

REF 1010 **R_x only** **IVD**

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).

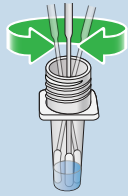
IMPORTANT: Read and follow the complete test procedure before performing the test. Refer to the Instructions for Use (IFU) and System Manual for more complete information. Refer to the Acucy System Calibration Procedure Quick Reference Guide for calibration of the system and the External Quality Control (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°C - 30°C/59°F - 86°F); humidity less than 70% (non-condensing); air pressure 700 hPa - 1060 hPa (altitude <3000 m, <9840 ft).

A. EXTRACT SAMPLE

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

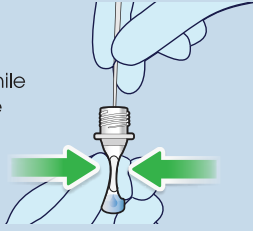
1 **NOTE:** Before setting up Reader, extract samples for testing.

Insert swab into extraction buffer vial and mix against side of vial 10 times.



vigorously mix 10x

2 Remove swab while squeezing middle of vial to remove liquid from swab.

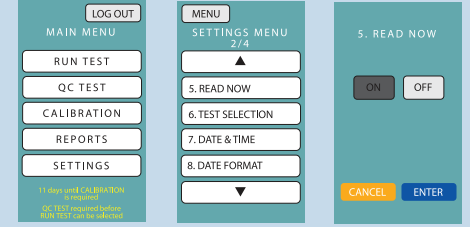


3 Attach dropper tip to vial. Press tightly to seal. Keep vial upright. Label vial with patient ID.



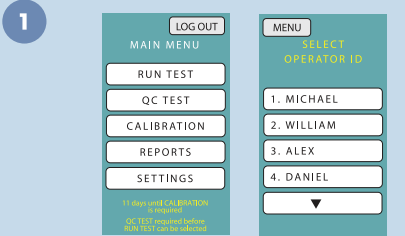
B. SET-UP READER (WALK AWAY / NORMAL MODE)

If needed, set Reader to WALK AWAY/NORMAL Mode.
1. Select SETTINGS from MAIN MENU
2. Enter SUPERVISOR PASSWORD and then ENTER
3. Scroll down and select READ NOW
4. Select OFF and then ENTER
5. Select MENU to return to MAIN MENU

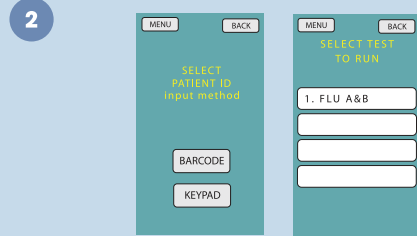


C. RUN TEST (WALK AWAY / NORMAL MODE)

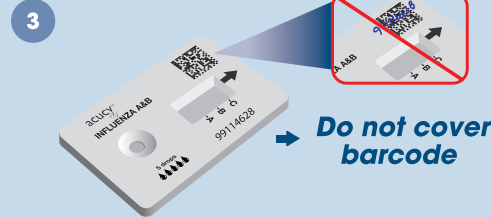
In WALK AWAY/NORMAL Mode, remove cassette from foil pouch and place into Reader, add sample to cassette, then close Reader drawer. Reader will time test and display results after 15 minutes. Dropped cassettes (regardless of whether samples were added to the cassettes) should be discarded.



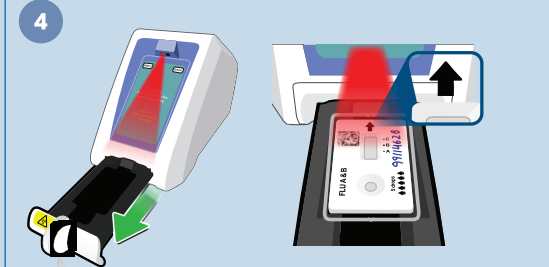
Select RUN TEST from MAIN MENU screen, then select OPERATOR ID.



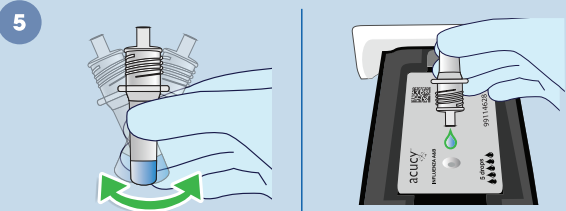
Select BARCODE or KEYPAD, then scan or manually enter PATIENT ID. Select FLU A&B test.



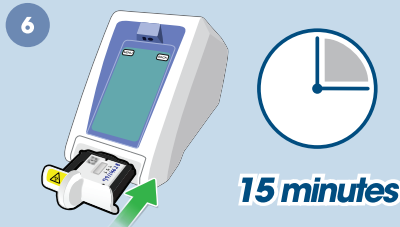
Remove cassette from foil pouch and label with patient ID. DO NOT cover barcode or write on back of cassette. Test cassette must be used within 30 minutes of opening or will need to be discarded.



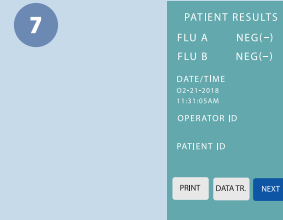
Open drawer until it clicks into place. Insert cassette with arrow facing Reader. Reader will beep when barcode is scanned.



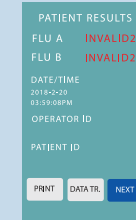
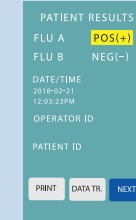
Gently mix sample. Invert vial carefully and add 5 drops to sample well. DO NOT add sample to the result well.



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



Results are displayed. If result is invalid, discard cassette. Repeat with new patient sample, reagent, and cassette. Select NEXT and follow prompts to return to MAIN MENU.



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

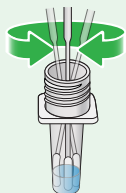
Because every result matters™

A. EXTRACT SAMPLE

NOTE: Sample must be placed in extraction buffer within 6 hours of collection

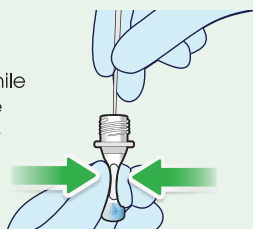
1 NOTE: Before setting up Reader, extract samples for testing.

Insert swab into extraction buffer vial and mix against side of vial 10 times.



vigorously mix 10x

2 Remove swab while squeezing middle of vial to remove liquid from swab.



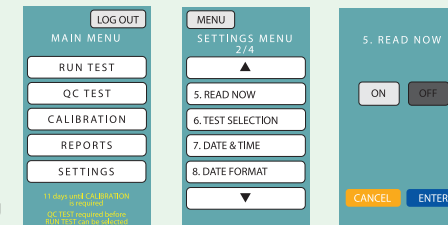
3 Attach dropper tip to vial. Press tightly to seal. Keep vial upright. Label vial with patient ID.



B. SET-UP READER (READ NOW MODE)

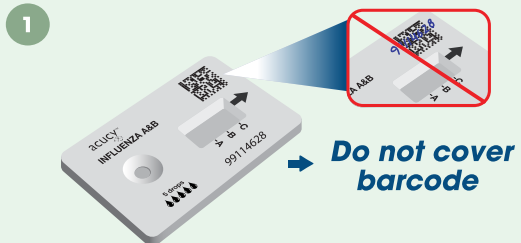
If needed, set Reader to READ NOW Mode.

1. Select SETTINGS from MAIN MENU
2. Enter SUPERVISOR PASSWORD and then ENTER
3. Scroll down and select READ NOW
4. Select ON and then ENTER
5. Select MENU to return to MAIN MENU

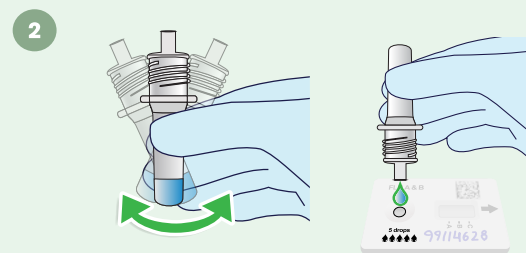


C. RUN TEST (READ NOW MODE)

In READ NOW Mode, process sample outside of Reader on a flat surface. After 15 minutes, place cassette into Reader. Dropped cassettes (regardless of whether samples were added to the cassettes) should be discarded.



Remove cassette from foil pouch and label with patient ID. DO NOT cover barcode or write on back of cassette. Test cassette must be used within 30 minutes of opening or will need to be discarded.



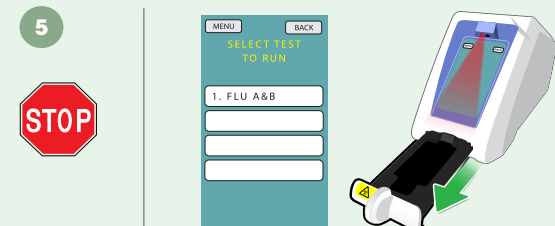
Gently mix sample. Invert vial and carefully add 5 drops to sample well. DO NOT add sample to the result well.



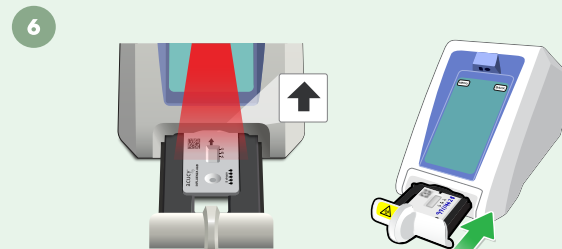
Start external timer for 15 minutes.



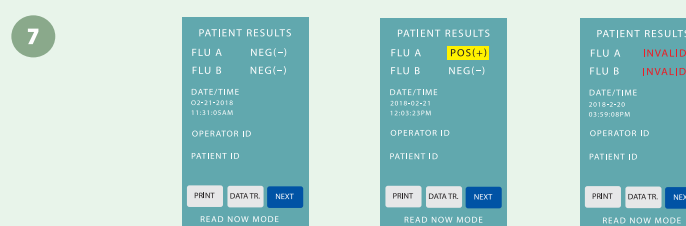
Select RUN TEST from MAIN MENU screen, then select OPERATOR ID. Select BARCODE or KEYPAD, then scan or manually enter PATIENT ID.



Wait FULL 15 minutes before selecting FLU A&B test. Once 15 minutes is complete, open drawer until it clicks into place. **NOTE:** Allowing the cassette to develop for more than 15 minutes may generate erroneous results.



Insert cassette with arrow facing Reader. Reader will beep when barcode is scanned. Close door tightly.



Results are displayed. If Result is invalid, discard cassette. Repeat with new patient sample, reagent, and cassette. Select NEXT and follow prompts to return to MAIN MENU or continue testing.

If the test does not perform as expected, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only), and 781-652-7800 (outside the U.S.)