INTENDED USE
The BioFire FilmArray® Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with the FilmArray Instrument. The FilmArray GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The test provides an overall sensitivity and specificity of 98.5% and 99.3%, respectively.

METHODOLOGY
• Real-time PCR and RT-PCR

TEST INCLUDES
22 Gastrointestinal Pathogens Detected in the FilmArray GI Panel

BACTERIA
Campylobacter (C. jejuni/C. coli/C. upsaliensis)
Clostridium difficile (C. difficile) toxin A/B (NOT REPORTED)* See note below
Plesiomonas shigelloides
Salmonella
Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae), including specific identification of Vibrio cholerae
Yersinia enterocolitica

DIARRHEAGENIC E. COLI/SHIGELLA
Enterogaugregative Escherichia coli (EAEC)
Enteropathogenic Escherichia coli (EPEC)
Enterotoxigenic Escherichia coli (ETEC) lt/st
Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2, including specific identification of the E. coli O157 serogroup within STEC
Shigella/Enteroinvasive Escherichia coli (EIEC)

PARASITES
Cryptosporidium
Cyclospora cayetanensis
Entamoeba histolytica
Giardia lamblia (also known as G. intestinalis and G. duodenalis)

VIRUSES
Adenovirus F 40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus (Genogroups I, II, IV, and V)

IMPORTANT:
• The laboratory will contact providers with any positive result.
• The C. difficile result will not be reported on the panel. If C. difficile testing is necessary, please order the C. difficile PCR (CDIFFPCR) assay.
• Negative FilmArray GI Panel results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn’s disease.
• Positive results do not rule out co-infection with organisms not included in the FilmArray GI Panel. The agent detected may not be the definite cause of the disease. Further, positive results do not distinguish between a viable/replicating organism and a nonviable organism.
• The performance of the FilmArray GI Panel has not been established for monitoring treatment of infection with any of the GI Panel organisms.
• The performance of the FilmArray GI Panel has not been established for patients without signs and symptoms of gastrointestinal illness.

SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>SPECIMEN</th>
<th>VOLUME</th>
<th>CONTAINER</th>
</tr>
</thead>
<tbody>
<tr>
<td>human stool</td>
<td>at least 1 gram or 5 cc</td>
<td>a stool collection container or other clean dry container with a tight-fitting lid</td>
</tr>
</tbody>
</table>
**Patient Preparation**
Patient should not use antacids, barium, bismuth, antibiotics, antimalarial agents, antidiarrheal medications or oily laxatives prior to specimen collection. After administration of any of these compounds, specimen collection should be delayed for 5–10 days, or at least two weeks after barium or antibiotics.

**Collection**
Specimens must be collected in such a way as to avoid contamination with urine or water.

1. Wash hands with soap and water.
2. Label the stool container with patient’s full name, date of birth, and date and time of collection.
3. Lift the toilet seat and place plastic wrap or wax paper over the toilet seat opening. DO NOT expel the specimen directly into the stool container.
4. Make a depression in the wax paper or plastic wrap before securing it with adhesive tape. Make sure the sample won’t fall into the toilet bowl.
5. Lower the toilet seat and proceed with bowel movement. DO NOT expel the specimen into the toilet. DO NOT urinate on the specimen.
6. Using a disposable tool, transfer the stool to the stool container.
7. Carefully place the lid on the container and place the container in the plastic bag and seal it. Place this bag into a larger paper or plastic bag.
8. Dispose of any remaining stool into the toilet and place the soiled paper or wrap in a plastic or paper bag prior to putting it in the garbage.
9. Wash hands thoroughly with soap and water.
10. Store the specimen (in paper or plastic bag) in the refrigerator until you can transport the specimen to the Berkshire Health Systems Laboratory, preferably the same day. DO NOT wait more than 24 hours.

**Storage & Transport**
- Stool should be processed as soon as possible but may be stored at 2–8°C for up to 24 hours prior to processing in Cary Blair medium.
- Specimens in Cary Blair medium should be tested as soon as possible, though they may be stored at room temperature (18–30°C) or under refrigeration (2–8°C) for up to 4 days.

**Causes for Rejection**
- stool received more than 24 hours after collection

**INTERFERING SUBSTANCES**
Rotavirus A vaccine may be shed in stool following oral administration and Rotavirus A will be detected by the FilmArray GI Panel if vaccine is present in the test sample.

**REFERENCE RANGE**
Not Detected

**ADDITIONAL INFORMATION**
Despite advances in food safety, sanitation, and medical treatment, infectious gastroenteritis remains a significant problem in industrialized countries among all age groups. In the United States, around 76 million cases of foodborne disease, resulting in 325,000 hospitalizations and 5,000 deaths, are estimated to occur each year. Additionally, there are over 300,000 C. difficile diagnoses per year in the U.S. resulting in estimated costs of at least $1 billion. Globally, infectious diarrheal illness is a significant cause of mortality in young children resulting in an estimated 800,000 deaths per year in children under the age of 5. In addition to this significant morbidity and mortality, diarrhea in children contributes to malnutrition, increased susceptibility to other infections, and may lead to delays in growth and intellectual development.
<table>
<thead>
<tr>
<th>MEDITECH CODE</th>
<th>GIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT CODES</td>
<td>87507: Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen, 12–25 targets</td>
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<tr>
<td>LABORATORY</td>
<td>Molecular Pathology Department</td>
</tr>
<tr>
<td>AVAILABILITY</td>
<td>Monday–Friday, 7:30 AM–4:00 PM</td>
</tr>
<tr>
<td>TURNAROUND TIME</td>
<td>less than 24 hours M–F</td>
</tr>
</tbody>
</table>

Revised 04/08/16