

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

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.

REF 1010 Rx_{only} IVD

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.

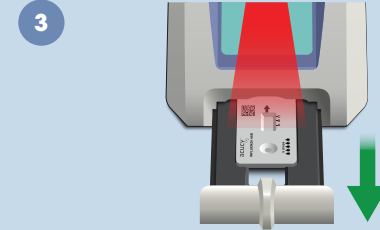
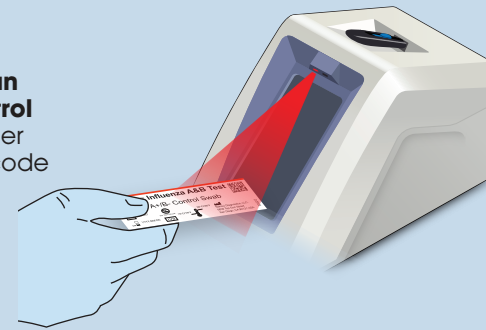
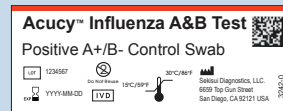
A. RUN QC TEST (A+/B- CONTROL SWAB)

Running external control requires running both positive control samples (A+/B- & A-/B+) requiring a total of 30 minutes. Dropped cassettes (regardless of whether samples were added to the cassettes) should be discarded.



- 1- Select QC TEST from MAIN MENU
- 2- Select OPERATOR ID
- 3- Select test FLU A&B

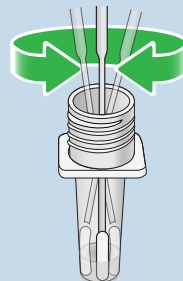
2 When prompted by Reader, scan barcode on Positive A+/B- Control swab pouch. (RED LABEL). Reader will beep when swab pouch barcode has been detected.



3 Remove cassette from foil pouch. Open drawer slowly until it clicks into place. Insert cassette with arrow facing Reader. Reader will beep when cassette has been detected. Test cassettes must be used within 30 minutes of opening or will need to be discarded.

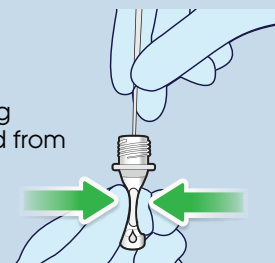
B. EXTRACT CONTROL SWAB

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



vigorously mix 10x

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

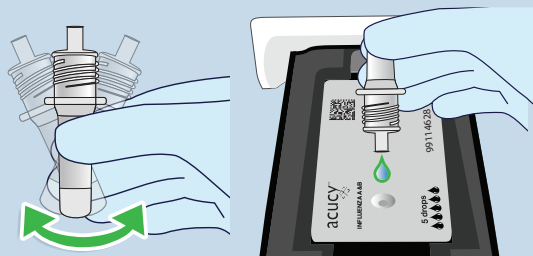


6 Attach dropper tip to vial. Press tightly to seal.



C. RUN QC TEST

7



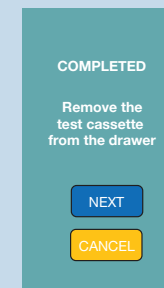
Gently mix sample. Hold vial vertically and gently add 5 drops to sample well. DO NOT add sample to the results window.

8



Immediately close drawer tightly. Reader will automatically time the 15-minute development.

9

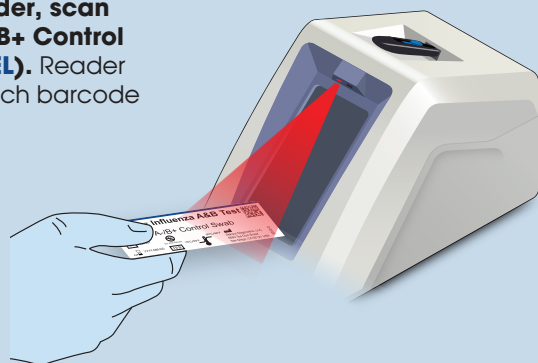
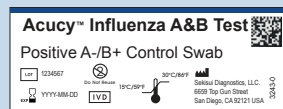


When Flu A+/B- is complete, open drawer, remove cassette and press NEXT.

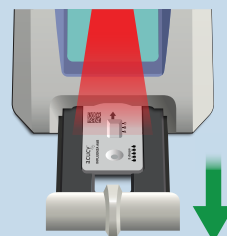
D. RUN QC TEST (A-/B+ CONTROL SWAB)

10

When prompted by Reader, scan barcode on Positive A-/B+ Control swab pouch. (**BLUE LABEL**). Reader will beep when swab pouch barcode has been detected.



11

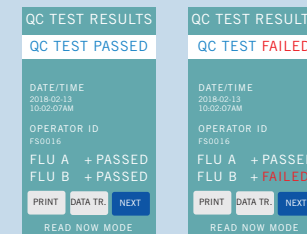


Remove cassette from foil pouch. Insert cassette with arrow facing Reader. Reader will beep when cassette has been detected. Test cassette must be used within 30 minutes of opening or will need to be discarded.

12

Follow Steps 4-8 to Extract Control Swab and Run QC Test with the Influenza A-/B+ Control Swab.

13



QC TEST results will be displayed as PASSED or FAILED. If External QC testing fails, repeat the test using new control swabs, reagents and cassettes.

TECHNICAL SUPPORT

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