REF DFA2-ASY-0006

BIOFIRE® SHIELD™ Control Kit

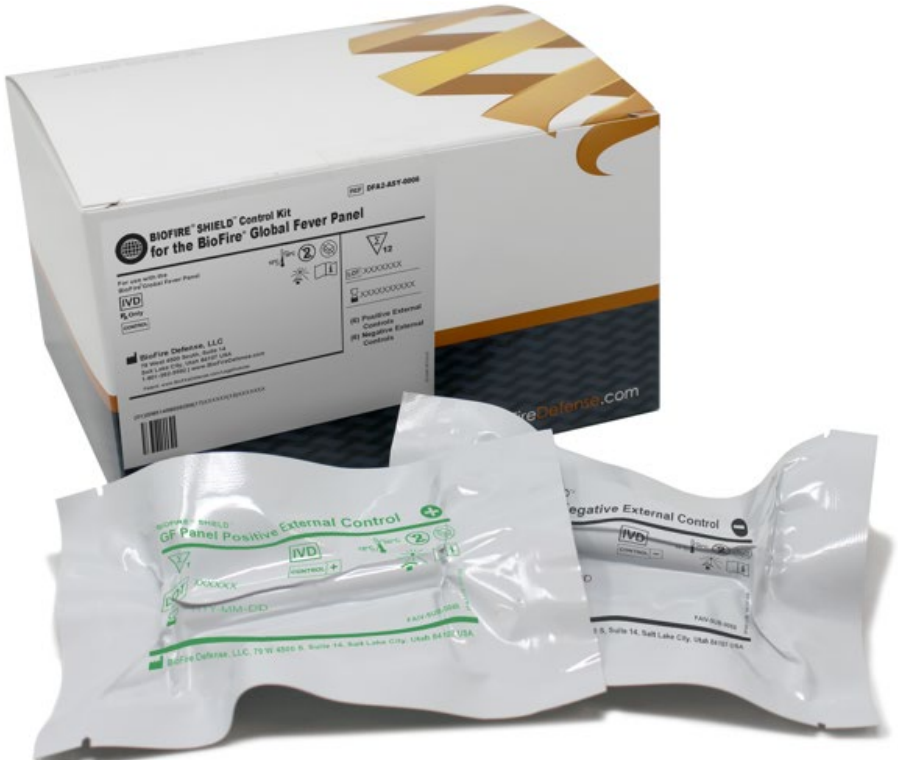
for the BioFire® Global Fever Panel

Instructions for Use

IVD

℞ Only

CONTROL



The Symbols Glossary is provided on Page 12 of this booklet.

For In Vitro Diagnostic Use

Manufactured by

BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, UT 84107 USA

TABLE OF CONTENTS

INTENDED USE

The BIOFIRE® SHIELD™ Control Kit for the BioFire® Global Fever Panel contains Positive and Negative External Controls intended for use as assayed quality controls to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of chikungunya virus, dengue virus (serotypes 1, 2, 3, and 4), *Leptospira* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum* and *Plasmodium vivax/ovale*) on the BioFire® Global Fever Panel performed on BioFire® FilmArray® 2.0 and BioFire® FilmArray® Torch Systems. The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is designed for and intended to be used solely with the BioFire Global Fever Panel. This product does not replace manufacturer internal controls provided as part of the BioFire Global Fever Panel device.

Both the Positive and Negative External Controls are provided in a FilmArray Control Injection Vial format. The Positive Control Injection Vial contains dried synthetic DNA segments in buffer and stabilizer to assess the presence of each individual assay on the BioFire Global Fever Panel. The Negative Control Injection Vial contains no DNA and is non-reactive with the BioFire Global Fever Panel assays.

PRODUCT SUMMARY AND PRINCIPLE

The BIOFIRE® SHIELD™ Control Kit for the BioFire® Global Fever (GF) Panel is a surrogate control to monitor performance of the BioFire GF Panel analytes. The BIOFIRE SHIELD Control Kit for the BioFire GF Panel is designed to mitigate the risk of control contamination or misuse when evaluating clinical specimens on the BioFire® FilmArray® systems. Good laboratory practice recommends running positive and negative external controls regularly. Evaluation of external controls is recommended prior to using a new shipment or new lot of BioFire GF Panel Kits, when there is a new operator, and following replacement/repair of a BioFire FilmArray 2.0 or Torch system. It is the responsibility of each laboratory to determine the frequency of external control testing with the BioFire GF Panel as part of the laboratory's Quality Control program. Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.

COMPOSITION

The BIOFIRE SHIELD Positive External Control for the BioFire GF Panel is a surrogate external assayed quality control material composed of a pool of synthetic target DNA sequences that each produce a signature melting temperature (Tm) value that is distinct from that produced by the corresponding pathogen to reduce the risk of false positive results. No synthetic target DNA sequences are present in the BIOFIRE SHIELD Negative External Control for the BioFire GF Panel. The SHIELD Control Kit for the BioFire GF Panel contains no biological hazards and is 100% non-infectious.

STORAGE AND STABILITY

- Store the BIOFIRE SHIELD Control Kit for the BioFire GF Panel at room temperature (18-30°C).
- Avoid storage of any materials near heating or cooling vents, or in direct sunlight.
- Once the BIOFIRE SHIELD External Control packaging has been opened, the control should be loaded as soon as possible (within approximately 30 minutes). See the *BioFire Global Fever Panel Instructions for Use* for more information.

MATERIALS PROVIDED

Each BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel contains sufficient reagents for six positive external control runs and six negative external control runs (Part No. DFA2-ASY-0006). Materials include:

- Six individually packaged Positive External Control Injection Vials
- Six individually packaged Negative External Control Injection Vials
- Instructions available online at www.biofiredefense.com/globalfeverpanel
    - *BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel - Instructions for Use*
    - *BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel - Quick Guide*

    NOTE: *Additional documentation is available online at www.biofiredefense.com*

MATERIALS REQUIRED BUT NOT PROVIDED

- 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 if not already installed on the instrument system.
- 10% bleach solution or a similar disinfectant
- BioFire® Global Fever Panel (Part No. DFA2-ASY-0004)

PROCEDURE

Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and BIOFIRE SHIELD Controls. Only prepare one BioFire GF Panel pouch at a time and change gloves between handling of External Controls and pouches. Refer to the *BIOFIRE SHIELD Control Kit Quick Guide for the BioFire Global Fever Panel* for detailed instructions on how to load the BIOFIRE SHIELD Controls. Once an External Control is loaded into the pouch, promptly transfer the pouch to the instrument to start the run.

NOTE: *There are individual Protocols for the BIOFIRE SHIELD Positive and Negative External Controls for the BioFire GF Panel; therefore, it is necessary to ensure that the appropriate Protocol is selected prior to running the test. Dispose of the controls and the pouch in a biohazard container.*

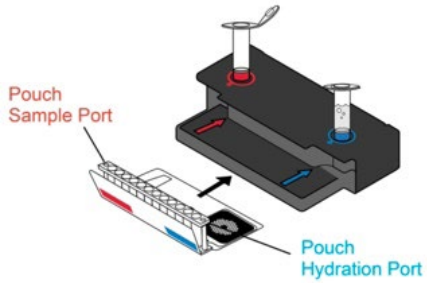
Refer to the appropriate BioFire® FilmArray® operator's manual for more details regarding BioFire FilmArray systems.

STEP 1: PREPARE POUCH

a. Insert pouch into Pouch Loading Station.

b. Remove cap from either Positive or Negative Control Injection Vial and place into red well.

c. Place Hydration Injection Vial into blue well.



STEP 2: HYDRATE POUCH

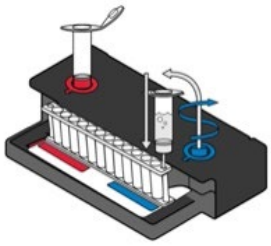
a. Unscrew Hydration Injection Vial from cover.

b. Remove Hydration Injection Vial, leaving blue cover in Pouch Loading Station.

c. Insert Hydration Injection Vial into Hydration port.

d. Push down to puncture seal and wait as Hydration Solution is drawn into the pouch.

NOTE: *Verify the pouch has been hydrated.*



STEP 3: PREPARE EXTERNAL CONTROL

a. Hold the Sample Buffer Tube with the tip facing up and firmly pinch at textured plastic tab on side of tube until the seal snaps.

NOTE: *Do not touch the tip of the tube.*

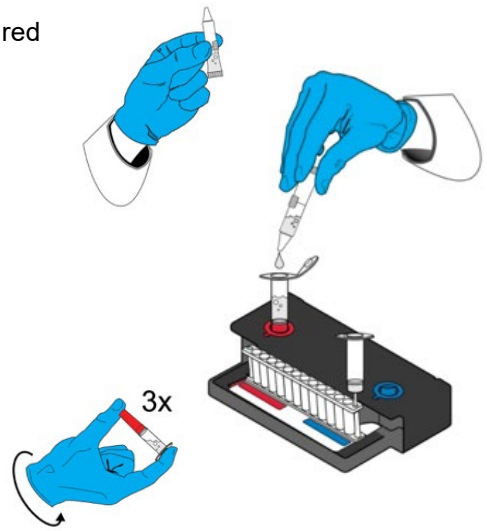
b. Dispense Sample Buffer into Control Injection Vial using a slow, forceful squeeze, followed by a 2nd squeeze.

NOTE: *Avoid generating excessive foam.*

c. Tightly close lid and invert the Control Injection Vial 3 times.

d. Return Control Injection Vial to red well of Pouch Loading Station.

WARNING: Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.



STEP 4: LOADING EXTERNAL CONTROL

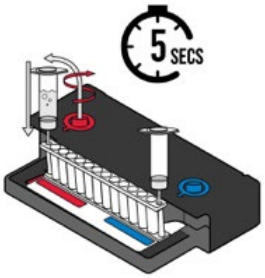
a. Unscrew Control Injection Vial from red cover.

b. Wait for 5 second, then remove Control Injection Vial, leaving red cover in Pouch Loading Station.

NOTE: *Waiting 5 seconds decreases the contamination risk.*

c. Insert Control Injection Vial into pouch sample port.

d. Push down to puncture seal, then wait as control material is drawn into the pouch.



STEP 5: RUN POUCH

a. Screw vials back into covers in Pouch Loading Station before disposing of them in a biohazard container.

b. Remove pouch from Pouch Loading Station and load into the instrument.

c. Follow instructions on screen for starting a test.

NOTE: *Either Positive External Control or Negative External Control protocol.*

WARNINGS AND PRECAUTIONS

- The BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel is designed only for use with the BioFire Global Fever Panel and should not be used with any other test.
- Only trained laboratory personnel should perform and interpret this test.
- The BIOFIRE SHIELD Positive and Negative External Control Protocols should only be used to test External Controls as described in the procedure section above. The Positive and Negative External Control Protocols are only for use with the BIOFIRE SHIELD Control Kit. Do not use External Control Protocols to test human specimens.
- Always check the expiration date on the control kits. Do not use controls after the expiration date.
- Although rare, contamination from synthetic DNA in the BIOFIRE SHIELD Positive External Controls can contaminate the work area and may cause Negative External Controls to fail. For accurate test results:
    - Follow the instructions in the BIOFIRE SHIELD Control Kit Quick Guide for the BioFire Global Fever Panel exactly.
    - Wear appropriate personal protective equipment (PPE), including (but not limited to) lab coats and disposable, powder-free gloves. Change gloves often when handling External Controls.
    - Decontaminate the work area with 10% bleach or a similar disinfectant after every use of an External Control.
- Bleach introduced in an External Control may damage nucleic acids, which may lead to a false negative result.
- Dispose of materials used in this assay, including reagents and used buffer vials, according to federal, state, and local regulations.

INTERPRETATION OF RESULTS

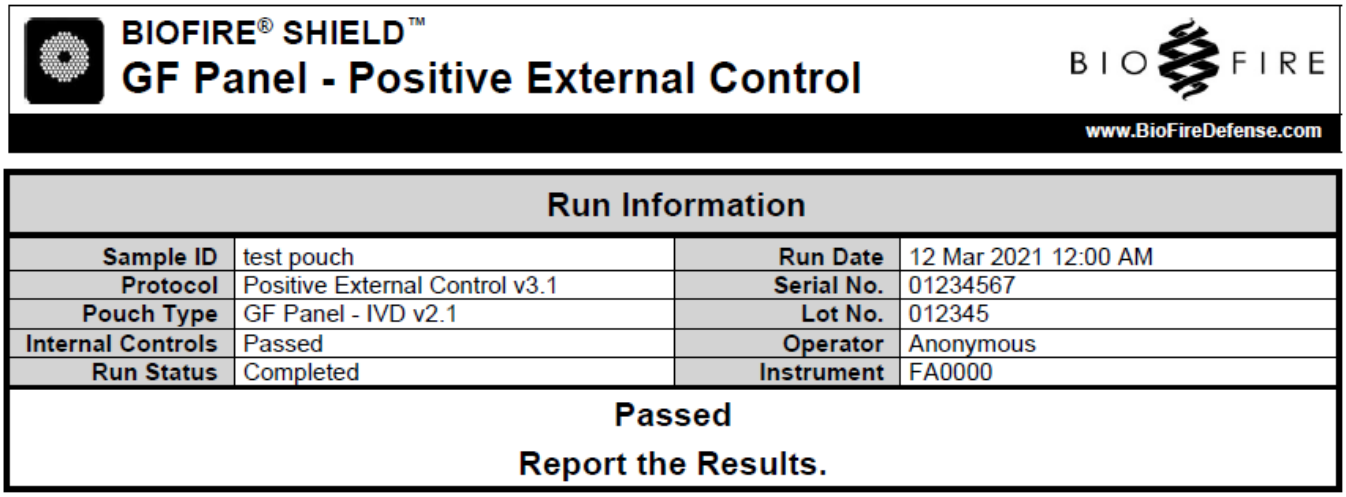
The External Control Report is automatically displayed upon completion of a run and can be printed or saved as a PDF file.

The Run Information section of the report provides the Sample ID, time and date of the run, and the Internal Controls results. Refer to the BioFire Global Fever Panel Instructions for Use for more information about Internal Controls results. The Run information section also includes pouch information (type, lot number and serial number), run status (Completed, Aborted, Instrument Error, or Software Error), the protocol used to perform the test, the identity of the operator who performed the test, and the instrument used to perform the test.

When the BioFire Global Fever Panel pouch is used with the External Controls, the results presented are for the BioFire Global Fever Panel pathogen targets only.

EXTERNAL CONTROL REPORT WHEN USING THE BIOFIRE GLOBAL FEVER PANEL

When running the BIOFIRE SHIELD Control Kit on the BioFire Global Fever Panel the results are listed in the Result Banner as either Passed (See **Figures 1** and **3**), Failed (See **Figures 2** and **4)** or Invalid (not shown).



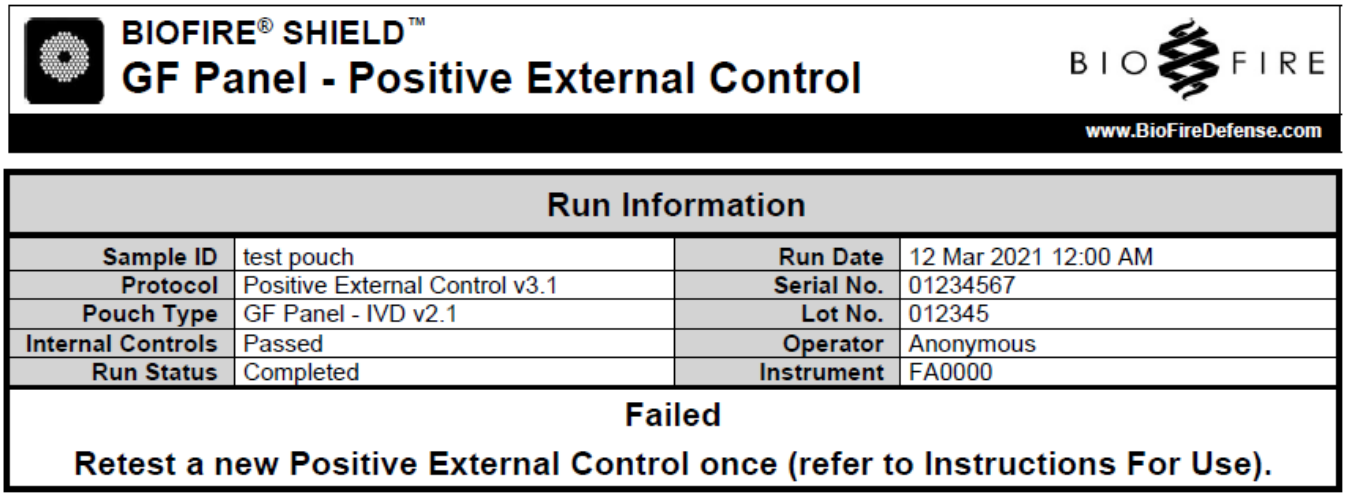
BIOFIRE® SHIELD™
GF Panel - Positive External Control
BIOFIRE
www.BioFireDefense.com

Run Information			
Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	Positive External Control 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

Passed

Report the Results.

Figure 1. BioFire Global Fever Panel External Control Report for a Passed Positive External Control



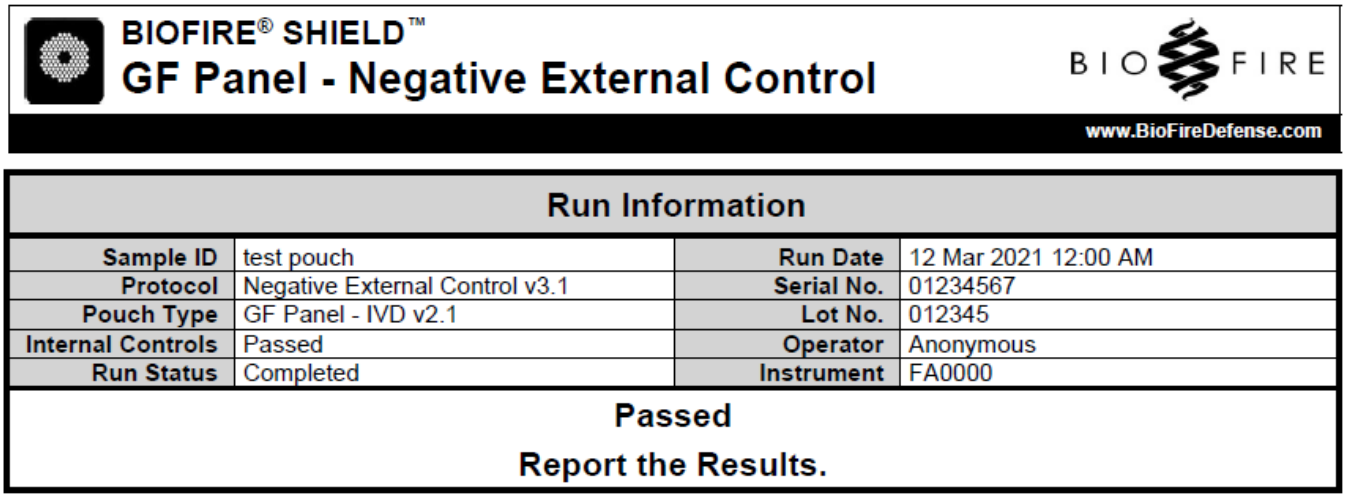
BIOFIRE® SHIELD™
GF Panel - Positive External Control
BIOFIRE
www.BioFireDefense.com

Run Information			
Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	Positive External Control 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

Failed

Retest a new Positive External Control once (refer to Instructions For Use).

Figure 2. BioFire Global Fever Panel External Control Report for a Failed Positive External Control



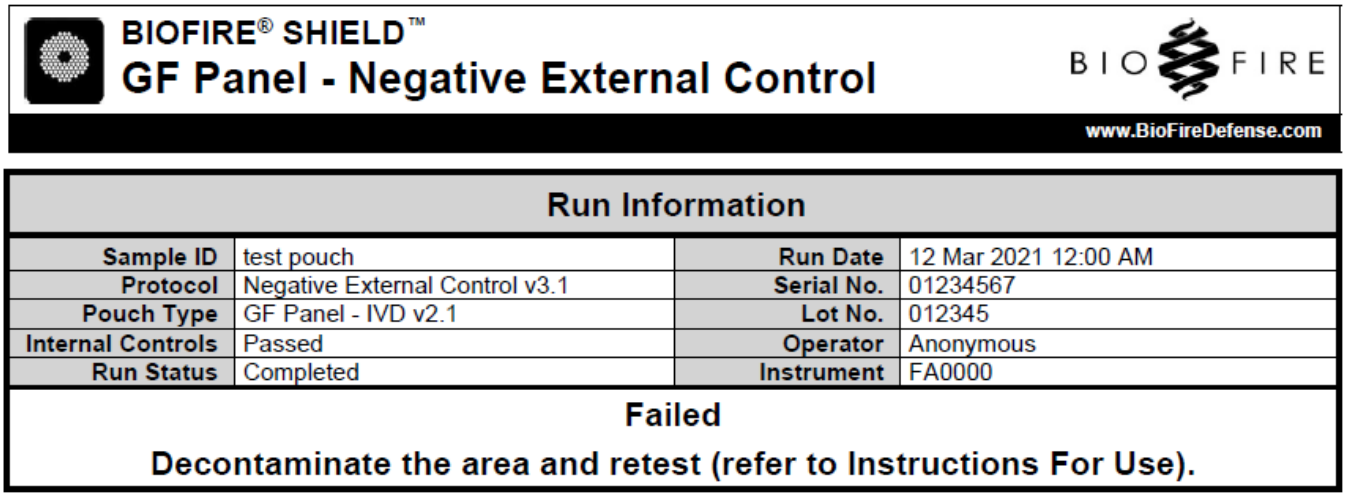
BIOFIRE® SHIELD™
GF Panel - Negative External Control
BIOFIRE
www.BioFireDefense.com

Run Information			
Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	Negative External Control 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

Passed

Report the Results.

Figure 3. BioFire Global Fever Panel External Control Report for a Passed Negative External Control



BIOFIRE® SHIELD™
GF Panel - Negative External Control
BIOFIRE
www.BioFireDefense.com

Run Information			
Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	Negative External Control 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

Failed

Decontaminate the area and retest (refer to Instructions For Use).

Figure 4. BioFire Global Fever Panel External Control Report for a Failed Negative External Control

BIOFIRE SHIELD CONTROL KIT RESULT EXPLANATION

The Positive External Controls produce a signature melting temperature (Tm) value that is distinct from that produced by the corresponding pathogen to reduce the risk of false positive results. The Positive External Control passes when the software detects amplification within the control melting temperature window for all assays. The Negative External Control passes when the software detects no amplification within both the control melting temperature window or the pathogen melting temperature window for all assays. See **Table 1** for an explanation of how the Positive External Control results are analyzed, possible results, and required actions. See **Table 2** for an explanation of how the Negative External Controls are analyzed, possible results, explanations, and required actions.

If any error persists, contact BioFire Defense Technical Support for further instruction.

Table 1. Positive External Control Results Explanation and Required Actions

Positive External Control Result	Explanation	Action Required
Passed	The run was successfully completed AND All Positive External Control targets were Detected.	Follow the instructions provided in the Result Banner.
Failed	The run was successfully completed BUT One or more of the Positive External Control targets were Not Detected.	Repeat the test once using a new pouch and new Positive External Control. If the error persists, call BioFire Defense Technical Support for further instructions.
Invalid	The result is invalid because the run did not complete. OR One or more of the pouch internal controls failed.	Note any error codes displayed by the software during the run. Refer to the appropriate BioFire FilmArray Operator's Manual or call BioFire Defense Technical Support for further instruction. If the error can be resolved, repeat the test using a new pouch.

Table 2. Negative External Control Results Explanation and Required Actions

Negative External Control Result	Explanation	Action Required
Passed	The run was successfully completed AND All Negative External Control targets were Not Detected.	Follow the instructions provided in the Result Banner.
Failed	The run was successfully completed BUT One or more of the Negative External Control targets were Detected.	Decontaminate the area and repeat the test once using a new pouch and new Negative External Control. If the error persists, call BioFire Defense Technical Support for further instructions.
Invalid	The result is invalid because the run did not complete. OR One or more of the pouch internal controls failed.	Note any error codes displayed by the software during the run. Refer to the appropriate BioFire FilmArray Operator's Manual or call BioFire Defense Technical Support for further instruction. If the error can be resolved, repeat the test using a new pouch.

LIMITATIONS

1. For in vitro diagnostic use only.
2. This product is only for use with the BioFire Global Fever Panel. It does not contain the entire genome of the target analytes.
3. This product is not intended to replace the internal controls contained in the BioFire Global Fever Panel.
4. Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.

REPRODUCIBILILTY

The following are reproducibility data for the BioFire SHIELD Control Kit for the BioFire Global Fever Panel.

Three different lots of the BIOFIRE SHIELD Control Kit for the BioFire GF Panel were evaluated at three test sites. At each site, two operators used three BioFire FilmArray 2.0 instruments over five days to test 45 positive and 45 negative BIOFIRE SHIELD External Controls. Results are shown below in **Table 3**.

Table 3. Reproducibility Test Results of the BIOFIRE SHIELD Positive and Negative External Control for the BioFire GF Panel on FilmArray 2.0 Systems

External Control Type	Expected Result	Observed/Expected (Percent Agreement) [95% Confidence Interval]			
		Site 1	Site 2	Site 3	All Sites
Positive	Passed	43/45 (95.6%)	45/45 (100%)	45/45 (100%)	**133/135 (98.5%)** [94.8-99.6%]
Negative	Passed	45/45 (100%)	45/45 (100%)	44/45 (97.8%)	**134/135 (99.3%)** [95.9-99.9%]
Overall Agreement with Expected Result		**267/270 (98.9%)** [96.8-99.6%]			

Separate reproducibility studies were performed for BioFire FilmArray 2.0 and BioFire FilmArray Torch systems. Results for the FilmArray Torch systems are shown in **Table 4**; the site variable was simulated by using three different FilmArray Torch Systems.

Table 4. Reproducibility Test Results of the BioFire SHIELD Positive and Negative External Control for the BioFire GF Panel on FilmArray Torch Systems.

External Control Type	Expected Result	Observed/Expected (Percent Agreement) [95% Confidence Interval]			
		System 1	System 2	System 3	All Systems
Positive	Passed	45/45 (100%)	45/45 (100%)	45/45 (100%)	**135/135 (100%)** [97.2-100%]
Negative	Passed	44/45 (97.8%)	45/45 (100%)	45/45 (100%)	**134/135 (99.3%)** [95.9-99.9%]
Overall Agreement with Expected Result		**269/270 (99.6%)** [97.9-99.9%]			

CLINICAL EVALUATION

Six clinical sites evaluated the BIOFIRE SHIELD External Controls for the BioFire GF Panel (positive and negative) prior to clinical specimen testing. The results are shown in **Table 5**.

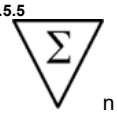
Table 5. BIOFIRE SHIELD Control Performance as Compared to the Expected (Passed) Result

External Control Type	Completed with Expected Result	Total Completed	%
Positive	159[a]	160	98.8%
Negative	155[a]	157	98.7%
Overall	**313**	**317**	**98.7%**

[a] Site tested a Positive and a Negative External Control on the same day. Controls were most likely swapped as the Negative External Control failed because all External Control targets were detected, and the Positive External Control failed because all External Control targets were not detected.

SYMBOLS GLOSSARY

The following symbols can be found on labeling for the BIOFIRE SHIELD Control Kit for the BioFire GF Panel and throughout accompany packaging.

ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements					
5.1.1 	Manufacturer	5.1.4 	Use-By date (YYYY-MM-DD)	5.1.5 	Batch Code (Lot Number)
5.1.6 	Catalog Number	5.1.7 	Serial Number	5.2.8 	Do Not Use if Package Is Damaged
5.5.2 	Material used as part of Quality Control Procedure	5.5.3 	Material used as a Negative Control of the Quality Control Procedure	5.5.4 	Material used as a Positive Control of the Quality Control Procedure
5.3.2 	Keep Away from Sunlight	5.3.7 	Temperature Limit	5.4.2 	Do not re-use
5.4.3 	Consult Instructions for Use	5.5.1 	*In vitro* Diagnostic Medical Device	5.5.5 	Contains sufficient for <n> tests
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC.10/30)					
	Serious eye damage, Category 1		Acute aquatic hazard, Category 1 & Long-term aquatic hazard, Category 1		Acute toxicity, oral, Category 4 & Skin corrosion, irritation, Category 2
Use of Symbols in Labeling – 81 FR 38911, Docket No. (FDA-2013-N-0125)					
℞ Only		Prescription Use Only CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.			
Manufacturer Symbols (BioFire Defense, LLC)					
	BioFire Defense Logo		BioFire Global Fever Panel		

CONTACT AND LEGAL INFORMATION

Customer and Technical Support	
Contact Us on the Web http://www.BioFireDefense.com **Contact Us by Mail** 79 West 4500 South, Suite 14 Salt Lake City, Utah USA 84107	**Contact Us by E-mail** support@BioFireDefense.com **Contact Us by Phone** 1-801-262-3592 – US and Canada 1-801-262-3592 – International **Contact Us by Fax** 1-801-447-6907

REVISION HISTORY

Version	Revision Date	Description of Revision(s)
01	June 2021	Initial Release
02	December 2022	Revised to include information for use with BioFire FilmArray Torch system, Reformatted to 8.5 x 11

BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, Utah 84107 USA

 DFA2-PRT-0132-02, December 2022

For additional information regarding our products and applications, contact BioFire Defense Customer Support.