### BioFire Gastrointestinal Panel Testing

### Purpose

This procedure provides instructions for testing stool samples in Cary Blair transport medium using the BioFire® Gastrointestinal Panel (GI) Kit.

### Background

The BioFire GI Panel is a multiplexed nucleic acid test intended for use with the BioFire® FilmArray®, FilmArray® 2.0, or FilmArray® Torch Systems for the simultaneous qualitative detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport medium obtained from individuals with signs and/or symptoms of gastrointestinal infection.

The following bacteria (including several diarrheagenic E. coli/Shigella pathotypes), parasites, and viruses are identified using the BioFire GI Panel:

* *Campylobacter* (*C. jejuni/C. coli/C. upsaliensis*)
* *Clostridium difficile* (*C. difficile*) toxin A/B
* *Plesiomonas shigelloides*
* *Salmonella*
* *Vibrio* (*V. parahaemolyticus/V. vulnificus/V. cholerae*), including specific identification of *Vibrio cholerae*
* *Yersinia enterocolitica*
* Enteroaggregative *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)
* *Cryptosporidium*
* *Cyclospora cayetanensis*
* *Entamoeba histolytica*
* *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
* Adenovirus F 40/41
* Astrovirus
* Norovirus GI/GII
* Rotavirus A
* Sapovirus (Genogroups I, II, IV, and V)

### Principle of the Procedure

### The BioFire GI Panel pouch is a closed system disposable 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 (fitment) of the BioFire GI Panel pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the BioFire GI Panel loads the sample into the BioFire GI Panel pouch, places the pouch into the BioFire® FilmArray® Instrument, and starts the run. All other operations are automated.

### The following is an overview of the operations and processes that occur during a BioFire® FilmArray® Pouch run:

### 1. 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.

### 2. 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.

### 3. 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.

### 4. 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 BioFire® 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 BioFire FilmArray Software controls the operation of the instrument, collects and analyzes data, and automatically generates a test report at the end of the run.

### Sample Requirements

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results.

|  |  |
| --- | --- |
| **Specimen Type** | Stool specimens should be collected in Cary Blair transport media according to manufacturer’s instructions. |
| **Minimum Sample Volume** | 0.2 mL (200 µL) |
| **Transport and Storage** | Specimens should be processed and tested with the BioFire GI Panel as soon as possible.  If storage is required, specimens can be held:   * At room temperature for up to 4 days (15-25 °C) * Refrigerated for up to 4 days (2-8 °C) |

***NOTE: Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.***

### Materials

|  |  |
| --- | --- |
| **Materials Provided** | **Materials Required but Not Provided** |
| Each kit contains sufficient reagents to test 30 or 6 specimens:   * Individually packaged BioFire GI Panel pouches * Single-use (1.0 mL) Sample Buffer ampoules * Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue) * Single-use Sample Injection Vials (red) * Individually packaged Transfer Pipettes | BioFire FilmArray System including:   * BioFire FilmArray, FilmArray 2.0, or FilmArray Torch Systems * Software * Pouch Loading Station compatible with the use of the BioFire® FilmArray® Injection Vials |

### Quality Control

**Process Controls**

Two process controls are included in each pouch:

1. **RNA Process Control**

The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. 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 indicates that all steps carried out in the BioFire GI pouch were successful.

1. **PCR2 Control**

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates 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 (upper right hand corner) will display “Failed” and all results will be listed as “Invalid”. If the controls fail, the sample should be retested using a new pouch.

**Monitoring Test System Performance**

The BioFire FilmArray Software will automatically fail the run if the melting temperature (Tm) for either the RNA Process Control or the PCR2 Control is outside an acceptable range (80.2-84.2 for the RNA Process Control and 74.1-78.1 for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices. The PCR2 Control is used in all pouch types and can therefore be used to monitor the system when multiple pouch types (e.g., RP, RP2, GI, ME, and BCID) are used on the same BioFire FilmArray Instrument.

Good laboratory practice recommends running external positive and negative controls regularly. Enteric transport media can be used as an external negative control. Previously characterized positive stool samples or negative samples spiked with well characterized organisms can be used as external positive controls. External controls should be used in accordance with the appropriate accrediting organization requirements, as applicable.

### Procedure

Refer to the BioFire® FilmArray® Gastrointestinal Panel Quick Guide for a more detailed and pictorial representation of these instructions.

Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and specimens. Only one BioFire GI Panel pouch should be loaded at a time. Once the pouch is loaded, it should be promptly transferred to the instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

Step 1: Prepare Pouch

1. Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Obtain the following required materials and place in the clean hood:
   * BioFire GI Panel pouch
   * Sample Buffer ampoule
   * Hydration Injection Vial (blue cap)
   * Sample Injection Vial (red cap)
   * Transfer pipette
3. Place a blue capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
4. Place a red capped Sample Injection Vial in the red well of the Pouch Loading Station.
5. Obtain patient sample and place into hood.
6. Remove the BioFire GI pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

**NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.**

1. Slide the pouch into the Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the base of the Pouch Loading Station.

Step 2: Hydrate Pouch

1. Twist the Hydration Injection Vial (blue cap), leaving cap in Pouch Loading Station, and insert the tip of the cannula into the hydration port of the pouch located directly below the blue arrow of the 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.
2. 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. If the pouch fails to hydrate (dry reagents appear as white pellets), verify that the seal of the port was broken by ensuring the vial cannula was fully inserted into the hydration port. If the pouch fails to hydrate, retrieve a new pouch and repeat from Step 2 of the Prepare Pouch Section.
3. Discard the Hydration Injection Vial in a suitable puncture proof container.

Step 3: Prepare Sample Mix

1. Hold the Sample Buffer ampoule so that the tip is facing up.

**NOTE: Use care to avoid touching the tip during handling, as this may introduce contamination.**

1. Gently pinch the textured plastic tab on side of ampoule until the seal snaps.
2. Re-position thumb and forefinger to grip between the textured plastic tab and the bottom of the ampoule, then invert over the red Sample injection Vial and dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.
3. Thoroughly mix the patient specimen.
4. 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.

**NOTE: DO NOT use the transfer pipette to mix the sample once it is loaded into the Sample Injection Vial.**

1. Tightly close the lid of the Sample Injection Vial and mix by gently inverting at least 3 times.
2. Return the Sample Injection Vial to the Pouch Loading Station.

Step 4: Load Sample Mix

1. Slowly unscrew Sample Injection Vial from the cap and pause for 3-5 seconds.

**NOTE: It is important to pause after unscrewing the Sample Injection Vial to avoid sample leakage and contamination of the work area.**

1. Remove 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 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.
2. 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. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.
3. Discard the Sample Injection Vial in a suitable biohazard and puncture proof container. Do not re-cap the vial.
4. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

Step 5: Run Sample Mix

The BioFire FilmArray Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for BioFire FilmArray, FilmArray 2.0, and FilmArray Torch systems are given below. Refer to the appropriate BioFire® FilmArray® Operator’s Manual for more detailed instructions.

BioFire FilmArray

1. Ensure that the computer and BioFire FilmArray Instrument have been turned on. Launch the Instrument Control Software by double clicking on the desktop icon.
2. Open the instrument lid (if not already open).
3. Insert the loaded pouch into the instrument. Position the pouch so that the array is on the right and the film is inserted first. The red and blue labels on the BioFire pouch should align with the red and blue arrows on the BioFire FilmArray Instrument. The pouch will click into place. If inserted correctly, the barcode is visible and the label is readable on the top of the pouch. The instrument and software must detect that the pouch has been inserted correctly before continuing to the next step.

**NOTE: If the pouch does not slide into the instrument easily, gently push the lid of the instrument back to be sure that it is completely open.**

1. Scan the barcode on the pouch using the barcode scanner. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the barcode located on the pouch and will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

**NOTE: The barcode cannot be scanned prior to placing the pouch in the instrument. A “Cannot scan now” message will be displayed.**

1. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
2. If necessary, select a protocol from the Protocol drop down list.
3. Enter a user name and password in the Name and Password fields.
4. Close the BioFire FilmArray Instrument lid.
5. Click Start Run. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

**NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.**

1. When the run is finished, results are automatically displayed in the report section of the screen. The report is automatically saved into the database.
2. Select Print to print the report, or Save to save the report as a PDF file.
3. Follow the on-screen instructions to open the instrument and remove the pouch.
4. Immediately discard the pouch in a biohazard container.

BioFire FilmArray 2.0

1. Ensure that the BioFire FilmArray 2.0 system (instrument and computer) is powered on and the software is launched.
2. Follow on-screen instructions and procedures described in the Operator’s Manual to place the pouch in an instrument, enter pouch, sample, and operator information.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

**NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire GI pouch.**

1. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
2. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire GI Panel has a “Stool FA” protocol available in the drop-down list.
3. Enter a user name and password in the Name and Password fields.

**NOTE: The font color of the username is red until the user name is recognized by the software.**

1. Review the entered run information on the screen. If correct, select Start Run. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

**NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.**

1. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard waste container.
2. The run file is automatically saved in the software database, and the test report can be viewed, printed, and/or saved as a PDF file.

BioFire FilmArray Torch

1. Ensure that the BioFire FilmArray Torch system is powered on.
2. Select an available Module (instrument) on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

**NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the FilmArray GI Panel pouch.**

1. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
2. Insert the pouch into the available Module (instrument).
   * Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module (instrument) will grab onto the pouch and pull it into the chamber.
3. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire GI Panel has a “Stool FA” protocol available in the drop-down list.
4. Enter operator user name and password, then select Next.

**NOTE: The font color of the username is red until the user name is recognized by the software.**

1. Review the entered run information on the screen. If correct, select Start Run. Once the run has started, the screen displays a list of the steps being performed by the Module (instrument) and the number of minutes remaining in the run.

**NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.**

1. At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.

The run file is automatically saved in the software database, and the test report can be viewed, printed, and/or saved as a PDF file.

### Interpretation

The BioFire Software automatically analyzes and interprets the assay results and displays the final results in a test report (see the BioFire Gastrointestinal Panel Quick Guide to view an example of a test report). The analyses performed by the BioFire Software and details of the test report are described below.

**Assay Interpretation**

When 2nd stage PCR is complete, the BioFire FilmArray Instrument performs a high resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see BioFire FilmArray Operator’s Manual). The BioFire FilmArray Software then performs several analyses and assigns a final assay result.

Analysis of melting curves.The BioFire FilmArray Software evaluates the DNA melting curve for each well of the 2nd stage PCR array 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 (Tm) of the curve. The Tm value is then compared against the expected Tm range for the assay. If the software determines that the melt is positive and the melt peak falls inside the assay-specific Tm range, the curve is called positive. If the software determines that the melt is negative or is not in the appropriate Tm range, the curve is called negative.

Analysis of replicates.Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, *and* the Tm for at least two of the three positive curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

Organism Interpretation.For many organisms detected by the BioFire GI Panel, the organism is considered to be Detected if a single corresponding assay is positive. For example, *Plesiomonas shigelloides* will have a result of “*Plesiomonas shigelloides* Detected” if at least two of the three replicates of the one *Plesiomonas shigelloides* assay have similar positive melt peaks with Tm values that are within the assay specific Tm range.

The following organisms are detected using a single assay: toxigenic *C. difficile*, *P. shigelloides, Salmonella, Y. enterocolitica*, EAEC, *Shigella/*EIEC, Adenovirus F 40/41, Astrovirus, Sapovirus (Genogroups I, II, IV, and V), *C. cayetanensis, E. histolytica* and *G. lamblia*.

In contrast, the test results for several organisms rely on the combination of multiple assays. These include *Campylobacter (C. jejuni/C. coli/C. upsaliensis), Vibrio* (*V. parahaemolyticus/ V. vulnificus/V. cholerae)* and *Vibrio cholerae*, *Cryptosporidium,* Norovirus GI/GII, and Rotavirus A. The test results for several Diarrheagenic *E. coli*(s) include multiple assays for genetic markers to identify various classic pathotypes of *E. coli* including EPEC, ETEC, and STEC (including O157), (as well EAEC and *Shigella*/EIEC included above). Interpretation rules for these assays are described in the Gastrointestinal Panel Instruction Booklet.

**NOTE: If four or more distinct organisms are detected in a specimen, retesting is recommended to confirm polymicrobial results.**

**BioFire GI Panel Test Report**

The BioFire GI Panel test report is automatically displayed upon completion of a run and contains three sections, the Run Summary, the Result Summary, and the Run Details (see the BioFire Gastrointestinal Panel Quick Guide to view an example of a test report). The test report can be saved as a PDF or printed.

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. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the tests were negative than None will be displayed in the Detected field. Controls are listed as Passed, Failed or Invalid. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures.

The **Result Summary** section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, Not Applicable (N/A), or Invalid. See Results Summary section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results.

The **Run Details** section provides additional information about the run including: pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called **Change History** will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

### Control Field

The Controls field on the test report will display Passed, Failed, or Invalid. The Controls field will display Passed only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (RNA Process Control and PCR2 Control) were successful. The Controls field will display Failed if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed. If the control result is Failed, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.

Table 1 provides a summary and explanation of the possible control results and follow-up actions.

Table 1. Interpretation of Controls Field on the BioFire GI Panel Test Report

| **Control Result** | **Explanation** | **Action Required** | **Outcome** |
| --- | --- | --- | --- |
| Passed | The run was successfully completed  AND  Both pouch controls were successful. | None | Report the results provided on the test report. |
| Failed | The run was successfully completed  BUT  At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed. | Repeat the test using a new pouch. | 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 BioFire 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. | Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction. |

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### Result Reporting

The Results Summary – Interpretations section provides a complete list of the test results. Possible results for each organism include Detected, Not Detected, N/A, and Invalid. Table 2 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 2. Reporting of Results and Required Actions

| **Result** | **Explanation** | **Action** |
| --- | --- | --- |
| Detected | The run was successfully completed  AND  The pouch controls were successful (Passed)  AND  The 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 completed  AND  The pouch controls were successful (Passed)  AND  The 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 completed  AND  The pouch controls were successful (Passed)  AND  For *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)  OR  The pouch controls were not successful (Failed). | See Table 1, *Interpretation of Controls Field on the BioFire GI Panel Test Report*, for instruction. |

### Change Summary

### It is possible to edit the Sample ID once a run has completed. If this information has been changed, an additional section called Change Summary will be added to the test report. This Change Summary section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

### References/Related Documents

BioFire Gastrointestinal Panel (GI) Instruction Booklet (RFIT-PRT-0143), BioFire Diagnostics, LLC.