



# BIOFIRE<sup>®</sup> SHIELD<sup>™</sup> Control Kit

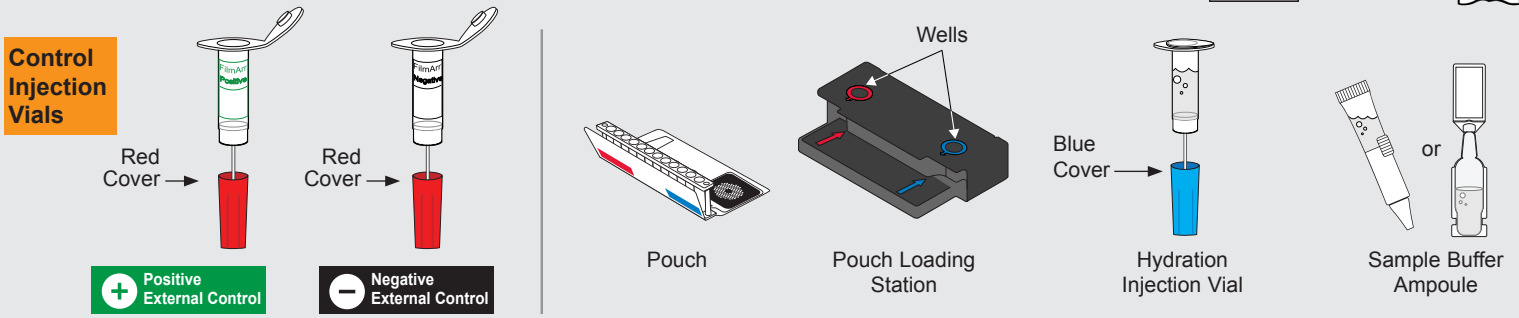
for the BioFire<sup>®</sup> Global Fever Panel - Quick Guide



## 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.

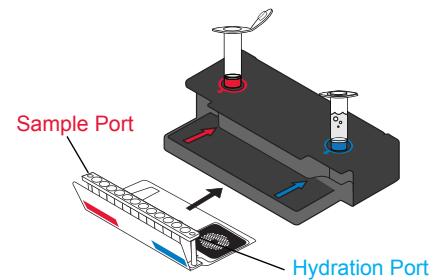
REF DFA2-ASY-0006 IVD  
CONTROL R<sub>x</sub> Only



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

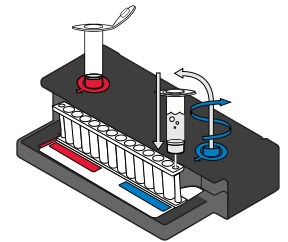
### Step 1: Prepare Pouch

- 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 cover** in Pouch Loading Station.
- Insert **Hydration Injection Vial** into **hydration port**.
- Push down to puncture seal and wait as **Hydration Solution** is drawn into the pouch.

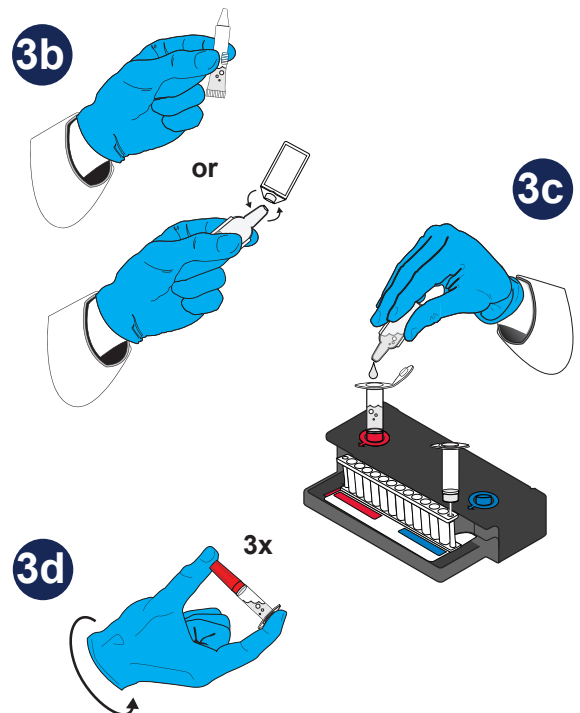


**NOTE:** Verify the pouch has been hydrated.

### Step 3: Prepare External Control

**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 Control Injection Vial using a slow, forceful squeeze, followed by a 2<sup>nd</sup> squeeze.  
**NOTE:** Avoid generating excessive foam.
- Tightly close lid and invert the Control Injection Vial 3 times.
- Return Control Injection Vial to **red well** of Pouch Loading Station.



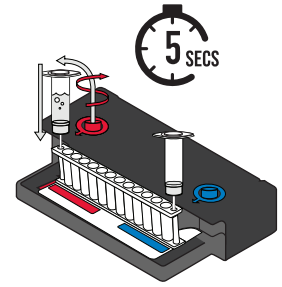
**WARNING:** Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.





## Step 4: Load External Control

- Unscrew Control Injection Vial from **red cover**.
- Wait for **5 seconds**, then remove Control Injection Vial, leaving **red cover** in Pouch Loading Station.  
**NOTE: Waiting 5 seconds decreases the contamination risk.**
- Insert Control Injection Vial into **pouch sample port**.
- Push down to puncture seal, then wait as control material is drawn into the pouch.



## Step 5: Run Pouch

- Screw vials back into covers in Pouch Loading Station before disposing of them in a biohazard container.
- Remove pouch from Pouch Loading Station and load into the instrument.
- 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.

- Internal Controls:**
  - If 'Passed', results are valid.
  - If 'Failed' or 'Invalid', **RETEST EXTERNAL CONTROL** once.
- Run Status:**
  - If 'Completed', run is complete.
  - If 'Incomplete', 'Aborted', or any other error message, **RETEST EXTERNAL CONTROL** once.
- 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		BIO FIRE	
<a href="http://www.BioFireDefense.com">www.BioFireDefense.com</a>			
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
<b>1</b>		<b>3</b>	
<b>Passed</b>			
<b>Report the Results.</b>			

**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*.

