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| FilmArray Gastrointestinal Panel |
| **Purpose** | This procedure provides instructions for performing the Gastrointestinal Panel on the BioFire FilmArray system. |
| **Policy Statements** | This procedure applies to all technical staff performing testing on the BioFire FilmArray. |
| **Principle and Clinical Significance** | The FilmArray Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for the use with FilmArray systems. The FilmArray GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from the stool sample in Cary Blair transport media obtained from individuals with signs and symptoms of gastrointestinal infection. The FilmArray GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory and epidemiological data. The FilmArray simultaneously tests for 22 pathogens from stool samples collected in Cary Blair Transport media. Results from the FilmArray GI Panel are available in about an hour. The FilmArray is a closed disposable system that houses all the chemistry required to isolate, amplify and detect nucleic acid from multiple gastrointestinal pathogens within a single stool specimen. The rigid plastic component of the GI pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments where the required chemical processes are carried out. The user of the FilmArray GI Panel loads the sample in the GI pouch, places the pouch in the FilmArray instrument/Module and starts the run. All other operations are automated.The following is an overview of the operations and processes that occur during a FilmArray run:Nucleic Acid Purification - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by a combination of chemical and mechanical (bead beating) mechanisms and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes, and the bead-beater apparatus can be heard as a high-pitched whine during the first few minutes of operation.Reverse Transcription and 1st Stage Multiplex PCR - Since the GI Panel includes RNA viruses, a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.2nd Stage PCR - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen® Plus, BioFire Diagnostics). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are ‘nested’ or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.DNA Melting Analysis – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray Software automatically evaluates the data from replicate wells for each assay to report results. For a description of data interpretation and reporting see the Interpretation of Results section of this booklet.The FilmArray Software controls the operation of the instrument, collects and analyzes data, and automatically generates a test report at the end of the run.  |
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| **Test Code** | GI |
| **Materials** |  |  |  |  |
|  | **Reagents** | **Supplies** | **Equipment** | **Reagent Storage** |
|  | * Individually packaged FilmArray GI panel pouches
* Single-use Sample Buffer ampoules
* Single-use pre-filled Hydration Injection Vials (blue)
* Single-use Sample Injection vials (red)
 | * Individually packaged Transfer Pipettes
* Cary Blair media
* MMQCI controls (Cat No. M238)
 | * FilmArray Torch and software
* FilmArray Pouch Loading Station
* Biosafety Hood
 | * Store kit at room temperature-Do Not Freeze.
* Avoid storage near heating or cooling vents.
* All kit components should be stored and used together. Do not mix components from one kit with another kit.
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| **Sample** | Stool sample in Cary Blair transport media. 0.2 ml of sample required for testing. If fresh stool is received it must be transferred to Cary Blair within 2 hours of collection. Specimens should be processed and tested as soon as possible though they may be stored at room temperature or refrigerated for up to 4 days. |
| **Special Safety Precautions** | Microbiologists/virologists are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology* and *Virology Policy Manual*:1. *Biohazard Containment*
2. *Safety in the Microbiology/Virology Laboratory*
* *Biohazardous Spills*
1. Wear appropriate personal protective equipment (PPE) including disposable gloves and lab coats.
2. Change gloves often when handling reagents or samples.
3. Dispose of materials used in this assay, including reagents, used buffer vials is biohazdardous waste.
4. Sample buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.
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| **Organisms Identified** |

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| --- | --- | --- |
| **Bacteria**  | **Viruses** | **Parasites** |
| *Salmonella* | *Adenovirus* F 40/41 | *Cryptosporidium* |
| *Shigella/Enteroinvasive E. coli (EIEC)* | *Astrovirus* | *Cyclospora cayetanensis* |
| *Campylobacter*  | *Norovirus* GI/GII | *Entamoeba histolytica* |
| *Clostridium difficile toxin A/B* | *Rotavirus* | *Giardia lamblia* |
| *Plesiomonas shigelloides* | *Sapovirus* (Genogroups I,II,IV,V) |  |
| *Vibrio* |  |  |
| * *V. cholerae*
 |  |  |
| *Yersinia enterocolitica* |  |  |
| Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* |  |  |
| * *E. coli 0157*
 |  |  |
| Enteroaggregative *E. coli* (EAEC) |  |  |
| Enteropathogenic *E. coli* (EPEC) |  |  |
| Enterotoxigenic *E. coli* (ETEC) *lt/sst* |  |  |

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| **Quality Control** | There are two process controls included in each pouch.1. RNA Process Control-The RNA Process Control assay targets RNA transcript from the yeast Schizosaccharomyces pombe. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR, and DNA melting. A positive control result indicated that all steps carried out in the pouch were successful.
2. PCR2 Control-The PCR2 Control assay detects a DNA target that is dried into the wells of the array along with the corresponding primers. A positive result indicated that 2nd stage PCR was successful.

Both control assays must be positive for the test run to pass. If either control fails, the Controls field of the test report will display FAILED and all results will be listed as INVALID. The sample should be retested using a new pouch.**External Quality Controls**Perform QC using external positive and negative controls every 30 days, with new lots/shipments, and after major instrument repairs or relocation. **NOTE:** rotate modules used to test controlsCary Blair transport media will be used for the external Negative ControlMMQCI positive controls: stored at -70°C1. Allow to come to room temp
2. Vortex for 10 seconds and test as a patient sample
3. Rotate which vial is tested (M2393718 and M2402818)
4. Record results on FilmArray GI Panel QC log

**Acceptable results:** **Positive:** See [MB 10.2.F2 FilmArray GI Panel QC Worksheet](file:///G%3A%5CLAB%5CMicrobiology%5CBioFire%20FilmArray%5CFilmArray%20-%20GI%5CGI%20panel%20forms%5CFilmArray%20GI%20Panel%20QC%20Worksheet.docx) for acceptable results**Negative:** all organisms NOT detected**New Lot/Shipment Quality control:**Perform QC using external positive and negative controls with each new lot or shipment before putting into service. Record results in QC binder**Wipe Testing:**To be performed every 30 days to monitor for contamination.1. Clean the hood and supplies with 10% bleach followed by water
2. Prepare a sterile cryovial or conical by aliquoting approximately 500µL nuclease free water.
3. Set up the loading block as if testing a patient specimen
4. Soak a culturette swab in the nuclease free water for approximately 1 minute.
5. Swab working areas including processing hood surface, vortex and any other high touch surfaces in the **sample prep** area.
6. Using a biohazard pad as a barrier, break swab off into the red sample injection vial, add the sample buffer to the vial and test as a patient specimen.
7. Positive results are cause for alert and decontamination. Stop reporting patient results, and consult Technical Specialist to discuss contaminant testing.
8. See [the FilmArray Torch Operator’s Manual](file:///G%3A%5CLAB%5CMicrobiology%5CBioFire%20FilmArray%5Chtfa-prt-0001_filmarray_torch_operator_s_manual_ivd_en.pdf) for decontamination instructions
9. Record and file results on the wipe testing log in the FilmArray binder

**Desirable results:** All organisms NOT detected |
|  **Laboratory Precautions** | 1. **Prevent organism contamination**
2. Samples that contain high concentrations of organisms should be processed in a biosafety hood.
3. Prior to processing a sample, thoroughly clean both the work area and FilmArray Pouch Loading Station using freshly prepared 10% bleach. Wipe disinfected surfaces with water.
4. Use clean gloves to remove materials from bulk packaging bags and reseal bulk packaging bags when not in use.
5. Samples and pouches should be handled at a time
6. Change gloves and clean work area between each sample
7. **Prevent amplicon contamination**
8. Discard pouches in biohazard container immediately after the run has completed.
9. Avoid excessive handling of pouches after test runs.
10. Avoid exposing pouches to sharp edges or anything that might cause a puncture.
11. If liquid is observed on the exterior of a pouch, immediately contain and discard in a biohazard container. The instrument/Module and work space must be decontaminated.
 |
| **Procedure-Prepare the Pouch** | 1. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Change gloves.
3. Remove FilmArray Pouch, Sample Injection Vial (RED), Hydration Injection Vial (BLUE), Sample Buffer ampoule and a transfer pipette from the box. Avoid touching the open well of the Sample Injection vial and the tip of the Sample Buffer ampoule as this may introduce contamination.
4. Place the blue-capped hydration injection vial in the blue well of the FilmArray Pouch Loading Station.
5. Place the red-capped sample injection vial in the red well of the FilmArray pouch loading station.
6. Obtain patient sample and place into hood.
7. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.
8. Label the pouch with the small accession label. Do not cover the bar code. Slide the pouch into the FilmArray pouch loading station.
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| **Procedure-Hydrate the Pouch** | 1. Twist counterclockwise and lift the hydration injection vial, leaving blue cap in the well of the FilmArray pouch loading station.
2. Insert the cannula tip into the port in the pouch located directly below the blue arrow of the FilmArray pouch loading station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Discard tip into the sharps container.
4. Verify that the pouch has been hydrated:

 Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen**NOTE:** If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the port was broken. If the pouch still vails to hydrate retrieve a new pouch and repeat from Step 2 of the prepare pouch section. Document issue in the problem log.  |
| **Procedure-Prepare Sample Mix** | 1. Hold the Sample Buffer ampoule so that the tip is facing up.
2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
3. Re-position thumb and forefinger to grip between the textured plastic tab and the bottom of the ampoule, then invert the ampoule over the red-capped sample injection vial and re-position thumb and forefinger to grip the bottom of the ampoule. Dispense sample buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided.
4. Thoroughly mix the patient specimen by vortexing for 10 seconds.
5. Using the transfer pipette provided in the test kit, draw sample to the second line (approximately 0.2 mL). Add sample to the red sample injection vial.
6. Tightly close the lid of the sample injection vial and mix by gently inverting at least three times.
 |
| **Procedure-Load Sample Mix** | 1. Slowly unscrew the sample injection vial so it loosens from its red cap and pause for 3-5 seconds.
2. Remove the sample injection vial leaving cap in pouch loading station and insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the FilmArray pouch loading station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of the liquid will be pulled into the pouch by vacuum.
3. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.

**NOTE:** If the pouch fails to pull sample from the sample injection vial, the pouch should be discarded. Retrieve a new pouch and repeat from the prepare pouch section. Document issue in the problem log. 1. Discard the sample injection vial and the hydration injection vial in an appropriate biohazard sharps container.
2. Record the sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the FilmArray pouch loading station.
3. Change gloves.
 |
| **Procedure-Run Pouch** | 1. Ensure that the FilmArray torch system is on.
2. Select an available module on the touch screen.
3. Scan the barcode on the FilmArray pouch using the barcode scanner. If the barcode cannot be scanned the required information can be manually entered into the appropriate fields.
4. Enter the sample ID. This can be done manually or scanned in by the using the barcode scanner when a barcoded sample ID is used.
5. Insert the pouch into the module.
6. If necessary, select and/or confirm a protocol from the protocol drop down list.
7. Enter the operator user name and password (micro and micro), then select next.
8. Review the entered run information on the screen. If correct, select start run.
9. Change gloves.
10. Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
11. At the end of the run, the status of the module changes to finished and the pouch is partially ejected.
12. Select the finished module on the dashboard to view the report and print if necessary.

**NOTE:** to save report as a PDF to a thumb drive:1. Insert drive into USB port on the front of the instrument
2. Select “Save” on the View Report page
3. Choose location and filename; then select “Save”, tap OK once saving is complete
4. Wearing gloves, remove the pouch from the module, place in a biohazard bag, seal and immediately discard the pouch in the biohazard container under the O&P bench.

**NOTE:** if a pouch has leaked take the instrument out of service until a full decontamination has been performed. See the user manual for instructions. Perform wipe testing before patient testing resumes. Document issue in the problem log.1. Change gloves.
 |
| **Interpretation/ Results****Troubleshooting** | 1. The FilmArray Software automatically analyzes and interprets the assay results and displays the final results in a test report.
2. The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results.

**NOTE:** Any organism with a Detected result will be listed in the corresponding field of the summary. 1. Controls are listed as Passed, Failed or Invalid. See **Table 1** below for Control Result Interpretation.
2. The **Result Summary** section of the test report lists the result for each target tested by the panel. See **Table 2** below for Result Interpretation.

**NOTE:** If **four** or more distinct organisms are detected repeat testing from the original sample. Only report results if both runs match. 1. The **Run Details** section provides additional information about the run.

**Table 1: Control Result Interpretation Table**

| **Control Result** | **Explanation** | **Action Required** | **Outcome** |
| --- | --- | --- | --- |
| Passed | The run was successfully completed ANDBoth pouch controls were successful. | None | Report the results provided on the test report. |
| Failed | The run was successfully completed BUTAt least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed. | Repeat the test using a new pouch. Record failure in the problem log. | Accept the results of the repeat testing. If the error persists, contact technical support for further instruction. |
| Invalid | The controls are invalid because the run did not complete.(Typically this indicates a software or hardware error). | Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator’s Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument.If the error occurred in the first 30 seconds of the run, the same pouch may be used for the repeat test (within 60 minutes of pouch loading) using the same instrument or another instrument, as available.If the error occurred later in the run or you are unsure when the error occurred, return to the original sample to load a new pouch. Repeat the test with the new pouch on the same instrument or another instrument, as available.Record invalid results in the problem log.  | Repeat testing from the original sample. Accept the valid results from the repeat testing. If the error persists, contact Technical Support and, see reporting procedure below. |

**Table 2 Sample Result Interpretation Table**

| **Result** | **Explanation** | **Action** |
| --- | --- | --- |
| Detected | The run was successfully completedANDThe pouch controls were successful (Passed)ANDThe assay(s) associated with the interpretation were positive based on the following requirements for at least 2 of the 3 assay replicates:-a positive melt curve, and-the Tm for the melt data were within the assay specific limits, and-the Tm for the melt data were within 1°C of each other. | None. Report results. |
| Not Detected | The run was successfully completedANDThe pouch controls were successful (Passed)ANDThe assay(s) associated with the interpretation were negative (did not meet the requirements for a positive assay described in Detected). | None. Report results. |
| N/A(applies to *E. coli* O157 and EPEC only) | The run was successfully completedANDThe pouch controls were successful (Passed)ANDFor *E. coli* O157: Shiga-like toxin-producing *E. coli* was Not Detected.For EPEC: Shiga-like toxin-producing *E. coli* was Detected. | None. Report results. |
| Invalid | The run did not complete successfully (Aborted, Incomplete, Instrument Communication Error, Instrument Error, or Software Error)ORThe pouch controls were not successful (Failed). | Repeat testing from the original sample. Accept the valid results from the repeat testing. If the error persists, contact Technical Support and, see reporting procedure below.  |

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| **Result Reporting** | 1. Results will automatically transmit to the LIS.

**NOTE:** C. diff results will NOT be transmitted to the patient’s chart. 1. Log into Sunquest to release results.
2. Select Result Entry from Menu options
3. In the Configuration field select TORCH from the dropdown box.

1. Click on the  button located in the lower right corner to populate the transmitted results.
2. Ensure the correct specimen ID (accession number) is shown. Review messages located on the top and results. Compare results to the FilmArray report.
3. If all results match, click  button located on the lower left corner. Click  when the “Verify Release Destination” window opens.
4. Place in the FilmArray GI result binder.
 |
| **Critical Results** | **Alert Values:** Report ***Salmonella, Shigella/Enteroinvasive E. coli (EIEC),* Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2****,* ***E. coli* 0157** and ***Campylobacter***sp. by telephone to the physician or patient’s nurse.1. Add the code **RP**, press tab, enter semi-colon, and record who the result was relayed to with the time/date. See example below in **Figure 1**.

**Figure 1: Reporting Critical Results** |
|  |  |
| **Reporting Invalid Results** | **NOTE:** If Invalid results are obtained after testing the original sample twice, the results will be reported as unresolved. **NOTE:** Invalid results will NOT be transmitted to the LIS, the report must be generated manually. 1. Call invalid results to the patient’s provider or RN.
2. Click on **Result Entry** and switch to manual resulting mode.
3. Under configuration select **GI**.

1. Click on the first analyte (AVI) and enter **unresolved** (UNRE), tab and enter the code **SIA,** and the following comment will append: “This sample is inhibitory to amplification and the results are inconclusive. Consider repeat collection if clinically indicated.”
2. Press tab and add the code **RP**, press tab, enter semi-colon, and record who the result was relayed to with the time/date.
3. Click on each additional analyte and enter the code **HIDE.** See example below.
4. Click  button located on the lower left corner. Click  when the “Verify Release Destination” window opens. See the example below in **Figure 2**.

**Figure 2: Reporting Invalid Results**1. Record invalid results on the problem log.
 |
| **Sample Storage** | 1. Store samples at room temp. Place labels with saved samples.
2. Day shift microbiology – check for isolates to send to MDH daily.
3. Day shift microbiology – check for samples to be subbed for susceptibilities daily (Shilgella/EIEC pos).
4. Discard samples after four days.
 |
| **Organism Interpretation** | 1. The GI Panel will detect both species of ***Salmonella: S. enterica*** and ***S. bongori.*** Cross-reactivity may occur with certain strain of E. coli.
2. The GI Panel will detect ***Campylobacter jejuni, C. coli*** and ***C. upsaliensis,*** but will not differentiate between them. Other ***Campylobacter*** species will not be detected.
3. The GI Panel will detect ***Clostridium difficile*** toxin A (*tcdA*) and toxin B (*tcdB*).
4. The GI Panel will detect ***Plesiomonas shigelloides.***
5. The ***Vibrio*** assay detects ***V. parahaemolyticus, V. vulnificus, and V. cholera.*** It does not differentiate between them. It may cross-react ***with V. alginolyticus, V. fluvialis, and V. mimicus***. The chorera assay will detect ***V. cholera.***
6. The GI Panel will detect all known serotypes of ***Yersinia Enterocolitica***. Cross-reactivity may occur will ***Y. kristensenii,*** and ***Y. frederiksenii.***
7. The GI Panel will detect ***(STEC) Shiga-like toxin 1 (stx1) and Shiga-like toxin 2 (stx2***) but does not indicate which one is detected. Shiga Toxin stx (identical to stx1 of STEC) is found in ***Shigella dysenteriae,*** therefore the GI Panel report with positive test results for ***Shiga-like toxin E. coli (STEC) and Shigella/Enteroinvasive E. coli (EIEC***) in the same sample may indicate the presence of ***S. dysenteriae.***
8. The GI Panel will detect ***E. coli 0157*** but it is not reported unless a ***Shiga-like toxin is also detected (STEC).*** If ***STEC*** is not detected, the result for the ***E. coli 0157*** is indicated as N/A.
9. The GI Panel will detect ***Shigella species*** as well as ***Enterovasive E. coli (EIEC).*** It is not possible to differentiate ***Shigella*** and ***Enterovasive E. coli (EIEC)***.
10. The GI Panel will detect ***Enteroaggregative E .coli (EAEC).***
11. The GI Panel will detect ***Enterotoxigenic E. coli (ETEC).*** Possible cross-reactivity with ***Hafnia alvei, C. koseri, C.sedlakii, and Cedecea davisae.***
12. The GI Panel will detect ***Enteropathogenic E. coli (EPEC)*** by the eae gene. The eae gene is also found in some ***Shiga-like toxin producing E. coli (STEC, 0157 and non-0157***) strains. Therefore***, EPEC*** is only reported when the ***STEC*** is not detected. When ***STEC*** is detected, ***EPEC*** will be reported as N/A.
13. The GI Panel will detect approximately 23 different ***Cryptosporidium*** and ***Cyclospora cayetenensis.***
14. The GI Panel will detect ***Entamoeba histolytica****.* The assay may cross-react with ***E. dispar*** when present at high levels.
15. The GI Panel detects ***Giardia lamblia (aka G. intestinalis, G. duodenalis).*** Very low frequency of cross-reactivity with ***Bifidobacterium and Ruminococcis.***
16. The GI Panel detects ***Adenovirus F40 and F41*** but does not differentiate between them. The assay will not detect other *adenovirus* species, such as B, C and E.
17. The GI Panel will detect eight subtypes of ***Astrovirus.***
18. The GI Panel will detect ***Norovirus GI and GII*** but does not differentiate between them.
19. The GI Panel will detect all strains of ***Rotavirus A.*** It will not cross-react with Rotavirus B, C, D, E, or F.
20. The GI Panel will detect, but not differentiate ***Sapovirus I, II, IV,*** and ***V.***
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| **MDH Submission** | 1. Positive samples that require submission to MDH should be sent as soon as possible. Microbiology day shift is to review results daily.
2. Send samples positive for any of the analytes listed below:

*Campylobacte*r*Salmonella**Vibrio**Vibrio cholera**Yersinia enterocolitica*EAECEPECETECSTECSTEC O157*Shigella*/EIEC*Cryptosporidium**Cyclospora*1. Label a conical tube, vortex the sample for 10 seconds, and using a sterile disposable pipette aliquot 2-3 mL of sample (1mL minimum) into the conical tube.
2. Fill out a submission form:
	1. Submission forms and instructions for submission are located here: <https://www.health.state.mn.us/diseases/idlab/forms.html>
	2. Indicate **Project 1935** in the Project # field at the top of the page.
	3. In the comment section of the laboratory submission form, please write:
		1. The name of the pathogen(s) detected
		2. The test your laboratory used to detect the pathogen(s) (Biofire FilmArray)
 |
| **Limitations** | 1. This test is a qualitative test and does not provide a quantitative value for the organism in the sample.
2. The performance of this test has only been validated with human stool collected in Cary Blair transport medium. It has not been validated for use with other stool transport, media, raw stool, rectal swabs, endoscopy stool aspirates, or vomitus.
3. This product should not be used to test stool samples in fixative (e.g. formalin and PVA).
4. The performance of the test has not be established for patients without signs and symptoms of gastrointestinal illness.
5. Virus, bacteria, and parasite nucleic acid may persist in vivo independently of organism viability. Some organisms may be carried asymptomatically. Detection of organism’s targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.
6. Results of this test must be correlated with the clinical history. Due to the high rates of asymptomatic carriage of *Clostridium difficile,* especially in very young children and hospitalized patients, the detection of toxigenic *C. difficile* should be interpreted within the context of guidelines developed by the testing facility.
7. The performance of this test has not been established for monitoring treatment of infection.
8. Freezing may affect analyte integrity and subsequent test results.
9. A negative FilmArray GI Panel result does not exclude the possibility of gastrointestinal infection. Negative test results may occur from sequence variants in the region targeted by the assay, presence of inhibitors, technical error, sample mix-ups, or an infection caused by an organism not detected by the panel. Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions.
10. If four or more distinct organisms are detected, retesting is recommended to confirm the polymicrobial result.
11. The performance of the FilmArray has not been established in individuals who received the Rotavirus A vaccine. Recent oral administration of a Rotavirus A vaccine may cause positive results for the Rotavirus A if the virus is passed in the stool.
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| **Method Performance Specifications** | 1. For *in vitro* diagnostic use only.
2. FilmArray GI panel pouches are only for use with FilmArray systems.
3. A trained healthcare professional should carefully interpret the results from the FilmArray GI Panel in conjunction with patient signs and symptoms and results from other diagnostic tests.
4. FilmArray pouches are stored under vacuum in individually-wrapped canister. To preserve the integrity of the pouch vacuum for proper operation, be sure that a FilmArray instrument/module is available and operational before unwrapping any pouches for loading
5. Always check the expiration date on the pouch and do not use a pouch after its expiration date.

**NOTE:** the instrument WILL allow you to run an expired pouch. Dates must be checked prior to inoculation.  |
| **Alternate Methods** | Stool culture, O&P, send-out viral culture to Mayo Medical Laboratory GIP: BioFire Panel at Mayo Medical Laboratories  |
| **Customer and Technical Support** | Web information at [www.biofiredx.com](http://www.biofiredx.com). Email at support@biofiredx.com. Call at 1-800-735-6544 or fax to 801-588-0507. |
| **Proficiency Testing** | CAP survey: GIP5: Five 1.0 mL simulated stool specimens. Three shipments per year.  |
| **Training Plan/ Competency Assessment** |

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| **Training Plan** | **Initial Competency Assessment** |
| 1. Employee must read the procedure.
2. Employee will demonstrate the ability to perform procedure, record results, and document corrective action after instruction by the trainer.
 | 1. Direct observation
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| **References** | FilmArray Gastrointenstinal (GI) Panel Instruction Booklet, RFIT-PRT-0143-03 April 2016. Salt Lake City, UT: BioFire Diagnostics.BioFire FilmArray Torch Operator's Manual, HTFA-PRT-0001-02 May 2016. Salt Lake City, UT: BioFire Diagnostics. |
| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Susan DeMeyere/Julie Laramie | 08/05/2019 | Initial Version |
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