Overview

Useful For

Rapid detection of gastrointestinal infections caused by:
-*Campylobacter* species (*Campylobacter jejuni/Campylobacter coli/Campylobacter upsaliensis*)
-*Clostridioides difficile* toxin A/B
-*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

This test is **not recommended** as a test of cure.

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
RMALD	Ident by MALDI-TOF mass spec	No, (Bill Only)	No
GID	Bacteria Identification	No, (Bill Only)	No
ISAE	Aerobe Ident by Sequencing	No, (Bill Only)	No
REFID	Additional Identification Procedure	No, (Bill Only)	No
VIBC	Vibrio Culture, Stool	Yes	No

Testing Algorithm

If positive for *Vibrio* species or *Vibrio cholerae,* a *Vibrio* culture will be performed at an additional charge.

The following algorithms are available:
-Parasitic Investigation of Stool Specimens Algorithm
-Laboratory Testing for Infectious Causes of Diarrhea

Special Instructions

- Parasitic Investigation of Stool Specimens Algorithm
- Laboratory Testing for Infectious Causes of Diarrhea

Highlights

The FilmArray gastrointestinal panel is a multiplex polymerase chain reaction (PCR) test capable of qualitatively detecting DNA or RNA of 22 pathogens (bacteria, parasites, and viruses) in approximately 1 hour from feces in Cary-Blair transport medium.

This test provides diagnosis of infections caused by *Campylobacter* species, *Clostridioides difficile* (previously *Clostridium difficile*), *Plesiomonas shigelloides, Salmonella* species, *Vibrio* species*, Vibrio 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.

Method Name

Multiplex Polymerase Chain Reaction (PCR)

NY State Available

No

Specimen

Specimen Type

Fecal

Ordering Guidance

It is **not recommended** that the following tests be concomitantly ordered if this test is ordered:
-VIBC / *Vibrio* Culture, Feces
-ROTA / Rotavirus Antigen, Feces
-LADV / Adenovirus, Molecular Detection, PCR, Varies
-GIAR / *Giardia* Antigen, Feces
-CRYPS / *Cryptosporidium* Antigen, Feces
-CYCL / *Cyclospora* Stain, Feces
-STL / Enteric Pathogens Culture, Feces
-CAMPC / *Campylobacter* Culture, Feces
-SHIGC / *Shigella* Culture, Feces
-SALMC / *Salmonella* Culture, Feces

-YERSC / *Yersinia* Culture, Feces
-E157C / *Escherichia coli* O157:H7 Culture, Feces
-STFRP / Shiga Toxin, Molecular Detection, PCR, Feces
-CDPCR / *Clostridioides difficile* Toxin, PCR, Feces
-LNORO / Norovirus PCR, Molecular Detection, Feces

Additional Testing Requirements

In some cases, there may be local public health requirements that impact Mayo Clinic Laboratories (MCL) clients and require additional testing on specimens with positive results from this panel. Clients should familiarize themselves with local requirements. MCL recommends clients retain an aliquot of each specimen submitted for this test to perform additional testing themselves, as needed. If necessary, see Interpretation for detailed information about how to obtain this testing.

Shipping Instructions

Specimen must arrive within 4 days of collection.
Do not freeze. Testing will be canceled on specimens received frozen.

Specimen Required

Supplies: Culture and Sensitivity Stool Transport Vial (T058)
Container/Tube:
Preferred: Specific modified Cary-Blair transport system; see Additional Information for acceptable collection media
Acceptable: Approved Cary-Blair transport system (15 mL of non-nutritive transport medium containing phenol red as a pH indicator)
Specimen Volume: Representative portion of feces
Collection Instructions:
1. Collect fresh fecal specimen and submit 1 gram or 5 mL in container with transport medium.
2. Within 2 hours of collection, place feces in preservative.
3. Submit preserved feces in original container. **Do not aliquot**.
4. **If unpreserved specimens are received, testing will be canceled**.
Additional Information:
If collection media other than those listed is utilized, testing may be canceled. Media listed have been verified for use by Mayo Clinic Laboratories.
Modified Cary-Blair media:
Preferred: Culture and Sensitivity Stool Transport Vial (T058)
Acceptable: Meridian Para-Pak C and S, Cardinal Health Culture and Sensitivity Stool transport Vial
Cary Blair media: Remel Cary-Blair, Remel; Protocol Cary-Blair

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Gastroenterology and Hepatology Test Request (T728)
-Microbiology Test Request (T244)
-Kidney Transplant Test Request

Specimen Minimum Volume

1 mL

Reject Due To

Unapproved commercial transport media (eg, AlphaTec Enteric Transport Medium [ETM], Para-Pak Enteric Plus, Medical Chemical Corporation C and S Transport Medium [MCC])	Reject
Copan FecalSwab/ESwab	Reject
Products containing formalin (eg, Sodium Acetate-Acetic Acid Formalin fixative [SAF]; PolyVinyl Alcohol fixative [PVA]; EcoFix preservative	Reject
Swabs (eg, Cary-Blair gel swab; Rectal swab)	Reject
Stool swab; Gel swab	Reject
Endoscopy specimen	Reject
Unpreserved stool	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Ambient (preferred)	4 days	
	Refrigerated	4 days	

Clinical & Interpretive

Clinical Information

Acute diarrheal syndromes are usually self-limiting but may be complicated by dehydration, vomiting, and fever. Diagnostic testing and treatment may be required in some instances. Many bacterial enteric infections in the United States originate within the food supply chain. According to the Centers for Disease Control and Prevention (CDC), in 2012 there were 19,531 laboratory-confirmed cases of infection with pathogens potentially transmitted through food in the United States. The numbers of infections, by pathogen, were as follows: *Salmonella* species (7800), *Campylobacter* species (6793), *Shigella* species (2138), *Cryptosporidium* species (1234), Shiga toxin-producing *Escherichia coli* non-O157 (551), Shiga toxin-producing *E coli* O157 (531), *Vibrio* species (193), *Yersinia* species (155), and *Cyclospora cayetanensis* (15). *Giardia* may also be transmitted through ingestion of contaminated food and water. There were 15,178 cases of giardiasis reported to the CDC in 2012. Since the clinical presentation may be very similar to many of these bacterial, viral, and parasitic pathogens, laboratory testing is required for definitive identification of the causative agent.

Rapid multiplex panel detection of the most common agents of bacterial, viral, and parasitic enteric infections directly from stool specimens is sensitive, specific, and provides same-day results, obviating the need for culture, antigen testing, microscopy, or individual nucleic acid amplification tests.

For other diagnostic tests that may be of value in evaluating patients with diarrhea, the following are available:
-Parasitic Investigation of Stool Specimens Algorithm
-Laboratory Testing for Infectious Causes of Diarrhea

Reference Values

Negative (for all targets)

Interpretation

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.

In some cases, there may be local public health requirements that impact Mayo Clinic Laboratories (MCL) clients and require additional testing on specimens with positive results from this panel. Clients should familiarize themselves with local requirements. MCL recommends clients retain an aliquot of each specimen submitted for this test to perform

additional testing themselves, as needed. If necessary, selected add-on tests can be performed by MCL at an additional charge, as detailed below. **Call 800-533-1710 within 4 days of specimen collection** to request supplemental testing for positive test results:

Gastrointestinal pathogen panel positive for	**Client action**
Campylobacter species	Request add on test CAMPC / *Campylobacter* Culture, Feces
Salmonella species	Request add on test SALMC / *Salmonella* Culture, Feces
Shigella/Enteroinvasive E coli	Request add on test SHIGC / *Shigella* Culture, Feces (for the *Shigella*/Enteroinvasive *E coli* target, the culture will assess for *Shigella* species only)
Yersinia species	Request add on test YERSC / *Yersinia* Culture, Feces
Shiga toxin-producing *E coli* *E coli* O157	Request add on test E157C / *Escherichia coli* O157:H7 Culture, Feces

Mayo Clinic Laboratories will report results to the client for additional cultures when ordered. If cultures are positive and the client needs the isolated organism (eg, *Campylobacter*, *Salmonella*, *Shigella*, *Yersinia* or *Vibrio* species, or *E coli* O157:H7) for submission to a public health laboratory, the client needs to call MCL and request that the isolates be returned to them (the client). The client will be responsible for submitting the isolates to the appropriate public health department. Positive culture results will also be reported via the Electronic Clinical Laboratory Reporting System.

Alternatively (not preferred), clients who want a patient specimen returned from MCL should call 800-533-1710 as soon as possible, at the latest within 96 hours of specimen collection, to request that MCL return an aliquot of the submitted specimen to them. Clients will be responsible for submitting specimens to appropriate public health departments.

Cautions

The detection of microbial DNA or RNA is dependent upon proper sample collection, handling, transportation, storage, and preparation. There is a risk of false-negative results due to the presence of strains with sequence variability or genetic rearrangements in the target regions of the assays.

Repeat testing should not be performed on specimens collected less than 7 days apart.

The presence of blood or mucous in the specimen may interfere with testing.

Aeromonas species are not detected by this panel but may be detected by tests: STL / Enteric Pathogens Culture, Feces or AERMC / *Aeromonas* Culture, Feces.

The following information is provided by the test manufacturer:
Cary-Blair media, used for dilution and processing of clinical stools, is screened by manufacturers for viable organisms but may not be specifically tested for microbial nucleic acids. The presence of nucleic acids at levels that can be detected by the FilmArray GI Panel may lead to false-positive test results.(BioFire Technical Notes FLM1-PRT-0239-01 and QS-339B-01)

***Campylobacter* species:** Detects but does not differentiate *Campylobacter jejuni*, *Campylobacter coli*, and *Campylobacter upsaliensis.* Other species will not be detected. *Helicobacter pullorum* may cross react.

***Clostridioides difficile*:** Detects but does not differentiate toxin A gene (*tcdA*) and toxin B gene (*tcdB*). A positive result may reflect asymptomatic carriage or *C difficile*-associated diarrhea. Because of asymptomatic carriage of toxigenic *C difficile* in infants, treatment for *C difficile* may not be needed in those aged 12 months or younger.

***Salmonella* species:** Detects but does not differentiate *Salmonella enterica* and *Salmonella bongori*. Cross-reactivity may occur with some strains of *Escherichia coli,* which have the cryptic ETT2 type-III secretion system.

***Vibrio* species:** Detects but does not differentiate *Vibrio parahaemolyticus* and *Vibrio vulnificus*. The assay may also react with less common *Vibrio* species such as, *Vibrio alginolyticus*, *Vibrio fluvialis*, and *Vibrio mimicus*. The assay is not expected to detect rare species of *Vibrio* such as: *Vibrio cincinnatiensis*, *Vibrio furnissii* and *Vibrio metschnikovii*. *Grimontia hollisae* may cross react.

***Vibrio cholerae*:** *V cholerae* is specifically reported when detected. *V cholerae* strains that do not carry the *toxR* gene or which carry highly divergent *toxR* genes may not be detected. Rare non-*cholerae* strains of *Vibrio* that have acquired the *toxR* gene may cross-react *(*eg, *Vibrio harveyi*, *Vibrio mimicus, Vibrio alginolyticus*, *Vibrio vulnificus*).

***Yersinia* species:** Detects *Yersinia enterocolitica* but does not differentiate known serotypes or biotypes. *Yersinia kristensenii, Yersinia frederiksenii*, and *Yersinia intermedia* cross-react at high levels with *Y enterocolitica*; detection is reported to genus level only.

Diarrheagenic *E coli*: Detects genetic determinants associated with classic diarrheagenic *E coli/Shigella* pathotypes. Transfer of these genes between organisms has been documented; therefore, detected results for multiple diarrheagenic *E coli/Shigella* may be due to the presence of multiple pathotypes or a single strain containing the genes characteristic of multiple pathotypes.

Enteroaggregative *E coli* (EAEC): Detects but does not differentiate 2 gene targets typically associated with enteroaggregative *E coli*; the *aggR* regulatory gene and the putative outer membrane protein, *aatA*, both located on the partially conserved pAA plasmid. pAA is not present in all strains phenotypically identified as EAEC, and not all pAA plasmids carry *aggR* and *aatA* genes; therefore, the assay will not detect all members of this diverse pathotype but is likely to detect most pathogenic strains.

Enterotoxigenic *E coli* (ETEC): Detects but does not differentiate heat-labile (LT) enterotoxin (*ltA*) and 2 heat-stable (ST) enterotoxin variants (*st1a* and *st1b*). Cross-reactivity may occur with strains of *Hafnia alvei, Citrobacter koseri, Citrobacter sedlakii,* and *Cedecea davisae.* LT-II and the STB/ST2 toxins are not detected.

Enteropathogenic *E coli* (EPEC): Detects *eae* gene but does not differentiate typical and atypical EPEC. The LEE pathogenicity island, which includes the *eae* gene, is also found in some Shiga toxin-producing *E coli* (STEC; O157 and non-O157 strains). Therefore, the results of the *eae* assay (positive or negative) are only reported when STEC is not detected. When STEC is detected, EPEC will not be reported, regardless of the EPEC assay result. Consequently, the assay cannot distinguish between STEC containing *eae* and a coinfection of EPEC and STEC. Rare instances of other organisms carrying *eae* have been documented (eg, *Aeromonas* species, *Citrobacter* species, *Escherichia albertii*, *Shigella boydii*). Other assays target *bfp* to detect EPEC and, if positive, reflex to *eae* detection to characterize isolates as typical or atypical EPEC. The *bfp* gene is not used to detect EPEC in this assay. For the reasons described above, EPEC may be missed or overcalled.

Shiga toxin-producing *E coli* (STEC): Detects but does not differentiate Shiga toxin 1 (*stx1*) and Shiga toxin 2 (*stx2*) sequences. Shiga toxin-positive results indicate the likely presence of STEC. Rare instances of detection of Shiga-like toxin genes in other genera and species have been reported (eg, *Aeromonas caviae*, *Acinetobacter haemolyticus*, *Shigella sonnei*, *Enterobacter cloacae*, *Citrobacter freundii*, *Klebsiella pneumoniae*).

***E coli* O157:** The *E coli* O157 assay is not reported as detected unless a Shiga-like toxin gene is also detected. The assay cannot distinguish between infections with a single toxigenic STEC O157 or rare coinfections of STEC (non-O157) with a *stx1/stx2*-negative *E coli* O157.

***Shigella*/Enteroinvasive *E coli* (EIEC):** Detects but does not differentiate *Shigella* species from enteroinvasive *E coli*.

***Cryptosporidium* species:** Detects but does not differentiate approximately 23 different *Cryptosporidium* species,

including the most common species (eg, *Cryptosporidium hominis* and *Cryptosporidium parvum*), as well as less common species (eg, *Cryptosporidium meleagridis*, *Cryptosporidium felis*, *Cryptosporidium canis*, *Cryptosporidium* cuniculus, *Cryptosporidium muris*, and *Cryptosporidium suis*), but is not expected to detect the very rare species *Cryptosporidium bovis*, *Cryptosporidium ryanae,* and *Cryptosporidium xiaoi*.

Entamoeba histolytica: Detects *E histolytica*. *Entamoeba dispar* present in high levels may cross-react.

Giardia: Detects *Giardia lamblia* (also known as *Giardia intestinalis, Giardia duodenalis*). A very low frequency of cross-reactivity with the commensal microorganisms *Bifidobacterium* and *Ruminococcus* species was observed in the clinical evaluation.

Adenovirus F40/41: Detects but does not differentiate F40 and F41. Does not detect respiratory adenovirus species such as B, C, and E.

Astrovirus: Detects but does not differentiate 8 subtypes (HAstV1-8).

Norovirus GI/GII: Detects but does not differentiate GI and GII. Does not detect genogroup GIV, nonhuman genogroups, or closely related Caliciviruses.

Rotavirus: Detects all strains of rotavirus A. In silico sequence analysis indicates that these assays will not cross-react with rotavirus B and C, which are less common in human disease, or rotavirus D, E, and F, which have not been found in humans. Recent oral rotavirus A vaccines may result in patients passing the virus in stool and be detectable in stool polymerase chain reaction (PCR) testing. Contamination of specimens with vaccine can cause false-positive rotavirus PCR results. Specimens should not be collected or processed in areas that are exposed to rotavirus A vaccine material.

Sapovirus: Detects but does not differentiate genogroups I, II, IV, V. Genogroup III will not be detected.(FilmArray Gastrointestinal [GI] Panel. BioFire Diagnostics, LLC)

Clinical Reference

1. Khare R, Espy MJ, Cebelinski E, et al. Comparative evaluation of two commercial multiplex panels for detection of gastrointestinal pathogens by use of clinical stool specimens. J Clin Microbiol. 2014;52(10):3667-3673

2. Centers for Disease Control and Prevention (CDC). Incidence and trends of infection with pathogens transmitted commonly through food-foodborne diseases active surveillance network, 10 U.S. sites, 1996-2012. MMWR Morb Mortal Wkly Rep. 2013;62(15):283-287

3. Centers for Disease Control and Prevention. Summary of notifiable diseases-United States, 2012. MMWR Morb Mortal Wkly Rep. 2014;61(53):1-121

4. DuPont HL. Persistent diarrhea: A clinical review. JAMA. 2016;315(24):2712-2723. doi:10.1001/jama.2016.7833

5. Lawson PA, Citron DM, Tyrrell KL, Finegold SM. Reclassification of *Clostridium difficile* as *Clostridioides difficile* (Hall and O'Toole 1935) Prevot 1938. Anaerobe. 2016;40:95-99. doi:10.1016/j.anaerobe.2016.06.008

6. Oren A, Garrity GM. Validation List No. 169. List of new names and new combinations previously effectively, but not validly, published. Int J Syst Evol Microbiol. 2016;66(6):2456-2458. doi:10.1099/ijsem.0.001181

Performance

Method Description

The FilmArray Gastrointestinal Panel is a closed system that performs the chemistry required to isolate, amplify, and detect nucleic acid from multiple viral, bacterial, and parasitic gastrointestinal pathogens from a single stool specimen of patients suspected to have a gastrointestinal infection. A panel contains reagents in freeze-dried form and is divided into discrete segments where the required chemical processes are carried out. Patient sample and hydration fluid are drawn by vacuum into the panel and then placed into the FilmArray instrument. The detection process operations are

automated (nucleic acid purification, first-stage polymerase chain reaction [PCR], second-stage PCR, and melt analysis) and complete in about an hour in this closed system:
-Nucleic Acid Purification:
The sample is lysed by a combination of chemical and mechanical mechanisms and the liberated nucleic acid is captured, washed, and eluted using magnetic bead technology.

-First-Stage PCR:
A reverse transcription step is performed to convert viral RNA into complementary DNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the reverse transcription step and subsequent thermocycling for multiplex PCR.

-Second-Stage PCR:
Products of first stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen Plus, BioFire Diagnostics), which is distributed over the second stage PCR array. The individual wells of the array contain primers for different assays (in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material.

-DNA Melting Analysis:
Temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve.

-Analysis of Melt Curves:
The software evaluates the DNA melt curve for each well to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature of the curve, which is then compared against the expected range for the assay. When the software determines that the melt curve is positive and in range, it is called positive. When it determines that the melt curve is negative or is not in the appropriate range, it is called negative.

-Analysis of Replicates:
Melt curves of each of the 3 replicates for each assay are evaluated to determine the assay result. For an assay to be called positive, at least 2 of the 3 associated melt curves must be called positive, and the temperature for at least 2 of the 3 positive melt curves must be similar (within 1 degree C). Assays that do not meet these criteria are called negative.(Instruction manual: FilmArray Gastrointestinal [GI] Panel CE IVD. BioFire Diagnostics, LLC; RFIT-PRT-0143-05, 05/2021)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
1 to 2 days

Specimen Retention Time
2 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87507

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GIP	GI Pathogen Panel, PCR, F	82195-9

Result ID	Test Result Name	Result LOINC® Value
SRCGI	Specimen Source	31208-2
37081	Campylobacter species	82196-7
37082	C. difficile toxin	82197-5
37083	Plesiomonas shigelloides	82198-3
37084	Salmonella species	82199-1
37085	Vibrio species	82200-7
37086	Vibrio cholerae	82201-5
37087	Yersinia species	82202-3
37088	Enteroaggregative E. coli (EAEC)	80349-4
37089	Enteropathogenic E. coli (EPEC)	80348-6
37090	Enterotoxigenic E. coli (ETEC)	80351-0
37091	Shiga toxin producing E. coli	82203-1
37092	Escherichia coli O157 serotype	82204-9
37093	Shigella/Enteroinvasive E. coli	80350-2
37094	Cryptosporidium species	82205-6
37095	Cyclospora cayetanensis	82206-4
37096	Entamoeba histolytica	82207-2
37097	Giardia	82208-0

37098	Adenovirus F40/41	82209-8
37099	Astrovirus	82210-6
37100	Norovirus GI/GII	82211-4
37101	Rotavirus	82212-2
37103	Sapovirus	82213-0
37262	Interpretation	59464-8