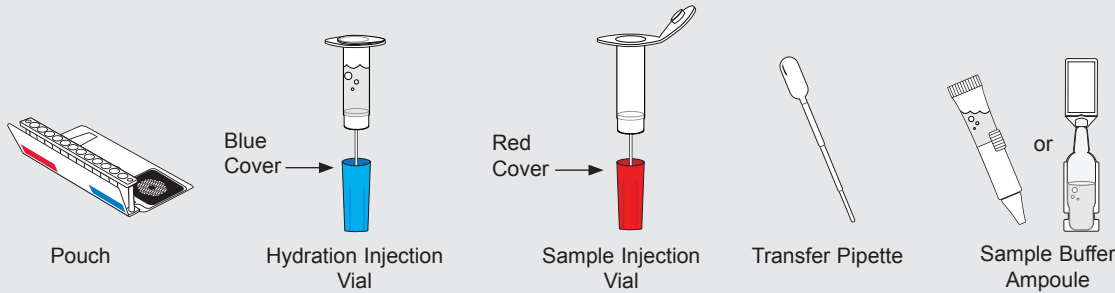


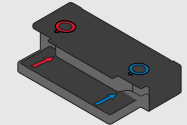
For In Vitro Diagnostic Use

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

REF DFA2-ASY-0018 **IVD**
Rx Only



Materials required
but not provided

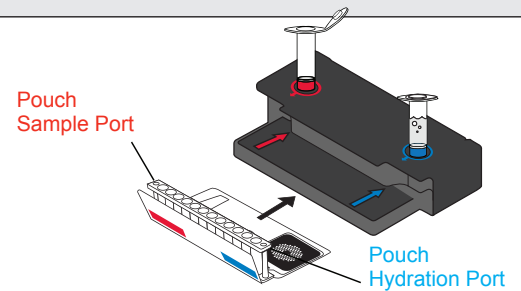


Pouch Loading Station
(Included with Instrument)

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

Step 1: Prepare Pouch

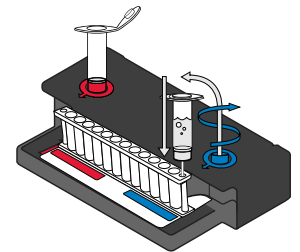
- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



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.



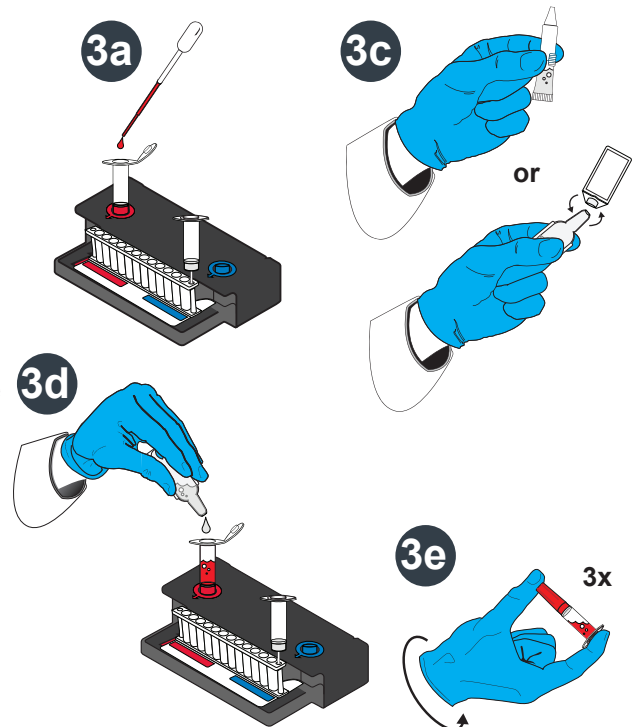
Step 3: Prepare Sample Mix

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.

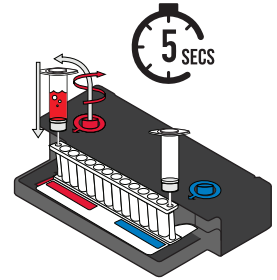


WARNING: Contact with sample buffer can cause serious eye damage and skin irritation and is harmful if swallowed.



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



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 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**.

- 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.

- 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**.
- 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 Special Pathogens Panel Instructions for Use* for reporting information. If repeated error messages are obtained, contact *BioFire Defense Technical Support*.



BioFire® Global Fever

Special Pathogens Panel

BIO FIRE

www.BioFireDefense.com

Run Information

Sample ID	JW43822	Run Date	07 Apr 2023 12:00 AM
Protocol	GF Blood 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

2

3

Plasmodium Detected

Note: See Instructions for Use for additional information on Plasmodium results

4

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Report the Results

Result Summary

Detected	Not Detected
<i>Plasmodium</i> spp.	Chikungunya virus Crimean-Congo hemorrhagic fever virus Dengue virus Ebola virus Lassa virus Marburgvirus West Nile virus Yellow fever virus Bacillus anthracis Francisella tularensis Leptospira spp. Yersinia pestis Leishmania spp. Plasmodium falciparum Plasmodium vivax/ovale