For use with Acucy System

Influenza A&B Test

Walk Away / Normal Mode

Quick Reference Guide

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).

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MPORTANT: 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.

Because every result matters™

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).

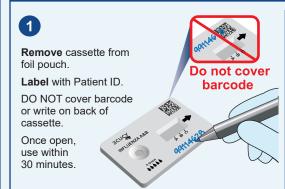
Operate the System at room temperature 15 - 30°C (59 - 86°F); humidity less than 70% (non-condensing); air pressure 700 hPa - 1060 hPa (altitude <3000 m. <9840 ft).

READER SETUP (WALK AWAY / NORMAL MODE)

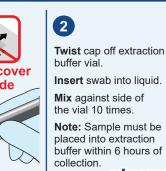
If needed, set Reader to WALK AWAY/NORMAL

- 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



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



buffer within 6 hours of collection. vigorously





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

Dispose swab in biohazard waste.





Attach dropper tip to vial.

Press tightly to seal.

Keep vial upright. Label vial with Patient ID.





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 |

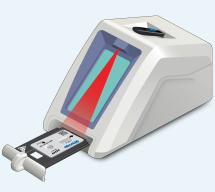
- 5.4 Scan or manually enter PATIENT ID.
- 5.5 From SELECT TEST screen. select FLU A&B



Open drawer until it clicks into place.

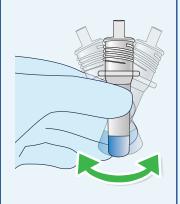
Insert cassette with arrow facing Reader.

Reader will beep when barcode is scanned.





Mix sample gently.





Hold vial vertically.

Slowly add 5 drops to sample well.





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.



Dispose cassette in biohazard waste.

Select NEXT and follow prompts to return to MAIN MENU.

For technical questions or assistance, please contact Technical Services at (800) 332-1042 or techservices@sekisuidiagnostics.com Acucy® is a registered trademark of SEKISUI Diagnostics, LLC. Because every result matters™ is a trademark of SEKISUI Diagnostics, LLC

Influenza A&B Test

Read Now Mode

Quick Reference Guide

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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).

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



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



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



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

Dispose swab in biohazard waste.





Attach dropper tip to vial.

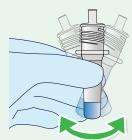
Press tightly to seal.

Keep vial upright. Label vial with Patient ID.





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.



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

15 minutes



Patient ID



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



Once 15 minutes from step 7 is complete,

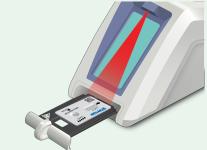
Select FLU A&B from test menu. Open drawer until it clicks into place.

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.





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



RESULTS INTERPRETATION Display Interpretation FLU A POS (+) Influenza A Positive Result FLU B NEG (-) Influenza B Positive Result

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



Dispose cassette in biohazard waste.

Select NEXT and follow prompts to return to MAIN MENU.

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