



# 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

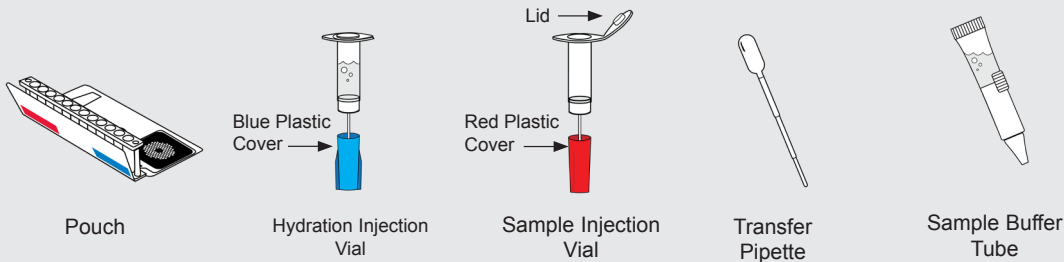
For in vitro diagnostic use under Emergency Use Authorization (EUA) only

**UPPER RESPIRATORY OR SALIVA**

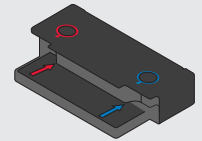
**REF** 423745 (6 pk)  
423744 (30 pk)

**IVD** Rx Only

## Package Contents



Materials required but not provided

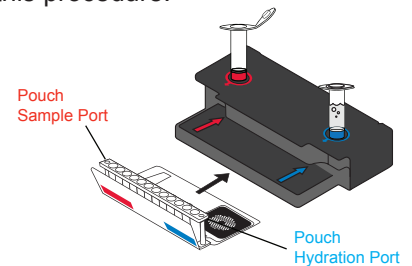


Pouch Loading Station  
(included with FilmArray® System)

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

## Step 1: Prepare Pouch

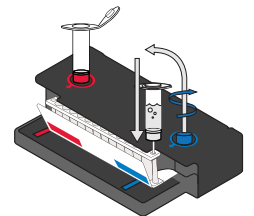
- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



## Step 2: Hydrate Pouch

- Unscrew **Hydration Injection Vial** from cover.
- Remove **Hydration Injection Vial**, leaving **blue plastic cover** in Pouch Loading Station.
- Insert **Hydration Injection Vial** into **pouch hydration port**.
- 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 Upper Respiratory Sample Mix

- Use the transfer pipette to draw specimen to the 3rd line. Add specimen to **Sample Injection Vial**.
- Hold Sample Buffer Tube tip facing up and firmly pinch at textured plastic tab on side of tube until seal snaps.

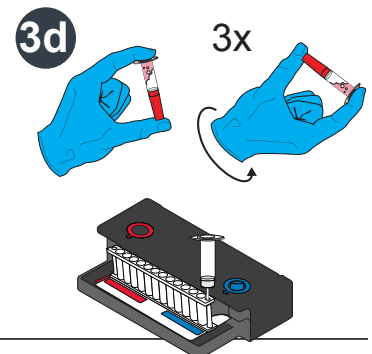
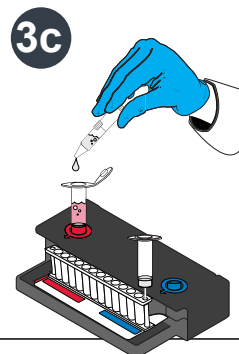
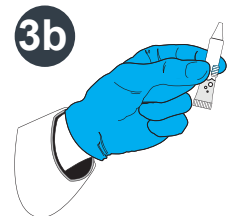
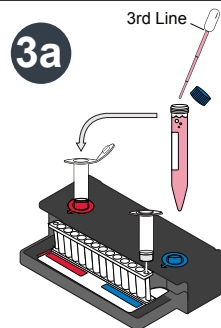
**NOTE:** Do not touch tube tip.

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

**NOTE:** Avoid generating excessive foam.

- Tightly close the lid on the **Sample Injection Vial**, invert it 3 times, and 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.



## UPPER RESPIRATORY OR SALIVA

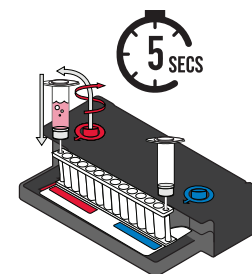
### Step 4: Load Upper Respiratory Sample Mix

- Unscrew **Sample Injection Vial** from **red plastic cover**.
- 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.

- Insert **Sample Injection Vial** into **pouch sample port**.
- 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

- Discard the **Sample Injection Vial** and the **Hydration Injection Vial** in a biohazard sharps container.
- 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*.



BioFire®

COVID-19 Test v1.1

BIO FIRE

www.BioFireDefense.com

Run Summary

Sample ID: Example Report

Detected: None

Run Date: 31 Dec 2019 8:00 AM

Internal Controls: Passed

Result Summary

Viruses

Not Detected SARS-CoV-2

Not Detected SARS-CoV-2a

Not Detected SARS-CoV-2c

Not Detected SARS-CoV-2d

Not Detected SARS-CoV-2e

Not Detected SARS-CoV-2f

Not Detected SARS-CoV-2g

Not Detected SARS-CoV-2h

Run Details

Pouch: COVID-19 Test v1.1

Run Status: Completed

Serial No.: 01234567

Lot No.: 012345

Protocol: Sample v3.2

Operator: Anonymous

Instrument: FA0000

#### 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.