BioFire® COVID-19 Test v1.1 Quick Guide
For use with FilmArray® 2.0 and FilmArray® Torch Systems

DO NOT DISCARD: Important product-specific information
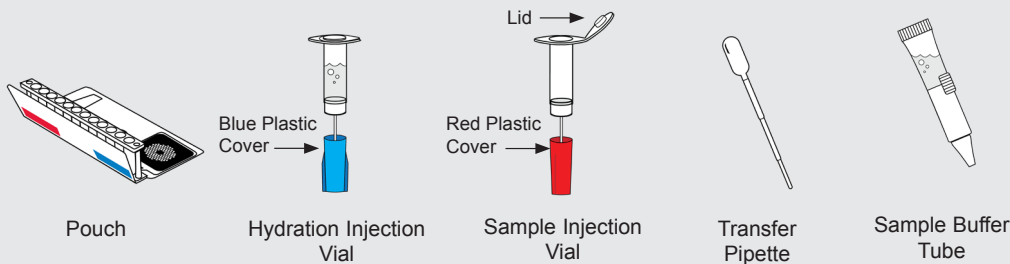
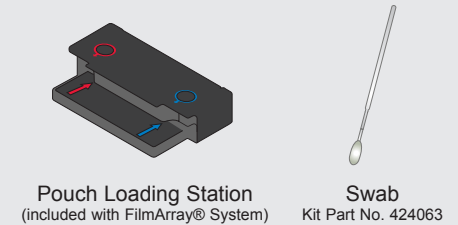*For in vitro diagnostic use under Emergency Use Authorization (EUA) only*

REF	423745 (6 pk) 423744 (30 pk)	IVD	R_X Only

Package Contents

Materials required but not provided

Pouch

Blue Plastic Cover → Hydration Injection Vial

Lid →
Red Plastic Cover → Sample Injection Vial

Transfer Pipette

Sample Buffer Tube
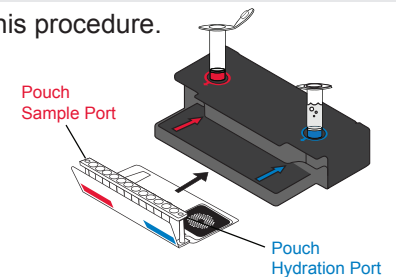
Pouch Loading Station
(included with FilmArray® System)

Swab
Kit Part No. 424063

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

Step 1: Prepare Pouch

a. Insert pouch into Pouch Loading Station.
b. Place Sample Injection Vial into red well.
c. Place Hydration Injection Vial into blue well.

Pouch Sample Port

Pouch Hydration Port

Step 2: Hydrate Pouch

a. Unscrew Hydration Injection Vial from cover.
b. Remove Hydration Injection Vial, leaving blue plastic cover in Pouch Loading Station.
c. Insert Hydration Injection Vial into pouch hydration port.
d. Push down to puncture seal and wait as Hydration Solution is drawn into the pouch.
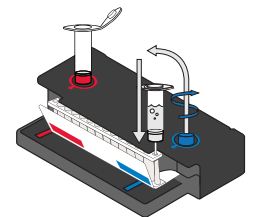
NOTE: Verify the pouch has been hydrated.

Step 3: Prepare Lower Respiratory Sample Mix

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

   NOTE: Do not touch tube tip.

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

   NOTE: Avoid generating excessive foam.

c. Use the Sample Swab to stir the entire specimen for **~10** seconds.

d. Place the swab end into the Sample Injection Vial then break off at the scored breakpoint. Discard the swab handle into an appropriate waste container and close Sample Injection Vial lid tightly.

e. Invert the Sample Injection Vial **3** times then return to red well of Pouch Loading Station.
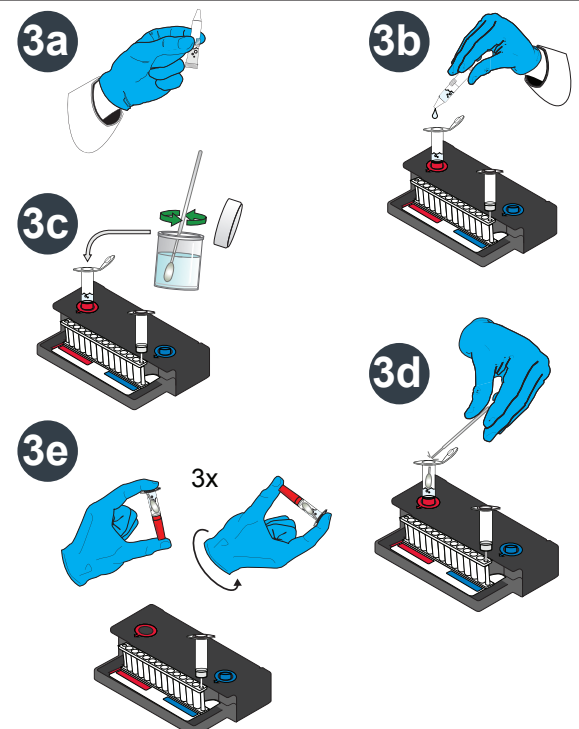
WARNING: Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.

3a **3b** **3c** **3d** **3e** 3x

BioFire® COVID-19 Test v1.1 Quick Guide
For use with FilmArray® 2.0 and FilmArray® Torch Systems

LOWER RESPIRATORY

Step 4: Load Lower Respiratory Sample Mix

**a.** Unscrew Sample Injection Vial from red plastic cover.
b. Wait for **5** seconds, then lift Sample Injection Vial, leaving red plastic cover in Pouch Loading Station.

NOTE: Waiting **5** seconds decreases the contamination risk.

c. Insert Sample Injection Vial into pouch sample port.
d. Push down to puncture seal and wait as Sample Mix is drawn into the pouch.

NOTE: Verify the sample has been loaded.
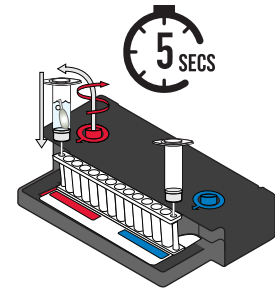
Step 5: Run Pouch

a. Discard the Sample Injection Vial and the Hydration Injection Vial in a biohazard sharps container.
b. Follow instructions on computer for starting a test.

Step 6: Review Results

Run Summary - Displays information about the sample and a summary of the Internal Controls and test results.

1 Internal Controls:
- If 'Passed', results are valid.
- If 'Failed' or 'Invalid', **RETEST SAMPLE** and refer to *Instructions for Use*.

Result Summary - Displays overall SARS-CoV-2 test result on the first line, followed by each individual assay result.

2
- If overall 'SARS-CoV-2' test result is 'Detected' or 'Not Detected', report the results.
- If 'Invalid', **RETEST SAMPLE** and refer to *Instructions for Use*.

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

3 Run Status:
- If 'Completed', run is complete.
- If 'Incomplete', 'Aborted', or any other error message, **RETEST SAMPLE** and refer to *Instructions for Use*.

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 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.

©2021 BioFire Defense, LLC. All Rights Reserved.

BioFire Defense, LLC | 79 West 4500 South, Suite 14, Salt Lake City, Utah 84107 USA | 801-262-3592 | www.BioFireDefense.com

2 of 2