

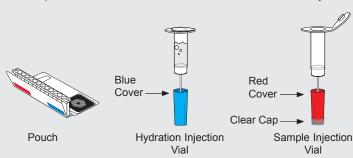
# BioFire® Global Fever Special Pathogens Panel Quick Guide

For use with BioFire® FilmArray® Systems



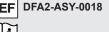
#### For In Vitro Diagnostic Use

NOTE: Components from this kit should not be stored or used with any other kit.



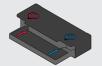








Materials required but not provided

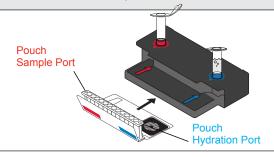


Pouch Loading Station (Included with Instrument)

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

# Step 1: Prepare Pouch

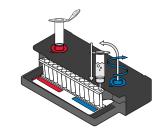
- a. Insert pouch into Pouch Loading Station.
- b. Remove clear cap from Sample Injection Vial and place into red well.
- c. Place Hydration Injection Vial into blue well.



### 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 Sample Mix

**NOTE:** Gently invert whole blood sample container until thoroughly mixed.

- **a.** Use the Transfer Pipette to draw sample to the **2**<sup>nd</sup> line. Add the sample to Sample Injection Vial.
- **b.** 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.

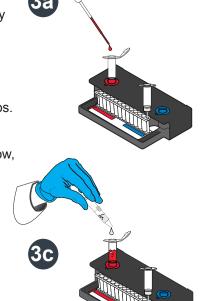
**NOTE:** Do not touch the tip of the tube.

**c.** Dispense Sample Buffer into Sample Injection Vial using a slow, forceful squeeze, followed by a **2**<sup>nd</sup> squeeze.

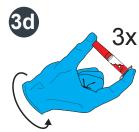
**NOTE:** Avoid generating excessive foam.

- d. Tightly close lid and invert the Sample Injection Vial 3 times.
- e. Return Sample 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.







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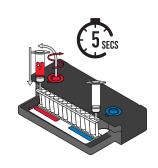
## Step 4: Load Sample Mix

- a. Unscrew Sample Injection Vial from red cover.
- **b.** Wait for **5** seconds, then remove Sample Injection Vial, leaving red cover in Pouch Loading Station.

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

- c. Insert Sample Injection Vial into pouch sample port.
- **d.** Push down to puncture seal, then wait as sample mix is drawn into the pouch.

**NOTE:** Verify the sample has been loaded.



### 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.

**Optional added operator protection:** Before removal from Pouch Loading Station, run a bleach wipe, a paper towel with 10% bleach (one part bleach to nine parts water), across the top of the pouch from the pouch hydration port to the pouch sample port and follow with a water wipe. This reduces the potential for contact with small amounts of sample mixed with sample buffer that may be retained in the pouch sample port.

**c.** Follow instructions on computer for starting a test.

NOTE: Select the GF Blood protocol.

## Step 6: Review Report

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

- 1 Internal Controls:
  - If 'Passed', results are valid.
  - · If 'Failed' or 'Invalid', RETEST SAMPLE.
- 2 Run Status:
  - If 'Completed', run is complete.
  - If 'Incomplete', 'Aborted', or any other error message, RETEST SAMPLE.
- Results Banner: Displays the test results.
  - Follow the instructions listed in the banner.

**Result Summary** - Displays the test results for each organism.

- 4 'Detected': Lists names of any detected organisms.
- 5 'Not Detected': Lists names of organisms that were not detected.

**NOTE:** Refer to the *BioFire Global Fever Special Pathogens Panel Instructions for Use* for reporting information. If repeated error messages are obtained, contact *BioFire Defense Technical Support*.

