



BioFire® Global Fever Panel Quick Guide

For use with BioFire® FilmArray® 2.0 and BioFire® Torch® Systems

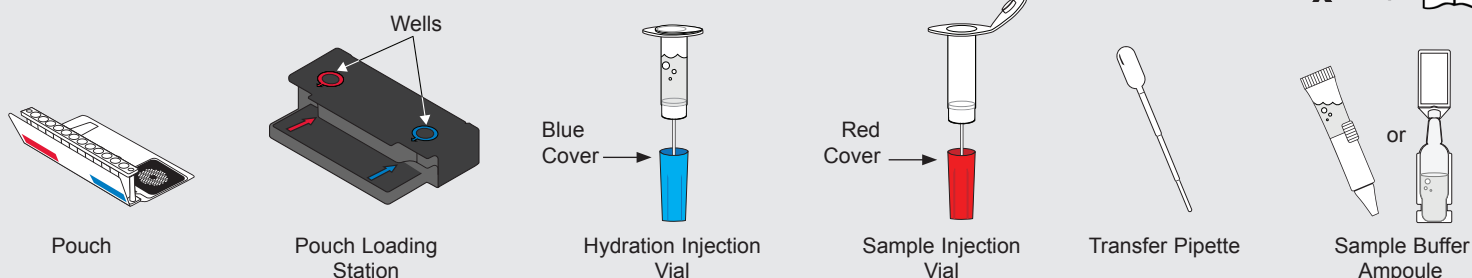


For In Vitro Diagnostic Use.

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

REF DFA2-ASY-0004 IVD

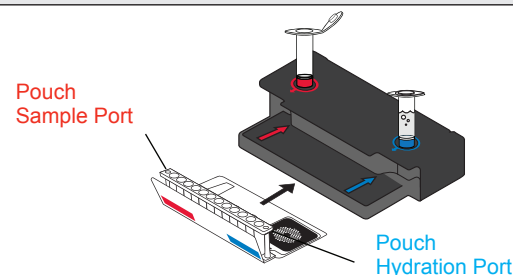
Rx Only



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

Step 1: Prepare Pouch

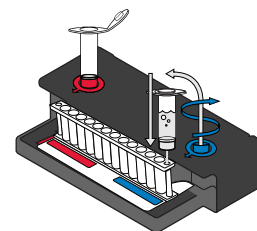
- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



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 Sample Mix

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

- Use the Transfer Pipette to draw sample to the **2nd** line. Add the sample to **Sample Injection Vial**.

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

- Hold the Sample Buffer Ampoule with the tip facing up.

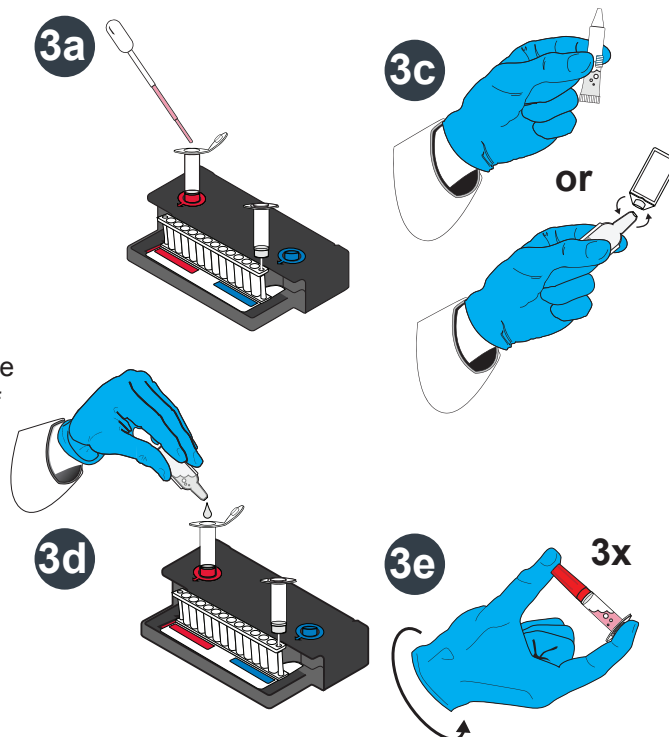
NOTE: Do not touch the tip of the ampoule.

- 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 **Sample Injection Vial** using a slow, forceful squeeze, followed by a **2nd** squeeze.

NOTE: Avoid generating excessive foam.

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





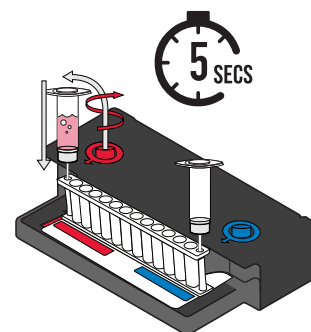
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Step 4: Load Sample Mix

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

Optional added operator protection: Before removal from biosafety cabinet, 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 at the sample injection port.

- Follow instructions on screen for starting a test.

NOTE: Select the **GF Blood** protocol.

Step 6: Review Report


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

Internal Controls:

- If 'Passed', results are valid.
- If 'Failed' or 'Invalid', **RETEST SAMPLE**.


Run Status:

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



BioFire®

GF Panel - IVD v2.1



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Run Information

Sample ID	test pouch	Run Date	12 Mar 2021 12:00 AM
Protocol	GF Blood 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

2

Negative

3

Report the Results

Result Summary

Detected	Not Detected
	Chikungunya virus
	Dengue virus
	Leptospira spp.
	Plasmodium spp.
	Plasmodium falciparum
	Plasmodium vivax/ovale

- Results Banner:** Displays the test results.

- Follow the instructions listed in the banner.

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

'Detected': Lists names of any detected organisms.

'Not Detected': Lists names of organisms that were not detected.

NOTE: Refer to the *BioFire Global Fever Panel Instructions for Use* for reporting information.

If repeated error messages are obtained, contact *BioFire Defense Technical Support*.