



FilmArray® BioThreat-E Quick Guide

For use with FilmArray® 2.0 systems



For Use Under the Emergency Use Authorization (EUA) by CLIA Moderate and High Complexity Laboratories.

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

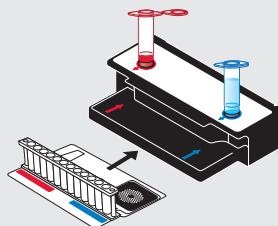
For use with whole blood or urine samples.

Complete Instructions for Use are available on the FDA and BioFire Defense websites.

IVD

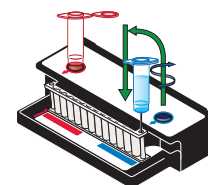
Step 1: Prepare Pouch

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



Step 2: Hydrate Pouch

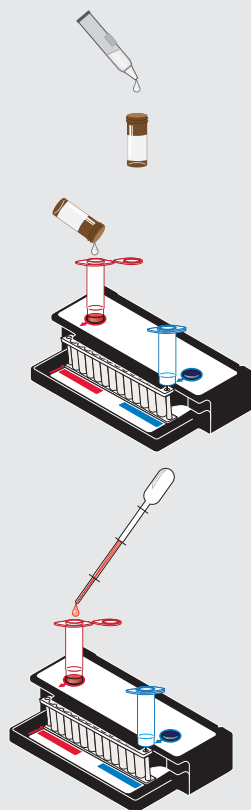
- ❑ Twist off **Hydration Injection Vial**, leaving cap in Pouch Loading Station and insert in **pouch hydration port**.
- ❑ Forcefully push down to puncture port seal and wait as **Hydration Solution** is drawn into the pouch.



Step 3: Prepare Sample Mix

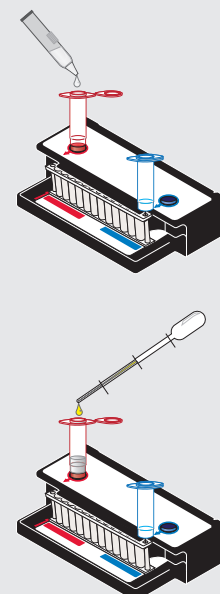
For Whole Blood Samples:

- ❑ Remove Protease Vial from mylar bag and set the cap aside.
- ❑ Add Sample Buffer to Protease Vial:
 - ❑ Invert Sample Buffer Ampoule so that the tip faces up.
Note: Do not touch the tip of the ampoule.
 - ❑ Firmly pinch textured plastic tab on side of ampoule until seal snaps.
 - ❑ With the tip facing down, dispense Sample Buffer into Protease Vial using a slow, forceful squeeze, followed by a **2nd** squeeze. Avoid excessive bubbles.
- ❑ Re-cap Protease Vial and invert **3** times to mix.
- ❑ Uncap vial and pour buffer and protease mixture into the **Sample Injection Vial**.
- ❑ Using a transfer pipette, draw up specimen to **2nd** line.
- ❑ Add to **Sample Injection Vial**.
- ❑ Tightly close lid of **Sample Injection Vial**.
- ❑ Mix sample by gently inverting **Sample Injection Vial 3** times.
- ❑ Return **Sample Injection Vial** to **red well** in Pouch Loading Station.



For Urine Samples:

- ❑ Add Sample Buffer to **Sample Injection Vial**:
 - ❑ Invert Sample Buffer Ampoule so that the tip faces up.
Note: Do not touch the tip of the ampoule.
 - ❑ Firmly pinch textured plastic tab on side of ampoule until seal snaps.
 - ❑ With tip facing down, dispense Sample Buffer into **Sample Injection Vial** using a slow forceful squeeze, followed by a **2nd** squeeze. Avoid excessive bubbles.
- ❑ Using a transfer pipette, draw up specimen to **2nd** line.
- ❑ Add to **Sample Injection Vial**.
- ❑ Tightly close lid of **Sample Injection Vial**.
- ❑ Mix sample by gently inverting **Sample Injection Vial 3** times.
- ❑ Return **Sample Injection Vial** to **red well** in Pouch Loading Station.

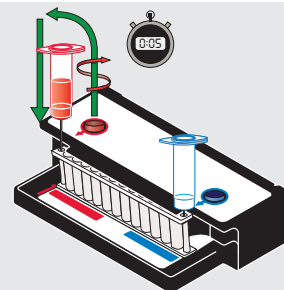


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Step 4: Load Sample Mix

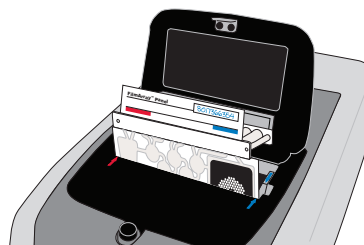
- ☐ Unscrew **Sample Injection Vial** from cap.
- ☐ Pause for 3-5 seconds, then remove **Sample Injection Vial**, leaving cap in Pouch Loading Station.
- ☐ Insert **Sample Injection Vial** into **pouch sample port**.
- ☐ Forcefully push down to puncture port seal.
- ☐ Wait as **Sample Mix** is drawn into the pouch.



Step 5: Load and Run Pouch

- ☐ Remove **Sample Injection Vial** and **Hydration Injection Vial** from pouch and discard into appropriate container.
- ☐ Remove pouch from Pouch Loading Station.
- ☐ With system software running, open instrument lid.
- ☐ Insert larger film portion of pouch into instrument's pouch loading slot.
- ☐ Snap pouch into place.
- ☐ Scan pouch barcode.
- ☐ Follow instructions on software screen to:
 - ☐ Enter Sample ID
 - ☐ Select the appropriate protocol; either blood or urine
 - ☐ Enter your username and password
 - ☐ Click "Start Run"

Note: You will hear an audible "click" when pouch is seated properly.



Warning: If the pouch does not load easily ensure that lid is opened completely.