

TARGET	SENSITIVITY	SPECIFICITY
<i>Campylobacter</i> ( <i>jejuni</i> , <i>coli</i> , and <i>upsaliensis</i> )	97.1-100%	98.4-99.3%
<i>Clostridium difficile</i> (toxin A/B)	91.6-98.8%	97.1-92.0%
<i>E. coli</i> O157	100%	97.1-99.3%
Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	100%	99.4-99.6%
<i>Salmonella</i>	100%	97.2-99.6%
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>	100%	99.7-98.6%
Shigella/Enteroinvasive <i>E. coli</i> (EIEC)	95.9-100%	99.7-99.9%
<i>Vibrio cholerae</i>	-	99.9%
<i>Cryptosporidium</i>	92.3-100%	98.4-99.6%
<i>Entamoeba histolytica</i>	-	98.4-100%
<i>Giardia lamblia</i>	100%	98.3-99.5%
Adenovirus 40/41	95.5%	99.1-99.8%
Norovirus GI/GII	94.5-95.9%	94.5-98.8%
Rotavirus A	100%	99.2-99.8%
Enteroaggregative <i>E. coli</i> (EAEC)	98.8%	98.2%
Enteropathogenic <i>E. coli</i> (EPEC)	99.1%	97.2%
<i>Plesiomonas shigelloides</i>	100%	99.0%
<i>Vibrio</i> ( <i>parahaemolyticus</i> , <i>vulnificus</i> ) -		99.9%
<i>Yersinia enterocolitica</i>	100%	100%
<i>Cyclospora cayetamesis</i>	100%	100%
Astrovirus	100%	99.9%
Sapovirus (I, II, IV, and V)	100%	99.1%

Traditional testing methods are slow, labor intensive, and fail to reveal the true cause of a patient's gastrointestinal symptoms.



TEST INFORMATION

- Description** Gastrointestinal Panel
- Method** Integrated multiplex PCR and bead array technology
- Specimen Type** Stool in Cary Blair
- Turnaround Time** 24-48 hours
- Testing Performed** Mon-Sat
- Shipping** Pickup service available Mon-Fri



GASTROINTESTINAL (GI) PANEL

FDA APPROVED CLINICALLY PROVEN TEST FOR 22 BACTERIAL, PARASITIC, AND VIRAL INFECTIONS

STANDARD PANEL

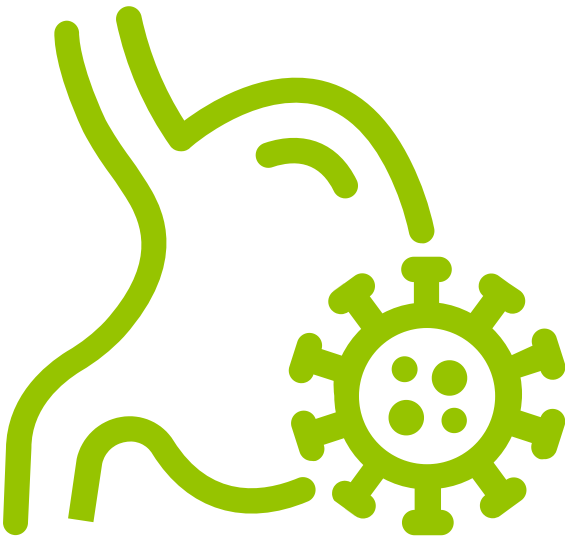
- Bacteria**
- Campylobacter*
  - Clostridium difficile* toxin A/B
  - Plesiomonas shigelloides*
  - Salmonella*
  - Vibrio*
  - Vibrio cholerae*
  - Yersenia enterocolitica*
- Diarrheagenic E. coli/ Shigella**
- Enteroaggregative *E. coli* (EAEC)
  - Enteropathogenic *E. coli* (EPEC)
  - Enterotoxigenic *E. coli* (ETEC) *lt/st*
  - Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2*
  - E. coli* O157
  - Shigella/* Enteroinvasive *E. coli* (EIEC)

- Parasites**
- Cryptosporidium*
  - Cyclospora cayetanensis*
  - Entamoeba histolytica*
  - Giardia lamblia*

- Viruses**
- Adenovirus F 40/41
  - Astrovirus
  - Norovirus GI/GII
  - Rotavirus A
  - Sapovirus

ADD-ON PANEL

- Calprotectin
  - Clostridium difficile* EIA
  - Helicobacter pylori* Stool Antigen EIA
  - Pancreatic Elastase
  - Fecal Fat
  - Occult Blood
  - Zonulin Family Peptide
- (7-10 day turn-around time for all add-on tests)



Genesys Diagnostics' GI Panel simultaneously tests for common gastrointestinal pathogens including viruses, bacteria, and parasites that cause infectious diarrhea.

Target	Signs and Symptoms	Commonly Affected Demographic
<i>Campylobacter (jejuni, coli, and upsaliensis)</i>	Diarrhea, cramping, abdominal pain, and fever within 2-5 days after exposure	Infants and young adults
<i>Clostridium difficile</i> (toxin A/B)	Pseudomembranous colitis, bloody diarrhea, severe abdominal pain and fever	Older adults
<i>E. coli</i> O157	Stomach cramps, diarrhea (often bloody) and vomiting	All ages
Enterotoxigenic <i>E. coli</i> (ETEC) <i>It/st</i>	Profuse watery diarrhea and abdominal cramping	All ages
<i>Salmonella</i>	Diarrhea, fever and abdominal cramps 12-72 hours after infection	Children under the age of 5
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i>	Stomach cramps, diarrhea (often bloody) and vomiting	All ages
Shigella/Enteroinvasive <i>E. coli</i> (EIEC)	Abdominal cramps, diarrhea, vomiting, fever, chills and a generalized malaise	All ages
<i>Vibrio cholerae</i>	Diarrhea, primary septicemia, wound infections, other extra-intestinal infections. 5-10% have profuse watery diarrhea, vomiting, leg cramps, rapid heart rate	All ages
<i>Cryptosporidium</i>	Watery diarrhea, dehydration, lack of appetite, weight loss, stomach cramps, fever, nausea, vomiting	All ages
<i>Entamoeba histolytica</i>	Bloody diarrhea, weight loss, fatigue, abdominal pain and amoeba in stool	All ages
<i>Giardia lamblia</i>	Diarrhea, gas, greasy stool, stomach or abdominal cramps, nausea/vomiting, dehydration	All ages
Adenovirus 40/41	Gastroenteritis, persistent diarrhea, fever, vomiting of short duration	Children under the age of 28 months
Norovirus GI/GII	Moderate to severe gastroenteritis, nausea, vomiting, diarrhea, and fever	All ages, mostly adults
Rotavirus A	Diarrhea, vomiting, fever and abdominal pain, loss of appetite, dehydration	All ages, mostly infants and young children
Enteraggregative <i>E. coli</i> (EAEC)	Watery, mucoid, secretory diarrhea with low grade fever and little to no vomiting, persistent diarrhea	All ages, mostly infants and small children
Enteropathogenic <i>E. coli</i> (EPEC)	Infantile diarrhea	Infants and children
<i>Plesiomonas shigelloides</i>	Fever, chills, abdominal pain, nausea, vomiting, watery diarrhea	All ages
<i>Vibrio (parahaemolyticus, vulnificus)</i>	Diarrhea, primary septicemia, wound infections, other extra-intestinal infections	All ages
<i>Yersinia enterocolitica</i>	Children: fever, abdominal pain, and diarrhea Older children/Adults: right-sided abdominal pain and fever	All ages, children more than adults
<i>Cyclospora cayetamesis</i>	Watery diarrhea, loss of appetite, weight loss, cramping, bloating, increased gas, nausea, fatigue	All ages
Astrovirus	Diarrhea, vomiting, abdominal pain and fever	All ages
Sapovirus (I, II, IV, and V)	Diarrhea, vomiting, nausea, and fever	All ages

It is difficult, if not impossible, to determine the likely cause of a gastrointestinal illness on the basis of clinical features alone. Laboratory investigatios are **essential** for the identification of causative pathogens in gastrointestinal dysregulation.

ADVANTAGES OF OUR GI PANEL

- Comprehensive:

Tests for 22 different bacterial, parasitic, and viral targets in a single test and is capable of detecting and identifying multiple pathogens in a sample.
- Reliable:

This assay exhibits excellent clinical sensitivity and specificity, as well as high reproducibility.
- Fast:

Genesys Diagnostics 24-48 hour turn-around-time is fast enough to impact patient treatment decisions.
- Reduces testing:

One test covering multiple pathogens and can rule out other causes
- Reduces risk of antibiotic resistance:

Fast and accurate identification of causative pathogens leads to the timely and accurate prescription of antibiotics.
- Reduce spread:

When a causative pathogen is known, patients with the same type of infections can be kept together to limit the spread of the pathogen.
- Improve health outcomes and reduce cost:

CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases [1]. The U.S. Department of Agriculture (USDA) estimates that foodborne illnesses cost the United States more than \$15.6 billion each year [2].

RESULTS INTERPRETATION

The detection of 22 gastrointestinal pathogens occurs simultaneously in each sample using an integrated, multiplex PCR and bead hybridization platform. Our easy to read report is available electronically in real time. Based upon the presence (detected) or absence (not detected) of the viruses, bacteria, or parasites within the panel, clients are able to rapidly choose a treatment option.

DIAGNOSTIC TESTING  
Comparison of the available platforms for detecting viruses

	Genesys Integrated Multiplex PCR	Culture	Enzyme Immunoassays
Sensitivity	84.6-100%	70-75%	98%
Turnaround Time	24-48 hours	2-3 days (up to 2 weeks)	24 hours
# of targets detected	22	Typically 3, up to 8	1
Detects co-infection	Yes	Yes	No

1)<https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>  
2)<https://www.cdc.gov/foodsafety/cdc-and-food-safety.html#:~:text=Foodborne%20illness%20is%20common%2C%20costly,than%20%2415.6%20billion%20each%20year>