



# Targeted molecular stool testing

**Identification** of the infectious organisms responsible for **gastroenteritis** is largely done by traditional microbiology methods, including culture, microscopy or immunoassay. The **limitations** of traditional methods include:

- Results being delayed for several days<sup>1</sup>
- Some organisms are not easily grown on culture media<sup>2</sup>
- False negatives can result from the subjective interpretation of microscopy<sup>3</sup>
- Immunoassays have poor sensitivity and do not detect all targets<sup>4</sup>

Each year, billions of people worldwide are afflicted by infectious diarrhea, posing diagnostic and patient management challenges with its clinical presentation.

**IDSA Guidelines** reinforce the importance of determining a specific diagnosis which can benefit a patient with infectious diarrhea by:<sup>5</sup>

- Directing appropriate therapy
- Allowing the judicious use of antimicrobial agents
- Improving patient satisfaction and life planning

Our laboratory is introducing a **new targeted testing methodology to decrease turnaround time** plus **increase accuracy** and **sensitivity** in an effort to aid in both **patient management** and **antimicrobial stewardship**. Because not all patient needs are the same, this comprehensive testing method will allow you to test patients according to their individual histories and clinical presentations.

There will be no changes in sample type or collection requirements. *Please read on for more information about the organisms and available testing panels.*



# BD MAX™ Enteric Suite allows for testing of a specific class of enteric pathogens following IDSA-Guideline based patient exposure, risk factors and clinical presentations, providing the most appropriate and cost-effective diagnostic solution for patients.

## IDSA-guideline based targeted testing with the BD MAX™ System for acute infectious diarrhea

Patient exposure Clinical presentation		Foodborne or waterborne	MILK	(Raw/Undercooked Meat)	(Fruits, Juices, Vegetables)	(Undercooked Eggs)	(Raw Shellfish)	(Swimming/Drinking Untreated Water)	(Healthcare/Long-term Care)	(Recent Antimicrobial Therapy)	(Child Care)	(Travel to Resource-Challenged Countries)	(Immunocompromised)	(Certain Sexual Practices)	(Contact with Animals)			
		Foodborne outbreak of diarrheal illness	Consumption of unpasteurized milk or dairy products	Consumption of raw or undercooked meat (beef/pork/poultry) or chitterlings	Consumption of fruits, juices or vegetables	Consumption of undercooked eggs	Consumption of raw shellfish	Swimming in or drinking treated water or untreated fresh water							Exposure to house pets with diarrhea	Visiting a farm or petting zoo/contact with young poultry or reptiles		
<p>Persistent or chronic diarrhea</p>	All 4 apply	BD MAX™ Enteric Parasite Panel						BD MAX™ Enteric Parasite Panel	BD MAX™ Enteric Parasite Panel			BD MAX™ Enteric Parasite Panel	BD MAX™ Enteric Parasite Panel			BD MAX™ Enteric Parasite Panel		
	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	BD MAX™ Enteric Bacterial Panel	
	BD MAX™ Extended Enteric Bacterial Panel	BD MAX™ Extended Enteric Bacterial Panel	BD MAX™ Extended Enteric Bacterial Panel		BD MAX™ Extended Enteric Bacterial Panel	BD MAX™ Extended Enteric Bacterial Panel			BD MAX™ Cdiff	BD MAX™ Cdiff		BD MAX™ Extended Enteric Bacterial Panel				BD MAX™ Extended Enteric Bacterial Panel		
<p>Fever/visible blood in stool/abdominal pain with bloody stools/persistent abdominal pain and fever</p>	BD MAX™ Extended Enteric Bacterial Panel																BD MAX™ Extended Enteric Bacterial Panel	
<p>Vomiting and nonbloody diarrhea lasting 2-3 days or less</p>	BD MAX™ Enteric Viral Panel		BD MAX™ Enteric Viral Panel			BD MAX™ Enteric Viral Panel			BD MAX™ Enteric Viral Panel			BD MAX™ Enteric Viral Panel					BD MAX™ Enteric Viral Panel	

### Enteric Bacterial Panel

Among reported outbreaks of bacterial diarrhea, four of the major pathogens isolated are *Campylobacter* spp., *Salmonella* spp., *Shigella* spp., and Shiga toxin producing *E. coli*. Of these, non-typhoidal *Salmonella* species are the leading cause of hospitalization and death among food borne bacteria.<sup>6</sup>

### Extended Enteric Bacterial Panel

Some pathogens are **seasonally** and **regionally** implicated in bacterial gastroenteritis. Therefore, an extended panel is also available which will include the above mentioned bacterial targets plus *Vibrio*, *Yersinia*, ETEC and *Plesiomonas*. This test should be ordered with Enteric Bacterial Panel when additional food or waterborne bacteria are suspected. Alternatively, this panel may be ordered for every stool specimen if extended coverage is desired.<sup>4</sup>

### Enteric Parasite Panel

The most common parasites in developed countries are *Giardia lamblia*, *Cryptosporidium* spp. and *Entamoeba histolytica*. Using microscopy, pathogenic *E. histolytica*<sup>7</sup> cannot be differentiated from the non-pathogenic species *Entamoeba dispar*<sup>3</sup> which is essential for treatment decisions and public health information.

### Enteric Viral Panel

Globally, norovirus is estimated to be the most common cause of acute gastroenteritis. It is responsible for 685 million cases every year, 200 million of these cases are among children younger than 5 years old.<sup>8</sup> For a nosocomial outbreak situation, we offer a targeted viral panel for both Norovirus and Rotavirus with extended coverage for Adenovirus, Sapovirus and Astrovirus.

### *C. difficile*

*Clostridium difficile* is recognized as the primary pathogen responsible for antibiotic-associated colitis and for 10%–20% of cases of nosocomial antibiotic-associated diarrhea<sup>9</sup> These test results should be used in conjunction with clinical diagnosis.

Test	Sample Type <sup>10-14</sup>	Storage and Stability <sup>10-14</sup>	Targets
<b>BD MAX™ Enteric Bacterial Panel</b>	<ul style="list-style-type: none"> <li>Unpreserved soft to diarrheal stool</li> <li>Cary-Blair preserved stool</li> </ul>	<ul style="list-style-type: none"> <li>Specimens can be stored for up to 5 days at 2–8 °C or for up to 24 hours at 2–25 °C before testing.</li> <li>BD MAX Enteric Bacterial Panel components are stable at 2–25 °C through the stated expiration date.</li> <li>Do not use expired components.</li> </ul>	<ul style="list-style-type: none"> <li><i>Salmonella</i> spp.</li> <li><i>Campylobacter</i> spp.</li> <li><i>Shigella</i> spp. (including EIEC)</li> <li>Shiga toxin (<i>E. coli</i> [STEC])</li> </ul>
<b>BD MAX™ Extended Enteric Bacterial Panel</b>	<ul style="list-style-type: none"> <li>Unpreserved soft to diarrheal stool</li> <li>Cary-Blair preserved stool</li> </ul>	<ul style="list-style-type: none"> <li>Specimen can be stored for up to 120 hours (5 days) at 2–8 °C or for up to 24 hours at 2–25 °C before testing.</li> <li>BD MAX Extended Enteric Bacterial Panel Master Mix is stable at 2–25 °C through the stated expiration date.</li> <li>Do not use expired components.</li> </ul>	<ul style="list-style-type: none"> <li><i>Plesiomonas shigelloides</i></li> <li><i>Vibrio</i> (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>)</li> <li>Enterotoxigenic <i>E. coli</i> (ETEC)</li> <li><i>Yersinia enterocolitica</i></li> </ul>
<b>BD MAX™ Enteric Parasite Panel</b>	<ul style="list-style-type: none"> <li>Unpreserved soft to diarrheal stool</li> <li>10% formalin-fixed stool</li> </ul>	<ul style="list-style-type: none"> <li>Specimens, either unpreserved or 10% formalin fixed stool, can be stored for up to 120 hours (5 days) at 2–8 °C or for a maximum of 48 hours at 2–25 °C before testing.</li> <li>BD MAX Enteric Parasite Panel components are stable at 2–25 °C through the stated expiration date.</li> <li>Do not use expired components.</li> </ul>	<ul style="list-style-type: none"> <li><i>Giardia lamblia</i></li> <li><i>Cryptosporidium</i> (<i>C. hominis</i> and <i>C. parvum</i>)</li> <li><i>Entamoeba histolytica</i></li> </ul>
<b>BD MAX™ Enteric Viral Panel</b>	<ul style="list-style-type: none"> <li>Unpreserved soft to diarrheal stool</li> <li>Cary-Blair preserved stool</li> </ul>	<ul style="list-style-type: none"> <li>Specimen can be stored for up to 120 hours (5 days) at 2–8 °C or for up to 48 hours at 2–25 °C before testing.</li> <li>BD MAX Enteric Viral Panel Master Mix is stable at 2–25 °C through the stated expiration date.</li> <li>Do not use expired components.</li> </ul>	<ul style="list-style-type: none"> <li>Norovirus GI &amp; GII</li> <li>Rotavirus A</li> <li>Adenovirus F40/41</li> <li>Sapovirus (genogroups I, II, IV, V)</li> <li>Human Astrovirus (hAstro)</li> </ul>
<b>BD MAX™ Cdiff</b>	<ul style="list-style-type: none"> <li>Unpreserved soft to diarrheal stool</li> </ul>	<ul style="list-style-type: none"> <li>Specimens can be stored for up to 5 days at 2–8 °C or for up to 48 hours at 2–25 °C before testing.</li> <li>BD MAX Cdiff assay components are stable at 2–25 °C through the stated expiration date.</li> <li>Do not use expired components.</li> </ul>	<ul style="list-style-type: none"> <li><i>Clostridium difficile</i> toxin B gene (<i>tcdB</i>)</li> </ul>

\* A single unpreserved soft to diarrheal stool specimen can be used to test across the available molecular options our laboratory offers.

#### Common Storage and Stability of Specimens and Reagent Tubes<sup>10-14</sup>

- Collected specimens should be kept between 2 °C and 25 °C during transport.
- Specimen can be stored for up to 120 hours (5 days) at 2–8 °C.
- Master mix tubes are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening.
- Reagent tubes are stable for up to 14 days at 2–25 °C after initial opening and re-sealing of the pouch.

- Mortensen et al. Comparison of time-motion analysis of conventional stool culture and the BD MAX™ Enteric Bacterial Panel; BMC Clinical Pathology 2015; 15:9
- Anderson et al. Comparison of the BD MAX Enteric Bacterial Panel to routine culture methods for detection of *Campylobacter*, Enterohemorrhagic *Escherichia coli* (O157), *Salmonella* and *Shigella* isolates in preserved stool specimens; JCM 2014; 52:4
- Centers for Disease Control and Prevention. Parasites – Amebiasis – *Entamoeba histolytica* Infection. <https://www.cdc.gov/parasites/amebiasis/index.html>. Updated December 16, 2015.
- Humphries, R et al. Laboratory Diagnosis of Bacterial Gastroenteritis. Clin. Microbiol. Rev. vol. 28 no. 1 3-31. 1 January 2015
- Fang, F and Patel, R. 2017 Infectious Diseases Society of America Infectious Diarrhea Guidelines: A View from the Clinical Laboratory. CID 2017;65 (15 December)
- Scallan et al. Foodborne illness acquired in the United States – Major Pathogens; Emerg Infect Dis 2011; 17:7-15
- Madison-Antenucci, S et al. Multicenter Evaluation of BD Max Enteric Parasite Real-Time PCR Assay for Detection of *Giardia duodenalis*, *Cryptosporidium hominis*, *Cryptosporidium parvum*, and *Entamoeba histolytica*. Journal of Clinical Microbiology. Vol 54 no. 11. November 2016.
- Centers for Disease Control and Prevention. Norovirus Worldwide. <https://www.cdc.gov/norovirus/trends-outbreaks/worldwide.html>. Page last updated: July 16, 2018
- Polage, C et al. Nosocomial Diarrhea: Evaluation and Treatment of Causes Other Than *Clostridium difficile*. CID 2012 55(7) 982-989.
- BD MAX™ Enteric Bacterial Panel [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2016.
- BD MAX™ Extended Enteric Bacterial Panel [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2017.
- BD MAX™ Extended Enteric Parasite Panel [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2016.
- BD MAX™ Enteric Viral Panel [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2017.
- BD MAX™ Cdiff [Package Insert]. Sparks, MD: Becton, Dickinson and Company; 2017.

BD, Sparks, MD, 21152, USA  
800.638.8663

[bd.com](http://bd.com)

© 2019 BD. BD, the BD Logo and BD MAX are trademarks of Becton, Dickinson and Company.  
223028-US January 2019

