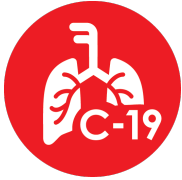


REF

424062 (6 pack test)



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

v1.1

IVD

R_x Only



The Symbols Glossary is provided on Page 11 of this booklet.

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

Please visit us at www.biofiredefense.com/covid-19test

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.

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.

The emergency use of 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.

Manufactured by



BioFire Defense, LLC

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

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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 BIOFIRE® FILMARRAY® 2.0 and BIOFIRE® 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 BIOFIRE FILMARRAY TORCH system. External controls may also be used in initial laboratory verification of BIOFIRE FILMARRAY 2.0 or BIOFIRE FILMARRAY 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/ BIOFIRE® FILMARRAY® 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.*

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 to 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.

Steps 1 and 2: Prepare and Hydrate the Pouch

Refer to the *BioFire COVID-19 Test v1.1 Instructions for Use: Step 1: Prepare Pouch and Step 2: Hydrate pouch*

- To prepare a Positive External Control proceed to Step 3a.
- To prepare a Negative External Control proceed to Step 3b.

Step 3a: Prepare Positive External Control

1. Use the Transfer Pipette to draw the Transport Medium, PBS, or Saline to the third line. Add to the **Sample Injection Vial**.
2. Remove rubber cap from Positive External Control Vial and place on a clean surface (a paper towel may be used).
3. Add Sample Buffer to Positive External Control Vial

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

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

NOTE: *Avoid touching the ampoule 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.

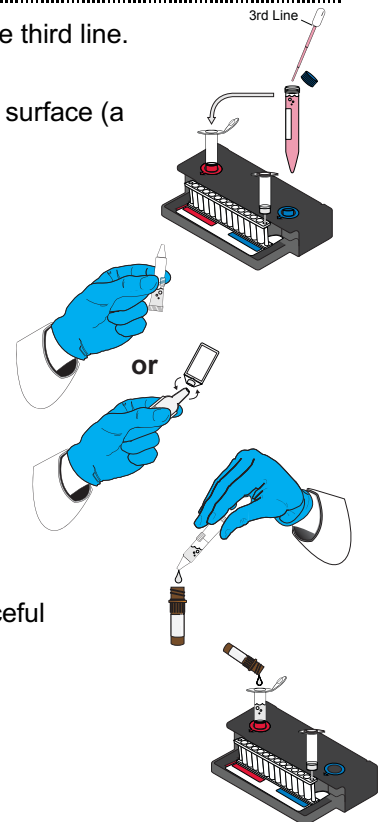
or

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

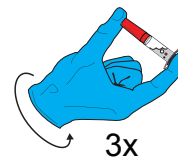
4. Dispense Sample Buffer into Positive External Control Vial using a slow, forceful squeeze, followed by a second squeeze.

NOTE: *Avoid generating excessive foam.*

5. Recap Positive External Control Vial and invert it **3** times to mix.
6. Pour mixture of Sample Buffer and Control into the **Sample Injection Vial**.



- Dispose of Positive External Control Vial and change gloves.
- Tightly close lid of Sample Injection Vial and invert it **3** times, return it to the **red well** of Pouch Loading Station.



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

- Proceed to *Step 4: Load Control Mix*.

Step 3b: Prepare Negative External Control

- Use the Transfer Pipette to draw the Transport Medium, PBS, or Saline to the third line. Add to the **Sample Injection Vial**.
- Add Sample Buffer to **Sample Injection Vial**.

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

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

NOTE: *Avoid touching the ampoule 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.

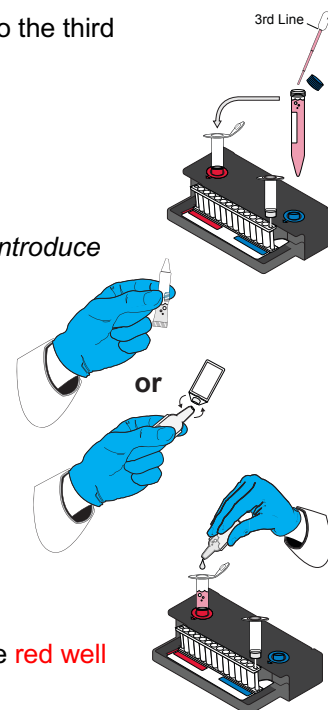
- Dispense Sample Buffer into **Sample Injection Vial** using a slow, forceful squeeze, followed by a second squeeze.

NOTE: *Avoid generating excessive foam.*

- Tightly close lid of **Sample Injection Vial** and invert **3** times, return it to the **red well** of Pouch Loading Station.

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

- Proceed to *Step 4: Load Control Mix*.



Step 4: Load Control Mix

Refer to the *BioFire COVID-19 Test v1.1 Instructions for Use: Step 4: Load Sample Mix*

Step 5: Run Pouch

Refer to the *BioFire COVID-19 Test v1.1 Instructions for Use: Step 5: Run Pouch*

- When prompted to select a protocol, select either the Positive External Control or Negative External Control protocol, as appropriate. Do not select the Sample protocol when running BIOFIRE SHIELD Controls.

NOTE: *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 appropriate BIOFIRE FILMARRAY operator's manual for more details regarding the BIOFIRE FILMARRAY System. Refer to the *BioFire COVID-19 Test v1.1 Instructions for Use* for additional information about the BioFire COVID-19 Test.

EXPECTED RESULTS


BioFire® COVID-19 Test External Control Reports

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 v1.1 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.



The header of the report features the BioFire logo on the left, the title "BioFire® COVID-19 Test - Positive External Control" in the center, and the BIOFIRE logo on the right. Below the title is the website address "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 |

Passed
Report the Results.

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



**BioFire®
COVID-19 Test - Negative External Control**



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 |

**Passed
Report the Results.**

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



**BioFire®
COVID-19 Test - Positive External Control**



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 |

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

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



**BioFire®
COVID-19 Test - Negative External Control**



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 |

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

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 SARS-CoV-2 assays.

If amplification for one or more of the 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.

PERFORMANCE EVALUATION

Three different lots of the BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test were evaluated on both BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY TORCH Systems. Two operators used three BIOFIRE FILMARRAY 2.0 instruments and three BIOFIRE FILMARRAY TORCH modules over five days to perform a total of 30 positive and 30 negative BIOFIRE SHIELD External Control tests split evenly between the BIOFIRE FILMARRAY platforms. Results are shown below in Table 1.




















Table 1. Summary of BioFire COVID-19 Test External Control Reproducibility Results

| BioFire COVID-19 External Control | Expected Result | Observed/Expected (Percent Agreement) [95% Confidence Interval] |
|-----------------------------------|-----------------|---|
| Positive | Passed | 30/30 (100%) [88.6-100%] |
| Negative | Passed | 30/30 (100%) [88.6-100%] |

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 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied | | | | | |
|--|--|--|---|--|--|
| 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 |
| Use of Symbols in Labeling - 81 FR 38911, Docket No. (FDA-2013-N-0125) | | | | | |
|  | 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

Contact Us on the Web

<http://www.BioFireDefense.com>

Contact Us by E-mail

support@BioFireDefense.com

Contact Us by Mail

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

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

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

Revision History

| Version | Revision Date | Description of Revision(s) |
|---------|---------------|--|
| 01 | February 2021 | Initial Release |
| 02 | May 2022 | Addition of performance data. Clarification of run procedure and removed reference to three assays. |
| 03 | June 2025 | Added 2 nd Sample Buffer Ampoule option to “prepare sample” steps. Updated to BIOFIRE FILMARRAY branding throughout document. |
| 04 | March 2026 | Branding Updates |



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DFA2-PRT-0118-04, March 2026

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