Gastrointestinal Pathogen Panel (GPP) PCR (15 results)
Test Code: 66008

Tests in this Panel

- Campylobacter
- Clostridium difficile Toxin A/B
- Cryptosporidium
- E. coli O157
- Enterotoxigenic E.coli (ETEC)
- Shiga Toxin-producing E. coli (STEC)
- Giardia lamblia
- Norovirus GI/GII
- Rotavirus A
- Salmonella
- Shigella
- Adenovirus 40/41
- Entamoeba histolytica
- Vibrio cholera
- Yersinia enterocolitica

Clinical and Procedure

Clinical Utility

The xTAG® Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, parasitic, and bacterial nucleic acids in human stool specimens from individuals with signs and symptoms of infectious colitis or gastroenteritis.

The detection and identification of specific gastrointestinal microbial nucleic acid from individuals exhibiting signs and symptoms of gastrointestinal infection aids in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation, laboratory findings, and epidemiological information. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.¹

About Gastrointestinal Infections

Gastrointestinal infections in both pediatric and adult patients account for significant morbidity and mortality worldwide.² In addition, immunocompromised hosts, including HIV patients, solid-organ transplant recipients or patients requiring therapy for chronic inflammatory diseases are susceptible to gastrointestinal infections.³ Mild diarrhea can lead to absenteeism from school or work and may require treatment by a health care provider. Patients with severe diarrhea may be hospitalized and some may develop more serious sequelae such as Guillain-Barré syndrome and hemolytic uremic syndrome (HUS), and in some cases death.⁴ Nearly three percent of neonatal mortality and 17 percent of under-five child mortality is attributable to diarrhea.⁵ Diarrheal disease can be caused by a number of pathogens including viruses, bacteria, and parasites. Presentations of gastroenteritis with an unidentified source pose a challenge to health care providers, as the same clinical presentation can be caused by different etiologies. Knowing the identity of the causal agent in symptomatic (both acute and chronic gastroenteritis) adult and pediatric patients can aid in diagnosis and patient management.¹

Procedure

Nucleic acid is extracted from the specimen, which undergoes reverse transcription to generate complementary DNA (cDNA). The target cDNA is amplified using polymerase chain reaction (PCR), then analyzed with Luminex® xTag® technology to detect the
presence or absence of each pathogen in the panel. This test has not been cleared or approved for diagnostic use by the U.S. Food and Drug Administration for fecal specimens only.

**Specificity**
Detects 15 gastrointestinal pathogen targets: Adenovirus (40/41), *Campylobacter* (*C. jejuni*, *C. coli* and *C. lari* only), *Clostridium difficile* toxin A/B, *Cryptosporidium* (*C. parvum* and *C. hominis* only), Entamoeba histolytica, *Escherichia coli* O157, Enterotoxigenic *Escherichia coli* (ETEC) LT/ST, *Giardia* (*G. lamblia* only, also known as *G. intestinalis* and *G. duodenalis*), Norovirus GI/GII, Rotavirus A, *Salmonella*, *Shiga Toxin-producing Escherichia coli* (STEC) stx1/stx2, *Shigella* (*S. boydii*, *S. sonnei*, *S. flexneri* and *S. dysenteriae*), *Vibrio cholera*, and *Yersinia enterocolitica*.

**Turnaround Time**
Same day (within 12-18 hours from receipt of specimen), Monday through Saturday.

**Specimen Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>fecal</td>
<td>66008</td>
<td>87507</td>
<td>Yes</td>
<td>Size of pea, or 2 mL liquid stool</td>
<td>Positive/Not Detected For Assay Limitations see below</td>
</tr>
</tbody>
</table>

**Special Instructions**
- Collect and place in a sterile, screw top tube.
- Store frozen and ship on dry ice for overnight delivery.
- Samples are stable for 2 days refrigerated or frozen for 14 days.

Qualitative (Positive, Not Detected) for: Adenovirus (40/41), *Campylobacter*, *Clostridium difficile*, *Cryptosporidium*, Entamoeba histolytica, *Escherichia coli* O157, Enterotoxigenic *Escherichia coli* (ETEC), *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*), Norovirus GI/GII, Rotavirus A, *Salmonella*, *Shiga Toxin-producing Escherichia coli* (STEC), *Shigella*, *Vibrio cholera*, and *Yersinia enterocolitica*.

**Assay Limitations**

1. Positive results obtained using the xTAG GPP assay are presumptive and must be confirmed with an FDA cleared or approved test or other acceptable reference method. All results should be used and interpreted in the context of a full clinical evaluation as an aid in the diagnosis of gastrointestinal infection. a. There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids or amplified product. b. There is a risk of false positive values resulting from non-specific signals in the assay. 2. Analyte targets (virus, bacteria or parasite nucleic acid sequences) may persist in vivo, independent of virus, bacteria or parasite viability. Detection of analyte target(s) does not guarantee that the corresponding live organism(s) is present, or that the corresponding organism(s) is the causative agent for clinical symptoms. 3. As with any hybridization-based assay, underlying polymorphisms in primer-binding regions can affect the targets being detected and subsequently the calls made. 4. *Campylobacter*: the xTAG GPP assay was designed to detect *C. jejuni*, *C. coli* and *C. lari*; however, some strains of *Campylobacter fetus* subsp. *fetus* may be detected, (*Campylobacter fetus* subsp. *fetus* (NCTC 10842, type strain [ATCC 27374]) at a concentration of 6 x10^8 cfu/mL resulted in a positive call for *Campylobacter*). 5. *Escherichia coli* (Migula) Castellani and Chalmers strain CDC EDL 1284 [929-78] (serotype O124:NM [ATCC 43893]) (enteroinvasive) resulted in a positive call for *Shigella*. 6. *Cryptosporidium*: the xTAG GPP assay detects *C. parvum* and *C. hominis* only. 7. *Giardia*: xTAG GPP assay detects *G. lamblia* only (also known as *G. intestinalis* and *G. duodenalis*). 8. Primers for *Shigella* are expected to cross-react with enteroinvasive *E. coli* (EIEC) and *Salmonella subterraeanae* (at a concentration of 6 x10^8 cfu/mL), *Entero-invasive E. coli* (strain CDC EDL 1284 [929-78], serotype O124:NM) cross-reacting with *Shigella* in the xTAG GPP kit is expected as EIEC is genetically, biochemically and physiologically closely related to *Shigella*. EIEC strains possess some of the biochemical characteristics of *E. coli*, but some strains can cause dysentery using the same method of invasion used by *Shigella*. Both *Shigella* and EIEC can be separated from other *E. coli* by PCR targeting the invasion plasmid antigen H (ipah) gene. However, PCR alone cannot distinguish between *Shigella* from EIEC. Additional physiological and biochemical typing, and serological typing must be used in combination with the ipaH gene PCR to distinguish between *Shigella* and EIEC. EIEC also causes diarrhea predominantly in tropical countries with occasional cases reported in the US. 9. There is a risk of false negative values due to the presence of strain/species sequence variability in the targets of the assay, procedural errors, amplification inhibitors in specimens, or inadequate numbers of organisms for amplification. 10. A target call of STEC stx1/stx2 may be from either *Shigella*.
dysenteriae or from STEC. 11. The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms. 12. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely prevalent when disease is high. False positive test results are more likely during periods when prevalence is low. 13. This test is a qualitative test and does not provide the quantitative value of detected organism present.

Shipping
Ship Monday through Friday. Friday shipments must be labeled for Saturday delivery. All specimens must be labeled with patient's name and collection date. A Viracor Eurofins test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: Viracor Eurofins, 1001 NW Technology Dr, Lee's Summit, MO 64086.

Causes for Rejection
Specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

Disclaimer
Specimens are approved for testing in New York only when indicated in the Specimen Information field above.

The CPT codes provided are based on Viracor Eurofins’ interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Viracor Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

Information derived from Gastrointestinal Pathogen Panel Package Insert (Luminex Corporation). Gastrointestinal Pathogen Panel is a product of Luminex® Corporation. xTAG is a registered trademark of Luminex Corporation. Luminex is a registered trademark of Luminex Corporation.

References
1 Information derived from the xTAG Gastrointestinal Pathogen Panel test kit package insert (Luminex, Inc.).


