



BIOFIRE® SHIELD™ Control Kit v1.1

Quick Guide for the BioFire® COVID-19 Test



STEP 6: Review Results

Run Information - Displays information about the pouch, protocol, run status, operator, serial number, instrument and lot number

1. Internal Controls:

- If 'Passed', results are valid.
- If 'Failed' or 'Invalid', **RETEST CONTROL** once.


2. Run Status:

- If 'Completed', run is complete.
- If 'Aborted', or any other error message, **RETEST CONTROL** once.

3. External Control Results:

- If 'Passed', results are valid.
- If 'Failed',
 - Positive External Control: **RETEST EXTERNAL CONTROL** once.
 - Negative External Control: Decontaminate the area; and **RETEST EXTERNAL CONTROL** once.
- If 'Invalid', **RETEST EXTERNAL CONTROL** once.

NOTE: Refer to *Instructions for Use* for reporting information. If repeated error messages are obtained, contact *BioFire Defense Technical Support*.



BioFire®

COVID-19 Test - Positive External Control

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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

2

3

Passed

Report the Results.

Conditions of Authorization

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.

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.

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DO NOT DISCARD: Important product-specific information

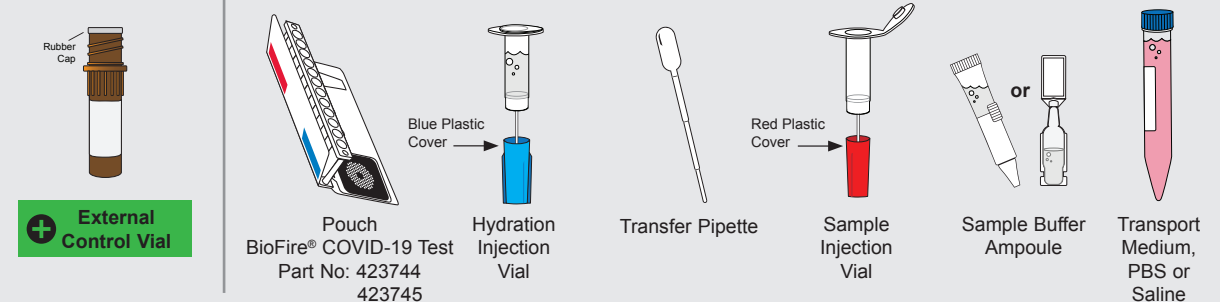
For in vitro diagnostic use under Emergency Use Authorization (EUA) only

REF 424062 (6 pk) IVD

Rx Only

Package Contents

Materials required but not provided

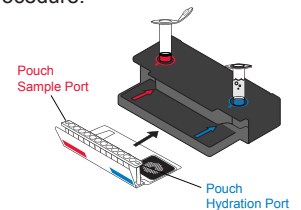


NOTE: Instrument should be powered on and ready for use prior to pouch preparation.

NOTE: Use clean gloves and other Personal Protective Equipment (PPE) when performing this procedure.

STEP 1: Prepare Pouch

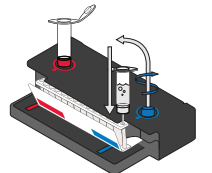
Refer to the *BioFire® COVID-19 Test Upper Respiratory Quick Guide*
STEP 1: Prepare Pouch



STEP 2: Hydrate Pouch

Refer to the *BioFire® COVID-19 Test Upper Respiratory Quick Guide*
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 COVID-19 Positive External Control

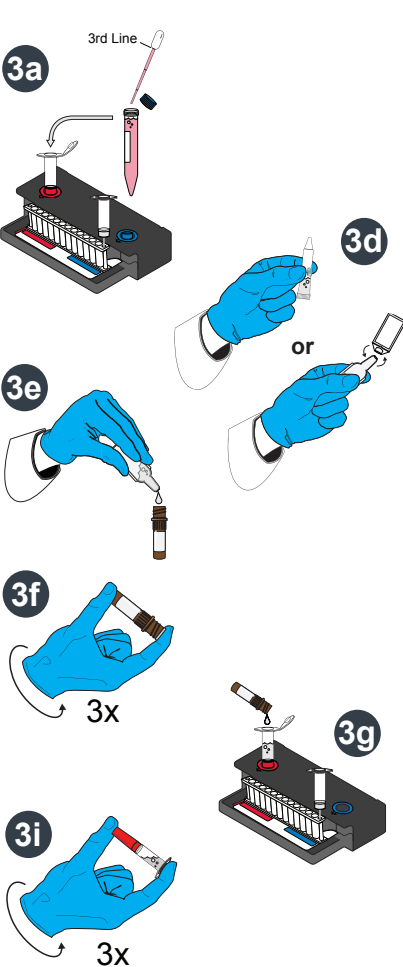
- a. Use the Transfer Pipette to draw the Transport Medium, PBS or Saline to the third line. Add to the **Sample Injection Vial**.
- b. Remove rubber cap from **Positive External Control Vial** and place on a clean surface (a paper towel may be used).

Add Sample Buffer to **Positive External Control Vial**

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

- c. Hold the Sample Buffer Ampoule with the tip facing up.
NOTE: Do not touch the tip of the ampoule.
- d. Firmly pinch textured plastic tab on the side of the ampoule until the seal snaps or if there is no textured tab on the side, gently twist off the plastic tab on the tip.
- e. Dispense Sample Buffer into **Positive External Control Vial** using a slow, forceful squeeze, followed by a second squeeze.
NOTE: Avoid generating excessive foam.
- f. Recap **Positive External Control Vial** and invert it 3 times to mix.
- g. Pour mixture of Sample Buffer and Control into the **Sample Injection Vial**.
- h. Dispose of **Positive External Control Vial** and change gloves.
- i. 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.



STEP 3b: Prepare COVID-19 Negative External Control

- a. 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

- b. Hold the Sample Buffer Ampoule with the tip facing up.
NOTE: Do not touch the tip of the ampoule.
- c. Firmly pinch textured plastic tab on the side of the ampoule until the seal snaps or if there is no textured tab on the side, gently twist off the plastic tab on the tip.
- d. Dispense Sample Buffer into **Sample Injection Vial** using a slow, forceful squeeze, followed by a second squeeze.
NOTE: Avoid generating excessive foam.
- e. 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.

STEP 4: Load Control Mix

Refer to the *BioFire® COVID-19 Test Upper Respiratory Quick Guide*
STEP 4: Load Sample Mix

STEP 5: Run Pouch

Refer to the *BioFire® COVID-19 Test Upper Respiratory Quick Guide*
STEP 5: Run Pouch

NOTE: Select either Positive External Control v3.2 or Negative External Control v3.2.

