

CLIA Waived for Nasal and Nasopharyngeal Swab Specimens. Facilities with a Certificate of Waiver may perform this test and must follow the manufacturer's instructions for performing the test. 42 USC263a(c).



For use with Acucy System

REF 1010  
IVD R<sub>ONLY</sub>

**IMPORTANT:** Read and follow the complete test procedure before performing the test. Refer to the Instructions for Use (IFU) and System Manual for more complete information.

Refer to the Acucy System Calibration Procedure Quick Reference Guide for calibration of the system and the External Quality Control (QC) Quick Reference Guide for running External Controls. Reader may be set to two different modes (WALK AWAY/NORMAL and READ NOW).

Operate the System at room temperature 15 - 30°C (59 - 86°F); humidity less than 70% (non-condensing); air pressure 700 hPa – 1060 hPa (altitude <3000 m, <9840 ft).

## READER SETUP (WALK AWAY / NORMAL MODE)

If needed, set Reader to **WALK AWAY/NORMAL** Mode.

- 1.1 From MAIN MENU, select **SETTINGS**.
- 1.2 Enter the supervisor password and press **ENTER**.
- 1.3 Press ▼ to scroll down and select **5. READ NOW**.
- 1.4 Select **OFF** which will highlight in white and press **ENTER**.
- 1.5 Select **MENU** to return to MAIN MENU.

## RUNNING A TEST

**1**

**Remove** cassette from foil pouch.

**Label** with Patient ID.  
DO NOT cover barcode or write on back of cassette.

Once open, use within 30 minutes.

Dropped cassettes (even if samples were added to the cassettes) should be discarded.

**2**

**Twist** cap off extraction buffer vial.

**Insert** swab into liquid.

**Mix** against side of the vial 10 times.

**Note:** Sample must be placed into extraction buffer within 6 hours of collection.

**vigorously mix 10x**

**3**

**Squeeze** sides of vial and pull out the swab to remove excess liquid.

**Dispose** swab in biohazard waste.

**4**

**Attach** dropper tip to vial.

**Press** tightly to seal.

Keep vial upright. Label vial with Patient ID.

- 5**
- 5.1 From MAIN MENU, select **RUN TEST**.
  - 5.2 From OPERATOR ID screen, select your **ID**.
  - 5.3 From Patient ID screen, select **BARCODE** OR **KEYPAD**.
  - 5.4 Scan or manually enter PATIENT ID.
  - 5.5 From SELECT TEST screen, select **FLU A&B**.

**6**

**Open** drawer until it clicks into place.

**Insert** cassette with arrow facing Reader. Reader will beep when barcode is scanned.

**7**

**Mix** sample gently.

**8**

**Hold** vial vertically.

**Slowly add** 5 drops to sample well.

**Dispose** vial in biohazard waste. DO NOT add sample to the result well.

**9**

**Immediately close** drawer tightly. Reader will display results after 15 minutes.

Display	Interpretation
FLU A POS (+) FLU B NEG (-)	Influenza A Positive Result
FLU A NEG (-) FLU B POS (+)	Influenza B Positive Result
FLU A NEG (-) FLU B NEG (-)	Negative for Influenza A and Influenza B
FLU A INVALID (1)-(7) FLU B INVALID (1)-(7)	Repeat the test using a new patient sample, reagents, and cassette.

- 10**
- Dispose** cassette in biohazard waste.
- Select NEXT** and follow prompts to return to MAIN MENU.

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Operate the System at room temperature 15 - 30°C (59 - 86°F); humidity less than 70% (non-condensing); air pressure 700 hPa – 1060 hPa (altitude <3000 m, <9840 ft).

Because every result matters™

### READER SETUP (READ NOW MODE)

If needed, set Reader to **READ NOW** Mode.

- 1.1 From MAIN MENU, select **SETTINGS**.
- 1.2 Enter the supervisor password and press **ENTER**.
- 1.3 Press **▼** to scroll down and select **5. READ NOW**.
- 1.4 Select **ON** which will highlight in white and press **ENTER**.
- 1.5 Select **MENU** to return to MAIN MENU.

### RUNNING A TEST

**1**

**Remove** cassette from foil pouch.  
**Label** with Patient ID.  
DO NOT cover barcode or write on back of cassette.  
Once open, use within 30 minutes.

**Do not cover barcode**

Dropped cassettes (even if samples were added to the cassettes) should be discarded.

**2**

**Twist** cap off extraction buffer vial.  
**Insert** swab into liquid.  
**Mix** against side of the vial 10 times.  
**Note:** Sample must be placed into extraction buffer within 6 hours of collection.

**vigorously mix 10x**

**3**

**Squeeze** sides of vial and pull out the swab to remove excess liquid.  
**Dispose** swab in biohazard waste.

**4**

**Attach** dropper tip to vial.  
**Press** tightly to seal.  
Keep vial upright. Label vial with Patient ID.

**5**

**Mix** sample gently.

**6**

**Hold** vial vertically.  
**Slowly add** 5 drops to sample well.  
**Dispose** vial in biohazard waste.  
Do not add sample to the result well.

**7**

**Start** timer for 15 minutes.  
While waiting, proceed on to step 8.

**15 minutes**

**8**

8.1 From MAIN MENU, select **RUN TEST**.

8.2 From OPERATOR ID screen, select your **ID**.

8.3 From PATIENT ID screen, select **BARCODE** OR **KEYPAD**.

8.4 Scan or manually enter Patient ID.

**9**

Once 15 minutes from step 7 is complete, **Select** **FLU A&B** from test menu.  
**Open** drawer until it clicks into place.  
**Insert** cassette with arrow facing Reader.  
Reader will beep when barcode is scanned.  
**Note:** Allowing the cassette to develop for more than 15 minutes may generate erroneous results.

**10**

**Immediately close** drawer tightly. Reader will display results after 15 minutes.

### RESULTS INTERPRETATION

Display	Interpretation
FLU A POS (+) FLU B NEG (-)	Influenza A Positive Result
FLU A NEG (-) FLU B POS (+)	Influenza B Positive Result
FLU A NEG (-) FLU B NEG (-)	Negative for Influenza A and Influenza B
FLU A INVALID (1)-(7) FLU B INVALID (1)-(7)	Repeat the test using a new patient sample, reagents, and cassette.

**11**

**Dispose** cassette in biohazard waste.  
**Select** **NEXT** and follow prompts to return to MAIN MENU.