



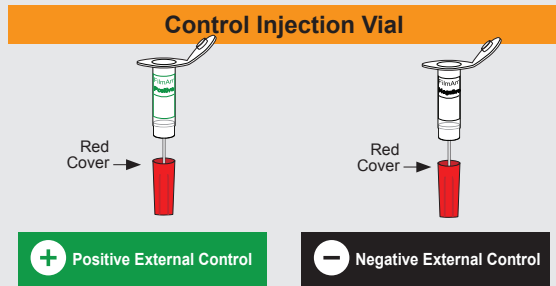
# BIOFIRE® SHIELD™ Control Kit for the BioFire® Global Fever Special Pathogens Panel - Quick Guide



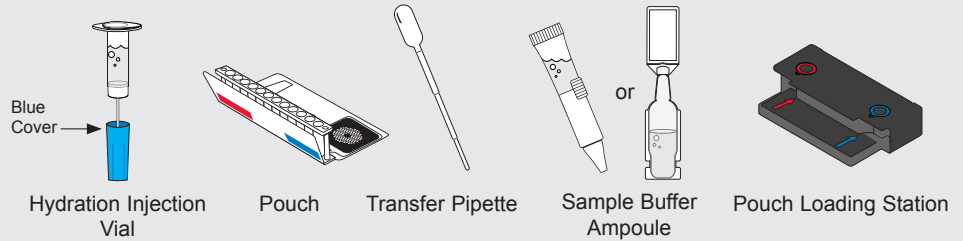
## For In Vitro Diagnostic Use

NOTE: For use with BioFire Global Fever Special Pathogens Panel (DFA2-ASY-0018) and should not be used with any other kit.

REF DFA2-ASY-0019 IVD  
Rx Only  
CONTROL



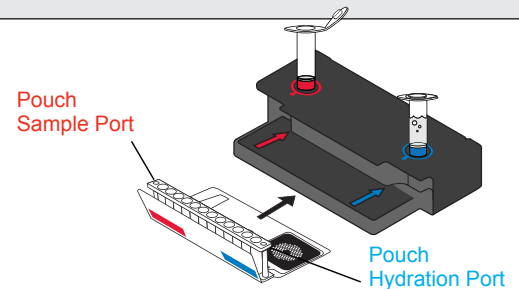
## Materials required but not provided in control kit.



To avoid contamination, clean work area and always wear gloves.

## Step 1: Prepare Pouch

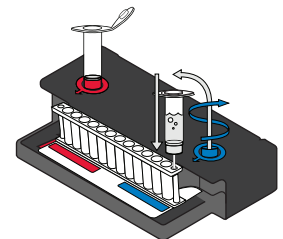
- Insert pouch into Pouch Loading Station.
- Place Positive or Negative Control Injection Vial into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



## 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.

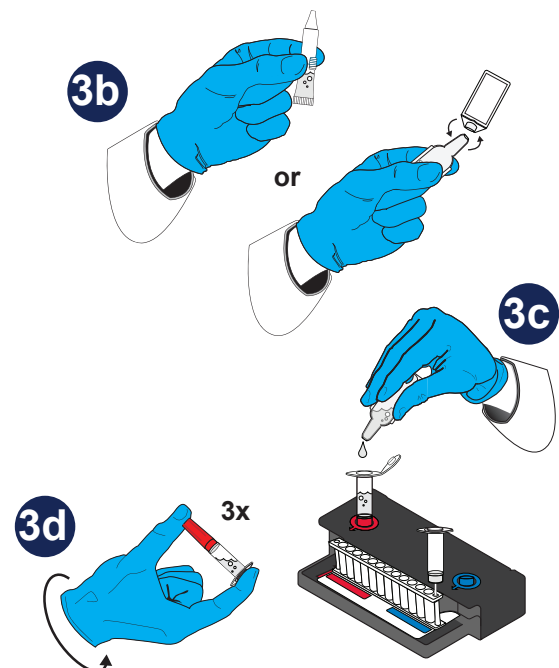
NOTE: Verify the pouch has been hydrated.



## 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.



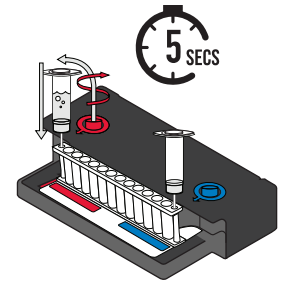
**WARNING:** Contact with sample buffer can cause serious eye damage and skin irritation and is harmful if swallowed.





## 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™ Positive External Control GF Special Pathogens Panel			BIO F I R E
			www.BioFireDefense.com
Run Information			
Sample ID	JW43822	Run Date	07 Apr 2023 12:00 AM
Protocol	Positive External Control v3.1	Serial No.	01234567
Pouch Type	GF SP Panel v1.0	Lot No.	012345
Internal Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0001
<b>Passed</b>			
<b>Report the Results</b>			
Result Summary			
Detected		Not Detected	
<i>Bacillus anthracis</i> <i>Chikungunya virus</i> <i>Crimean-Congo hemorrhagic fever virus</i> <i>Dengue virus</i> <i>Ebolavirus</i> <i>Francisella tularensis</i> <i>Lassa virus</i> <i>Leishmania spp.</i> <i>Leptospira spp.</i> <i>Marburgvirus</i> <i>Plasmodium spp.</i> <i>Plasmodium falciparum</i> <i>Plasmodium vivax/ovale</i> <i>West Nile virus</i> <i>Yellow fever virus</i> <i>Yersinia pestis</i>			

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

