BioFire® Global Fever (GF) Panel Testing CLSI Document

PURPOSE

This procedure provides instructions for testing human whole blood in EDTA tubes using the BioFire Global Fever (GF) Panel with the BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® FILMARRAY® TORCH Systems.

The BioFire Global Fever Panel detects and identifies selected bacterial, viral, and protozoan nucleic acids directly from EDTA whole blood collected from individuals with signs and/or symptoms of acute febrile illness or recent acute febrile illness and known or suspected exposure to the following target pathogens in about an hour:

Type	Organism
Bacterial	*Leptospira* spp.
Viral	Chikungunya virus
	Dengue virus (serotypes 1, 2, 3 and 4)
Protozoan	*Plasmodium* spp.
	Plasmodium falciparum
	Plasmodium vivax/ovale

PRINCIPLE OF THE PROCEDURE

The BioFire Global Fever Panel pouch is a closed-system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple pathogens within a single whole blood specimen. After sample collection, the user injects Hydration Solution and sample combined with BioFire FILMARRAY Sample Buffer into the pouch, places the pouch into a BIOFIRE FILMARRAY instrument module, and starts a run. The run process takes about an hour. Additional details can be found in the appropriate BIOFIRE® FILMARRAY® operator's manual.

During a run, the BIOFIRE FILMARRAY System:

- Lyses the sample by agitation (bead beading) in addition to chemical lysis mediated by the Sample Buffer.
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
  - First performing reverse transcription and a single, large volume, massively-multiplexed reaction (PCR1).
  - Then performing multiple singleplex second-stage PCR reactions (PCR2) to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect and generate a result for each target on the BioFire GF Panel.

SAMPLE REQUIREMENTS

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

Recommended Specimen Type	Human Whole Blood collected in EDTA tubes
Minimum Sample Volume	~0.2 mL (200 µL) of whole blood
Specimen Transport and Storage	Specimens should be tested with the BioFire Global Fever Panel as soon as possible. If storage is required, samples can be held: • At room temperature for up to 1 day (15-30ºC) • Refrigerated for up to 7 days (2-8ºC)

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.*

REAGENT STORAGE, HANDLING, AND STABILITY

- Store the test kit, including reagent pouches and buffers, at room temperature (18-30°C). **DO NOT REFRIGERATE**.
- Avoid storage of any materials near heating or cooling vents, or in direct sunlight.
- All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
- Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
- Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.
- Always check the kit expiration date and do not use reagents beyond the expiration date printed on the pouch or kit.

MATERIALS PROVIDED

Each BioFire Global Fever Panel kit contains sufficient reagents to test 6 samples (Part No. DFA2-ASY-0004). Materials include:

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NOT PROVIDED
Each kit contains sufficient reagents to test 6 samples **(6-test kit; Part no: DFA2-ASY-0004)** • Individually packaged BioFire® Global Fever Panel pouches • Single-use (1.0 mL) BIOFIRE® FILMARRAY® Sample Buffer tubes • Single-use pre-filled (1.5 mL) BIOFIRE® FILMARRAY® Hydration Injection Vials (blue) • Individually packaged BIOFIRE® FILMARRAY® Sample Injection Vials (red) • Individually packaged Transfer Pipettes • Instructions for Use available online at www.biofiredefense.com/globalfeverpanel	BIOFIRE® FILMARRAY® System including: • BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH instrument and accompanying software • BIOFIRE® FILMARRAY® Pouch Loading Station • BioFire® Global Fever Panel Pouch Module Software is required to run the BioFire Global Fever Panel and is available by request at www.biofiredefense.com if not already installed on the instrument system • 10% bleach solution or a similar disinfectant **Optional Material** • BIOFIRE® SHIELD™ Control Kit for the BioFire Global Fever Panel (Part No. DFA2-ASY-0006)

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, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the BioFire GF Panel pouch were successful.

2. **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 control result indicates that PCR2 was successful.

Both control assays must be positive for the test run to pass. If 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 of an acceptable range (80.0-84.0°C for the RNA Process Control and 74.0-78.0°C 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[20,21]. Refer to the appropriate BIOFIRE FILMARRAY operator's manual for instructions on obtaining control assay Tm values.

External Controls

Good laboratory practice recommends running positive and negative external controls regularly in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable. Molecular grade water or saline can be used as a negative external control. Previously characterized positive samples or negative samples spiked with well-characterized organisms can be used as positive external controls using the GF Blood pouch protocol.

The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is available for purchase directly from BioFire Defense. Contact BioFire Defense Customer Support for more information.

PROCEDURE

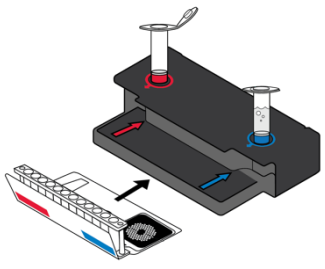
Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and samples. Only prepare one BioFire Global Fever Panel pouch at a time and change gloves between samples and pouches. Once sample is added to the pouch, promptly transfer to the instrument to start the run. After the run is complete, discard the pouch 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. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

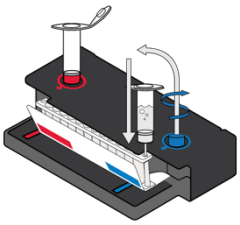
   NOTE: *The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.*

3. Check the expiration date on the pouch. Do not use expired products.
4. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
5. Remove the Sample Injection Vial from its package by tearing or cutting the notched outer packaging. Place the Sample Injection Vial (with red cover) into the red well of the Pouch Loading Station.



6. Place a Hydration Injection Vial (with blue cover) into the blue well of the Pouch Loading Station.

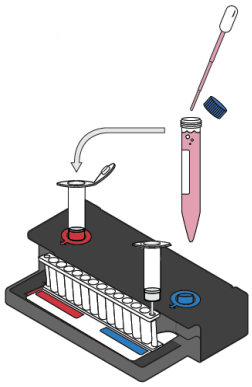
Step 2: Hydrate Pouch



1. Unscrew the Hydration Injection Vial from the blue cover.
2. Remove the Hydration Injection Vial, leaving the blue cover in the Pouch Loading Station.
3. Insert the Hydration Injection Vial cannula tip into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.
4. Forcefully push down in a firm and quick motion to puncture seal until a faint "pop" is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
    - If the Hydration Solution is not automatically drawn into the pouch, re-insert Hydration Injection Vial to ensure that the seal of the pouch hydration port was broken. If Hydration Solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
5. 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), re-insert Hydration Injection Vial to ensure that the seal of the pouch hydration port was broken. If Hydration Solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

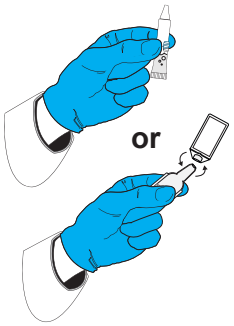
Step 3: Prepare Sample Mix

NOTE: *Gently invert whole blood container until thoroughly mixed. Do not centrifuge samples as this may affect sensitivity of the test. Do not use a sample if it has clotted.*



1. Use the Transfer Pipette provided in the test kit to draw the sample to the second line (approximately 0.2 mL) of the Transfer Pipette.
2. Add the sample to the Sample Injection Vial.
3. Discard the Transfer Pipette in a biohazard waste container.

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



4. Add Sample Buffer to the Sample Injection Vial.

   NOTE: *There are 2 possible designs of the Sample Buffer Ampoule.*

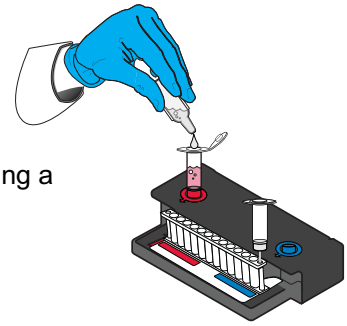
   - Hold the Sample Buffer Tube with the tip facing up.

   NOTE: *Avoid touching the tube tip during handling, as this may introduce contamination.*

   - If the ampoule has a textured tab on the side of it: firmly pinch the tab on the ampoule until the seal snaps.

   or

   - If the ampoule has a plastic tab on the tip: gently twist and remove the tab at the tip of the ampoule.

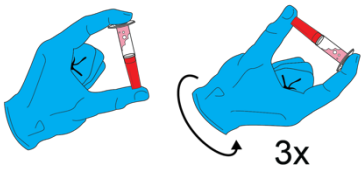


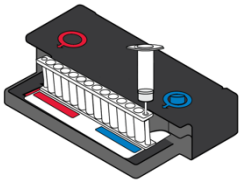
   - Invert the tube over the Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.

     NOTE: *Avoid squeezing the tube additional times. This will generate foaming, which should be avoided.*

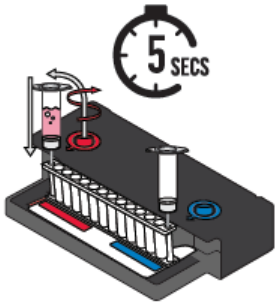
WARNING: Contact with sample buffer can cause serious eye damage and skin irritation and is harmful if swallowed.

5. Tightly close the lid of the Sample Injection Vial.
6. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 3 times to mix.
7. Return the Sample Injection Vial to the red well of the Pouch Loading Station.





Step 4: Load Sample Mix



1. Slowly twist to unscrew the Sample Injection Vial from the red cover and wait for 5 seconds with the vial resting in the cover.

   NOTE: *Waiting 5 seconds decreases the risk of dripping and contamination from the sample.*

2. Lift the Sample Injection Vial, leaving the red cover in the well of the Pouch Loading Station, and insert the Sample Injection Vial cannula tip into the pouch sample port located directly below the red arrow of the Pouch Loading Station.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint "pop" is heard) and sample is pulled into the pouch by vacuum.
4. 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 1: Prepare Pouch*.
5. Screw the injection vials back into their plastic covers in the Pouch Loading Station before disposing of them in a biohazard container.
6. 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.

   NOTE: *Optional added operator protection: Before removal from biosafety cabinet, run a bleach wipe, a paper towel with 10% bleach (one part bleach to nine parts water), across the top of the pouch from the pouch hydration port to the pouch sample port, and follow with a water wipe. This reduces the potential for contact with small amounts of sample mixed with Sample Buffer that may be retained at the pouch sample port.*

Step 5: Run Pouch

The BIOFIRE FILMARRAY Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for 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 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 appropriate BIOFIRE FILMARRAY 2.0 Operator's Manual to place the pouch in an instrument and enter pouch, sample, and operator information.
3. Pouch identification (Lot Number and Serial Number) and Pouch Type 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 and Pouch Type 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 Global Fever Panel pouch.*
4. 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.
5. Select and confirm the appropriate Protocol from the Select Protocol dialogue box. The BioFire Global Fever Panel has three Protocols available in the drop-down list: GF Blood, Positive External Control, and Negative External Control.

   NOTE: *Two additional protocols are provided for use with the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel. It is necessary to select the appropriate protocol prior to running the test. The Positive External Control and Negative External Control protocols are only for use with the BIOFIRE SHIELD Control Kit and should not be used to test clinical samples or other types of controls. Refer to the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel Instructions for Use for procedures to prepare and run BIOFIRE SHIELD Controls.*
6. Enter a username and password in the Name and Password fields.

   NOTE: *The font color of the username is red until the username is recognized by the software.*
7. 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 makes an audible, high-pitched noise during the first minute of operation.*
8. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard waste container.
9. The run file is automatically saved in the BIOFIRE FILMARRAY Software database, and the test report can be viewed, printed, and/or saved as a PDF file.
10. To view run data, double click on a run file, select the interpretation tab and click on an analyte for a specific assay.

BIOFIRE FILMARRAY TORCH

1. Ensure that the FILMARRAY TORCH system is powered on.
2. Select an available module on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number) and Pouch Type 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, and Pouch Type 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 Global Fever Panel pouch.*
4. 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.
5. Insert the pouch into the selected module.
   - Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the module will grab onto the pouch and pull it into the chamber.
6. Select and confirm the Sample protocol. The BioFire Global Fever Panel Test uses a single sample protocol for the testing of all clinical sample types.

   NOTE*: Two additional protocols are provided for use with the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel. It is necessary to select the appropriate protocol prior to running the test. The Positive External Control and Negative External Control protocols are only for use with the BIOFIRE SHIELD Control Kit and should not be used to test clinical samples or other types of controls. Refer to the BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel Instructions for Use for procedures to prepare and run BIOFIRE SHIELD Controls.*
7. Enter operator username and password, then select Next.

   NOTE: *The font color of the username is red until the username is recognized by the software.*
8. 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 and the number of minutes remaining in the run.

   NOTE: *The bead-beater apparatus makes an audible, high-pitched noise during the first minute of operation.*
9. At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.
10. The run file is automatically saved in the FILMARRAY Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

Assay Interpretation

When PCR2 is complete, the BIOFIRE FILMARRAY instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each PCR2 array well (for more information see the appropriate BIOFIRE FILMARRAY operator's manual). The BIOFIRE FILMARRAY Software then performs several analyses and assigns a final assay result for every well. The steps in the analyses are described below.

Analysis of Melt Curves. The BIOFIRE FILMARRAY Software evaluates the DNA melt curve for each well of the PCR2 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 and compares it against the expected Tm range for the assay in that well. If the software determines that the Tm of the curve is within the assay Tm range, the melt curve is called positive (i.e., the melt curve peak is located within the white area of the melt curve chart). If the software determines that the Tm of the curve is not in the appropriate Tm range, the melt curve is called negative (i.e., the melt curve peak is located in the grey area of the melt curve chart).

Analysis of Replicates. Once positive melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, at least two associated melt curves must be called positive, and both Tm values must be similar. Assays that do not meet these criteria are called negative.

Organism Interpretation

The reported BioFire Global Fever Panel organism interpretation of results (Detected or Not Detected) may be based on the result of a single assay or on results from a combination of multiple assays, as shown in **Table 2**. In cases where either or both control assays have failed, all analyte results are reported as Invalid (**Figure 1**). Nationally notifiable results are to be reported to public health authorities in accordance with local, state, and federal law. In the United States, when Detected, all of the pathogens on this panel must be reported to the Centers for Disease Control and Prevention.

Table 1. Assay Number and Interpretation Rules for the BioFire Global Fever Panel

Organism	No. of Assays	Assay Interpretation Rules
BACTERIA		
Leptospira spp.	1	Positive = Detected
VIRUSES		
Chikungunya virus	2	Any Positive = Detected
Dengue virus[a]	5	Any Positive = Detected
PROTOZOAN		
Plasmodium spp.	1	Positive = Detected
Plasmodium falciparum	1	Positive = Detected
Plasmodium vivax/ovale	1[b]	Positive = Detected

[a.] The BioFire Global Fever Panel contains multiple assays for the detection of the dengue virus serotypes. See dengue virus reporting section below for more information.

[b.] The BioFire Global Fever Panel contains one multiplexed assay for the detection of both *Plasmodium vivax* and *Plasmodium ovale*, which is reported with a single interpretation call.

Result Interpretation

Leptospira spp. Reporting

The BioFire Global Fever Panel contains a single pan assay for genus-level detection of all *Leptospira* Group 1 species. A positive Leptospira pan assay will result in a Detected call for *Leptospira* spp.

Chikungunya virus Reporting

The BioFire Global Fever Panel contains two assays for species-level detection of all chikungunya virus strains, and one or more positive Chikungunya virus assay(s) will result in a Detected call for Chikungunya virus.

Dengue virus Reporting

The BioFire Global Fever Panel contains five assays for the detection of the four dengue virus serotypes. Any positive assay call will result in a Detected call for Dengue virus.

Plasmodium Reporting

The BioFire Global Fever Panel contains three *Plasmodium* assays, one genus-level assay and two species-level assays. The genus-level assay (*Plasmodium* spp. assay) detects *Plasmodium* species including the five *Plasmodium* species known to infect humans (*P. falciparum, P. vivax, P. ovale, P. malariae*, and *P. knowlesi*). One species-level assay detects *Plasmodium falciparum*, and a combined species-level assay detects *Plasmodium vivax* and *Plasmodium ovale*. **Table 3** shows the reporting scheme for the three *Plasmodium* assays. This test cannot differentiate co-infections other than *Plasmodium falciparum* and *Plasmodium vivax*/*ovale*. Infection with additional *Plasmodium* species is always possible and should be considered.

WARNING: Before consideration of treatment for the hypnozoite liver form, confirm the presence of a *P. vivax* or *P. ovale* infection.

Table 2. *Plasmodium* Report Scheme

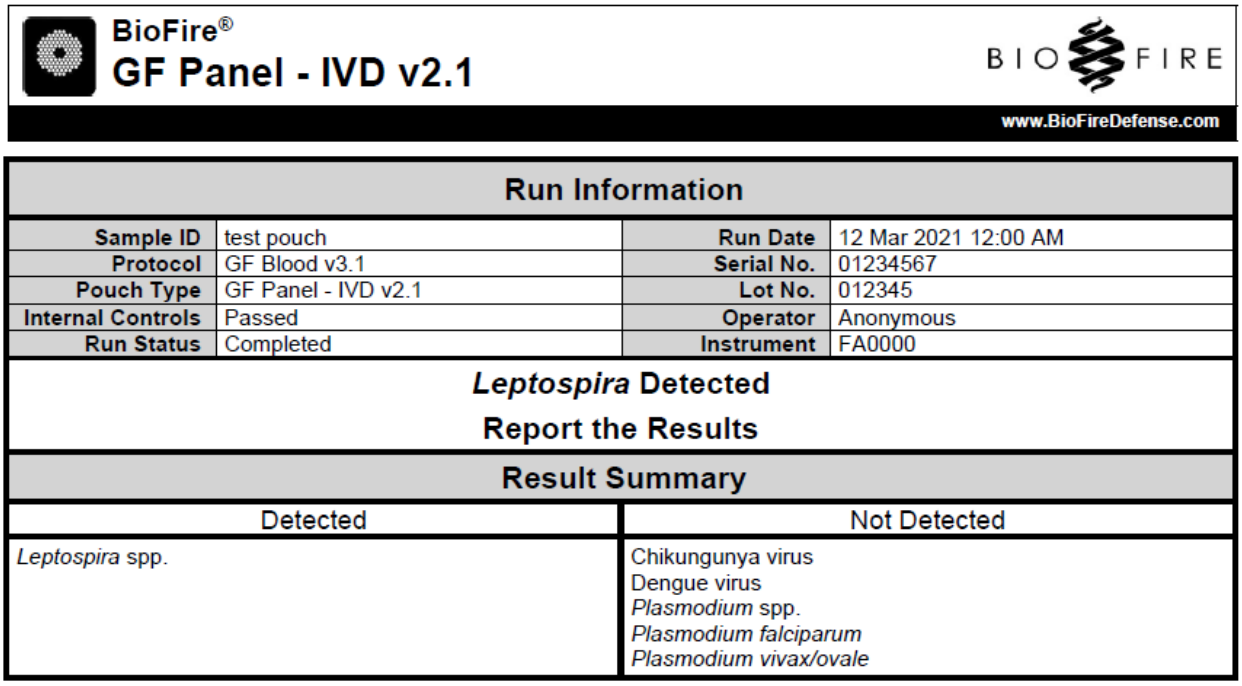
Assay Detection Outcomes			Result Banner	Result Summary[a]
***Plasmodium* spp.**	***Plasmodium falciparum***	***Plasmodium vivax/ovale***		
Negative	Negative	Negative	N/A - No *Plasmodium* species detected in the sample (no results shown in Report).	*Plasmodium* spp. Not Detected *Plasmodium falciparum* Not Detected *Plasmodium vivax/ovale* Not Detected
Positive	Negative	Negative	***Plasmodium* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Report the Results.	***Plasmodium* spp. Detected** *Plasmodium falciparum* Not Detected *Plasmodium vivax/ovale* Not Detected
Positive	**Positive**	Negative	***Plasmodium falciparum* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Report the Results.	***Plasmodium* spp. Detected** ***Plasmodium falciparum* Detected** *Plasmodium vivax/ovale* Not Detected
Positive	Negative	**Positive**	***Plasmodium vivax/ovale* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Report the Results.	***Plasmodium* spp. Detected** *Plasmodium falciparum* Not Detected ***Plasmodium vivax/ovale* Detected**

Assay Detection Outcomes			Result Banner	Result Summary[a]
***Plasmodium* spp.**	***Plasmodium falciparum***	***Plasmodium vivax/ovale***		
Positive	**Positive**	**Positive**	***Plasmodium falciparum* and *Plasmodium vivax/ovale* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Note: The detection of 2 or more organisms is uncommon. Retest the Sample ONCE then Report the Results.	***Plasmodium* spp. Detected** ***Plasmodium falciparum* Detected** ***Plasmodium vivax/ovale* Detected**
Negative	**Positive**	**Positive**	***Plasmodium falciparum* and *Plasmodium vivax/ovale* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Note: The detection of 2 or more organisms is uncommon. Retest the Sample ONCE then Report the Results.	*Plasmodium* spp. Not Detected ***Plasmodium falciparum* Detected** ***Plasmodium vivax/ovale* Detected**
Negative	**Positive**	Negative	***Plasmodium falciparum* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Report the Results.	*Plasmodium* spp. Not Detected ***Plasmodium falciparum* Detected** *Plasmodium vivax/ovale* Not Detected
Negative	Negative	**Positive**	***Plasmodium vivax/ovale* Detected** Note: See Instructions for Use for additional information on Plasmodium results. Report the Results.	*Plasmodium* spp. Not Detected *Plasmodium falciparum* Not Detected ***Plasmodium vivax/ovale* Detected**

[a] Bolded results are displayed in the Detected column of the Result Summary. Non-bolded results are shown in the Not Detected column of the Result Summary.

BioFire Global Fever Panel Test Report

The BioFire Global Fever Panel test report is automatically displayed upon completion of a run and contains two sections: Run Information and Result Summary (**Figure 2**). The test report can be saved as a PDF file or printed.



BioFire®
GF Panel - IVD v2.1

BIOFIRE

www.BioFireDefense.com

Run Information

Sample ID	test pouch	**Run Date**	12 Mar 2021 12:00 AM
Protocol	GF Blood v3.1	**Serial No.**	01234567
Pouch Type	GF Panel - IVD v2.1	**Lot No.**	012345
Internal Controls	Passed	**Operator**	Anonymous
Run Status	Completed	**Instrument**	FA0000

***Leptospira* Detected**

Report the Results

Result Summary

Detected	Not Detected
Leptospira spp.	Chikungunya virus Dengue virus *Plasmodium* spp. *Plasmodium falciparum* *Plasmodium vivax/ovale*

Figure 2. Example BioFire Global Fever Panel Run Report

The **Run Information** section of the test report is displayed at the top of the page. It provides information about the run including: Sample ID, Protocol, pouch information (including Pouch Type, Serial Number, and Lot Number), Run Date, Run Status (Completed, Incomplete, Aborted, Instrument Error, or Software Error), the identity of the operator who performed the test (Operator), and the instrument used to perform the test. Internal Control results are reported as Passed, Failed, or Invalid. The section also contains a Result Banner that lists the Detected results and required actions. If there are no Detected results, the Result Banner shown is Negative.

Table 4 provides additional information for each of the possible control field results. See **Table 5** for complete results interpretation and required actions.

Table 3. Interpretation of Internal Controls Field on the BioFire Global Fever Panel Test Report

Internal Control Results	Explanation	Action Required
Passed	The run was successfully completed AND Both pouch controls (RNA Process Control and PCR2 Control) were successful.	Follow any instructions provided in the Result Banner.
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. If the error persists, call Technical Support for further instructions.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error.)	Note any error codes displayed by the software during the run. Refer to the appropriate BIOFIRE FILMARRAY operator's manual or call Technical Support for further instruction. If the error can be resolved, repeat the test once using a new pouch.

The **Result Summary** section of the test report lists each target tested as either Detected, Not Detected, or Invalid. See the Results Explanation section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results. Within the Results Summary section, targets that are detected are listed in the left-hand column, and targets that are not detected are listed in the right-hand column.

Once a run has completed, it is possible to edit the Sample ID. 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 (**Figure 3**). Sample ID is the only field of the report that can be changed.

Change Summary

Field	Changed To	Changed From	Operator	Date
[1]Sample ID	New Example Id	Old Example Id	Anonymous	24 Mar 2021

Figure 3. Change Summary Field

Results Explanation and Required Actions

The **Result Summary** section provides a complete list of all test results. Possible results include Detected, Not Detected, and Invalid. **Table 4** provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 4. Interpretation of Results on the BioFire Global Fever Panel Test Report

Results	Explanation	Report
Not Detected <Organism Name(s)>	The run was successfully completed AND The pouch controls were successful (Pass) AND The assay(s) for the organism were NEGATIVE	Results are valid. Follow any instructions provided in the Result Banner.
Detected <Organism Name(s)>	The run was successfully completed AND The pouch internal controls were successful (Pass) AND The assay(s) for the organism were POSITIVE	Results are valid. Follow any instructions provided in the Result Banner.
Invalid	Run completed and pouch internal controls failed OR Run did not complete	All results are invalid because the run failed. Note any error codes displayed and refer to the appropriate BIOFIRE FILMARRAY operator's manual for more information. If the error persists, contact Technical Support for further instruction. Retest the sample.

NOTE: *Detection of two or more unique pathogens may indicate a possible contamination event. Follow the instructions in the Result Banner for retesting. If the two or more positive results are not duplicated, contact BioFire CustomerTechnical Support and discontinue testing until the test area has been decontaminated.*

References / Related Documents

- *BioFire Global Fever Panel – Instructions for Use* (DFA2-PRT-0026), BioFire Defense

CLSI Document Revision History

Part No: DFA2-PRT-0308-01

Version	Revision Date	IFU Revision	Description of Revision(s)
01	2026-08-11	DFA2-PRT-0026-06	Initial Release