

REF

DFA2-ASY-0006



BIOFIRE® SHIELD™ Control Kit for the BioFire® Global Fever Panel

Instructions for Use



IVD

Rx Only

CONTROL



The Symbols Glossary is provided on Page 9 of this booklet.

For In Vitro Diagnostic Use

Manufactured by

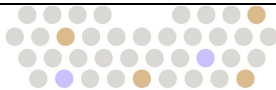


BioFire Defense, LLC

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

TABLE OF CONTENTS

Intended Use	2
Product Summary and Principle	2
Composition	3
Storage and Stability	3
Materials Provided	3
Materials required but not provided.....	4
Procedure	4
Warnings and Precautions	5
Expected Results	6
Performance Data	7
Symbols Glossary.....	9
Revision History.....	10
Manufactured By.....	10



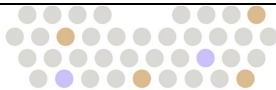
INTENDED USE

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 BioFire® Global Fever Panel targets on FilmArray® 2.0 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® 2.0 System. 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 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 (T_m) 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.

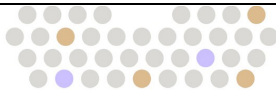
STORAGE AND STABILITY

- 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.
- All BIOFIRE SHIELD Control Kit for the BioFire GF Panel components should be stored together and only used with the BioFire GF Panel. Do not use components from this control kit with those of another panel.
- 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 and Documents
 - *BIOFIRE SHIELD Control Kit Quick Guide for the BioFire Global Fever Panel*

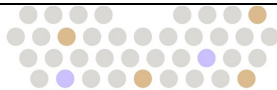
MATERIALS REQUIRED BUT NOT PROVIDED

- BioFire® FilmArray® System including:
 - BioFire® FilmArray® 2.0 instrument, computer, and 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

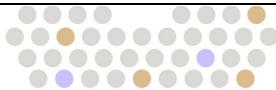
Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and BIOFIRE SHIELD Controls. Only prepare one BioFire GF Panel pouch at a time and change gloves between handling of External Controls and pouches. Refer to the *BIOFIRE SHIELD Control Kit Quick Guide for the BioFire 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 that 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® 2.0 Operator's Manual for more details regarding the BioFire FilmArray 2.0 System.



WARNINGS AND PRECAUTIONS

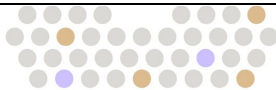
- The BIOFIRE SHIELD Control Kit for the BioFire GF Panel is designed only for use with the BioFire GF Panel and should not be used with any other test.
- Only trained laboratory personnel should perform and interpret this test.
- The BIOFIRE SHIELD Positive and Negative External Control Protocols should 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.



EXPECTED RESULTS

When performed properly, BIOFIRE SHIELD Controls for the GF Panel should yield the result 'Passed'.

If the result is 'Failed', the operator will be instructed to retest the External Control once, either immediately (Positive External Control) or after decontaminating the workspace (Negative External Control). If the result is 'Invalid', the operator will be instructed to retest the External Control once and to contact Technical Support if the problem persists.



PERFORMANCE DATA

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 1**.

Table 1. Multi-Site Reproducibility Test Results of the BIOFIRE SHIELD Positive and Negative External Control for the BioFire GF Panel

External Control Type	Expected Result	Observed/Expected (Percent Agreement) [95% Confidence Interval]			
		Site 1	Site 2	Site 3	All Sites
Positive	Passed	42/45 (93.3%)	45/45 (100%)	45/45 (100%)	132/135 (97.8%) [93.7-99.2%]
Negative	Passed	45/45 (100%)	44/45 ^a (97.8%)	44/45 ^b (97.8%)	133/135 (98.5%) [94.8-99.6%]
Overall Agreement with Expected Result		265/270 (98.1%) [95.7-99.2%]			

^a Unexpected detection of pathogen amplicon for an off-label assay, suspected laboratory contamination.

^b Unexpected detection of pathogen amplicon for DENV 2_1 assay, suspected laboratory contamination.

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 2**.

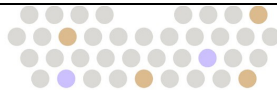
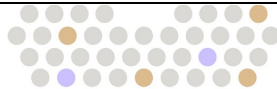


Table 2. BIOFIRE SHIELD Control Performance as Compared to the Expected (Passed) Result

















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%

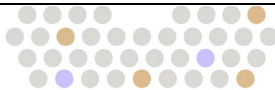
^a Site tested a Positive and a Negative External Control on the same day. Controls were most likely swapped as the Negative External Control failed because all External Control targets were detected, and the Positive External Control failed because all External Control targets were not detected.



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 Graphical symbols for use on equipment – Registered Symbols					
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 	<i>In vitro</i> Diagnostic Medical Device	5.5.5 	Contains sufficient for <n> tests
81 FR 38911					
Rx 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® Global Fever Panel				



REVISION HISTORY

Version	Revision Date	Description of Revision(s)
01	June 2021	Initial Release

MANUFACTURED BY



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

Email: support@BioFireDefense.com
Phone: 801-262-3592
Fax: 801-447-6907
[Web: www.BioFireDefense.com](http://www.BioFireDefense.com)

© Copyright 2021 BioFire Defense, LLC. All rights reserved.

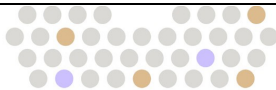
DFA2-PRT-0132-01, June 2021

The information contained in this document is subject to change without notice. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of BioFire Defense, LLC.

BioFire FilmArray Software, Detector, and Metacall software modules © 2002–2021 BioFire Diagnostics, LLC and/or BioFire Defense, LLC.

BioFire®, the BioFire logo, FilmArray®, and BIOFIRE® SHIELD™ are trademarks of BioFire Diagnostics, LLC and/or BioFire Defense, LLC and are registered trademarks in the United States. All other names of products and brands appearing in this manual are trademarks or registered trademarks of their respective owners.

The purchase of this product includes a limited, non-transferable license under specific claims of one or more U.S. patents as listed on BioFire Defense's website (<http://www.biofiredefense.com/LegalNotices/>) and owned by the University of Utah Research Foundation and/or BioFire.





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