical antimicrobial therapy may have severe consequences for some enteric bacterial infections, such as those caused by Shiga toxin-producing E. coli (STEC), potentially leading to serious complications, including hemolytic uremic syndrome (HUS). In persons with compromised immune systems, *Campylobacter* and *Salmonella* infections occasionally spread to the bloodstream and cause a serious life-threatening infection.

The BD MAX™ Enteric Bacterial Panel detects the following organisms (genes):

- Salmonella sp. (*spaO*)
- Shigella sp. (*ipaH*)*
- Campylobacter coli / jejuni (*tuf*)
- Shiga Toxin (*stx 1 and stx 2*)

**ipaH* is also found in Enteroinvasive E. coli (EIEC) and may cause a positive result in the BD MAX™ Enteric Panel. See additional information below.

How will the new BD MAX™ Enteric Bacterial Panel impact my practice?

Q: ***When should I order the BD MAX™ Enteric Panel?***
A: Most cases of uncomplicated, community-acquired diarrhea of <7 days duration do not require any stool testing. The BD MAX™ Enteric Panel is useful in the following clinical situations: community-acquired diarrhea ≥ 7 days duration, travel-related diarrhea (including recent immigrants) and diarrhea in patients with warning signs/risk factors for severe disease. Please refer to the attached Laboratory Testing Algorithm for additional ordering guidance.

Q: ***My office recommends the collection of raw stool for culture. How does the collection change for the BD MAX™ Enteric Panel?***
A: There is no change to the specimen collection or transport requirements for the BD MAX™ Enteric Bacterial Panel compared to Bacterial Stool Culture.

Q: ***What are the major benefits for performing an amplified enteric GI panel? Are there any drawbacks?***

A: The BD MAX™ Enteric Panel is significantly more sensitive than Stool culture and Shiga toxin detection. In some cases, including the detection of Shiga Toxin, the BD MAX™ Enteric Panel is more specific. Additionally, the assay will be performed once per day and will significantly shorten turnaround time. The drawback of implementing a targeted panel is that not all potential etiologies of gastroenteritis will be detected. However, we have selected the BD MAX™ Enteric Panel since it is a direct replacement for the basic Stool Culture and Shiga Toxin EIA.

Q: ***What do I order for other enteric GI pathogens that are not covered by the BD MAX™ Enteric GI Panel?***

A: The BD MAX™ Enteric Panel is designed to detect the most common enteric bacterial pathogens encountered in this area. However, there may be cases where additional enteric bacteria may be associated with GI infections – specifically Yersinia and Vibrio. In these cases, the following test options are available:

- For Yersinia:
  - Stool Culture, With Yersinia (05005)
- For Yersinia and Vibrio
  - Stool Culture, With Yersinia and Vibrio (03602)

Q: ***What do I order for non-bacterial GI pathogens or C. difficile?***

A: The BD MAX™ Enteric GI Panel does not detect viral etiologies of gastroenteritis, *C. difficile* or intestinal parasites. Rochester Regional Health Laboratories continues to offer specific tests for these pathogens. However, we are continually updating our Test Menu to ensure we are providing the most clinically sensitive and cost-effective assays and we may expand our molecular GI panel in the future.

Q: ***What about the Public Health Requirements for reporting and submitting positive stool specimens?***

A: Rochester Regional Health Laboratories will continue to report significant enteric pathogens to the New York State Department of Health as required by public health law through the Electronic Clinical Laboratory Reporting System (ECLRS). In addition, the laboratory will submit required specimens and/or isolates to the Wadsworth Laboratory, as required in the Communicable Diseases Guidelines.

Q: ***I have a positive report for Shigella / EIEC. How do I know if my patient has Shigella or Enteroinvasive E. coli?***

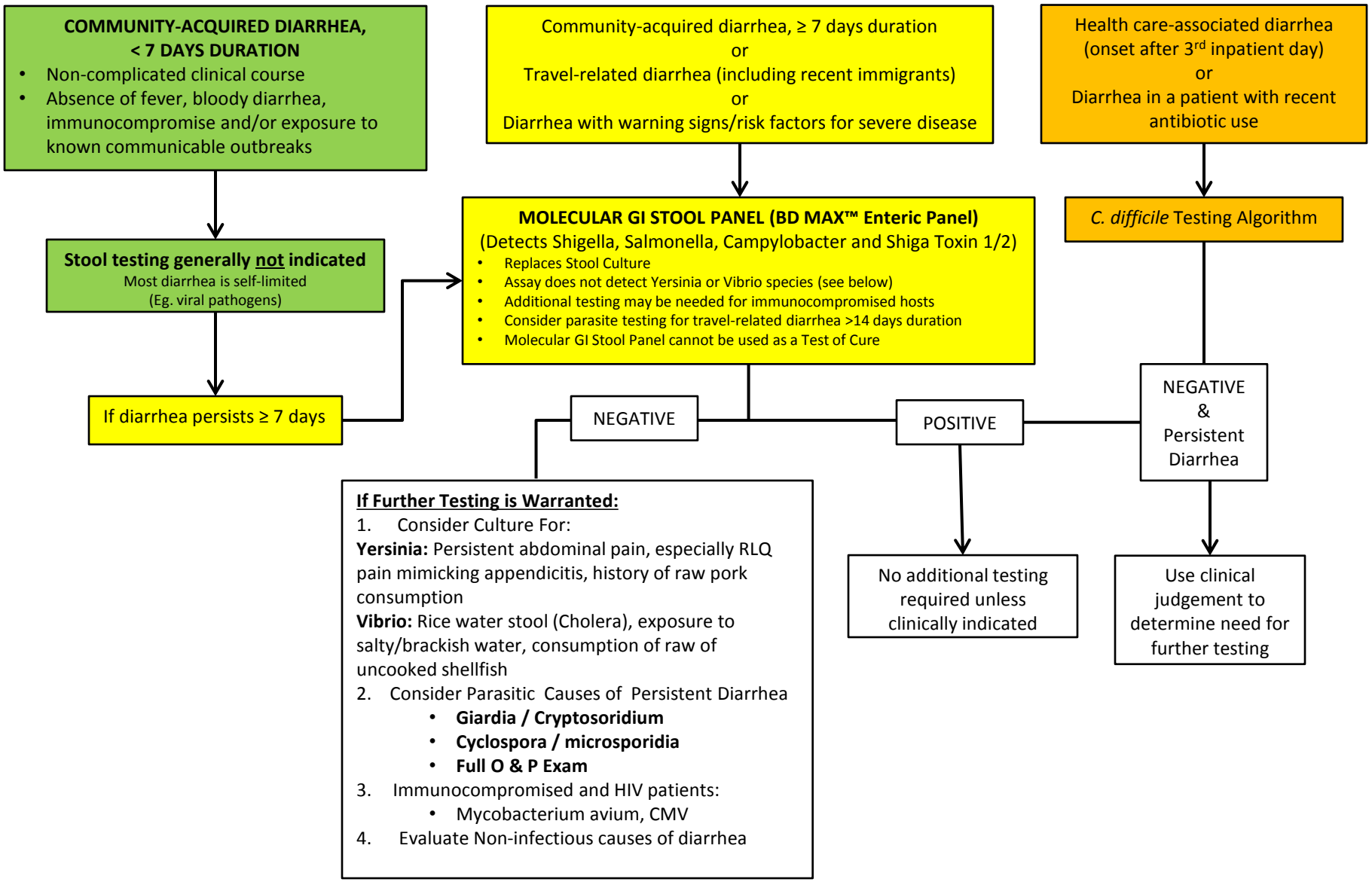
A: The BD MAX™ Enteric Bacterial panel detects *ipaH*, a gene found in *Shigella,* and a specific type of *E. coli* named Enteroinvasive *E. coli* (EIEC). Sequencing studies have shown that EIEC is more closely related to *Shigella* than non-invasive isolates of *E. coli.* All four species of *Shigella (flexneri, dysenteriae, boydii* and *sonnei*) and EIEC may cause a febrile presentation with mucoid or bloody diarrhea due to the same invasive mechanism of the intestinal epithelium. EIEC is thought to be less prevalent than *Shigella,* although may be underdiagnosed. Since the BD MAX™ Enteric panel does not differentiate *Shigella* from EIEC, current recommendations suggests that samples where *Shigella*/EIEC are reported, should be treated as probable *Shigella* cases.

Test Information:

Alternate Test Name:	Stool Culture, Fecal culture, Shiga Toxin, E. coli 0157 Culture
Test Number:	10543
Department:	Microbiology
SPECIMEN COLLECTION REQUIREMENTS	
Collection Container:	Sterile Cup *(shown here)* 
Collection Notes::	For unpreserved stool specimens, collect a liquid or soft stool in a clean, dry cup. Avoid mixing with urine, water, soap or toilet paper.
Transport Temperature:	Room Temperature
Specimen Volume:	Preferred Volume: 10 g or 10 mL
Also Acceptable:	Stool in a C&S ParaPak (Cary-Blair)
TECHNICAL SPECIFICATIONS	
Performed:	Monday-Sunday
Reported:	Same Day
Methodology:	Polymerase Chain Reaction (PCR)
CPT:	87505
LOINC:	79381-0
Stability:	Room temperature: 24 hours (Unpreserved or Preserved) Refrigerated: Up to 5 days (Unpreserved or Preserved) Frozen: Unacceptable
Reference Range:	All Analytes: Not Detected
Notes:	Testing using this method is very sensitive. It is not necessary to perform reflex testing for negative results.

Technical questions regarding this testing should be directed to Suzanne E. Dale, PhD, D(ABMM), Director, Microbiology and Molecular Diagnostics, p: (585) 429-2360. All other inquiries should be directed to Rochester Regional Health Laboratories Client Services, p: (585) 922-LABS.

Laboratory Testing for Infectious Causes of Diarrhea in the Ambulatory Setting



IDSA Guidelines for Diagnosis and Management of Infectious Diarrhea. CID 2017:65.