REF | Kit Part No: DFA2-ASY-0003

FilmArray®
Global Fever Panel - RUO
Instructions for Use

RUO

The Symbols Glossary is provided on Page 22 of this booklet.

For Research Use Only.
Not for use in diagnostic procedures.

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INTENDED USE

The FilmArray® Global Fever (GF) Panel – RUO is a qualitative, multiplexed, nucleic acid-based test intended for use with the BIOFIRE® FILMARRAY® Systems. The FilmArray GF Panel – RUO detects and identifies bacterial, viral, and protozoan nucleic acids directly from human whole blood. The following organisms may be identified using the FilmArray GF Panel – RUO: *Bacillus anthracis, Francisella tularensis*, *Leptospira* spp., *Salmonella enterica* serovar Paratyphi A, *Salmonella enterica* serovar Typhi*, Yersinia pestis*, Chikungunya virus, Crimean-Congo hemorrhagic fever virus, Dengue virus, *Ebolavirus* spp., Lassa virus, *Marburgvirus*, West Nile virus, Yellow fever virus, Zika virus, *Leishmania* spp., and *Plasmodium* spp. (including species differentiation of *Plasmodium falciparum and Plasmodium vivax/ovale*).

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SUMMARY AND EXPLANATION OF THE TEST

The FilmArray GF Panel – RUO pouch conducts 19 tests for the identification of bacterial, viral, and protozoan organisms (**Table 1**). The sample can be tested using the FilmArray GF Panel – RUO with results available in about one hour.

Table 1. Organisms Detected by the FilmArray GF Panel - RUO

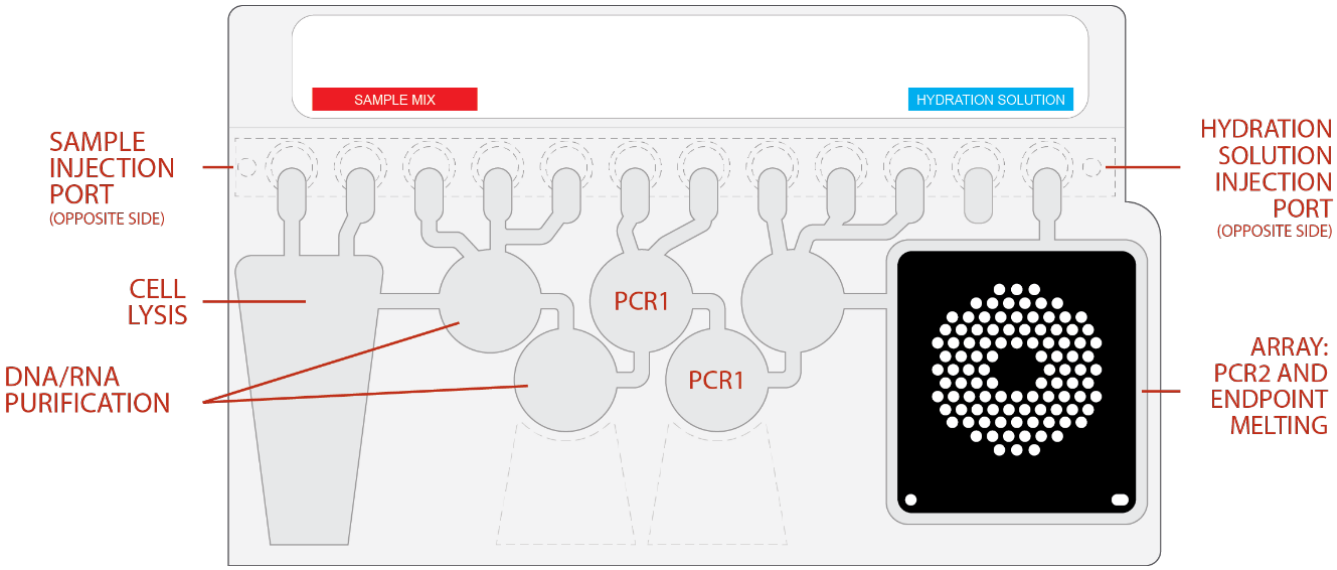
Type	Organism
Bacterial	*Bacillus anthracis*
	Francisella tularensis
	Leptospira spp.
	Salmonella enterica serovar Typhi
	Salmonella enterica serovar Paratyphi A
	Yersinia pestis
Viral	Chikungunya virus
	Crimean-Congo hemorrhagic fever virus
	Dengue virus (serotypes 1, 2, 3 and 4)
	Ebolavirus spp. (Bundibugyo, Reston, Sudan, Taï Forest, Zaire)
	Lassa virus
	Marburgvirus
	West Nile virus
	Yellow fever virus
	Zika virus
Protozoan	*Leishmania* spp.
	Plasmodium spp.
	Plasmodium falciparum
	Plasmodium vivax/ovale

PRINCIPLE OF THE PROCEDURE

The FilmArray GF Panel – RUO pouch is a closed system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple pathogens within a single sample. After sample collection, the user injects hydration solution, and sample combined with sample buffer into the pouch, places the pouch into a BIOFIRE FILMARRAY instrument, and starts a run. The entire run process takes about an hour. Additional details can be found in the appropriate BIOFIRE FILMARRAY Operator's Manual.

During a run, the BIOFIRE FILMARRAY **system:**

- Lyses the sample by agitation (bead beating).
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
  - First performing reverse transcription and a single, large volume, massively-multiplexed reaction (PCR1).
  - Then performing multiple singleplex second-stage PCR reactions (PCR2) to amplify sequences within the PCR1 products.
- Uses endpoint melting curve data to detect and generate a result for each target on the FilmArray GF Panel – RUO array.



MATERIALS PROVIDED

Each kit contains sufficient reagents to test 6 samples (DFA2-ASY-0003):

- Individually-packaged FilmArray GF Panel – RUO Pouches
- Single-use (1.0 mL) Sample Buffer Tubes
- Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)
- Single-use Sample Injection Vials (red)
- Individually-packaged Transfer Pipettes
- Instructions and Documents
    - FilmArray Global Fever Panel – RUO Instructions For Use
    - FilmArray Global Fever Panel – RUO Quick Guide

MATERIALS REQUIRED BUT NOT PROVIDED

BIOFIRE FILMARRAY system including:

- BIOFIRE® FILMARRAY® instrument, computer, and software
- BIOFIRE® FILMARRAY® Pouch Loading Station
- 10% bleach solution or a similar disinfectant

WARNINGS AND PRECAUTIONS

General Precautions

1. This product is for research use only. Not for use in diagnostic procedures.
2. FilmArray Global Fever Panel – RUO pouches are only for use with BIOFIRE FILMARRAY systems.
3. Always check the expiration date on the pouch. Do not use a pouch after its expiration date.
4. FilmArray pouches are stored under vacuum in individually-wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that a BIOFIRE FILMARRAY instrument/module will be available and operational before unwrapping any pouches for loading.
5. Initial evaluations for the FilmArray Global Fever Panel – RUO have only been for the human whole blood sample type.
6. Bleach introduced in a sample may damage nucleic acids in the sample, which may lead to a false negative result.

Safety Precautions

1. Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable clean powder-free gloves and lab coats. Protect skin, eyes, and mucus membranes. Change gloves often when handling reagents or samples.
2. Handle all samples and waste materials as if they were capable of transmitting infectious agents.

   Observe safety guidelines such as those outlined in:

   - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*[1]
   - CLSI Document M29 *Protection of Laboratory Workers from Occupationally Acquired Infections*.[2]
3. Follow your institution's safety procedures for handling biological samples.
4. Dispose of materials used in this assay, including reagents, samples, and used buffer tubes, according to federal, state, and local regulations.

   Sample Buffer is assigned the following classifications:

   - Acute toxicity (Category 4),
   - Serious eye damage (Category 1), and
   - Skin irritation (Category 2).

   Please refer to the FilmArray Sample Buffer Safety Data Sheet (SDS) for more information.

   Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.

WARNING: Never add bleach to Sample Buffer or sample waste.
Bleach, a recommended disinfectant, is corrosive and may cause severe irritation or damage to eyes and skin. Vapor or mist may irritate the respiratory tract.
Bleach is harmful if swallowed or inhaled.

- Eye contact: Hold eye open and rinse with water for 15-20 minutes. Remove contact lenses after the first 5 minutes and continue rinsing eye. Seek medical attention.
- Skin contact: Immediately flush skin with plenty of water for at least 15 minutes. If irritation develops, seek medical attention.
- Ingestion: Do not induce vomiting. Drink a glassful of water. If irritation develops, seek medical attention.

  Please refer to the appropriate Safety Data Sheet (SDS) for more information.

Laboratory Precautions

1. Preventing Organism Contamination

Due to the sensitive nature of the FilmArray GF Panel – RUO, it is important to guard against contamination of the sample and work area by carefully following the testing process outlined in this instruction document, including these guidelines:

- Samples should be processed in a biosafety cabinet. If a biosafety cabinet is not used, a protective shield should be used when preparing samples for testing.
- A biosafety cabinet used for culturing organisms should not be used for sample preparation or pouch loading.
- Prior to processing samples, thoroughly clean both the work area and the Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue buildup and potential damage to the sample or interference from disinfectants, wipe disinfected surfaces with water.
- Samples and pouches should be handled and/or tested one-at-a-time. Always change gloves and clean the work area between each pouch and sample.
- Use clean gloves to remove materials from bulk packaging bags, and reseal bulk packaging bags when not in use.

2. Preventing Amplicon Contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the FilmArray GF Panel – RUO pouch is a closed system, the risk of amplicon contamination is low provided that pouches remain intact after the test is completed. Adhere to the following guidelines, in addition to those above, to prevent amplicon contamination:

- Discard used pouches in a biohazard container immediately after the run has completed.
- Avoid excessive handling of pouches after test runs.
- Change gloves after handling a used pouch.
- Avoid exposing pouches or sample injection vials to sharp edges or anything that might cause a puncture.

WARNING: If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument and work space must be decontaminated as described below and in the appropriate BIOFIRE FILMARRAY Operator's Manual.

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

Precaution Related to Public Health

Local and/or national regulations for notification of reportable disease are continually updated and include a number of organisms for surveillance and outbreak investigations.[3,4] Laboratories are responsible for following their local and/or national regulations and should consult their local and/or national public health laboratories for isolate and/or sample submission guidelines.

REAGENT STORAGE, HANDLING, AND STABILITY

1. Store the test kit, including reagent pouches and buffers, at room temperature (18-30°C). **DO NOT REFRIGERATE**.
2. Avoid storage of any materials near heating or cooling vents, or in direct sunlight.
3. All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all pouches have been consumed.
4. Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).
5. Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

SAMPLE REQUIREMENTS

The following table describes the recommended requirements for sample collection, preparation, and handling that will help ensure accurate test results.

Recommended Sample Type	Human Whole Blood
Minimum Sample Volume	~0.2 mL (200 µL) of whole blood
Storage	Samples should be processed and tested with the FilmArray GF Panel – RUO as soon as possible.

NOTE: *Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided. Additionally, Human Whole Blood in EDTA is recommended for this panel (samples stored in Heparin may interfere with results).*

PROCEDURE

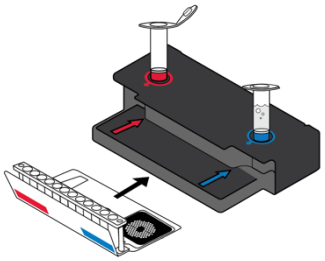
Use clean gloves and other Personal Protective Equipment (PPE) when handling pouches and samples. Only prepare one FilmArray GF Panel – RUO pouch at a time and change gloves between samples and pouches. Once sample is added to the pouch, promptly transfer to the instrument to start the run. After the run is complete, discard the pouch in a biohazard container.

Refer to the FilmArray GF Panel – RUO Quick Guide or the appropriate BIOFIRE FILMARRAY Operator's Manual for more details.

Step 1: Prepare Pouch

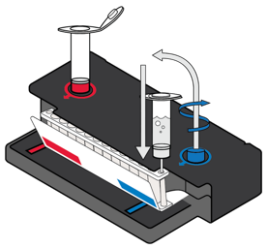
1. Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

   NOTE: *The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.*
3. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
4. Place a Sample Injection Vial (with red cover) into the red well of the Pouch Loading Station.
5. Place a Hydration Injection Vial (with blue cover) into the blue well of the Pouch Loading Station.



Step 2: Hydrate Pouch

1. Unscrew the Hydration Injection Vial from the blue cover.
2. Remove the Hydration Injection Vial, leaving the blue cover in the Pouch Loading Station.
3. Insert the Hydration Injection Vial into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.

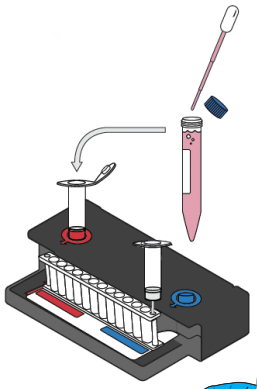


4. Forcefully push down in a firm and quick motion to puncture seal until a faint "pop" is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
5. If the hydration solution is not automatically drawn into the pouch, repeat *Step 2* to verify that the seal of the pouch hydration port was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
6. Verify that the pouch has been hydrated.
7. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.

8. If the pouch fails to hydrate (dry reagents appear as white pellets), repeat *Step 2* to verify that the seal of the pouch hydration port was broken. If hydration solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

Step 3: Prepare Sample Mix

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



1. Use the Transfer Pipette provided in the test kit to draw the sample to the second line (approximately 0.2 mL) of the Transfer Pipette.
2. Add the sample to the Sample Injection Vial.

   NOTE: *Use gauze pad to open vacutainer lid to minimize the risk of splatter or aerosol.*
3. Discard the Transfer Pipette in a biohazard waste container.

   NOTE: *DO NOT use the Transfer Pipette to mix the sample once it is loaded into the Sample Injection Vial.*
4. Add Sample Buffer to the Sample Injection Vial.

   NOTE: *There are 2 possible designs of the Sample Buffer Ampoule*.

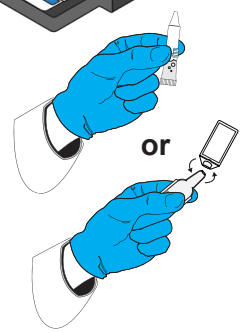
   - Hold the Sample Buffer Tube with the tip facing up.

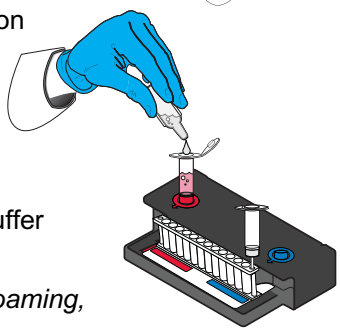
     NOTE: *Avoid touching the tube tip during handling, as this may introduce contamination.*
   - If the ampoule has a textured tab on the side of it: firmly pinch the tab on the ampoule until the seal snaps.

   or

   - If the ampoule has a plastic tab on the tip: gently twist and remove the tab at the tip of the ampoule.
   - Invert the tube over the Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.

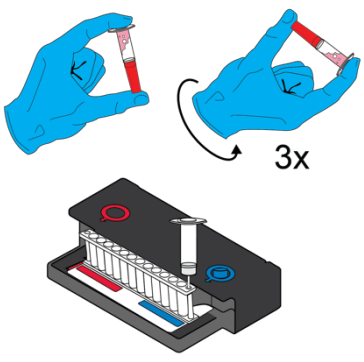
     NOTE: *Avoid squeezing the tube additional times. This will generate foaming, which should be avoided.*



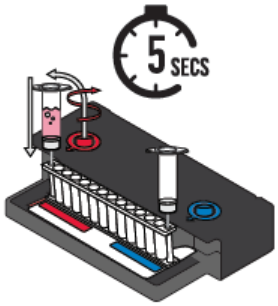


WARNING: Contact with sample buffer can cause serious eye damage and skin irritation and is harmful if swallowed.

5. Tightly close the lid of the Sample Injection Vial.
6. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 3 times to mix.
7. Return the Sample Injection Vial to the red well of the Pouch Loading Station.



Step 4: Load Sample Mix



1. Slowly twist to unscrew the Sample Injection Vial from the red cover and wait for 5 seconds with the vial resting in the cover.

   NOTE: *Waiting 5 seconds decreases the risk of dripping and contamination from the sample.*

2. Lift the Sample Injection Vial, leaving the red cover in the well of the Pouch Loading Station, and insert the Sample Injection Vial into the pouch sample port located directly below the red arrow of the Pouch Loading Station.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint "pop" is heard) and sample is pulled into the pouch by vacuum.
4. Verify that the sample has been loaded.
   - Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
   - If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.
5. Twist the Sample Injection Vial into its red plastic cover in the Pouch Loading Station. Twist the Hydration Injection Vial into its blue plastic cover in the Pouch Loading Station. Discard the Sample Injection Vial and the Hydration Injection Vial in a biohazard sharps container. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

NOTE: *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 hydration port to the 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.*

Step 5: Run Pouch

The BIOFIRE FILMARRAY Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for BIOFIRE FILMARRAY 2.0 and BIOFIRE FILMARRAY Torch Systems are given below. Refer to the appropriate BIOFIRE FILMARRAY operator's manual for more detailed instructions.

BioFire FilmArray 2.0

1. Ensure that the BIOFIRE FILMARRAY 2.0 System (instrument and computer) is powered on and the software is launched.
2. Follow on-screen instructions and procedures described in the appropriate BIOFIRE FILMARRAY 2.0 operator's manual to place the pouch in an instrument and enter pouch, sample, and operator information.
3. Pouch identification (Lot Number and Serial Number) and Pouch Type information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number and Pouch Type can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

   NOTE: *When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire GF Panel – RUO pouch.*
4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. Confirm the appropriate Protocol.
6. Enter a username and password in the Name and Password fields.

   NOTE: *The font color of the username is red until the username is recognized by the software.*
7. Review the entered run information on the screen. If correct, select Start Run. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

   NOTE: *The bead-beater apparatus makes an audible, high-pitched noise during the first minute of operation.*
8. When the run is finished, follow the on-screen instructions to remove the pouch, then immediately discard it in a biohazard waste container.
9. The run file is automatically saved in the BIOFIRE FILMARRAY Software database, and the test report can be viewed, printed, and/or saved as a PDF file.
10. To view run data, double click on a run file, select the interpretation tab and click on an analyte for a specific assay.

BIOFIRE FILMARRAY Torch

1. Ensure that the BIOFIRE FILMARRAY Torch system is powered on.
2. Select an available module on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number) and Pouch Type information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, and Pouch Type can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

   NOTE: *When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire GF Panel – RUO pouch.*
4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. Insert the pouch into the available Module (instrument).
6. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the module will grab onto the pouch and pull it into the chamber.
7. Enter operator username and password, then select Next.

   NOTE: *The font color of the username is red until the username is recognized by the software.*
8. Review the entered run information on the screen. If correct, select Start Run. Once the run has started, the screen displays a list of the steps being performed by the module and the number of minutes remaining in the run.

   NOTE: *The bead-beater apparatus makes an audible, high-pitched noise during the first minute of operation.*
9. At the end of the run, remove the partially ejected pouch, then immediately discard it in a biohazard waste container.
10. The run file is automatically saved in the BIOFIRE FILMARRAY database, and the test report can be viewed, printed, and/or saved as a PDF file.

QUALITY CONTROL

Process Controls

Two process controls are included in each pouch:

1. RNA Process Control

The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, PCR1, dilution, PCR2, and DNA melting. A positive control result indicates that all steps carried out in the FilmArray Global Fever – RUO pouch were successful.

2. PCR2 Control

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that PCR2 was successful.

Both control assays must be positive for the test run to pass. If one or both of the controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The BIOFIRE FILMARRAY software will automatically fail the run if the melting temperature (Tm) for either the RNA Process Control or the PCR2 Control is outside of an acceptable range (80-84°C for the RNA Process Control and 74-78°C for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices.[5, 6] Refer to the appropriate FilmArray operator's manual for instructions on obtaining control assay Tm values.

INTERPRETATION OF RESULTS

Assay Interpretation

When PCR2 is complete, the FilmArray instrument performs a DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray Operator's Manual). The BIOFIRE FILMARRAY Software then performs several analyses and assigns a final assay result for every well. The steps in the analyses are described below.

Analysis of Melt Curves. The BIOFIRE FILMARRAY Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve and compares it against the expected Tm range for the assay. If the software determines that the Tm falls inside the assay- specific Tm range, the melt curve is called positive (i.e., the melt curve peak is located within the white area of the melt curve chart). If the software determines that the melt curve is not in the appropriate Tm range, the melt curve is called negative (i.e., the melt curve peak is located in the grey area of the melt curve chart).

Analysis of Replicates. Once melt curves have been identified, the software evaluates the replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the associated melt curves must be called positive, and the Tm for at least two of the positive melt curves must be similar (within 1.5°C for assays with duplicate wells and 1.0°C for assays with triplicate wells). Assays that do not meet these criteria are called negative.

Organism Interpretation

The reported FilmArray GF Panel – RUO organism interpretation or results (Detected or Not Detected) may be based on the result of a single assay or on results from a combination of multiple assays, as shown in **Table 2**. In cases where either or both of the control assays have failed, all analyte results are reported as Invalid. An assay is positive when at least two replicates have similar positive melt peaks with Tm values that are within the assay-specific Tm range.

Table 2. Assay Number and Interpretation Rules for the FilmArray GF Panel – RUO

Organism	No. of Assays	Assay Interpretation Rules
BACTERIA		
Bacillus anthracis	1	Positive = Detected
Francisella tularensis	2	Any Positive = Detected
Leptospira spp.	1	Positive = Detected
Salmonella enterica serovar Typhi	1	Positive = Detected
Salmonella enterica serovar Paratyphi A	1	Positive = Detected
Yersinia pestis	2	Any Positive = Detected
VIRUSES		
Chikungunya virus	2	Any Positive = Detected
Crimean-Congo hemorrhagic fever virus	2	Any Positive = Detected
Dengue virus	5[a]	Any Positive = Detected
Ebolavirus spp.	5[b]	Any Positive = Detected
Lassa virus	2	Any Positive = Detected
Marburgvirus	1	Positive = Detected
West Nile virus	2	Any Positive = Detected
Yellow fever virus	1	Positive = Detected
Zika virus	2	Any Positive = Detected
PROTOZOAN		
Leishmania spp.	1	Positive = Detected
Plasmodium spp.	1	Positive = Detected
Plasmodium falciparum	1	Positive = Detected
Plasmodium vivax/ovale	1[c]	Positive = Detected

The FilmArray GF Panel – RUO contains multiple assays for the detection of the Dengue serotypes. See species reporting below for more information.

The FilmArray GF Panel - RUO contains multiplexed assays for the detection of *Ebolavirus* species. See species reporting below for more information.

The FilmArray GF Panel - RUO contains one multiplexed assay for the detection of both *Plasmodium vivax* and *Plasmodium ovale* species, and is reported with a single interpretation call.

Plasmodium spp. Reporting

The FilmArray GF Panel – RUO contains a genus level assay for the detection of five *Plasmodium* species (*P. falciparum, P. vivax, P. ovale, P. malariae*, and *P. knowlesi*). A species level result is also provided for *Plasmodium falciparum.* A combined species level result is provided for *Plasmodium vivax* and *Plasmodium ovale*.

Ebolavirus spp. Reporting

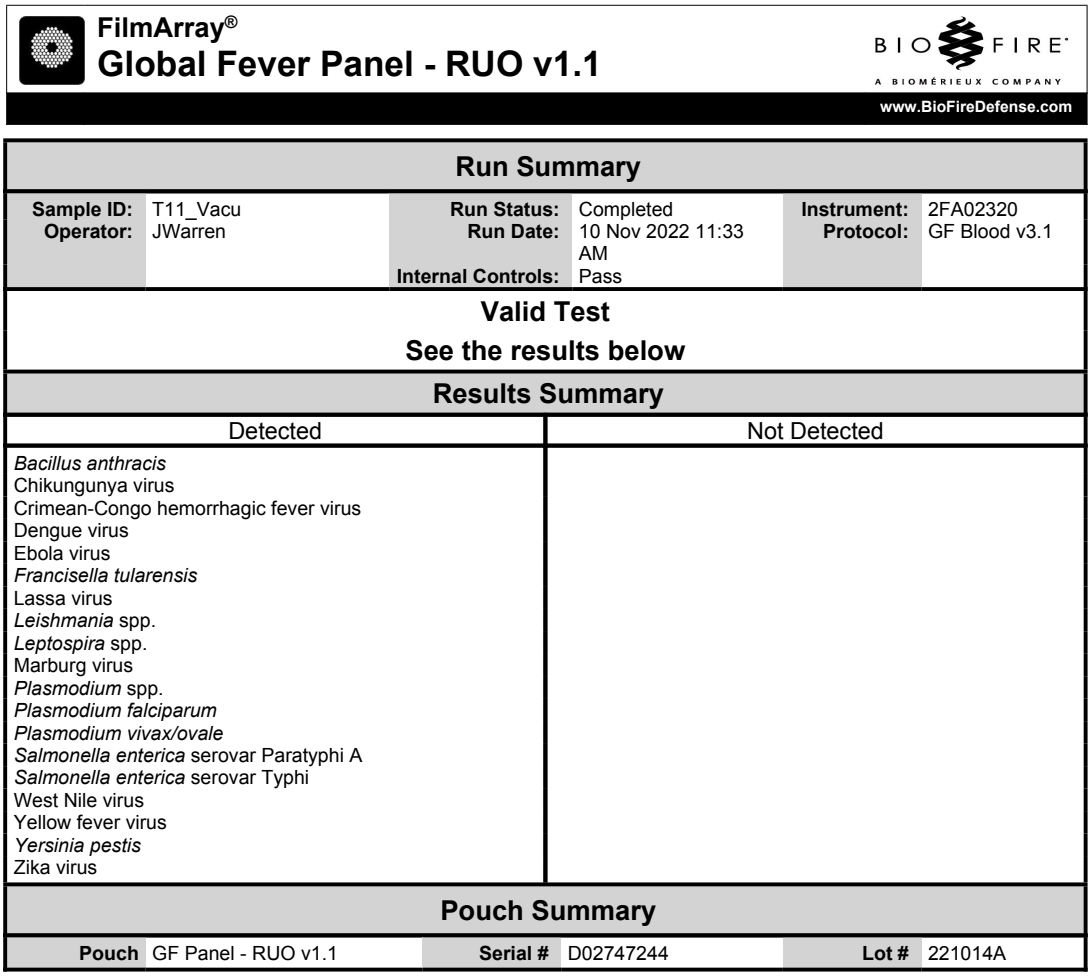
The FilmArray GF Panel – RUO contains assays for the detection of five species within the *Ebolavirus* genus (Bundibugyo, Reston, Sudan, Taï Forest, and Zaire). While assay detection is species specific, the result is provided at the genus level (i.e., Ebola virus Detected or Not Detected). A positive assay call from any of the assays will result in a Detected call for *Ebolavirus*.

Dengue virus Reporting

The FilmArray GF Panel – RUO contains assays for the detection of four dengue virus serotypes. A positive assay call will result in a Detected call for Dengue virus.

FilmArray Global Fever Panel – RUO Test Report

The FilmArray GF Panel – RUO test report is automatically displayed upon completion of a run and contains three sections: the Run Summary, the Results Summary, and the Pouch Summary. The test report can be saved as a file or printed (see **Figure 1**).



FilmArray®
Global Fever Panel - RUO v1.1

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Run Summary

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

Valid Test

See the results below

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	

Pouch Summary

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

The **Run Summary** section of the test report provides the Sample ID, Run Status, Internal Control results, the run's operator, date and time of the run, the instrument that was used, the protocol, and an overall summary of the test results. In the test result field, the overall test result (Valid, or Invalid) will be listed as well as the required action for that result (e.g., See the results below. Controls are listed as Pass, Fail, or Invalid. The Internal Control field will display Pass only if the run completed successfully (no instrument or software errors) and both of the pouch internal control assays (RNA Process Control and PCR2 Control) were successful. The Internal Control field will display Fail if the run was completed successfully (no instrument or software errors) but one or both of the pouch internal control assays failed (0 or 1 positive replicates for either of the controls, each of which is tested in triplicate). If the internal control result is Fail, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch. **Table 4** provides additional information for each of the possible control field results. See **Table 5** for complete result interpretation and required actions.

Table 4. Interpretation of Internal Controls Field on the Global Fever Panel – RUO Test Report

Internal Controls Result	Explanation
Pass	The run was successfully completed AND Both pouch controls were successful.
Fail	The run was successfully completed BUT At least one of the pouch controls failed.
Invalid	The controls are invalid because the run failed. (typically a software or hardware error)

The **Results Summary** section of the test report lists each target tested as either Detected, Not Detected, or Invalid. See the Results Explanation section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results. Within the Results Summary section, targets that are detected are listed in the left-hand column, and targets that are not detected are listed in the right-hand column.

The **Pouch Summary** section provides additional information about the pouch including the pouch type, serial number, and lot number.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called **Change Summary** will be added to the test report. This Change Summary section lists the field that was changed, the original entry, the revised entry, the operator that made the change and the date that the change was made. Sample ID is the only field of the report that can be changed.

Results Explanation and Required Actions

The Results Summary section provides a complete list of all test results. Possible results include Detected, Not Detected, and Invalid. **Table 5** provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 5. Interpretation of Results on the FilmArray GF Panel – RUO Test Report

Results	Explanation	Report
Not Detected <Organism Name(s)>	The run was successfully completed AND The pouch controls were successful (Pass) AND The assay(s) for the organism were NEGATIVE	Results are valid.
Detected <Organism Name(s)>	The run was successfully completed AND The pouch controls were successful (Pass) AND The assay(s) for the organism were POSITIVE	Results are valid.
Fail	Run completed and controls failed OR Run did not complete	All results are invalid because the run failed. Note any error codes displayed and refer to the BIOFIRE FILMARRAY Operator's Manual for more information. If the error persists, contact Technical Support for further instruction. Retest the sample.

WARNING: Detection of three or more pathogens may indicate a possible contamination event. Therefore, it is recommended to retest a sample that has three or more pathogen detected to confirm the result. If the three or more positive results are not duplicated, contact BioFire Technical Support and discontinue testing until the test area has been decontaminated.

CLEANING MATERIALS

This list provides items that are necessary in a laboratory to keep contamination to a minimum.

1. 10% bleach solution in a squeeze or spray bottle (1 part bleach to 9 parts water)
2. Distilled water in a squeeze or spray bottle
3. DNAZap™ or equivalent DNA degrading system
4. Paper towels
5. Bleach wipes

DECONTAMINATION PROCEDURES

The decontamination and cleaning procedures listed are intended to limit spread of contaminants as a result of a Global Fever Panel – RUO Detected pathogen, a suspected positive pouch, or a broken or leaked pouch. A suspected positive sample is one that the user strongly suspects may be positive for an analyte on the Global Fever Panel – RUO.

NOTE: *Use of distilled water is recommended for cleaning.*

Pouch Loading Station Decontamination

Routine cleaning of the Pouch Loading Station include a 10% bleach wipe followed by two water wipes before each new pouch is loaded.

In the event of work with a Global Fever Panel – RUO Detected pathogen, a suspected positive sample, or contamination from a sample spill, or a pouch leak, perform the following decontamination procedures:

1. Put on clean PPE, such as lab coat and gloves.
2. Fill a sink or bin with water and add bleach to create a 10% bleach solution.
3. Submerge the Pouch Loading Station until completely covered with bleach solution. Soak for 15 minutes.
4. Remove Pouch Loading Station from sink or bin. Replace bleach solution with water.
5. Rinse the Pouch Loading Station by completely submerging in water two additional times.

Decontamination Related to Pouch Leakage

If a pouch leaks, take the following precautions to avoid contamination:

1. Put on clean PPE, such as a lab coat and gloves.
2. Ensure no one uses the instrument or potentially contaminated areas until the decontamination is complete.
3. Decontaminate the instrument and work area and dispose of the pouch using the following steps:
4. Dispose of potentially contaminated gloves and put on clean gloves.

5. Dispose of the potentially contaminated lab coat and put on a clean lab coat.
6. Discard leaking pouch in biohazard container.
7. Change gloves.
8. Clean the instrument and affected work areas per the guidelines below.

CAUTION: Use only 10% bleach solution, water, and/or DNAZap to decontaminate the instrument and Pouch Loading Station.

Instrument Decontamination

Pouch Loading Chamber Decontamination

- Put on clean PPE, such as a lab coat and gloves.
- Remove pouch from instrument and discard in biohazard waste container. Change gloves.
- Wet a paper towel with 10% bleach (one part bleach to nine parts water), and wipe the inner chamber and under the lid. Change gloves.
- Repeat Step 3 twice with fresh paper towels for a total of three bleach wipes.
- Wet a paper towel with water and wipe the inner chamber.
- Repeat Step 5 with fresh gloves and paper towel.

Instrument Exterior Decontamination

- Put on clean PPE, such as a lab coat and gloves.
- Wet a paper towel with the 10% bleach solution and wipe all exterior surfaces of the instrument, including the bottom and the bench top where the instrument had contact. Change gloves.
- Repeat Step 2 twice with fresh paper towels and clean gloves, for a total of three bleach wipes.
- Change gloves, then wet a new paper towel with water and wipe the surfaces of the inner chamber, including under the lid, and the entire exterior of the instrument, including the bottom and the bench top where the instrument had contact.
- Repeat Step 4 with fresh gloves.

Decontamination of Bench Tops and Other Areas

- Put on clean PPE, such as a lab coat and gloves.
- Spray the 10% bleach solution on the area that may have been contaminated. Let it stand for at least three minutes to allow the bleach solution to react with any contaminants on the surface.
- Wipe the area with a clean paper towel. Change gloves.
- Repeat Steps 2 and 3 twice, for a total of three wipes.

- Change gloves. Spray the area with water.
- Wipe the area dry with a new paper towel. Change gloves.
- Spray the area with DNAZap™ or an equivalent product. Follow the product's instructions for correct use. Change gloves.
- Rinse the area by spraying it with water and wiping it dry.

Check Function of Decontaminated Instrument

- Test a negative sample by preparing a pouch, using water as the sample. Use distilled, sterile, or molecular grade water for the test.
- If run is successful and all results are negative, continue using the instrument as normal.
- If unexpected positive results are obtained or the run fails, please contact BioFire Defense Technical Support for further instructions.

Check for Environmental Contamination

After decontaminating instrument as described above, use environmental swabs to check for contamination by following the protocol below:

1. Prepare four aliquots of 0.2 mL of molecular grade water.
2. Place one environmental swab in each aliquot and let soak for five minutes.
3. Thoroughly swab exterior of instrument and accessories, including laptop, especially areas of operator contact.
4. Return each swab to its original aliquot and mix the sample well.
5. Dispose of swabs and combine the four aliquots into one.
6. Load pouch as described in Procedure section of this document.
    a. Load 0.2 mL of combined swabbing aliquot as the sample using Transfer Pipette, by drawing liquid up to the 2nd line.
    b. Add sample to Sample Injection Vial.
    c. Proceed with normal pouch loading procedure.
7. Run pouch using the GF Blood v3.0 protocol.
8. If positive result is found, repeat decontamination step, and contamination testing until no contamination is detected.
9. If problems persist, contact BioFire Defense Technical Support for further instructions.

LIMITATIONS

1. For Research Use Only. Not for use in diagnostic procedures.
2. This test is a qualitative test and does not provide a quantitative value for the organism(s) in the sample.
3. A false negative FilmArray Global Fever Panel – RUO result may occur when the concentration of organism(s) in the sample is below the device limit of detection.
4. The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive and false negative results caused by improperly collected, transported, or handled samples. The RNA process control, and the PCR2 control will not indicate whether or not nucleic acid has been lost due to inadequate collection, transport, or storage of samples.
5. The preliminary performance of the FilmArray Global Fever Panel – RUO was evaluated with human whole blood only.

Appendix A

Symbols Glossary

The following symbols can be found on labeling for the BIOFIRE FILMARRAY 2.0, BIOFIRE FILMARRAY Torch, FilmArray Global Fever Panel – RUO kits, kit components, and throughout accompanying packaging.

ISO 7000 Graphical symbols for use on equipment – Registered Symbols					
3082 	Manufacturer	2607 	Use-By date (YYYY-MM-DD)	2492 LOT	Batch Code (Lot Number)
2493 REF	Catalog Number	2498 SN	Serial Number	2606 	Do Not Use if Package Is Damaged
0624 	Keep Away from Sunlight	0632 	Temperature Limit	1051 	Do not re-use
1641 	Operator's Manual	0518 	Quantity		
United Nations Globally Harmonized System of Classification and Labeling of chemicals (GHS) (ST/SG/AC.10/30)					
	Serious eye damage, Category 1		Acute aquatic hazard, Category 1 & Long-term aquatic hazard, Category 1		Acute toxicity, oral, Category 4 & Skin corrosion, irritation, Category 2
Manufacture Symbols (BioFire Defense, LLC)					
	BioFire Defense Logo		FilmArray Global Fever Panel - RUO	RUO	For Research Use Only. Not for use in diagnostic procedures.

Appendix B

Customer and Technical Support	
Contact Us on the Web http://www.BioFireDefense.com **Contact Us by Mail** 79 West 4500 South, Suite 14 Salt Lake City, Utah USA 84107	**Contact Us by E-mail** support@BioFireDefense.com **Contact Us by Phone** 1-801-262-3592 – US and Canada 1-801-262-3592 – International **Contact Us by Fax** 1-801-447-6907

Revision History

Version	Revision Date	Description of Revision(s)
01	December 2018	Initial Release
02	November 2022	Updated report images, added steps for FilmArray Torch, removed melting curve review paragraph, updated symbols
03	May 2024	Removed Clear Cap from Step 1: Prepare Pouch Instructions
04	March 2025	Added 2nd Ampoule option and BIOFIRE FILMARRAY branding

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 DFA2-PRT-0036-04, March 2025

Appendix C

References

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5. CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline-Second Edition*. CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.
6. CLSI. *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Fourth Edition*. CLSI document C24-Ed4. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

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For additional information regarding our products and applications, contact BioFire Defense Customer Support.