Step 6: 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.

Test Interpretation:
- If ‘Detected’, or ‘Not Detected’, report the results. (Figure 1)
- If ‘Equivocal’, RETEST SAMPLE and refer to Instructions for Use. (Figure 2)

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.

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-19-test

Questions / Support

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

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 Sample Mix
a. Use the transfer pipette to draw specimen in transport media to the 3rd line. Add specimen to Sample Injection Vial.
b. Hold Sample Buffer Tube tip facing up and firmly pinch at textured plastic tab on side of tube until seal snaps.
c. Dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze followed by a second squeeze.
d. Tightly close the lid on the Sample Injection Vial and invert it 3 times, return it to the red well of Pouch Loading Station.

NOTE: Do not touch tube tip.

NOTE: Avoid generating excessive foam.

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

Step 4: Load 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.
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: Waiting five seconds decreases the contamination risk.

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.