FilmArray® BioThreat Panel Quick Guide
For use with BioFire® FilmArray® 2.0 System

For Environmental Surveillance and Research Use Only. Not for use in diagnostic procedures
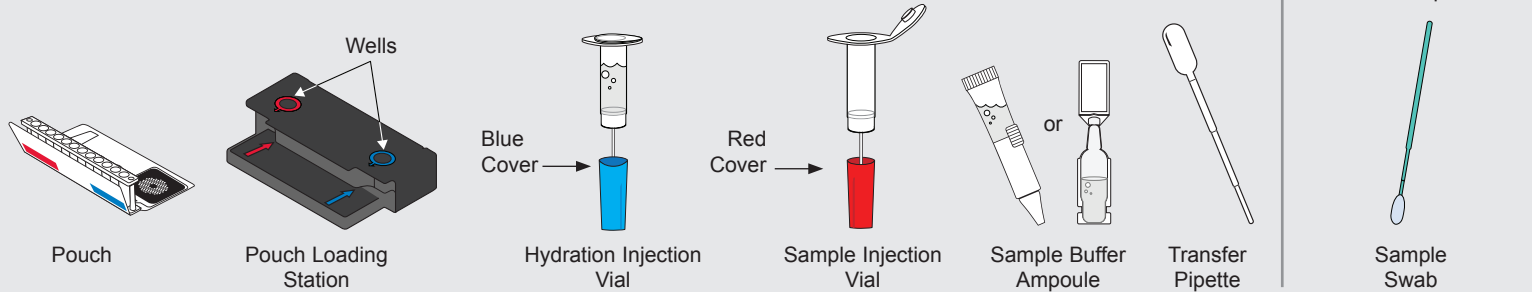**NOTE:** *To avoid contamination, clean work area and <u>always wear gloves</u>.*
Work according to appropriate biosafety conditions while manipulating potentially infectious samples.
NOTE: *Components from this kit should not be stored or used with any other kit.*
*Discard any extra components from the kit after all pouches have been used.*

REF RFIT-ASY-0094

Materials required
for powder and surface
swab but not provided

Wells

Blue
Cover →

Red
Cover →

or

Pouch | Pouch Loading Station | Hydration Injection Vial | Sample Injection Vial | Sample Buffer Ampoule | Transfer Pipette | Sample Swab

**NOTE:** *BioFire® FilmArray® 2.0 Instrument should be powered on and ready for use prior to pouch preparation.*

STEP 1: Prepare Pouch

a. Insert pouch into Pouch Loading Station.
b. Place Sample Injection Vial into red well.
c. Place Hydration Injection Vial into blue well.

Pouch
Sample Port

Pouch
Hydration Port
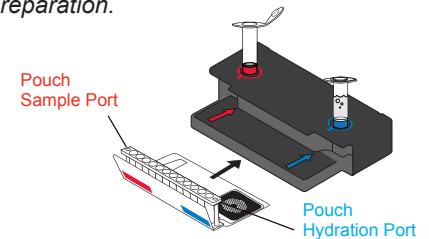
STEP 2: Hydrate Pouch

a. Twist off Hydration Injection Vial, leaving blue plastic cover in Pouch Loading Station, and insert into pouch hydration port.
b. Forcefully push down to puncture seal and verify that Hydration Solution has been drawn into pouch.
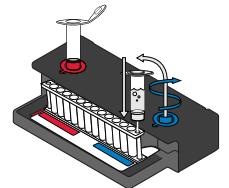
STEP 3: Prepare Sample Mix

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

a. Hold the Sample Buffer Ampoule with the tip facing up.
  NOTE: *Do not touch the tip of the ampoule.*
b. 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.
c. Dispense Sample Buffer by squeezing the liquid-filled end using a slow, forceful squeeze, followed by a **2nd** squeeze.
  NOTE: *Avoid generating excessive foam.*

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

For Liquid Samples (including Air-into-PBS / Dry Filter / Liquid):

d. After collecting the liquid sample, use Transfer Pipette to draw filter wash or liquid to the **3rd** line (approx. 300 uL) and add to Sample Injection Vial.
e. Tightly close the lid of the Sample Injection Vial and mix sample by gently inverting **3 times.**
f. Return the Sample Injection Vial to the red well of the Pouch Loading Station.
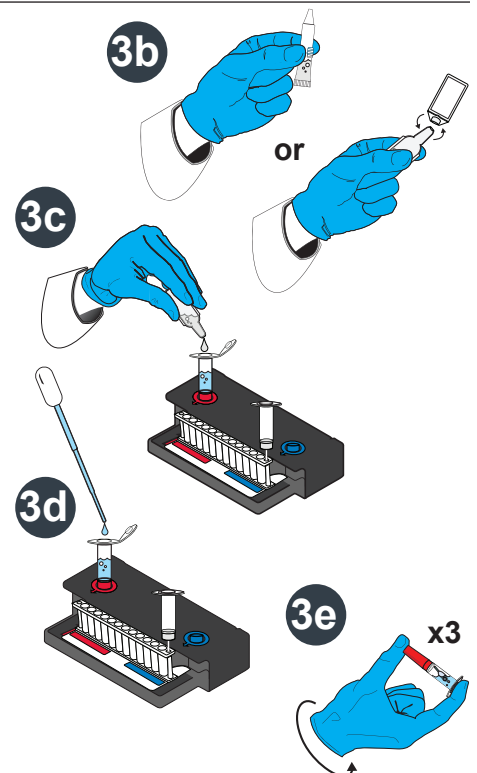
3b

or

3c

**3d**

3e x3

STEP 3: Prepare Sample Mix (cont.)

For Surface Swab Samples (including Powder / Surface):

a. After collecting sample, place the tip of the swab into the Sample Injection Vial and swirl for **5** seconds.

b. Break the swab handle at the molded break point, leaving the tip of the swab in the Sample Injection Vial.

   NOTE: If the swab handle does not have a molded break point, cut the tip of the swab with clean scissors, leaving the tip of the swab in the Sample Injection Vial.

c. Discard the handle in an appropriate waste container.

d. Tightly close lid of Sample Injection Vial and mix sample by gently inverting **3** times.

e. Return Sample Injection Vial to red well of Pouch Loading Station.
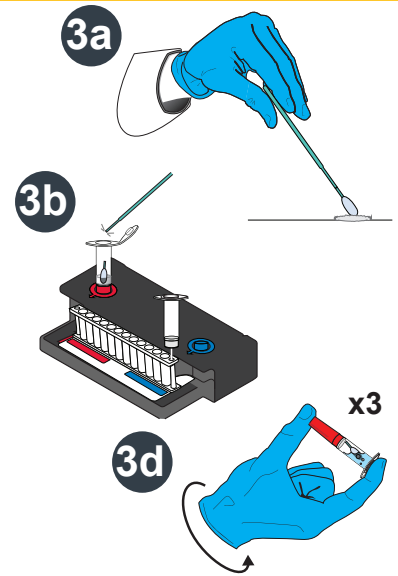
STEP 4: Load Sample Mix

a. With Sample Injection Vial in the Pouch Loading Station, twist to loosen it from the red plastic cover and pause for **5** seconds.

b. Lift Sample Injection Vial from red plastic cover and insert into Sample port.

c. Forcefully push down to puncture seal and verify that Sample Mix has been drawn into pouch.
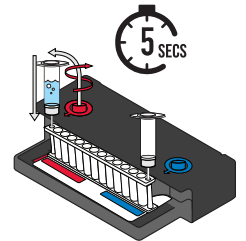
STEP 5: Run Pouch

a. Follow instructions on screen for starting a test.
   NOTE: Select **BT PBS** protocol.

Step 6: Review Report

1 **Run Summary** - *Displays information about the sample.*
   Internal Controls:
   • If 'Pass', results are valid.
   • If 'Fail' or 'Invalid', **RETEST SAMPLE**.

2 **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.
   • 'N/A', pathogen was not reported. Refer to Instruction Booklet for more information.

3 **Run Details** - *Displays information about the pouch, protocol, run status, operator, instrument, serial number, and lot number.*

   Run Status:
   • If 'Completed', run is complete.
   • If 'Incomplete', 'Aborted', or any other error message, **RETEST SAMPLE**.

FilmArray BioThreat Panel

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Run Summary

Sample ID:	32638-EN	Run Date:	01 Sep 2022 12:04 PM
Detected:	Orthopox genus virus	Controls:	Passed

Result Summary

	Bacteria
Not Detected	*Bacillus anthracis*
Not Detected	*Brucella melitensis*
Not Detected	*Burkholderia mallei/pseudomallei*
Not Detected	*Coxiella burnetii*
Not Detected	*Francisella tularensis*
Not Detected	*Rickettsia prowazekii*
Not Detected	*Yersinia pestis*

	Viruses
Not Detected	Ebola Zaire
Not Detected	Marburg virus
✓ Detected	Orthopox genus virus
Not Detected	Variola virus
Not Detected	EEE virus
Not Detected	VEE virus
Not Detected	WEE virus

	Toxins
Not Detected	*Clostridium botulinum*
Not Detected	*Ricinus communis*

Run Details

Pouch:	BioThreat Panel v2.5	Protocol:	BT PBS v3.0
Run Status:	Completed	Operator:	MJ - RktMn
Serial No.:	D07654321	Instrument:	2FA00045
Lot No.:	1234567		

NOTE: Refer to the *FilmArray BioThreat Panel Instructions for Use* for reporting information. If repeated error messages are obtained, contact *BioFire Defense Technical Suppor*t.

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DEFENSE

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