Manuals+ — User Manuals Simplified.

BIOFIRE 423745 Pouch Loading Station with FilmArray System User Guide

Contents

BIOFIRE 423745 Pouch Loading Station with FilmArray System

Intended Use

The BioFire® COVID-19 Test is a nested multiplexed real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs in transport media from individuals suspected of COVID-19 by their healthcare provider. Please see **www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd** for the Instructions for Use.

Storage Instructions

Store at 15 – 30ºC. Refer to the BioFire® COVID-19 Test Instructions for Use before opening and preparing pouch for use.

Procedure / Interpretation / Limitations

Users should refer to the BioFire® COVID-19 Test Instructions for Use available on the BioFire Defense Website: **www.biofiredefense.com/covid-19test**

Questions / Support

If you have questions or need additional support, please contact BioFire Defense Technical Support at **support@biofiredefense.com**

Package Contents

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

Step 1: Prepare Pouch

1. Insert pouch into Pouch Loading Station.
2. Place Sample Injection Vial into red well.
3. Place Hydration Injection Vial into blue well.
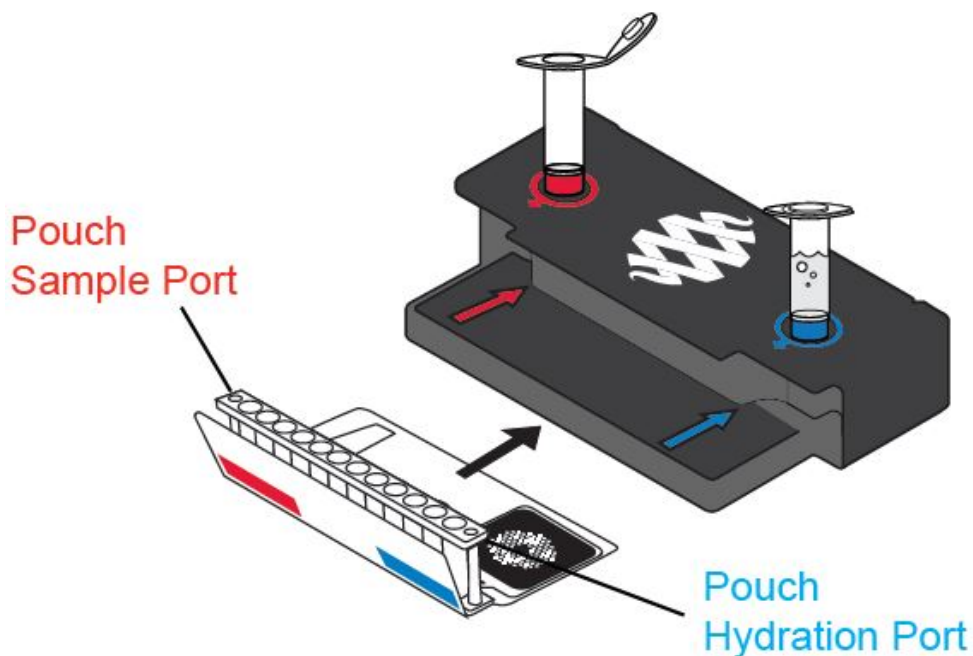
Step 2: Hydrate Pouch

1. Unscrew Hydration Injection Vial from cover.
2. Remove Hydration Injection Vial, leaving blue plastic cover in Pouch Loading Station.
3. Insert Hydration Injection Vial into pouch hydration port.
4. Push down to puncture seal and wait as Hydration Solution is drawn into the pouch.

Pouch Sample Port

Pouch Hydration Port
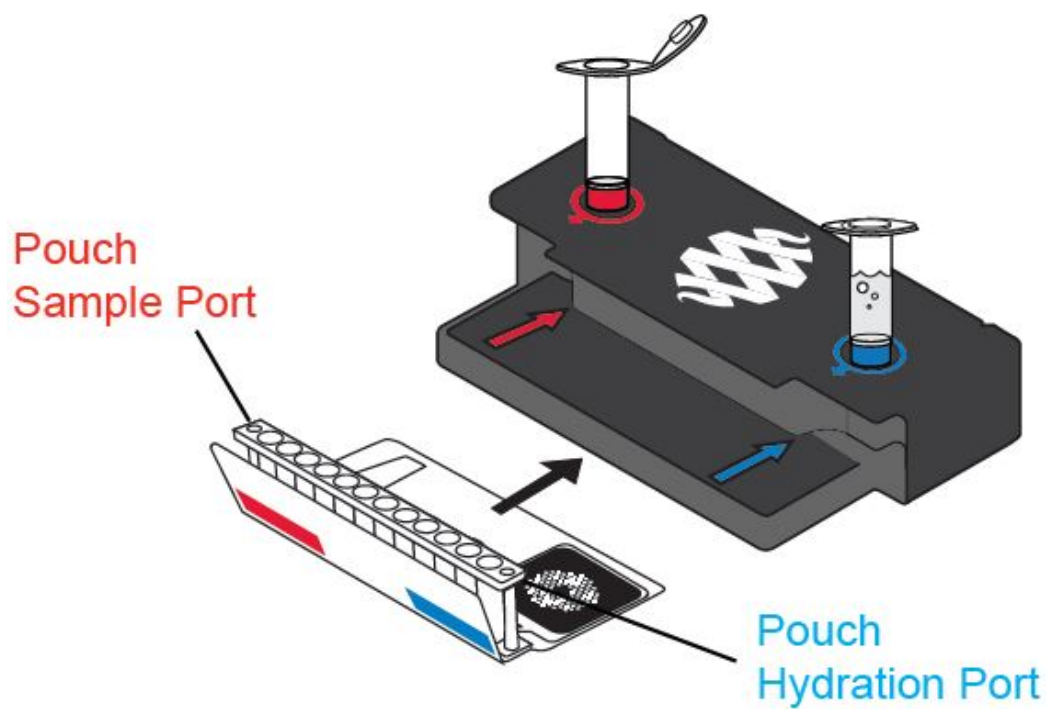
NOTE: Verify the pouch has been hydrated.

Step 3: Prepare Sample Mix

1. Use the transfer pipette to draw specimen in transport media to the 3rd line. Add specimen to Sample Injection Vial.
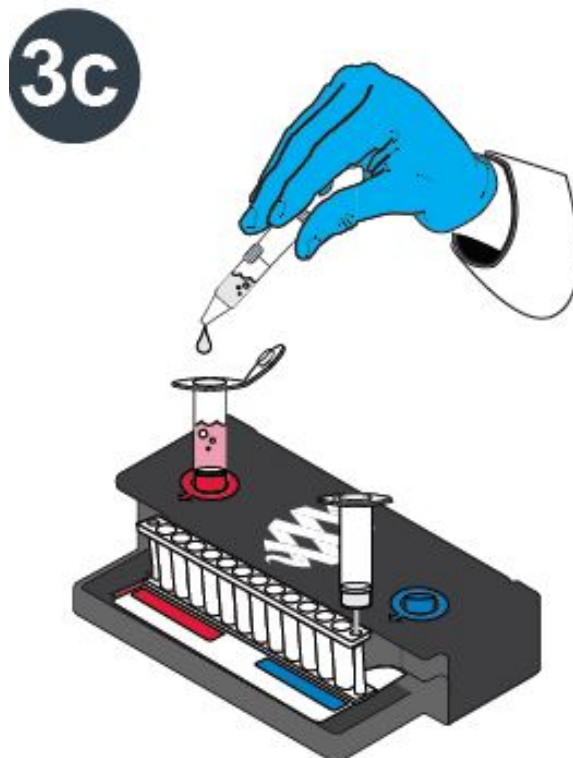

3a

3rd Line
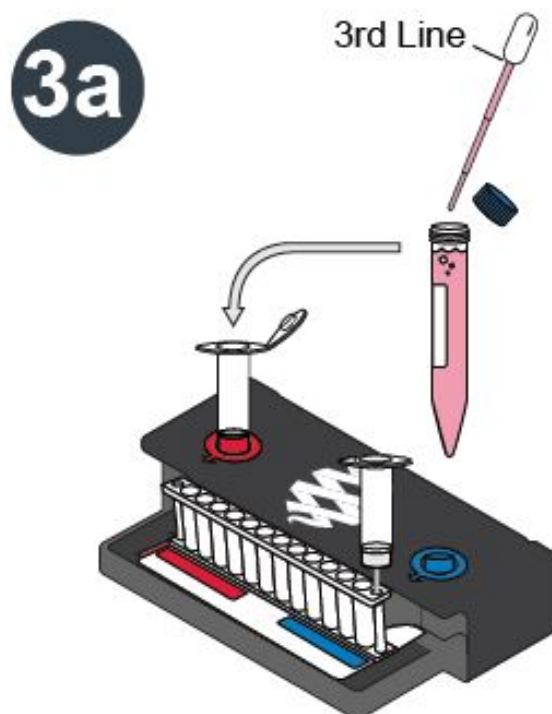
2. Hold Sample Buffer Tube tip facing up and firmly pinch at textured plastic tab on side of tube until seal snaps.
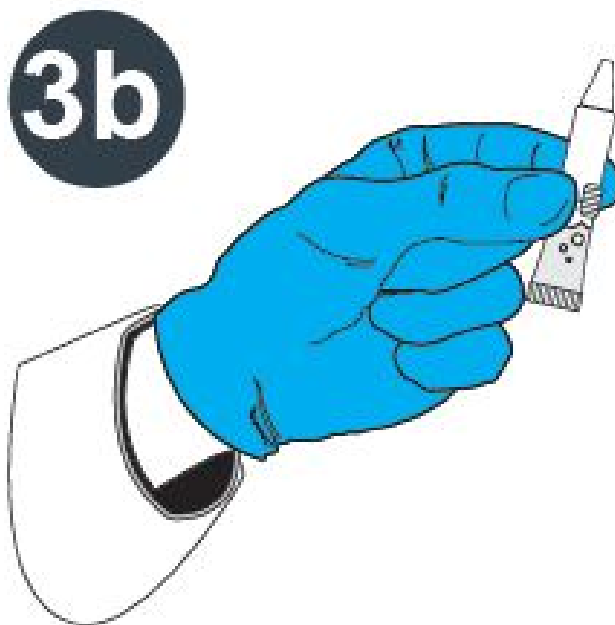
NOTE: Do not touch tube tip.

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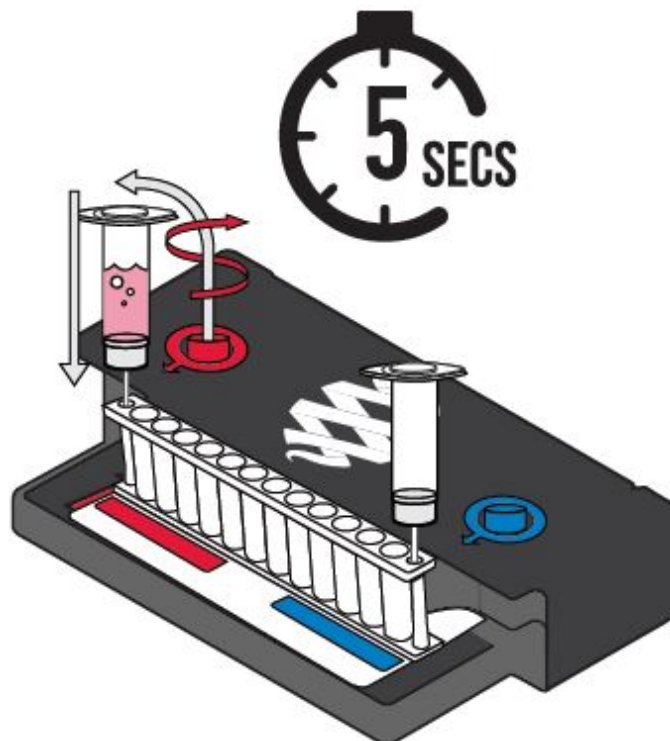

NOTE: Avoid generating excessive foam.

4. Tightly close the lid on the Sample Injection Vial and invert it 3 times, return it to the red well of Pouch Loading Station.
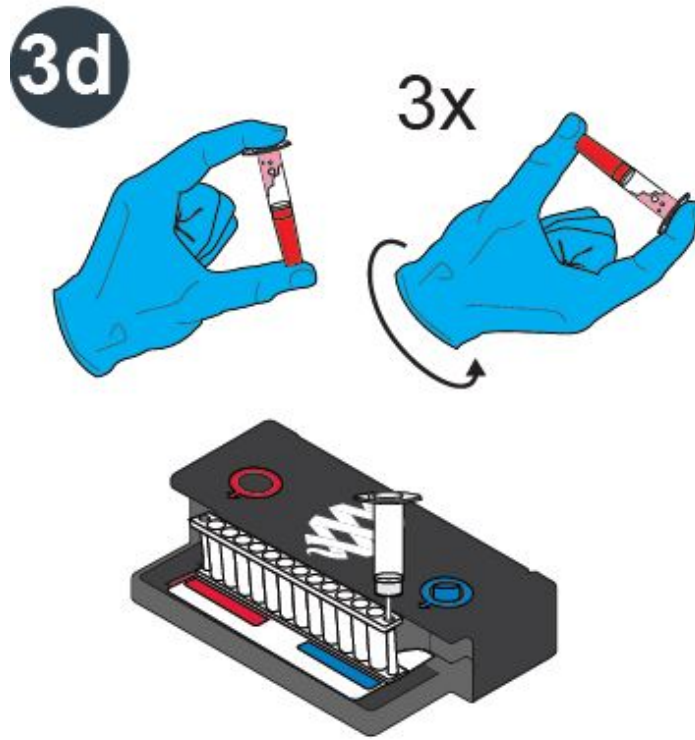
Step 4: Load Sample Mix

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

    NOTE: Waiting five seconds decreases the contamination risk.

3. Insert Sample Injection Vial into pouch sample port.
4. 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

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

Review Results

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

Internal Controls:

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

Figure 1. 'DETECTED' Report

Test Interpretation:

- If 'Detected', or 'Not Detected', report the results.(Figure 1)

- If 'Equivocal', RETEST SAMPLE and refer to Instructions for Use. (Figure 2)

Figure 2. 'EQUIVOCAL' Report

Result Summary – Displays test interpretation (Top Line) with detailed assay results.
Run Details – Displays information about the pouch, protocol, run status, operator, serial number, instrument, and lot number.

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 a 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 the 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

Documents / Resources

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