



# GPP

## Gastrointestinal Pathogen Panel

GA Test Code 7667  
 Method FDA-cleared FilmArray™ Gastrointestinal Panel by multiplex RT-PCR

| <b>Bacteria</b>   | <b>Sensitivity/PPA</b> | <b>Specificity/NPA</b> |
|---|------------------------|------------------------|
| <i>Campylobacter (jejuni, coli, and upsaliensis)</i>              | 97.1%                  | 98.4%                  |
| <i>Clostridium difficile</i> (toxin A/B)                          | 98.8%                  | 97.1%                  |
| <i>Plesiomonas shigelloides</i>                                   | 100%                   | 99.0%                  |
| <i>Salmonella</i>   | 100%                   | 99.6%                  |
| <i>Yersinia enterocolitica</i>                                    | 100%                   | 100%                   |
| <i>Vibrio (parahaemolyticus, vulnificus and cholerae)</i>         |                        | 99.9%                  |
| <i>Vibrio cholerae</i>  |                        |                        |
| Enteroaggregative <i>E. coli</i> (EAEC)                           | 98.8%                  | 98.2%                  |
| Enteropathogenic <i>E. coli</i> (EPEC)                            | 99.1%                  | 97.2%                  |
| Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>                | 100%                   | 99.4%                  |
| Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> | 100%                   | 99.7%                  |
| <i>E. coli</i> O157   | 100%                   | 97.1%                  |
| <i>Shigella</i> /Enteroinvasive <i>E. coli</i> (EIEC)             | 95.9%                  | 99.9%                  |
| <b>Parasites</b>  |                        |                        |
| <i>Cryptosporidium</i>  | 100%                   | 99.6%                  |
| <i>Cyclospora cayetanensis</i>                                    | 100%                   | 100%                   |
| <i>Entamoeba histolytica</i>                                      |                        | 100%                   |
| <i>Giardia lamblia</i>  | 100%                   | 99.5%                  |
| <b>Viruses</b>  |                        |                        |
| Adenovirus F 40/41  | 95.5%                  | 99.1%                  |
| Astrovirus  | 100%                   | 99.9%                  |
| Norovirus GI/GII  | 94.5%                  | 98.8%                  |
| Rotavirus A   | 100%                   | 99.2%                  |
| Sapovirus (I, II, IV, and V)                                      | 100%                   | 99.1%                  |

**Specimens**  
**Stool Swab (FecalSwab™ or white-capped eSwab™):** Collect stool in leakproof container. Rotate swab in stool and place in tube w/ liquid media. Break-off pre-scored swab and seal tube. Stability: 14 days at room temp.  
**Rectal Swab (FecalSwab™ or white-capped eSwab™):** Pass swab tip 1 inch beyond anal sphincter. Carefully rotate swab to sample anal crypts and withdraw. Fecal material must be *clearly visible* on swab. Place swab in tube w/ liquid media. Break-off pre-scored swab and seal tube. Stability: 14 days at room temp.  
**Raw Stool:** 0.2-1.0 g/mL liquid feces (conforms to container shape), screw-cap container, refrigerated (7 days). **Do not** dilute specimen or use preservatives.  
**Cary Blair (C&S) Medium - Stool:** Collect stool in leakproof container. Using scoop attached to cap, add stool to red FILL LINE. Recap vial and agitate it to permit adequate mixing of the stool w/ transport medium. Stability: 4 days at room temp.

**Causes for Rejection**  
 Fully-formed stool; no visible fecal matter; time and/or temperature instructions not followed as specified; quantity not sufficient (QNS) for analysis.

**Reference Range**  
 Not Detected

**Turnaround Time**  
 1-6 hours from receipt of sample

**CPT Code**  
 87507

**Description**  
 The FDA-cleared FilmArray GI Panel tests for 22 targets (bacteria, parasites, viruses) that cause infectious diarrhea.

**Clinical Utility**  
 A positive PCR result for any 1 of the specific targets indicates the presence of the respective organism in the specimen. A negative result indicates the absence of detectable DNA in the specimen, but does not rule out infection with these or other enteric pathogens. False-negative results may occur due to inhibition (rate of <1%) of PCR.

**Genetic Assays, Inc.**