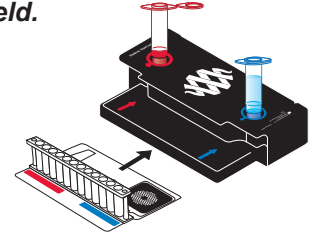


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**⚠ To avoid contamination always wear gloves and work behind a protective shield.**

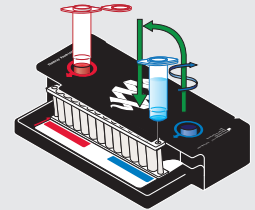
## Step 1: Prepare Pouch

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



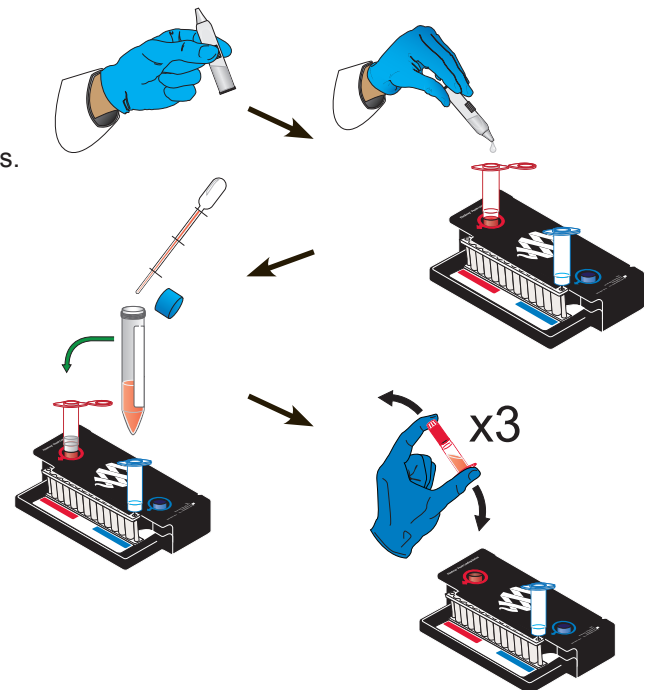
## Step 2: Hydrate Pouch

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



## Step 3: Prepare Sample Mix

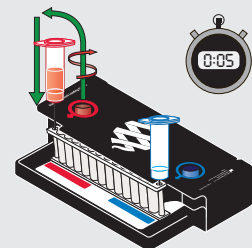
- Add Sample Buffer to **Sample Injection Vial**.
  - Invert Sample Buffer Ampoule so that tip is facing up.
  - Note:** Do not touch the tip of the ampoule.
  - Firmly pinch textured plastic tab on side of ampoule until seal snaps.
  - With the tip facing down, dispense Sample Buffer into **Sample Injection Vial** using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.
- Using Transfer Pipette, draw up specimen to third line.
- Add sample 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** of Pouch Loading Station.



**⚠ Warning: The Sample Buffer is harmful if swallowed and can cause serious eye damage and/or skin irritation.**

## 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 seal.
- Wait as **Sample Mix** is drawn into pouch.



## Step 5: Run Pouch

- Follow instructions on computer for initiating a test.



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The **Run Summary Section** displays information about the sample and a summary of the control and test results.

1. Detected:
  - Names of any detected pathogens
  - If 'None', no pathogens were detected
  - If '▲Invalid', RETEST SAMPLE
2. Equivocal ( ↔ ):
  - If 'None', no pathogens were equivocal
  - If a pathogen is listed, RETEST SAMPLE
  - If '▲Invalid', RETEST SAMPLE
3. Controls:
  - If 'Passed', results are valid
  - If '▲Failed', RETEST SAMPLE
  - If '▲Invalid', RETEST SAMPLE

The **Results Summary Section** lists the test results for each pathogen targeted by the Respiratory Panel.

4. If 'Not Detected', pathogen was not detected
5. If '✓ Detected', pathogen was detected
6. If ' ↔ Equivocal', result could not be determined, RETEST SAMPLE

If '▲Invalid', RETEST SAMPLE

**Note:** If repeated 'Invalid' results are obtained, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.

The **Run Details Section** displays information about the pouch, instrument, run status, and operator.

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

**Note:** If repeated 'Error' messages are obtained, contact BioFire Diagnostics, the local bioMérieux sales representative, or an authorized distributor.



Run Summary			
<b>Sample ID:</b>	1-214	<b>Run Date:</b>	23 Jan 2013 11:30 AM
<b>1. Detected:</b>	Human Rhinovirus/Enterovirus	<b>3. Controls:</b>	Passed
<b>2. Equivocal:</b>	↔ Influenza A H1-2009		

Result Summary	
4. Not Detected	Adenovirus
Not Detected	Coronavirus 229E
Not Detected	Coronavirus HKU1
Not Detected	Coronavirus NL63
Not Detected	Coronavirus OC43
Not Detected	Human Metapneumovirus
5. ✓ Detected	Human Rhinovirus /Enterovirus
6. ↔ Equivocal	Influenza A H1 2009
Not Detected	Influenza B
Not Detected	Parainfluenza Virus 1
Not Detected	Parainfluenza Virus 2
Not Detected	Parainfluenza Virus 3
Not Detected	Parainfluenza Virus 4
Not Detected	Respiratory Syncytial Virus
Not Detected	Bordetella pertussis
Not Detected	Chlamydomphila pneumoniae
Not Detected	Mycoplasma pneumoniae

Run Details			
<b>Pouch:</b>	Respiratory Panel	<b>Protocol:</b>	NPS v.2.0
<b>7. Run Status:</b>	Completed	<b>Operator:</b>	JDoe
<b>Serial No.:</b>	00026577	<b>Instrument:</b>	ITI FA "FA1115"
<b>Lot No.:</b>	100302A		

