

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

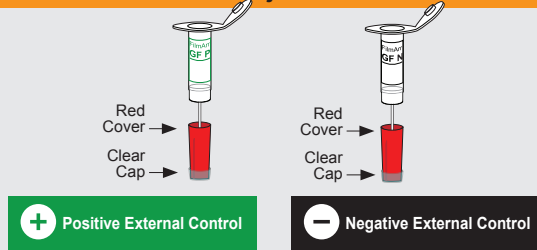


For In Vitro Diagnostic Use.

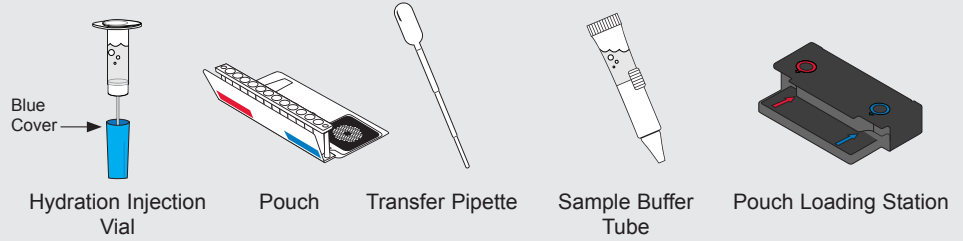
NOTE: For use with BioFire Global Fever Special Pathogens Panel (DFA2-ASY-0018) and should not be used with any other kit.

REF DFA2-ASY-0019 **IVD**
Rx Only
CONTROL

Control Injection Vial



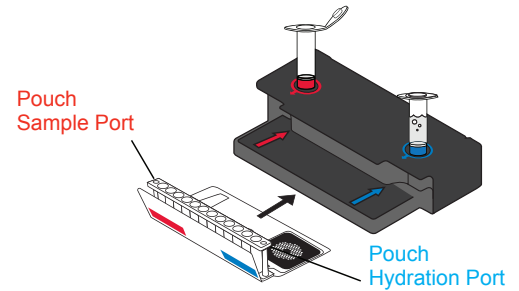
Materials required but not provided in control kit.



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

Step 1: Prepare Pouch

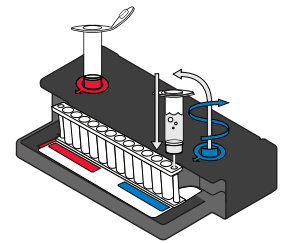
- Insert pouch into Pouch Loading Station.
- Remove clear cap from either Positive or Negative Control Injection Vial and place into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



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.

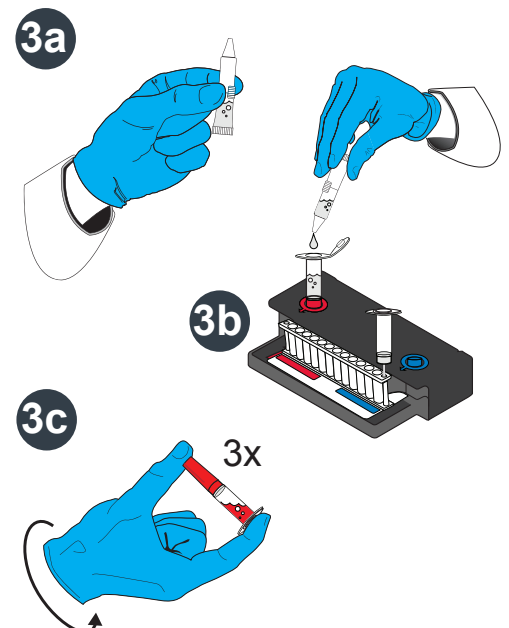
NOTE: Verify the pouch has been hydrated.



Step 3: Prepare Sample Mix

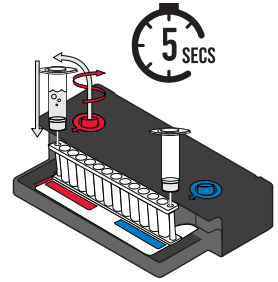
- Hold the Sample Buffer Tube with the tip facing up and firmly pinch at textured plastic tab on side of tube until the seal snaps.
NOTE: Do not touch the tip of the tube.
- Dispense Sample Buffer into Control Injection Vial using a slow, forceful squeeze, followed by a **2nd** squeeze.
NOTE: Avoid generating 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 Sample Mix

- 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.

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™ Positive External Control

GF Special Pathogens Panel

BIOFIRE

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
Initial Controls	Passed	Operator	Anonymous
Run Status	Completed	Instrument	FA0001
Passed			
Report the Results			
Result Summary			
Detected		Not Detected	
Bacillus anthracis			
Chikungunya virus			
Crimean-Congo hemorrhagic fever virus			
Dengue virus			
Ebola virus			
Francisella tularensis			
Lassa virus			
Leishmania spp.			
Leptospira spp.			
Marburg virus			
Plasmodium spp.			
Plasmodium falciparum			
Plasmodium vivax/ovale			
West Nile virus			
Yellow fever virus			
Yersinia pestis			

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.