



GPP

Gastrointestinal Pathogen Panel

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

Bacteria	Sensitivity/PPA	Specificity/NPA
<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/Enteroinvasive E. coli</i> (EIEC)	95.9%	99.9%
Parasites		
<i>Cryptosporidium</i>	100%	99.6%
<i>Cyclospora cayentanensis</i>	100%	100%
<i>Entamoeba histolytica</i>		100%
<i>Giardia lamblia</i>	100%	99.5%
Viruses		
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 ambient.
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 ambient.
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 ambient.

Rejection Causes 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

PLA Code 0097U* (for Medicare patients)

*This PLA Code is subject to a Medicare Limited Coverage Policy (MLCP) and may require a signed Advanced Beneficiary Notice (ABN) when ordering. Tests subject to an MLCP must meet medical necessity criteria in order to be covered by Medicare. MLCP tests ordered without a supportive ICD-10 code will not satisfy medical necessity and therefore will not be covered by Medicare. Physicians (or others authorized by law to order tests) should only order tests that are medically necessary for the diagnosis or treatment of a patient. These orders may require an ABN signed by the patient, which confirms they are responsible for payment.

Description

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