



Influenza A&B Test

External Quality Control (QC)

Quick Reference Guide

CLIA Waived for Nasal 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_{ON}LY



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

External QC requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, SEKISUI Diagnostics recommends that External Quality Control be run with each new lot, shipment received, and with each new operator.



QUALITY CONTROL

The Positive Influenza A+/B- Control Swab (**RED LABEL**) must be run first, followed by the Positive Influenza A-/B+ Control Swab (**BLUE LABEL**).

The total QC testing process will take 30 minutes to run.

Dropped cassettes should be discarded.

RUN QC TEST

1

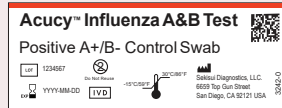
1.1 From MAIN MENU, select .

1.2 From OPERATOR ID screen, select your .

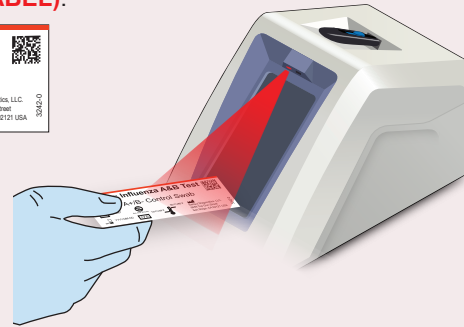
1.3 From TEST screen, select .

2

Scan control barcode on A+/B- Control Swab (**RED LABEL**).



Once you hear a beep, proceed to step 3.



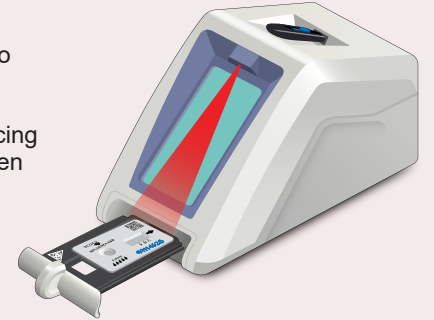
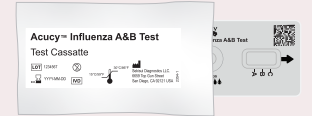
3

Remove Test Cassette from foil pouch. Once open, use within 30 minutes.

Open drawer until it clicks into place.

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

Keep drawer open.



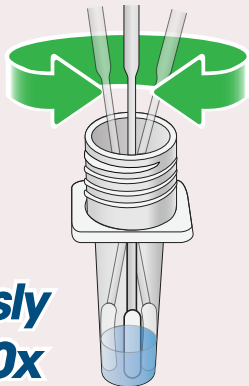
4

Twist cap off Extraction Buffer Vial.

Remove control swab from pouch.

Insert control swab into liquid.

Mix against side of the vial 10 times.

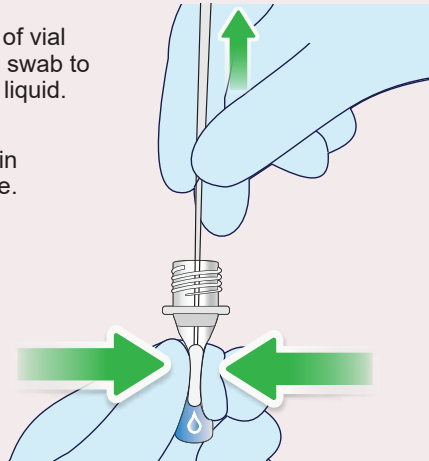


vigorously mix 10x

5

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

Dispose swab in biohazard waste.



6

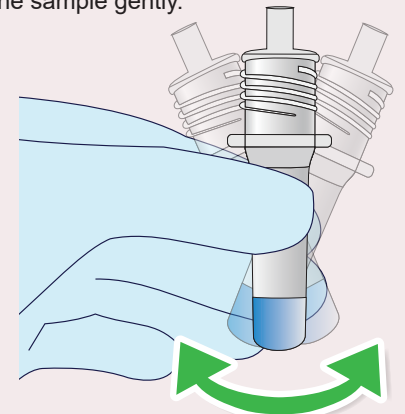
Attach dropper tip to vial.

Press tightly to seal.



7

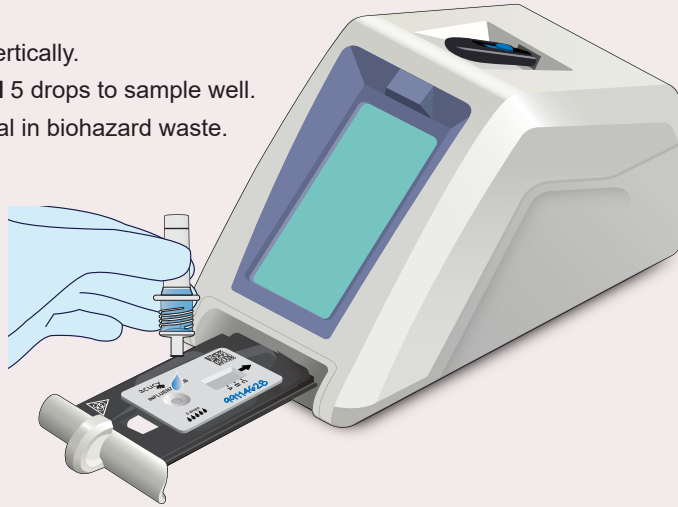
Mix the sample gently.



RUN QC TEST (continued from other side)

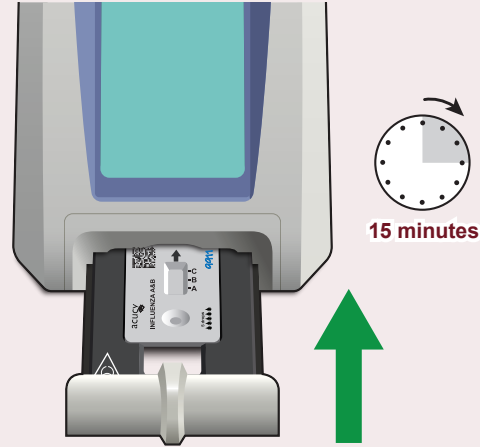
8

Hold vial vertically.
Slowly add 5 drops to sample well.
Dispose vial in biohazard waste.



9

Immediately close drawer tightly. Test will run for 15 minutes.



10

When Flu A+/B- (RED LABEL) Control is complete, open drawer, remove cassette and press NEXT.

Dispose cassette in biohazard waste.

COMPLETED

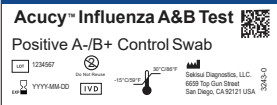
Remove the test cassette from the drawer

NEXT

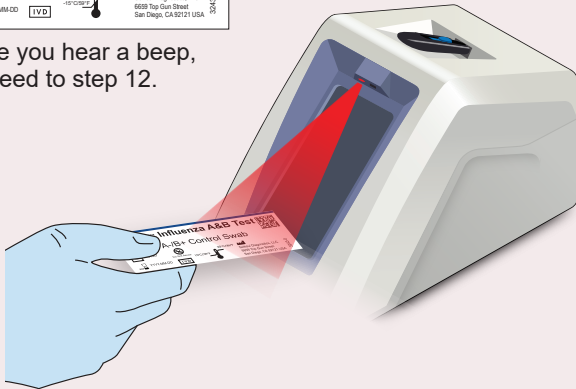
CANCEL

11

Scan control barcode on Positive A-/B+ Control Swab label (BLUE LABEL).



Once you hear a beep, proceed to step 12.



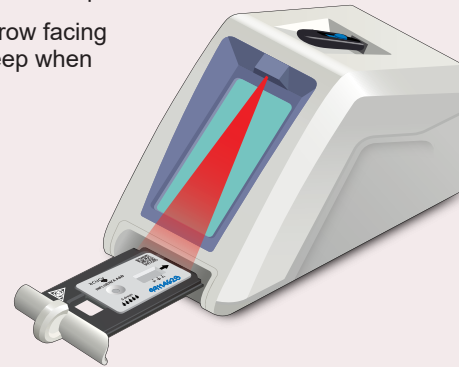
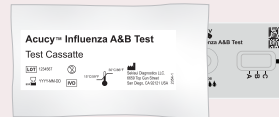
12

Remove Test Cassette from foil pouch. Once open, use within 30 minutes.

Open drawer until it clicks into place.

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

Keep drawer open.



Test cassette must be used within 30 minutes of opening or will need to be discarded.

13

Follow Steps 4-9 to Extract Control Swab and Run QC Test with the Influenza A-/B+ Control Swab.

14

QC RESULTS INTERPRETATION

| Display | Interpretation |
|----------------|-------------------|
| QC TEST PASSED | QC Results Passed |
| QC TEST FAILED | QC Results Failed |

QC TEST results will be displayed as PASSED or FAILED.

If External QC testing fails, repeat both tests using new control swabs, reagents and cassettes.