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Gastrointestinal Pathogen Panel (GPP) PCR utilizing Luminex® xTAG®

Test Code: 65008

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

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. xTAG GPP positive results are presumptive and must be confirmed by FDA-cleared tests or other acceptable reference methods.[1]

Procedure

Specificity

Detects 11 Gastrointestinal Pathogen targets: *Campylobacter* (*C. jejuni, C. coli* and *C. lari only*), *Clostridium difficile* toxin A/B, *Cryptosporidium* (*C. parvum* and *C. hominis* only), *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, and *Shigella* (*S. boydii, S. sonnei* , *S. flexneri* and *S. dysenteriae*).

Turnaround Time

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

Specimen Information

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Specimen Type	Order Code	CPT Code	NY Approved	Volume	Assay Range
fecal	65008	87506	Yes	Size of pea, or 2 mL liquid stool	Positive/Not Detected Assay Limitations??

Special Instructions
- Collect and place in a sterile, screw top tube.
- Store frozen and ship on dry ice for overnight delivery.

Qualitative (Positive, Not Detected) for: *Campylobacter* , *Clostridium difficile* toxin A/B, *Cryptosporidium* , *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), and *Shigella* . 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 x108 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* subterranean (at a concentration of 6 x 108 cfu/mL). Enteroinvasive *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

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

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