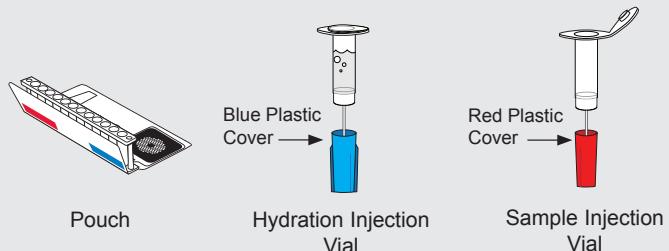




DO NOT DISCARD: Important product-specific information

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

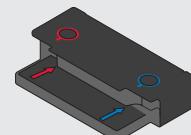
Package Contents



REF 423745 (6 pk)
423744 (30 pk)

IVD Rx Only

Materials required but not provided



Pouch Loading Station
(included with instrument)

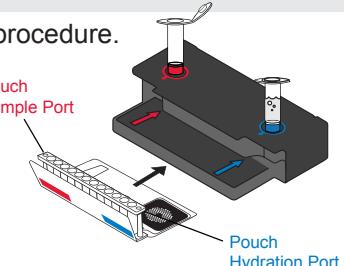


Swab
Kit Part No. 424063

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

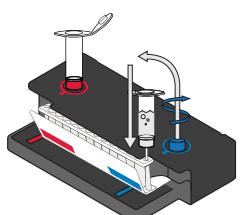
Step 1: Prepare Pouch

- 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.



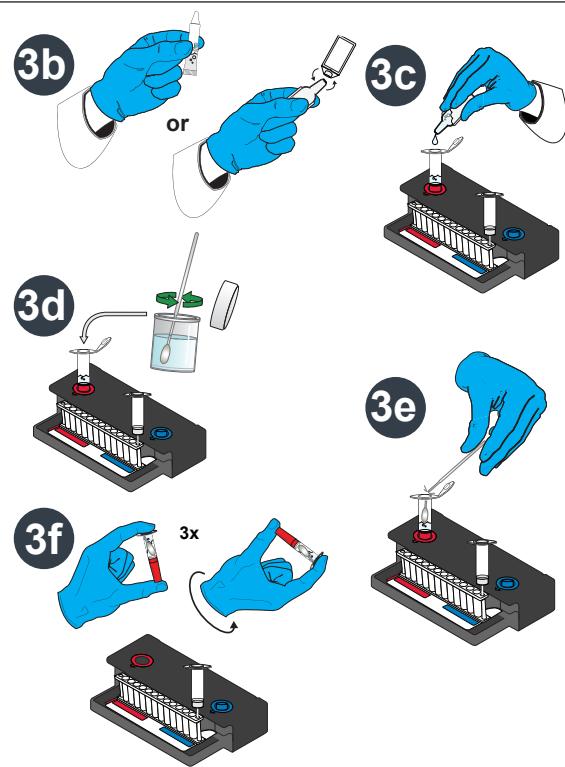
NOTE: Verify the pouch has been hydrated.

Step 3: Prepare Lower Respiratory Sample Mix

Add Sample Buffer

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

- Hold the Sample Buffer Ampoule with the tip facing up.
- NOTE:** Do not touch the tip of the ampoule.
- 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.
- Dispense Sample Buffer into **Sample Injection Vial** using a slow, forceful squeeze followed by a second squeeze.
- NOTE:** Avoid generating excessive foam.
- Use the Sample Swab to stir the entire specimen for ~10 seconds.
- 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.
- Invert the Sample Injection Vial 3 times then return to **red well** of Pouch Loading Station.



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



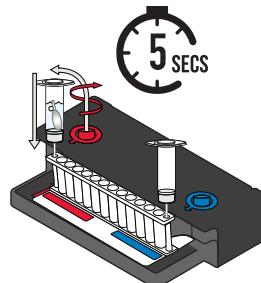


Step 4: Load Lower Respiratory Sample Mix

- 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.

LOWER RESPIRATORY



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		BIOFIRE
Run Summary		
Sample ID:	Example Report	Run Date: 31 Dec 2019 8:00 AM
Detected:	None	Internal Controls: Passed
Result Summary		
Viruses		
Not Detected	SARS-CoV-2	1
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	Protocol:
Run Status:	Completed	Operator:
Serial No.:	01234567	Instrument:
Lot No.:	012345	

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.