

Gastrointestinal Infection Array

Why is multiplex molecular testing for gastrointestinal (GI) pathogens important?

The spectrum of pathogens that cause GI infections is quite broad and typically requires an assortment of classical detection methods (fecal examination, bacterial culture, and PCR testing) to identify the causative agent. Many of these classical methods suffer from variable specificity and sensitivity, and are often poorly utilized due to a lack of understanding of each method's intended use. Molecular testing is more sensitive and faster than conventional methods for detection of gastrointestinal pathogens.

Common Pathogens Causing Diarrhea

Pathogen	Fever	Nausea/Vomiting	Bloody Stool	Fecal Inflammation
<i>Campylobacter</i> spp.	Common	Occurs	Occurs	Common
<i>Salmonella</i> spp.	Common	Occurs	Occurs	Common
<i>Shigella</i> spp.	Common	Common	Occurs	Common
Enterohemorrhagic <i>Escherichia coli</i>	Atypical	Occurs	Common	Often not found
<i>Clostridium difficile</i>	Occurs	Not characteristic	Occurs	Common
<i>Yersinia enterocolitica</i>	Common	Occurs	Occurs	Occurs
<i>Entamoeba histolytica</i>	Occurs	Variable	Variable	Variable
<i>Cryptosporidium</i> spp.	Variable	Occurs	Not characteristic	None to mild
<i>Cyclospora</i>	Variable	Occurs	Not characteristic	Not characteristic
<i>Giardia lamblia</i>	Not characteristic	Occurs	Not characteristic	Not characteristic
Viruses	Variable	Common	Not characteristic	Not characteristic

Modified from Thielman NM, Guerrant RL: Clinical practice. Acute infectious diarrhea, N Engl J Med 350:38, 2004.

Gastrointestinal Infection Array

The Gastrointestinal Infection Array tests for common gastrointestinal pathogens including 11 bacteria, 5 viruses, and 4 protozoa that cause infectious diarrhea. The GI Array is designed as a screening test for gastrointestinal infections where a rapid comprehensive answer is desired. **It is meant to be ordered in place of conventional testing such as routine stool culture, ova and parasite examinations, and antigen testing.**

Gastrointestinal Infection Array Analytes:

Bacterial	Diarrheagenic <i>E. Coli</i> / <i>Shigella</i>	Viruses	Protozoa
• <i>Campylobacter</i> spp. (<i>C. jejuni</i> / <i>C. coli</i> / <i>C. upsaliensis</i>)	• Enterotoxigenic <i>E. coli</i> (ETEC)	• Adenovirus F 40/41	• <i>Cryptosporidium</i>
• <i>Clostridium difficile</i> (Toxin A/B)	• Shiga-like toxin-producing <i>E. coli</i> (STEC)	• Astrovirus	• <i>Cyclospora cayetanensis</i>
• <i>Plesiomonas shigelloides</i>	• <i>E. coli</i> 0157	• Norovirus GI/GII	• <i>Entamoeba histolytica</i>
• <i>Salmonella</i>	• <i>Shigella</i> / Enteroinvasive <i>E. coli</i> (EIEC)	• Rotavirus A	• <i>Giardia lamblia</i>
• <i>Vibrio</i> (<i>V. parahaemolyticus</i> / <i>V. vulnificus</i>)		• Sapovirus	
• <i>Vibrio cholerae</i>			
• <i>Yersinia enterocolitica</i>			

(continued on back)

Laboratory Services

Specimen Handling

For optimal GI Array testing, stool specimens should be collected in a Cary-Blair collection container with media, and transported to a Nationwide Children's Laboratory Service Center within 24 hours at room temperature or 72 hours refrigerated. Testing is performed 24/7 with a turn-around time estimated at 8 hours of receipt.

Result Reporting

- A result for all reported analytes will be provided as **Detected** or **Not Detected**.
- Positive results for *Plesiomonas*, *Vibrio*, *Salmonella/Shigella*, and *Yersinia* will result in a culture and susceptibilities if the bacterium is recovered.
- *Clostridium difficile* will not be reported on patients <3 years of age, because asymptomatic carriage in this age group is common.(1)
- Enteropathogenic *E. coli* (EPEC) and Enteroaggregative *E.coli* (EAEC) are part of the manufacturer's panel, but will not be reported due to high detection rates in pediatric patients, unclear significance, and concern for misattribution of disease associate with asymptomatic carriage.(2)

Additional Stool Testing

Conventional stool testing should **not** be ordered in addition to the GI Array testing. If a stool culture, O&P exam, or parasite/viral antigen tests are ordered with the GI Array, the panel test will be performed and not the individual assays.

The following lists of tests should be utilized as indicated with, or instead of, the GI Array test.

Test Name	<i>Aeromonas</i> Culture	<i>Shigella</i> Test of Cure	<i>C. difficile</i>	O&P Exam
Test code	AERMC	SHIGC	CDIFTN	OAP
Additional Testing	<i>Aeromonas</i> is not included in the array panel. If this bacterium is suspected, a separate culture order and specimen is required.	Array testing should NOT be used for test of cure.	For individual patients where only <i>C. difficile</i> is highly suspected, the GI Array should not be used. Order the single analyte <i>C. difficile</i> molecular test.	If the GI Array test is negative and the patient has recent travel history, or is immunocompromised.
Specimen Type	Stool in Cary-Blair media (can use same sample if within Transport/Stability requirements)	Stool in Cary-Blair media	Soft (nonforming) or liquid stool	Stool in Total-Fix collection container with media

References:

- (1) Schutze et. al. AAP. *Clostridium difficile* infection in infants and children. Pediatrics. 2013 131:196-200.
- (2) Ardura et al. Hypothetical Impact of a Molecular Diagnostic for Pediatric Acute Gastroenteritis: The FilmArray GI Panel Hy-IMPACT Study. Presented at ASM Annual Meeting, 2015.

For more information regarding test availability or specimen requirements, please call (800) 934-6575 or visit NationwideChildrens.org/Lab.