Lab Dept: Microbiology

Test Name: GASTROINTESTINAL PATHOGEN PANEL PCR, STOOL

General Information

Lab Order Codes: GI

Synonyms: Multiplex PCR, GI Panel

CPT Codes:

87507 – GI Pathogen DNA 12-25 Targets

87045 – Culture, bacterial; feces, with isolation and preliminary examination, Salmonella and Shigella species (if appropriate)
87046 x2 – Culture, bacterial; stool, additional pathogens, isolation and preliminary examination, each plate (e.g. Campylobacter, E. coli 0157) (if appropriate)

87899 & 87899-59 – Infectious agent, not otherwise specified (EHEC) (if appropriate)

87015 – Concentration (any type), for infectious agents (EHEC) (if appropriate)

The following testing may be added if appropriate based on findings for organism identification (multiple additions are possible if more than one organism is identified).

87046 – For each individual additional pathogen (e.g. Yersinia, Vibrio, Aeromonas (if appropriate)

87077 – Aerobic isolate, additional methods required for definitive identification of isolates (if appropriate)

87106 – Culture, fungi definitive identification, each organism; yeast (if appropriate)

87147 – Culture, typing; immunologic method, other than immunofluorescence (e.g., agglutination grouping), per antiserum (if appropriate)

87184 – Susceptibility studies, disk method, per plate (if appropriate)

87186 – Susceptibility studies, microdilution or agar dilution, each multi-antimicrobial, per plate (if appropriate)

Test Includes:	-*Campylobacter* species (*Campylobacter jejuni/Campylobacter coli Campylobacter upsaliensis*) -*Plesiomonas shigelloides* -*Salmonella* species -*Vibrio* species (*Vibrio parahaemolyticus, Vibrio vulnificus, Vibrio cholerae*) -*Vibrio cholerae* -*Yersinia* species -Enteroaggregative *Escherichia coli* (EAEC) -Enteropathogenic *E coli* (EPEC) -Enterotoxigenic *E coli* (ETEC) -Shiga toxin -*E coli* O157 -*Shigella*/Enteroinvasive *E coli* (EIEC) -*Cryptosporidium* species -*Cyclospora cayetanensis* -*Entamoeba histolytica* -*Giardia* -Adenovirus F 40/41 -Astrovirus -Norovirus GI/GII -Rotavirus A -Sapovirus Note: If *Shigella* species or *Salmonella typhi* is detected, culture and susceptibility will be performed at an additional charge. Note: If *Salmonella* species is detected on admitted patients, culture and susceptibility will be performed at an additional charge.

Logistics

Test Indications:	The FilmArray gastrointestinal panel is a multiplex PCR test capable of qualitatively detecting DNA or RNA of 22 pathogens (bacteria, parasites, and viruses) in approximately 1 hour from stool in Cary Blair transport medium. This test is used to diagnose infection by *Campylobacter* species, *Plesiomonas shigelloides*, *Salmonella* species, *Vibrio* species, *V cholerae*, *Yersinia* species, enteroaggregative *Escherichia coli,* enteropathogenic *E coli*, enterotoxigenic *E coli,* Shiga toxin-producing *E coli, E coli O157*, *Shigella/*Enteroinvasive *E coli, Cryptosporidium* species, *Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia*, Adenovirus F 40/41, Astrovirus, Norovirus, Rotavirus, and Sapovirus.
Lab Testing Sections:	Microbiology
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	24 hours

Special Instructions: Specimen in Cary Blair must arrive within 96 hours of collection. Fresh stool must arrive within two hours of collection.

Specimen

Specimen Type:

- Stool, fresh
  - includes stool ostomy samples if not collected by endoscope or aspirate.
- Stool in Cary Blair

Container: Stool collection container

Para-Pak® C&S system (Cary-Blair transport media) for delayed transport of more than 1 hour (available in from Materials, Storeroom Item# 9976).

Draw Volume: 1 gram or 5mL (Minimum: 1mL) stool

Collection: Random stool collection

Instructions for Para Pak® (C & S) system when delayed transport >1 hour is expected:

1. Fill vial by using the spoon built into the lid of the vial and transferring small scoopfuls of stool from areas which appear bloody, slimy or watery until the contents rise to the “Fill Here” red line. **Do not overfill**.
2. If the stool is formed, sample small amounts from each end, sides and the middle.
3. Mix the contents of the vials with the spoon. Screw cap on tightly and shake the vial vigorously until the contents are well mixed. Make sure there is no leakage.
4. Label vials with patient’s name, date and time of collection.
5. Store vials at room temperature.
6. Return collection kit to laboratory within 96 hours.

Special Processing: Lab Staff: Place fresh stool in preservative within 2 hours of collection. Send at ambient temperatures.

Sample Rejection: **No diapers accepted**. Mislabeled or unlabeled specimens; specimen in Cary Blair media older than 96 hours, fresh stool >2 hours old; overfilled or underfilled Cary Blair vial, leaking container, stool aspirates; frozen specimen, commercial transport media other than liquid Cary Blair (eg, ETM, Para-Pak Enteric Plus; Copan FecalSwab/ESwab), Cary Blair gel swabs, products containing formalin, SAF, PVA fixative, EcoFix preservative, rectal swabs, stool swab, gel swabs, endoscopy specimens, unpreserved stool.

Interpretive

Reference Range: Negative (for all targets)

Alert Values: **The following will be called if found to be positive*:**

Salmonella
Shigella/Enteroinvasive *E. coli* (EIEC)
Shiga-like toxin producing *E. coli* (STEC) stx1/stx2
E. coli 0157
Vibrio
Vibrio cholera
Campylobacter species

*Note: Alert values are not called for ED patients.

Limitations: A negative result should not rule-out infection in patients with a high pretest probability for gastrointestinal infection. The assay does not test for all potential infectious agents of diarrheal disease.
Positive results do not distinguish between a viable or replicating organism and the presence of a nonviable organism or nucleic acid, nor do they exclude the potential for coinfection by organisms not contained within the panel.

Results of the panel are intended to aid in the diagnosis of illness and are meant to be used in conjunction with other clinical and epidemiological findings.

Methodology: Multiplex Polymerase Chain Reaction (PCR)

References: FilmArray Gastrointestinal (GI) Panel Instruction Booklet, RFIT-PRT-0143-03 April 2016. Salt Lake City, UT: BioFire Diagnostics

Updates: 8/20/2019: Previously performed at Mayo, now done in house.
9/4/2019: Test does not include - *Clostridioides (Clostridium) difficile* toxin A/B
11/5/2020: Update rejection criteria (stool aspirates added)
10/15/2021: Alert value info update.