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.

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.