Gastrointestinal Pathogen Panel (GPP)

GOPATH® LABORATORIES
Global Pathology Services

90% **One test** detects and identifies over 90% of diarrhea-causing pathogens[8]

"GoPath's Gastrointestinal Pathogen Panel (GPP) is used as a routine clinical screening test for infectious gastroenteritis"

Clinical Utility

GoPath Laboratories' Gastrointestinal Pathogen Panel (GPP) serves the purpose of detecting and identifying the 14 most causative pathogens in stool specimens from symptomatic patients. The Gastointestinal Pathogen Panel allows rapid screening for common diarrhea-causing pathogens ranging from viruses, bacteria and parasites in a single test. The simple work flow and enhanced test performance enable a more precise and effective diagnosis, which will greatly aid in guiding patient treatment and management.

•All-Inclusive Screening Test to Provide Accurate Answers

Detect and identify over 90% diarrhea-causing pathogens including bacteria, viruses and parasites in a single test[7,8]. This is important as the signs and symptoms of infectious gastroenteritis are often overlapping among different pathogens; using one test can save time over conventional diagnostic methods

•Simplify to a Lean Workflow

One test provides answers for multiple pathogens. Eliminate the hassle of managing multiple samples and testing methods into one confident test to reduce cost and increase patient care with a short turnaround time

•Rule Out Infectious Causes

Be confident to rule out infectious causes of diarrhea with the GPP's >99% NPV[8]

Methodology

GoPath's GPP FDA approved test is based on multiplex nucleic acid amplification followed by xTAG universal sorting system for amplicon detection. The sample(s) are pre-treated for nucleic acid extraction and purification. The samples then goes through the multiplex application and bead hybridization and detection stage where the data acquisition and analysis begins. Testing is completed within 48-72 hours.

Pathogen Detection

GoPath's GPP panel is qualitative (Positive or Not Detected) for the following pathogens (see figure 1):

Figure 1. 14 different pathogens in GoPath's GPP*

Bacteria	Campylobacter Clostridium difficile (C. difficile) Toxin A/B Escherichia coli (E. coli) O157 Salmonella Shiga-like Toxin producing E. coli (STEC) stx 1/ stx 2 Shigella Vibrio cholerae, cholera toxin gene (ctx) Enterotoxigenic E. coli (ETEC) LT/ST
Parasites	Giardia lambia Cryptosporidium Entamoeba hisolytica
Viruses	Adenovirus 40/41 Norovirus GI/GII Rotavirus A

*This is an FDA approved assay and all results can be used and interpreted for a full clinical evaluation and diagnosis of gastrointestinal infections.

Interpretation

Positive: Target pathogen is detected. The pathogen detected can lead to signs and symptoms of infectious colitis or gastroenteritis.
Negative: Targets cannot be detected. It may be due to pathogens not detected by this test or to non-infectious causes.
Indeterminate: An indeterminate result may be due to PCR inhibition/poor sample quality.

CPT Code: 87507

FDA Approved

Sample Submission

Collect required amount of diarrheal fecal material and fill to 25ml (red fill line) on a Protocol™ Cary-Blair Media specimen vial with a green top. Store at room temperature and ship the same day specimen is collected. (see Patient Instructions for Collecting Stool)

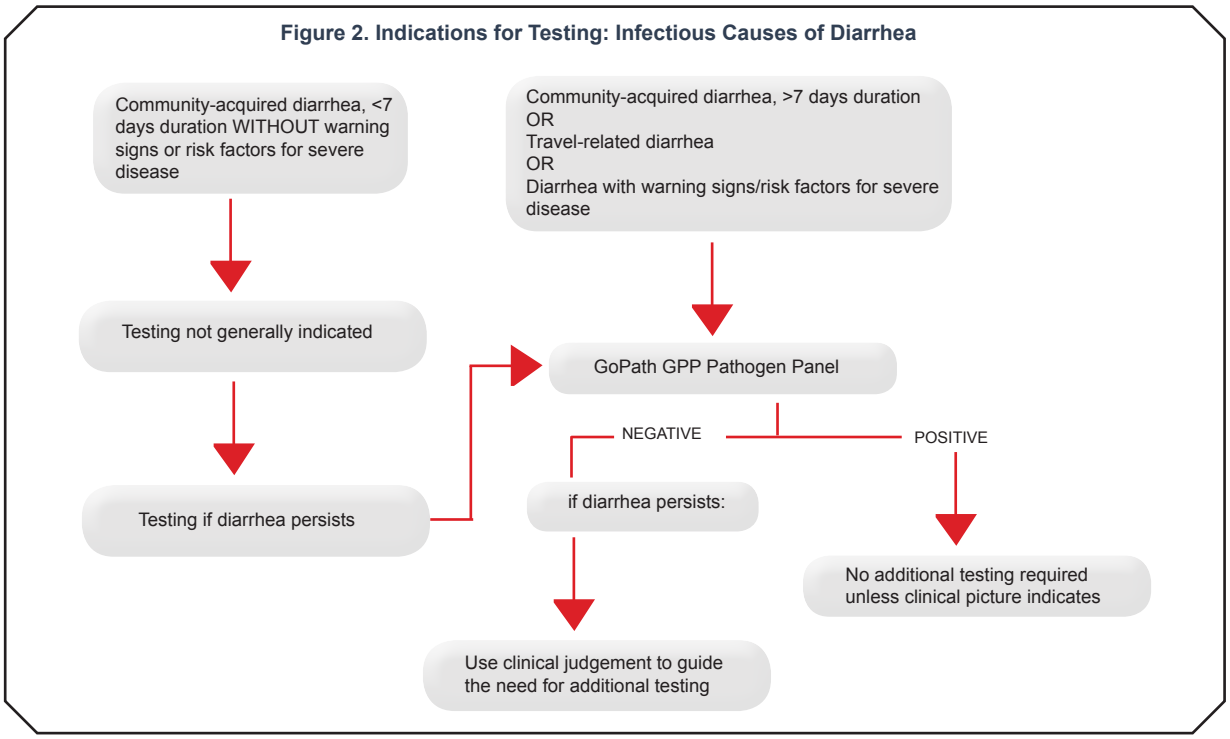
Causes For Specimen Rejection

- If the specimen is a fully-formed stool
- No visible fecal matter (specimen was not to the red fill line)
- Time and/or temperature instructions not followed as specified
- Quantity not sufficient (QNS) for analysis
- Following the Patient Instructions for Collecting Stool will prevent possible rejections.

Limitations

Negative result does not rule-out infection in patients with increased gastrointestinal infection pretest. The GPP test does not test for all potential infectious agents of diarrheal disease and results of this test must be correlated in conjunction with patient's other clinical and epidemiological findings.

Figure 2. Indications for Testing: Infectious Causes of Diarrhea



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