Gastrointestinal Pathogen Panel

For in vitro diagnostic use

CERNER ORDERABLE
Gastrointestinal Pathogen Panel PCR; GPP PCR

CPT CODE
87493 x 1, 87798, 87798-59 x 9

CLINICAL UTILITY
The 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 from stool specimens from individuals with signs and symptoms of infectious colitis or gastroenteritis. The following pathogen types, subtypes and toxin genes are identified using this assay: *Campylobacter* (*C. jejuni*, *C. coli* and *C. lari* only), Cryptosporidium (*C. parvum* and *C. hominis* only), *Escherichia coli* (*E. coli*) O157, Enterotoxigenic *E. coli* (ETEC) LT/ST, *Giardia* (*G. lamblia* only, also known as *G. intestinalis* and *G. duodenalis*), Norovirus GI/GII, Rotavirus A, *Salmonella*, Shiga-like Toxin producing *E. coli* (STEC) stx 1/stx 2, and *Shigella* (*S. boydii*, *S. sonnei*, *S. flexneri* and *S. dysenteriae*). 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].

METHODOLOGY
Multiplex RT-PCR/Array bead hybridization

SPECIMENS
Raw stool in sterile cup*
Raw stool collected in Cary Blair transport media**

SPECIMEN STABILITY
Refrigerated: up to 24 hours and after 24 hours place in freezer

SHIPPING
Ship specimen on ice packs or if greater than 24 hours ship frozen on dry ice

CAUSES FOR REJECTION
Specimens other than those listed above. Solid stool samples submitted.

SPECIFICITY
Detects 11 Gastrointestinal Pathogen targets: *Campylobacter*, Cryptosporidium, *Escherichia coli* (*E. coli*) O157, Enterotoxigenic *E. coli* (ETEC) LT/ST, *Giardia*, Norovirus GI/GII, Rotavirus A, *Salmonella*, Shiga-like Toxin producing *E. coli* (STEC) stx 1/stx 2, and *Shigella*

ASSAY RANGE

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.

Qualitative results (Detected/Not Detected) for: *Campylobacter*, Cryptosporidium, *Escherichia coli* (*E. coli*) O157, Enterotoxigenic *E. coli* (ETEC) LT/ST, *Giardia*, Norovirus GI/GII, Rotavirus A, *Salmonella*, Shiga-like Toxin producing *E. coli* (STEC) stx 1/stx 2, and *Shigella*

TURNAROUND TIME
Monday-Friday, 24-72 hours

*Raw stool has been cleared by the FDA for use in the GPP assay.
**In-house validation was performed to establish as suitable specimen type

1. Reference information can be found in the Indiana University Health Molecular Assay Procedures.