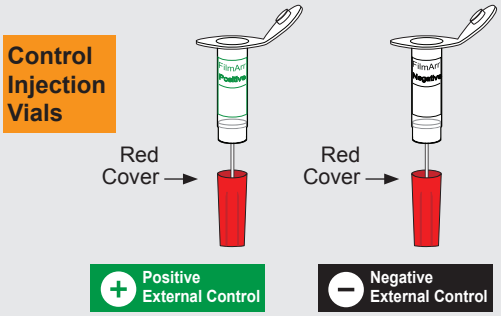
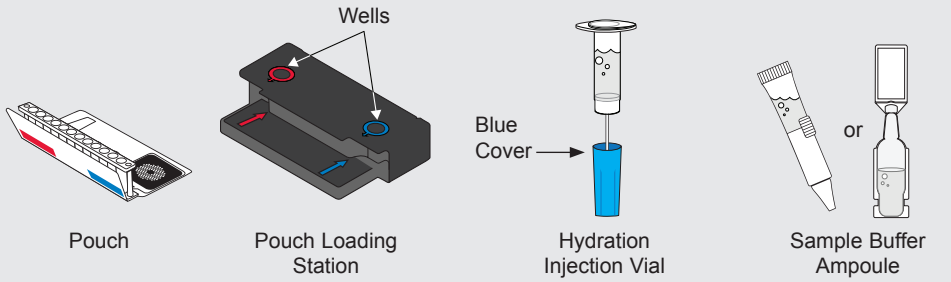
BIOFIRE® SHIELD™ Control Kit

for the BioFire® Global Fever Panel - Quick Guide

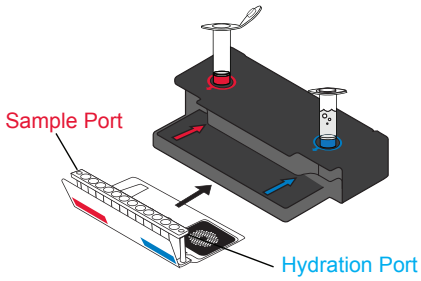
For In Vitro Diagnostic Use.
NOTE: For use with BioFire Global Fever Panel (DFA2-ASY-0004) and should not be used with any other kit.

REF DFA2-ASY-0006 IVD
CONTROL Rx Only





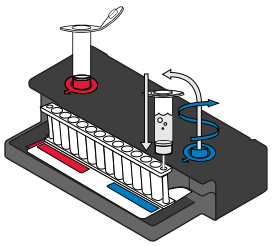
To avoid contamination, always wear clean gloves and work behind a protective shield.



Step 1: Prepare Pouch

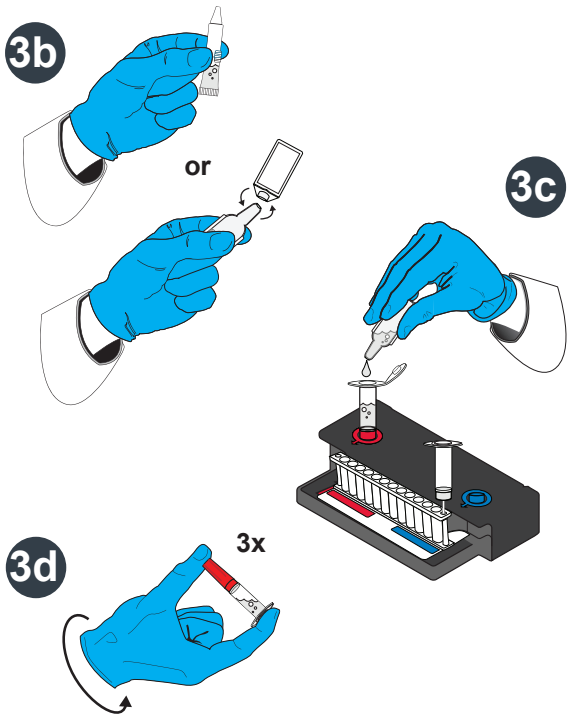
a. Insert pouch into Pouch Loading Station.
b. Place Sample Injection Vial into red well.
c. Place Hydration Injection Vial into blue well.

Step 2: Hydrate Pouch



a. Unscrew Hydration Injection Vial from cover.
b. Remove Hydration Injection Vial, leaving blue cover in Pouch Loading Station.
c. Insert Hydration Injection Vial into 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 External Control

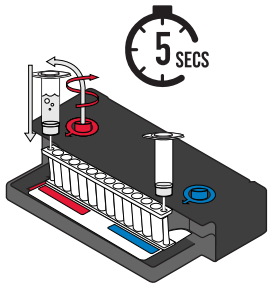


Add Sample Buffer (**NOTE:** There are 2 possible designs of the Sample Buffer Ampoule)

a. Hold the Sample Buffer Ampoule with the tip facing up.
NOTE: *Do not touch the tip of the ampoule.*
b. 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.
c. Dispense Sample Buffer into Control Injection Vial using a slow, forceful squeeze, followed by a **2nd** squeeze.
NOTE: *Avoid generating excessive foam.*
d. Tightly close lid and invert the Control Injection Vial **3** times.
e. Return Control Injection Vial to red well of Pouch Loading Station.

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

Step 4: Load External Control



a. Unscrew Control Injection Vial from red cover.

b. Wait for **5** seconds, then remove Control Injection Vial, leaving red cover in Pouch Loading Station.

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

c. Insert Control Injection Vial into pouch sample port.

d. Push down to puncture seal, then wait as control material is drawn into the pouch.

Step 5: Run Pouch

a. Screw vials back into covers in Pouch Loading Station before disposing of them in a biohazard container.

b. Remove pouch from Pouch Loading Station and load into the instrument.

c. Follow instructions on screen for starting a test.

NOTE: *Select either **Positive External Control** or **Negative External Control** protocol.*

Step 6: Review Report

Run Information - Displays information about the sample, protocol, pouch, instrument, run status, results, and recommended action.

1 Internal Controls:

- If 'Passed', results are valid.
- If 'Failed' or 'Invalid', **RETEST EXTERNAL CONTROL** once.

2 Run Status:

- If 'Completed', run is complete.
- If 'Incomplete', 'Aborted', or any other error message, **RETEST EXTERNAL CONTROL** once.

3 External Control Results:

- If 'Passed', report the results.
- If 'Failed':
  - Positive External Control: **RETEST EXTERNAL CONTROL** once.
  - Negative External Control: Decontaminate the area and **RETEST EXTERNAL CONTROL** once.
- If 'Invalid', **RETEST EXTERNAL CONTROL** once.

BIOFIRE® SHIELD™
GF Panel - Positive External Control
BIOFIRE
www.BioFireDefense.com

Run Information

Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	Positive External Control v3.1	Serial No.	01234567
Pouch Type	GF Panel - IVD v2.1	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0000

1 2 3 **Passed**
Report the Results.

NOTE: Refer to the *BIOFIRE SHIELD Control Kit for the BioFire Global Fever Panel Instructions for Use* for panel specific run reports and additional information. If repeated error messages are obtained, contact *BioFire Defense Technical Support*.

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