



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

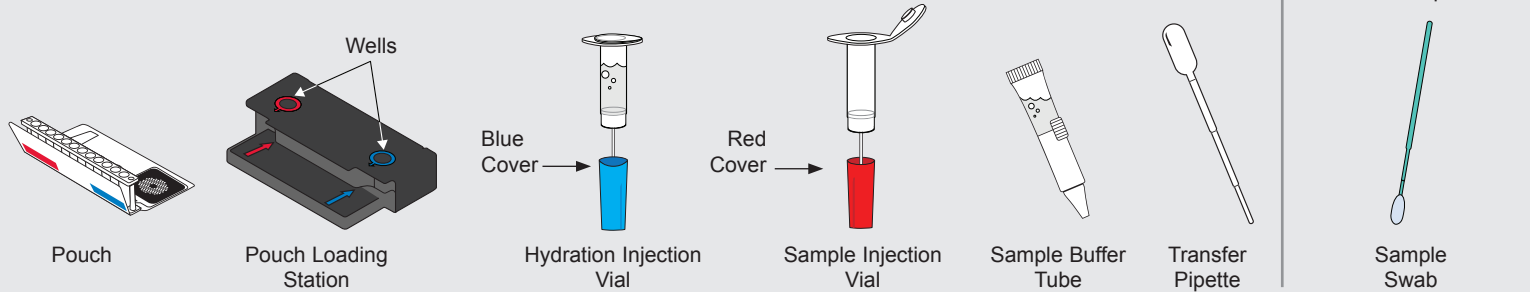
NOTE: To avoid contamination, clean work area and *always wear gloves*.

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.

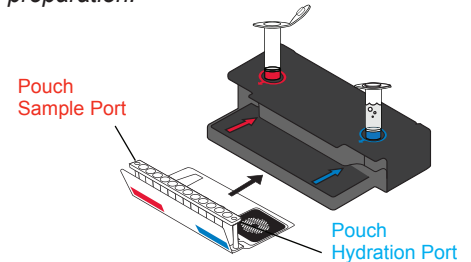
REF RFIT-ASY-0094



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

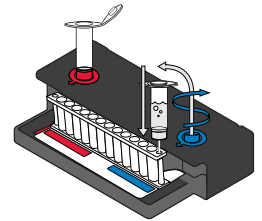
STEP 1: Prepare Pouch

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



STEP 2: Hydrate Pouch

- Twist off **Hydration Injection Vial**, leaving **blue plastic cover** in Pouch Loading Station, and insert into **pouch hydration port**.
- Forcefully push down to puncture seal and verify that **Hydration Solution** has been drawn into pouch.



STEP 3: Prepare Sample Mix

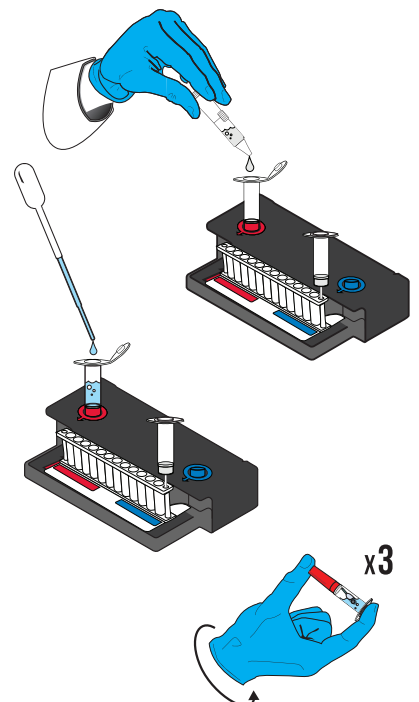
Add Sample Buffer:

- Hold the Sample Buffer Tube so that the tip is facing up.
- Gently pinch the textured plastic tab on the side of the tube until the seal snaps
NOTE: Do not touch the tip of the tube.
- Invert the tube over the **Sample Injection Vial**.
- Dispense Sample Buffer by squeezing the liquid-filled end using a slow, forceful squeeze, followed by a **2nd** squeeze.

NOTE: Squeezing the tube additional times will generate excessive foaming, which should be avoided.

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

- 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**.
- Tightly close the lid of the Sample Injection Vial and mix sample by gently inverting **3 times**.
- Return the **Sample Injection Vial** to the red well of the Pouch Loading Station.





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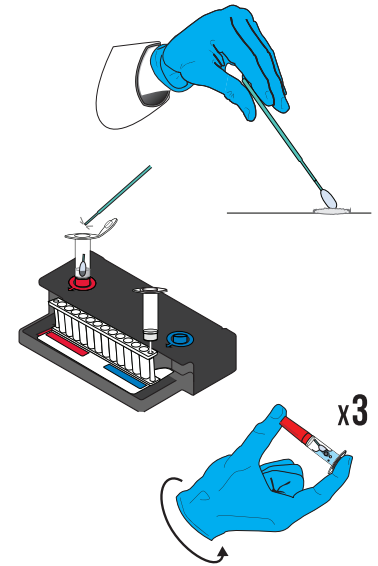
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STEP 3: Prepare Sample Mix (cont.)

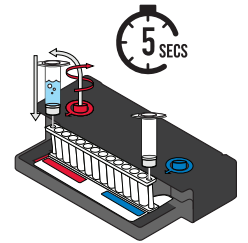
For Surface Swab Samples (including Powder / Surface):

- After collecting sample, place the tip of the swab into the **Sample Injection Vial** and swirl for **5 seconds**.
- 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**.
- Discard the handle in an appropriate waste container.
- Tightly close lid of **Sample Injection Vial** and mix sample by gently inverting **3 times**.
- Return **Sample Injection Vial** to **red well** of Pouch Loading Station.



STEP 4: Load Sample Mix

- With **Sample Injection Vial** in the Pouch Loading Station, twist to loosen it from the **red plastic cover** and pause for **5 seconds**.
- Lift **Sample Injection Vial** from **red plastic cover** and insert into **Sample port**.
- Forcefully push down to puncture seal and verify that **Sample Mix** has been drawn into pouch.





STEP 5: Run Pouch

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

Step 6: Review Report

- Run Summary** - Displays information about the sample.
Internal Controls:
 - If 'Pass', results are valid.
 - If 'Fail' or 'Invalid', **RETEST SAMPLE**.
- 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.
- 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		 <small>A BIODERIVE COMPANY</small> www.BioFireDefense.com	
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	<i>Bacillus anthracis</i>		
Not Detected	<i>Brucella melitensis</i>		
Not Detected	<i>Burkholderia mallei/pseudomallei</i>		
Not Detected	<i>Coxiella burnetii</i>		
Not Detected	<i>Francisella tularensis</i>		
Not Detected	<i>Rickettsia prowazekii</i>		
Not Detected	<i>Yersinia pestis</i>		
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	<i>Clostridium botulinum</i>		
Not Detected	<i>Ricinus communis</i>		
Run Details			
Pouch:	BioThreat Panel v2.5	Protocol:	BT PBS v3.0
Run Status:	Completed	Operator:	MJ - RkMn
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 Support*.