

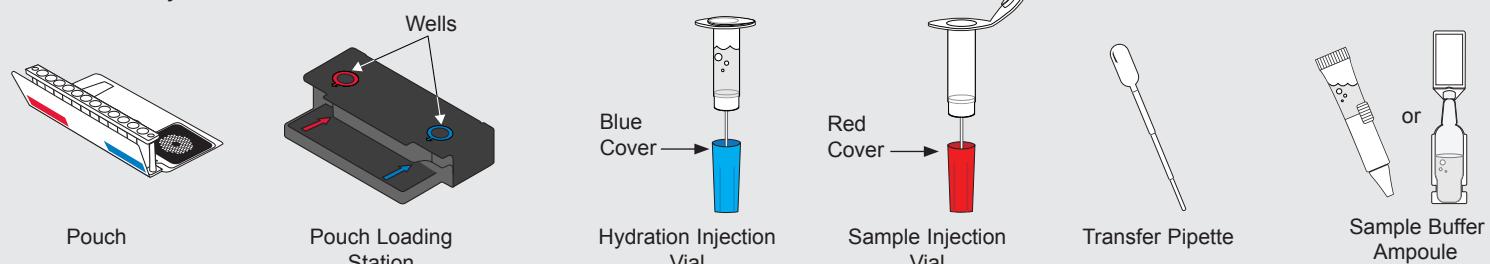


For Research Use Only. Not For Diagnostic Use.

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

REF DFA2-ASY-0003

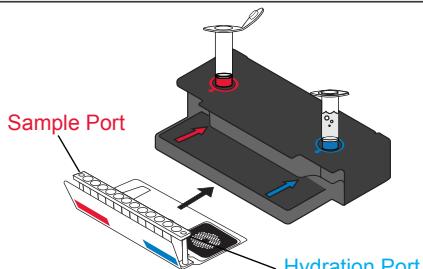
RUO



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

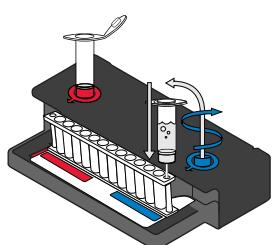
Step 1: Prepare Pouch

- 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.

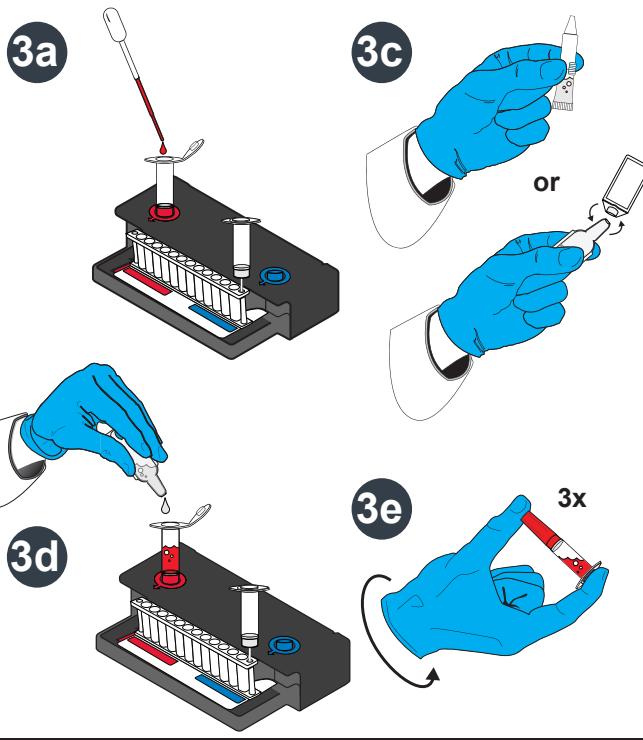


NOTE: Verify the pouch has been hydrated.

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.



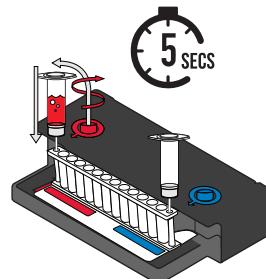


Step 4: Load Sample Mix

- 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.

1 **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.

2 **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.

3 **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*.

Run Summary

Sample ID: T11_Vacu	Run Status: Completed	Instrument: 2FA02320
Operator: JWWarren	Run Date: 10 Nov 2022 11:33 AM	Protocol: GF Blood v3.1
Internal Controls: Pass		

Results Summary

Detected	Not Detected
<i>Bacillus anthracis</i> <i>Chikungunya virus</i> <i>Crimean-Congo hemorrhagic fever virus</i> <i>Dengue virus</i> <i>Ebola virus</i> <i>Francisella tularensis</i> <i>Lassa virus</i> <i>Leishmania</i> spp. <i>Leptospira</i> spp. <i>Marburg virus</i> <i>Plasmodium</i> spp. <i>Plasmodium falciparum</i> <i>Plasmodium vivax/ovale</i> <i>Salmonella enterica</i> serovar Paratyphi A <i>Salmonella enterica</i> serovar Typhi <i>West Nile virus</i> <i>Yellow fever virus</i> <i>Yersinia pestis</i> <i>Zika virus</i>	

Pouch Summary

Pouch: GF Panel - RUO v1.1	Serial #: D02747244	Lot #: 221014A
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