

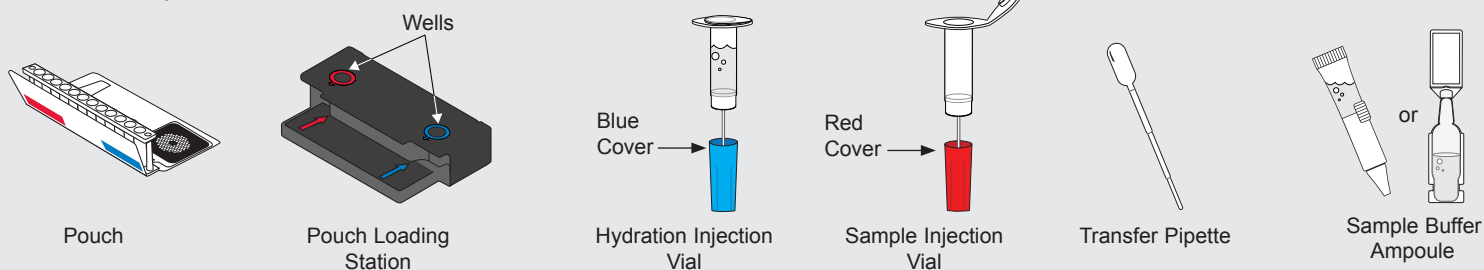


For Research Use Only. Not For Diagnostic Use.

NOTE: Components from the Global Fever Panel - RUO kit should not be stored or used with any other kit.

REF DFA2-ASY-0003

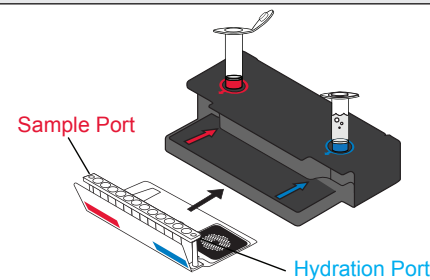
RUO



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

Step 1: Prepare Pouch

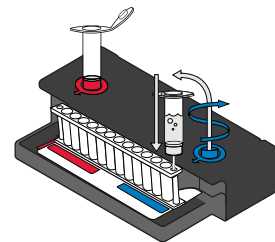
- Insert pouch into Pouch Loading Station.
- Place **Sample Injection Vial** into **red well**.
- Place **Hydration Injection Vial** into **blue well**.



Step 2: Hydrate Pouch

- Unscrew **Hydration Injection Vial** from cover.
- Remove **Hydration Injection Vial**, leaving **blue plastic 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.



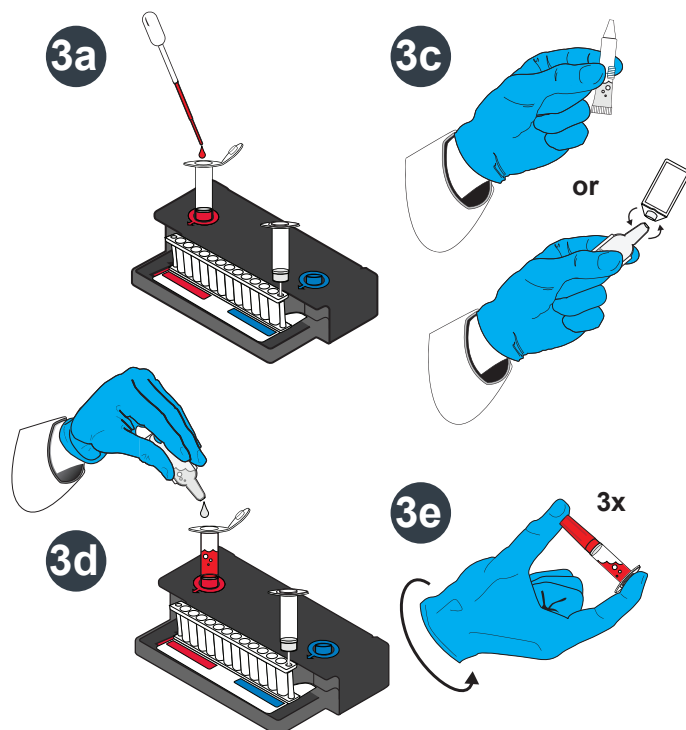
Step 3: Prepare Sample Mix

NOTE: Gently invert 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: Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.



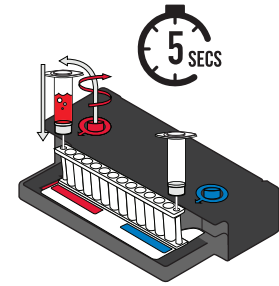


Step 4: Load Sample Mix

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

NOTE: Waiting five seconds decreases the contamination risk.

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



Step 5: Run Pouch

- Follow instructions on computer for starting a test.

- Run Summary** - Displays information about the sample, and a summary of the controls, test results and recommended action.

Run Status:

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

Internal Controls:

- If 'Pass', results are valid.
- If 'Fail' or 'Invalid', RETEST SAMPLE.

- Results 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.

- Pouch Summary** - Displays information about the pouch, serial number, and lot number.

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

FilmArray® Global Fever Panel - RUO v1.1		BIO FIRE® A RIDERREUX COMPANY www.BioFireDefense.com	
1 Run Summary			
Sample ID: T11_Vacu Operator: JWarren	Run Status: Completed Run Date: 10 Nov 2022 11:33 AM Internal Controls: Pass	Instrument: 2FA02320 Protocol: GF Blood v3.1	
Valid Test See the results below			
2 Results 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 Salmonella enterica serovar Paratyphi A Salmonella enterica serovar Typhi West Nile virus Yellow fever virus Yersinia pestis Zika virus			
3 Pouch Summary			
Pouch: GF Panel - RUO v1.1	Serial #: D02747244	Lot #: 221014A	