BIOFIRE® SHIELD™ Control Kit v1.1

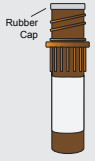
Quick Guide for the BioFire® COVID-19 Test

DO NOT DISCARD: Important product-specific information

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

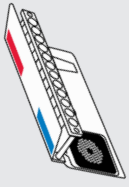
REF 424062 (6 pk) **IVD**

℞ Only

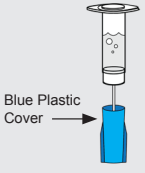


External Control Vial

Materials required but not provided

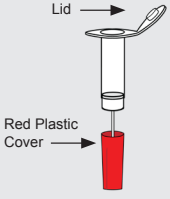


Pouch
BioFire® COVID-19 Test
Part No: 423744
423745

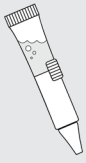


Hydration Injection Vial

Transfer Pipette



Sample Injection Vial



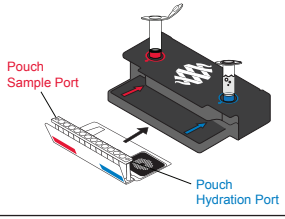
Sample Buffer Tube

Transport Medium, PBS or Saline

NOTE: FilmArray® 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

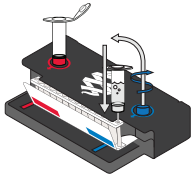
Refer to the *BioFire® COVID-19 Test Upper Respiratory Quick Guide STEP 1: Prepare Pouch*



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).

c. Add Sample Buffer to Positive External Control Vial

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

NOTE: Do not touch tube tip.

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

NOTE: Avoid generating excessive foam.

d. Recap Positive External Control Vial and invert it **3** times to mix.

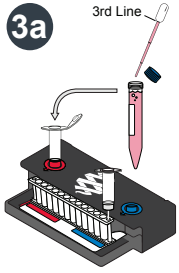
e. Pour mixture of Sample Buffer and Control into the Sample Injection Vial.

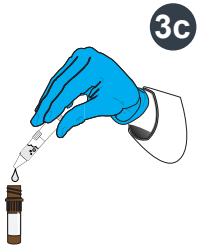
f. Dispose of Positive External Control Vial and change gloves.

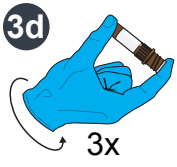
g. Tightly close lid of Sample Injection Vial and invert it **3** times, return it to the red well of Pouch Loading Station.

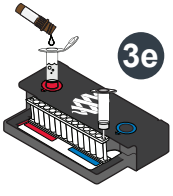
WARNING: Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.

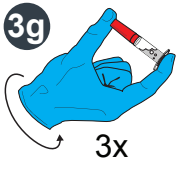
h. Proceed to *STEP 4: Load Control Mix*.



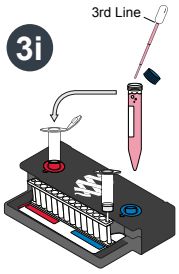








STEP 3b: Prepare COVID-19 Negative External Control



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

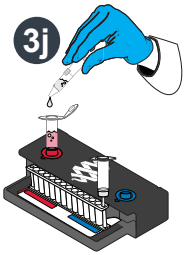
j. Add Sample Buffer to Sample Injection Vial.

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

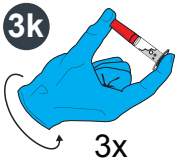
NOTE: Do not touch tube tip.

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

NOTE: Avoid generating excessive foam.



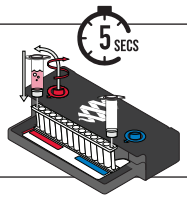
k. Tightly close lid of Sample Injection Vial and invert **3** times, return it to the red well of Pouch Loading Station.



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

l. Proceed to *STEP 4: Load Control Mix*.

STEP 4: Load Control Mix



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

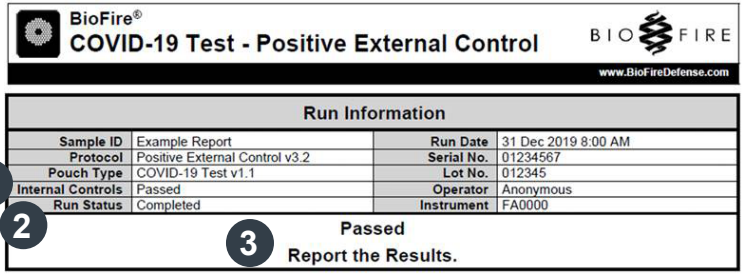
STEP 5: Run Pouch

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.

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*.

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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