

Influenza A&B Control Kit

Instructions For Use

REF 1011 IVD **R_x** only

INTENDED USE

Acucy™ Influenza A&B Control Kit is intended for in vitro diagnostic use in external quality control testing with the Acucy™ Influenza A&B Test and Acucy™ System.

SUMMARY

The Acucy Influenza A&B Control Kit provides swabs coated with dried, inactivated influenza A or B virus. The level of influenza A or B antigen applied to the swab is sufficient to provide a positive result when used with the Acucy Influenza A&B Test. The Influenza A control swab acts as a negative control for the influenza B antigen and conversely, the Influenza B control swab serves as a negative control for influenza A antigen. When used for external quality control in the Acucy Influenza A&B Test, these controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED

- 5 - Influenza A+/B- Control Swab (individually foil pouched with desiccant): Formalin inactivated Influenza A containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- 5 - Influenza A-/B+ Control Swab (individually foil pouched with desiccant): Formalin inactivated Influenza B containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- 1 - Instructions For Use (IFU)

MATERIALS REQUIRED BUT NOT PROVIDED

- Acucy Influenza A&B Test (Catalog # 1010)
- Acucy System (Catalog # 1039)
- Nitrile, Latex (or equivalent) Gloves

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Not for patient use.
- Do not use the Controls beyond the expiration date.
- Potential biohazard. Handle as if potentially infectious. Handle this product according to established good laboratory practices using appropriate precautions.

STORAGE AND STABILITY

- The Acucy Influenza A&B Control Kit must be stored at 15°C-30°C/59°F-86°F.
- The swabs should be kept in the pouch until ready for use.
- Controls are stable until the expiration date on the label.

EXTERNAL QUALITY CONTROL PROCEDURE

The control swabs provided should be tested using the **WALK AWAY/NORMAL** Mode provided in this Instructions For Use or the Quick Reference Guide in the Acucy Influenza A&B Test Instructions For Use.

NOTE: External Control Test Cassettes developed on the counter or benchtop will result in an INVALID result.

NOTE: Running external controls requires running both positive control swabs (Influenza A+/B- & Influenza A-/B+) requiring a total of 30 minutes.

NOTE: The Influenza A+/B- Control Swab (**RED LABEL**) must be run first, followed by the Influenza B+/A- Control Swab (**BLUE LABEL**). Do not discard External QC swab pouch. It is required for barcode scanning on the Reader.

1. From the MAIN MENU, select QC TEST, scroll down to select OPERATOR ID, and select test to run: FLU A&B.
2. When prompted by the Reader, scan the barcode on the Influenza A+/B- Control Swab pouch (**RED LABEL**). Reader will beep when swab pouch barcode has been read.
3. Remove Test Cassette from the foil pouch. Open the drawer slowly until it clicks into place and insert a Test Cassette.
4. Following the EXTRACT SAMPLE procedure, process the Control Swab in the Extraction Buffer vial.
5. Gently mix solution to agitate sample.
6. Invert the Extraction Buffer vial containing the prepared sample vertically above the Test Cassette so that the tip is approximately half an inch above the sample well.
7. Gently squeeze 5 drops into the sample well of the Test Cassette.
NOTE: Allow for full drops to form and fall freely from dropper tip.
8. Close the drawer within 10 seconds of adding the sample to Test Cassette. The Reader will automatically time the 15-minute development.
9. When the Influenza A+/B- control measurement is complete, open the drawer, remove the Test Cassette and press NEXT to advance to the Influenza B+/A- Control Swab (**BLUE LABEL**).
10. When prompted by the Reader, scan the barcode on the Influenza B+/A- Control Swab pouch (**BLUE LABEL**). Repeat steps 3 – 8 above using the Influenza B+/A- Positive Control Swab.

INTERPRETATION OF RESULTS

QC TEST Results will be displayed upon completion. The results will be displayed as "PASSED" or "FAILED" for the Influenza A+/B- Control and Influenza A-/B+ Control.

DISPOSING OF MATERIALS














Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

RE-ORDER NUMBER

Catalog No.1010 Acucy Influenza A&B Test
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TECHNICAL ASSISTANCE

If External QC testing fails, repeat the test using new control swabs, reagents and test cassettes or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.), before running patient samples.

 <p>Instructions For Use</p>	 <p>Temperature</p>	 <p>Contains sufficient for "n" tests</p>	 <p>Product Catalog Number</p>
 <p>In Vitro Diagnostics</p>	 <p>Manufacturer</p>	 <p>Positive Control</p>	 <p>Expiration Dating</p>
 <p>Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.</p>	 <p>Recycled content-packaging, kit box, Instructions For Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.</p>	 <p>Negative Control</p>	
 <p>Product Batch Number</p>		 <p>Single-use only. Do Not Reuse.</p>	



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Because every result matters™

