

REF

424062 (6 pack test)

# BIOFIRE® SHIELD™ Control Kit for the BioFire® COVID-19 Test Instructions for Use

v1.1

**IVD**  
**Rx Only**



The Symbols Glossary is provided on Page 7 of this booklet.

**For in vitro diagnostic use under an Emergency Use Authorization (EUA) only**

Please visit us at [www.biofiredefense.com/covid-19test](http://www.biofiredefense.com/covid-19test)

Manufactured by

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## INTENDED USE

The BIOFIRE® SHIELD™ Control Kit for the BioFire® COVID-19 Test is an optional surrogate external assayed quality control for monitoring performance of *in vitro* laboratory nucleic acid testing procedures using the qualitative BioFire COVID-19 Test on FilmArray® 2.0 and FilmArray® Torch systems.

The BIOFIRE SHIELD Positive External Control monitors for the presence of the PCR primers for SARS-CoV-2 assays in the BioFire COVID-19 Test. To reduce the risk of false positive results, the BIOFIRE SHIELD Positive External Control is composed of synthetic RNA sequences that produce signature melting temperature ( $T_m$ ) values that are distinct from the  $T_m$  values produced by amplification of SARS-CoV-2 RNA.

External quality controls should be used in accordance with appropriate federal, state, and local guidelines or accreditation requirements, as applicable.

This product is not intended to replace the internal controls contained in the BioFire COVID-19 Test.

**For use under an Emergency Use Authorization (EUA) only.**

## PRODUCT SUMMARY AND PRINCIPLE

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 COVID-19 Test Kits, when there is a new operator, and following replacement/repair of a BioFire FilmArray 2.0 or FilmArray Torch system. External controls may also be used in initial laboratory verification of BioFire FilmArray 2.0 or Torch systems used with the BioFire COVID-19 Test.

It is ultimately the responsibility of each laboratory to determine the frequency and type of material used for external control testing as part of the laboratory's Quality Control program. Information on the selection of appropriate external control material and how to design a verification protocol is posted on the BioFire Defense webpage.

## COMPOSITION

The BIOFIRE SHIELD Positive External Control is composed of a pool of synthetic RNA sequences that each produce a signature melting temperature ( $T_m$ ) value that is distinct from the  $T_m$  value produced by SARS-CoV-2 RNA target to reduce the risk of false positive results. The BIOFIRE SHIELD Control Kit contains no biological hazards and is 100% non-infectious.

## STORAGE AND STABILITY

- Store the BIOFIRE SHIELD Control Kit at room temperature (15-30°C). **DO NOT REFRIGERATE.**
- Avoid storage of any materials near heating or cooling vents, or in direct sunlight.
- Once the mylar bag containing the Positive External Control vial has been opened, the positive external control should be loaded as soon as possible.



## MATERIALS PROVIDED

Each BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test contains sufficient reagents for six positive external control runs (6-pack; part no. 424062). Materials include:

- Individually packaged BIOFIRE SHIELD Positive External Control Vials for the BioFire COVID-19 Test
- Instructions and Documents
  - *BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test Quick Guide*

## MATERIALS REQUIRED BUT NOT PROVIDED

- BioFire® FilmArray system including:
  - BioFire® FilmArray 2.0/Torch Instrument Systems and accompanying software
  - BioFire® FilmArray® Pouch Loading Station
- 10% bleach solution or a similar disinfectant
- Transport medium, PBS, or normal saline solution
- BioFire COVID-19 Test v1.1 (Part No. 423745 (6 pack test) or 423744 (30 pack test))

**NOTE:** Negative controls may be run using negative matrix such as transport medium, PBS, or normal saline solution. Negative matrix is not included in this kit.

**NOTE:** Examples of verification protocols (for laboratory verifications with either the BIOFIRE SHIELD Control Kit or alternative external controls) are available online at [www.biofiredefense.com/covid-19test](http://www.biofiredefense.com/covid-19test).

## WARNINGS AND PRECAUTIONS

1. This BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test is designed for use only with the BioFire COVID-19 Test (v1.1) and should not be used with any other BioFire panel.
2. The BIOFIRE SHIELD Positive and Negative External Control FilmArray protocols should only be used to test external controls as described in the procedure section below. The Negative and Positive External Control protocols are only for use with the BIOFIRE SHIELD Control Kit.
3. The BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
4. The BioFire COVID-19 Test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
5. The emergency use of the BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. Always check the expiration date on the control kits. Do not use controls after the expiration date.
7. Although rare, contamination from small amounts of synthetic RNA in the BIOFIRE SHIELD Positive External Controls can contaminate the work area and may cause Negative External Controls to fail. For accurate tests results:
  - a. Follow the instructions in the *BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test - Quick Guide* exactly.
  - b. Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable, powder-free gloves. Change gloves often when handling BIOFIRE SHIELD Positive External Control materials.



- c. Decontaminate the work area after every use of an External Control.
8. Bleach introduced in a sample may damage nucleic acids in the sample and may result in a failed Positive External Control result.
9. Dispose of materials used in the assay, including reagents and used buffer vials, according the federal, state, and local regulations.

## BIOFIRE SHIELD CONTROL PROCEDURE

Use clean gloves and other PPE when handling pouches and the BIOFIRE SHIELD Positive External Control. Only prepare one BioFire COVID-19 Test pouch at a time and change gloves between handling of External Controls and pouches. Refer to the *BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test Quick Guide* for detailed instructions on how to prepare and load the Positive and Negative External Controls. Once a Positive or Negative External Control is loaded into the pouch, promptly transfer the pouch to the instrument to start the run. Ensure the correct protocol is selected before starting the run. After the run is complete, discard the pouch in a biohazard container.

Refer to the appropriate BioFire *FilmArray operator's manual* for more details regarding the BioFire FilmArray System. Refer to the *BioFire COVID-19 Test Instructions for Use* for additional information about the BioFire COVID-19 Test.

**NOTE:** *There are individual software protocols for the Positive and Negative External Controls. It is necessary to ensure that the appropriate protocol is selected prior to starting the test. DO NOT select the sample protocol.*

## EXPECTED RESULTS

### BioFire® COVID-19 Test External Control Reports

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The BioFire COVID-19 Test External Control Report is automatically displayed upon completion of a run and can be printed or saved as a PDF file. Each report contains Run Information and results.

The **Run Information** section of the test report provides the Sample ID, time and date of the run, and the internal controls run status. Internal controls are listed as 'Passed', 'Failed', or 'Invalid'. For more information on internal controls, reference the *BioFire COVID-19 Test Instructions for Use*. The **Run Information** section also includes pouch information (type, lot number, and serial number), run status (Completed, Incomplete, Aborted, Instrument 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.

When performed properly, the BIOFIRE SHIELD External Controls should yield the result 'Passed' (See **Figures 1** and **2**). 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) - See **Figures 3** and **4**. 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.

For further instructions on decontaminating the workspace, refer to the appropriate BioFire FilmArray operator's manual.





 <b>BioFire®</b> <b>COVID-19 Test - Positive External Control</b>			
www.BioFireDefense.com			
Run Information			
Sample ID	Example Report	Run Date	31 Dec 2019 8:00 AM
Protocol	Positive External Control v3.2	Serial No.	01234567
Pouch Type	COVID-19 Test v1.1	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0000
<p><b>Passed</b></p> <p><b>Report the Results.</b></p>			

Figure 1. BioFire COVID-19 Test External Control Report for a passed Positive External Control



 <b>BioFire®</b> <b>COVID-19 Test - Negative External Control</b>			
www.BioFireDefense.com			
Run Information			
Sample ID	Example Report	Run Date	31 Dec 2019 8:00 AM
Protocol	Negative External Control v3.2	Serial No.	01234567
Pouch Type	COVID-19 Test v1.1	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0000
<p><b>Passed</b></p> <p><b>Report the Results.</b></p>			

Figure 2. BioFire COVID-19 Test External Control Report for a passed Negative External Control



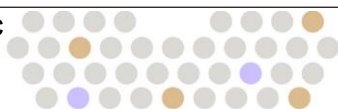
 <b>BioFire®</b> <b>COVID-19 Test - Positive External Control</b>			
www.BioFireDefense.com			
Run Information			
Sample ID	Example Report	Run Date	31 Dec 2019 8:00 AM
Protocol	Positive External Control v3.2	Serial No.	01234567
Pouch Type	COVID-19 Test v1.1	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0000
<p><b>Failed</b></p> <p><b>Retest a new Positive External Control once (refer to Instructions For Use).</b></p>			

Figure 3. BioFire COVID-19 Test External Control Report for a Failed Positive External Control





 <b>BioFire®</b> <b>COVID-19 Test - Negative External Control</b>			
www.BioFireDefense.com			
Run Information			
Sample ID	Example Report	Run Date	31 Dec 2019 8:00 AM
Protocol	Negative External Control v3.2	Serial No.	01234567
Pouch Type	COVID-19 Test v1.1	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0000
<b>Failed</b> <b>Decontaminate the area and retest (refer to Instructions For Use).</b>			

Figure 4. BioFire COVID-19 Test External Control Report for a Failed Negative External Control

## Analysis of BIOFIRE SHIELD Positive and Negative External Control Assays

The BIOFIRE SHIELD Positive External Control passes when the software detects amplification within the specified melting temperature window for all three SARS-CoV-2 assays.

If amplification for one or more of the three SARS-CoV-2 assays is not detected, the Positive External Control fails and should be repeated. If the failure persists, contact BioFire Defense Technical Support for further instruction.

Laboratories may decide to perform negative control testing on the system. Negative control testing may be performed using transport medium, PBS, or saline in place of a patient sample. If amplification of Positive External Control material and/or SARS-CoV-2 RNA is detected, the Negative External Control fails and should be repeated after a thorough cleaning of the area. If the error persists, contact BioFire Defense Technical Support for further instruction.

## LIMITATIONS




















1. For in vitro diagnostic use under Emergency Use Authorization (EUA) only.
2. This product is only for use with the BioFire COVID-19 Test (v1.1). It does not contain the entire genome of SARS-CoV-2. This product is not intended to replace the internal controls contained in the BioFire COVID-19 Test.
3. Transport medium, PBS, or saline may be used as a Negative External Control. Negative External Controls are not provided.
4. Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.



# APPENDIX A

## Symbols Glossary

The following symbols can be found on labeling for the BIOFIRE SHIELD Control Kit, and throughout accompanying 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
5.3.2 	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
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC.10/30)					
	Corrosive (Skin Corrosion/Burns, Eye Damage, Corrosive to Metals)		Exclamation Mark (Irritant, Acute Toxicity, Narcotic Effects, Respiratory Tract Irritant)		Hazardous to the aquatic environment, long-term hazard
81 FR 38911					
	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		Positive External Control		COVID-19 symbol





## APPENDIX B

### Contact and Legal Information

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#### 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](mailto: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

### Ordering Information

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<b>BIOFIRE SHIELD Control Kit for use with the BioFire COVID-19 Test</b>	
<b>Kit Part No:</b>	424062
<b>Contents:</b>	6 Positive External Control Vials

### Revision History

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<b>Version</b>	<b>Revision Date</b>	<b>Description of Revision(s)</b>
01	February 2021	Initial Release

**BioFire Defense, LLC**

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