acucy™

INFLUENZA A&B TEST
INSTRUCTIONS FOR USE

acucy™ INFLUENZA A&B TEST WITH THE ACUCY SYSTEM

REF 1010 IVD Rx only

For use with nasal or nasopharyngeal swab specimens.

CLIA COMPLEXITY: WAIVED

A Certificate of Waiver is required to perform this test in a CLIA Waived environment. To obtain CLIA waiver information and a Certificate of Waiver, contact your state health department. Additional information is available at www.cms.hhs.gov/CLIA.

INTENDED USE

The Acucy™ Influenza A&B Test for the rapid qualitative detection of influenza A&B is composed of a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients that is automatically analyzed on the Acucy™ Reader. The Acucy Influenza A&B Test is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single Test Cassette. The test is intended for use with the Acucy™ System as an aid in the diagnosis of influenza A and B viral infections. The test is not intended for the detection of influenza C viruses. Negative test results are presumptive and should be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2017-2018 influenza season when influenza A/H3N2 and A/H1N1pdm09 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.[2]

SUMMARY AND EXPLANATION

Along with the common cold, influenza is one of the most common acute respiratory infections, producing symptoms such as headache, chills, dry cough, body aches and fever. It affects 5% – 20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths.[1] The influenza A virus is typically more prevalent and is associated with the most serious influenza epidemics, while influenza B infections usually present with more mild symptoms. Diagnosis is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Accurate diagnosis and the ability to distinguish between A or B antigens can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an antiviral therapy. Initiation of antiviral therapy should begin as soon as possible after onset, ideally within 48 hours of the appearance of symptoms, as treatment may reduce the duration of symptoms and hospitalization.[2] The Acucy Influenza A&B Test can provide rapid detection of influenza A and/or B viral antigens from symptomatic patients.

PRINCIPLE OF THE PROCEDURE

The Acucy Influenza A&B Test allows for the differential detection of influenza A and influenza B antigens, when used with the Acucy Reader. The patient sample is placed in the Extraction Buffer vial, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. From the sample well, the sample migrates along the membrane surface. If influenza A or B viral antigens are present, they will form a complex with mouse monoclonal antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by a rat anti-influenza A and/or mouse anti-influenza B antibody coated on the nitrocellulose membrane.

NOTE: Depending upon the operator's choice, the Test Cassette is either placed inside the Acucy Reader for automatically timed development mode (WALK AWAY/NORMAL Mode) or placed on the counter or bench top for a manually timed development and then placed into Acucy Reader to be scanned (READ NOW Mode).

The Acucy Reader will scan the Test Cassette and measure the absorbance intensity by processing the results using method-specific algorithms. The Acucy Reader will display the test results POS (+), NEG (-), or INVALID on the screen. The results can also be automatically printed on the Acucy Printer if this option is selected.

KIT CONTENTS

- 25 Test Cassettes: individually foil pouched with desiccant
- 25 Sterile Nasal Swabs
- 25 Extraction Buffer vials each containing: 0.4 mL phosphate buffered salt solution (with 0.09% sodium azide as a preservative)
- 25 Extraction Vial Dropper Tips
- 1 Influenza A+/B- Control Swab (packaged with a desiccant tablet): Formalin inactivated influenza A containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- 1 Influenza A-/B+ Control Swab (packaged with a desiccant tablet): Formalin inactivated influenza B containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- 1 Instructions for Use (IFU)
- 1 Quick Reference Guide (READ NOW and WALK AWAY/NORMAL Modes)
- 1 Workstation
- 1 External Quality Control (QC) Quick Reference Guide

NOTE: Two extra Test Cassettes and reagents have been included in the kit for External Quality Control (QC) testing.

MATERIALS REQUIRED BUT NOT PROVIDED

- Acucy System (Reader, Printer, and accessories) (Catalog # 1039)
- Acucy Calibration Device (Catalog # 1031)
- Timer or watch
- If needed, sterile nasopharyngeal swabs (Copan Catalog # 534CS01)
- If needed, additional external quality controls may be purchased separately (Acucy Influenza A&B Control Kit # 1011)

MATERIALS NOT REQUIRED BUT AVAILABLE

- Acucy Influenza A&B Test Training Module is accessible at www.sdxacademy.com

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.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- To obtain accurate results, the Instructions For Use must be followed.
- Swabs, Extraction Buffer vials, Extraction vials dropper tips, and Test Cassettes are for single use only (do not reuse).
- Do not interchange or mix components from different kit lots.
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient samples and all items exposed to patient samples.[3]
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.[3]
- Use of nitrile, latex (or other equivalent) gloves is recommended when handling patient samples.[3]
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- For optimal results use the nasal swabs provided in the kit.
- Do not write over the barcode of the Test Cassette. This is used by the Reader to identify the type of test to be run.
- Use the Extraction Vial Dropper Tips provided when adding the sample to the Test Cassette. Do not pour sample from the Extraction Buffer vial into the Test Cassette sample well.
- Discard and do not use any damaged or dropped Test Cassette or materials.

STORAGE AND STABILITY

- Store the Acucy Influenza A & B Test at room temperature (15℃ - 30℃/59℉ - 86℉) in the original packaging, away from direct sunlight.
- Kit contents are stable until the expiration date printed on the pouch or box.
- Do not freeze any of the test components.
- The user should not open the foil pouch of the Test Cassette until the cassette is ready for immediate use. **Once the foil pouch is opened, the Test Cassette must be used within 30 minutes or discarded.**

QUALITY CONTROL

There are three types of Quality Control for the Acucy System and Acucy Influenza A&B Test: Acucy Reader Calibration, Test Cassette Built-In Internal Control, and External Quality Control.

ACUCY READER CALIBRATION

Refer to the Acucy System Manual for complete instructions.

The Reader calibration is a required function that checks the Reader optics and calculation systems using a specific CAL-Device. The CAL-Device is required and supplied in a calibration storage case separately. The Calibration Procedure is performed upon installation to activate the QC TEST and RUN TEST functionality and is required every 30-days. The operator will be prompted by the Reader to conduct calibration with the CAL-Device after the 30-days has elapsed. The Calibration Procedure may also be performed, as directed during troubleshooting or whenever the Reader date and time has been changed.

Calibration Procedure:

1. Press the power switch located on the rear panel of the Reader. The Reader must complete a 5 second power on self-test before it is ready for use.
2. Input OPERATOR PASSWORD then press ENTER.
3. Select CALIBRATION from the MAIN MENU.
4. Following the prompts, open the drawer slowly until it clicks into place and insert the CAL-Device into the drawer of the Reader. The Reader will read the information from the 2D barcode on the CAL-Device automatically.
5. Once barcode is read and “Close the drawer” is displayed, close the drawer completely and the Reader will automatically begin the test.

   NOTE: Insert the drawer all the way in until it stops.
6. When the calibration is complete in approximately 10 seconds, the Reader displays CALIBRATION RESULTS.
7. The results will be displayed as PASSED or FAILED.
8. Select NEXT on the screen.
9. Open the drawer and remove the CAL-Device. Return the CAL-Device to the storage case.
10. Touch the screen to return to the MAIN MENU.

NOTE: Ensure that the CAL-Device is stored in the provided storage case between uses to protect from exposure to light.

NOTE: If the CAL-Device has reached its expiration dating, a new Calibration Device can be purchased from a distribution retailer. (Acucy Calibration Device Catalog # 1031)

If the Calibration Device has been damaged or is not working properly, contact Sekisui Diagnostics Technical Support at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

NOTE: If the Calibration does not pass, notify the on-site Supervisor or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.).

Test Cassette Built-In Internal Control

The Acucy Influenza A&B Test Cassette contains a built-in internal control feature. Each time a test is run in the Reader, the internal control zone is scanned by the Reader. An "VALID" test result displayed by the Reader indicates that the internal control was present, demonstrates that the test flowed correctly, and that the functional integrity of the Test Cassette and reagents was maintained. An "INVALID" test result displayed by the Reader indicates that the internal control was not present, demonstrates that the test did not flow correctly, and that the functional integrity of the Test Cassette and reagents was not maintained. Should this occur, review the procedure and repeat the test using a new patient sample, Test Cassette, and reagent.

External Quality Controls

The Acucy Influenza A&B Test includes one Influenza A+/B- Control Swab **(RED LABEL)** and one Influenza A-/B+ Control Swab **(BLUE LABEL)**, each of which contains inactivated virus, for external quality control testing. The Influenza A+/B- Control Swab acts as a negative control for influenza B antigen and conversely, Influenza A-/B+ Control Swab serves as a negative control for influenza A antigen.

Use the External Quality Controls to help ensure that the assay-specific reagents, Test Cassettes, and Reader are functioning properly, and to demonstrate proper performance by the operator.

External Quality Control requirements should be established in accordance with local, state, and federal regulations or accreditations requirements.

Minimally, Sekisui Diagnostics recommends the External Quality Controls be run with each new lot, shipment received, and with each new untrained operator.

Additional controls may be purchased separately. (Acucy Influenza A&B Control Kit Catalog # 1011)

External Quality Control Procedure

Refer to the QUALITY CONTROL MANAGEMENT section of the Acucy System Manual for detailed instructions.

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

NOTE: The Influenza A+/B- Control Swab **(RED LABEL)** must be run first, followed by the Influenza A-/B+ Control Swab **(BLUE LABEL)**. Do not discard the External Quality Control 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 A-/B+ Control Swab **(BLUE LABEL)**.
10. When prompted by the Reader, scan the barcode on the Influenza A-/B+ Control Swab pouch **(BLUE LABEL)**. Repeat steps 3 – 8 above using the Influenza A-/B+ Control Swab.

QC TEST results will be displayed upon completion. The results will be displayed as PASSED or FAILED. To continue to the MAIN MENU, select NEXT, and follow the on-screen prompts.

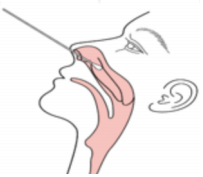
If External Quality Control testing fails, repeat the test using new control swabs, reagents and Test Cassettes or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the U.S.) before running patient samples.

SAMPLE COLLECTION AND PREPARATION

Only nasal/nasopharyngeal swabs can be used with this test. Use of nasal washes or aspirates has not been validated. Use of samples in viral transport medium has not been validated.

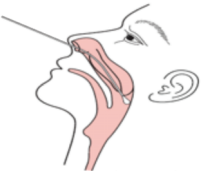
NOTE: Test samples as soon as possible after collection. Freshly collected patient samples should be processed in the Extraction Buffer vial within 6 hours of collection. If the sample is not processed immediately, the patient swab may be stored at room temperature (15℃ - 30℃/59℉ - 86℉) or refrigerated (2℃-8℃/36℉ – 46℉) for up to 6 hours prior to testing.

NOTE: For optimal results, use only the nasal swabs supplied in the Acucy Influenza A&B Test kit (or the nasopharyngeal swab - Copan Catalog # 534CS01). Do not use swabs that have cotton, rayon, or polyester tips or wooden shafts.



Nasal Swab Sample (Provided in the kit)

1. Gently insert the sterile swab into the nostril that appears to have the most secretion. Insert until resistance is met at the level of the turbinates (less than one inch into the nostril).
2. Rotate the swab several times against the nasal wall and remove from the nostril.
3. Sample should be processed in the Extraction Buffer within 6 hours after collection.



Nasopharyngeal Swab Sample (use a nylon flocked nasopharyngeal swab, not provided)

1. Gently insert the sterile swab into the nostril that appears to have the most secretion.
2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx.
3. Rotate the swab several times and remove from nostril.
4. Sample should be processed in the Extraction Buffer within 6 hours after collection.

SAMPLE HANDLING

- The test performance depends on the quality of the sample obtained as well as the handling and transport of the sample. Negative results can occur from inadequate sample collection and/or handling.
- **If immediate testing is not possible**, the sample can be extracted according to the extract sample procedure, recap the vial and store the extracted sample at room temperature (15℃ - 30℃/59℉ - 86℉) or refrigerated (2℃-8℃/36℉ – 46℉) for up to 12 hours. Samples must be allowed to come to room temperature before testing.
- To obtain accurate results, do not use visually bloody or overly viscous samples.
- To transport patient samples, place swab in a clean, dry container such as a plastic or glass tube.
- If a culture result is desired, a separate swab must be collected for the culture.

TEST PROCEDURE: EXTRACT SAMPLE

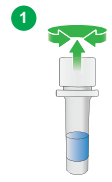
Samples should be at room temperature before testing.

1. Remove cap off an Extraction Buffer vial.

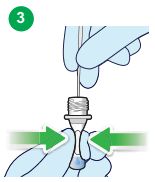
NOTE: Sample must be extracted in the Extraction Buffer vial within 6 hours of collection.

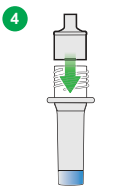
2. Hold the Extraction Buffer vial with one hand and the swab with the other. Insert swab sample into Extraction Buffer vial and while pressing down on the swab, vigorously mix against the side of the vial 10 times (while submerged).

NOTE: Best results are obtained when the sample is vigorously mixed in the buffer.



3. Remove the swab while squeezing the middle of the vial to remove the liquid from the swab. Properly discard the swab.
4. Add Extraction Vial Dropper Tip to the Extraction Buffer vial. Press tightly to seal. Label with patient identification.





NOTE: The operator should not open the foil pouch exposing the Test Cassette to the ambient environment until ready for immediate use. Once the foil pouch is opened, the Test Cassette must be used within 30 minutes or discarded.

ACUCY READER MODES

WALK AWAY/NORMAL and READ NOW Modes
When using the Reader, the procedure for evaluating the Test Cassettes will depend on the workflow configuration chosen by the operator.

NOTE: Before running a test, it is critical to use the correct test procedure for either the WALK AWAY/NORMAL or READ NOW modes.

NOTE: The Reader will remain in the mode that was last used during testing. Running a test in the wrong mode will produce invalid results.

Refer to the Acucy System Manual for operating instructions.
The Reader may be set to two different modes (WALK AWAY/NORMAL and READ NOW). The procedures for each mode are described separately below.

WALK AWAY/NORMAL Mode
In the WALK AWAY/NORMAL Mode, Test Cassettes are inserted into the Reader. Then, after the addition of the sample, the development and timing of the test occur within the Reader. This allows the user to “walk away” until the test result has been completed.

SET-UP READER TO WALK AWAY/NORMAL Mode (If needed, set Reader to WALK AWAY/NORMAL Mode.)

1. From the MAIN MENU screen, select SETTINGS. **2.** Input SUPERVISOR PASSWORD, press ENTER.	1  2 
3. Use the up ▲ and down ▼ arrow buttons to scroll through the SETTINGS MENU. Scroll to SETTING MENU 2/4, then select 5. READ NOW. **4.** Confirm the READ NOW Mode is in the OFF position (highlighted white). If not, press the OFF button, which will highlight white and press ENTER to turn off the READ NOW Mode.	3  4 

WALK AWAY/NORMAL MODE TEST PROCEDURE

1. From the MAIN MENU select RUN TEST
2. Select appropriate OPERATOR ID
   (Use the down ▼ arrow buttons to scroll, if needed)
3. The PATIENT ID screen will be displayed. Press BARCODE or KEYPAD.

4. If barcode is selected, scan patient's ID barcode using the Reader scanner and press ENTER.

   OR

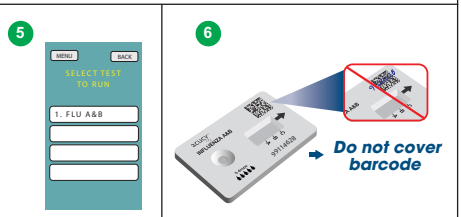
   If KEYPAD is selected, use the keypad to enter PATIENT ID and press ENTER.

5. From the SELECT TEST TO RUN screen, select FLU A&B.
6. Open the Test Cassette foil pouch and label the Test Cassette with the PATIENT ID.

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

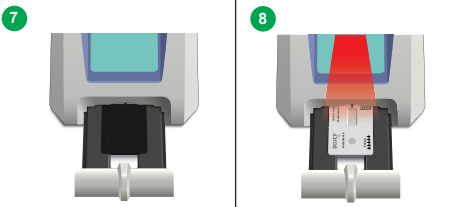
NOTE: Do not cover barcode with PATIENT ID.

NOTE: Do not write on back of cassette.



7. Open the drawer slowly until it clicks into place.
8. Insert Test Cassette with arrow facing the Reader.

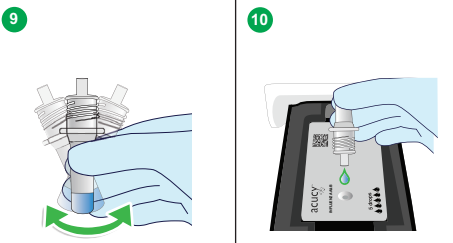
NOTE: The Reader will automatically scan the Test Cassette. Once the beep is heard, the test is detected and you can proceed with adding the sample.



9. Gently mix the Extraction Buffer vial to agitate sample.
10. While Test Cassette is in the drawer, invert the Extraction Buffer vial vertically above the Test Cassette so that the tip is approximately half an inch above the sample well.

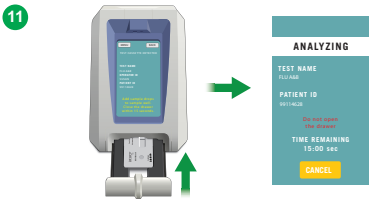
    Gently and carefully squeeze 5 drops into the sample well of the Test Cassette. DO NOT add sample to the result well of the Test Cassette.

NOTE: Allow for full drops to form and freely fall from dropper tip. Adding more than 5 drops of sample to the sample well of the Test Cassette may generate invalid or false results.



11. Close the drawer within 10 seconds. The Reader will automatically time the 15-minute development.

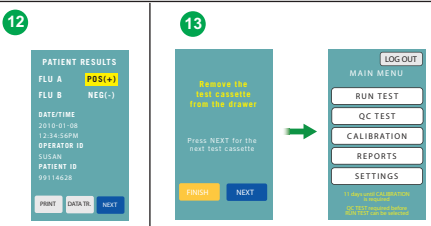
NOTE: After the 15 minutes is complete, the Reader will automatically display and print the test results.



12. Press the NEXT button, open the drawer and remove the Test Cassette.

13. Dispose of the Test Cassette in the proper biohazard container and press the NEXT button on the screen to return to the MAIN MENU.

SEE INTERPRETATION OF RESULTS SECTION



READ NOW Mode

In READ NOW Mode the Reader analyzes the results after manually timing the development of the Test Cassette on a flat surface for the full 15 minutes. This mode is helpful if you are running multiple samples in a batch format.

Please note that Test Cassettes prepared on the bench in READ NOW Mode cannot be run in WALK AWAY/NORMAL Mode. Running the tests in the wrong mode will produce invalid results.

NOTE: Allow the Test Cassettes to develop for the FULL 15 minutes BEFORE placing a Test Cassette into the Reader. Allowing the Test Cassette to develop for more than 15 minutes may generate erroneous results.

Tips for Batch Testing Using READ NOW Mode

Depending on the workload, options exist to make batch testing easier and more efficient (READ NOW Mode).

1. When batch testing, it is suggested that the operator extract each sample and stagger the initiation of each test by approximately 2 minutes to process the sample efficiently.
2. Label an Extraction Buffer vial and Test Cassette for each sample with the PATIENT ID. Match each labeled Extraction Buffer vial with the labeled Test Cassette.
3. For sample #1, add 5 drops of the extracted sample into the sample well of Test Cassette #1. Start a timer for 15 minutes.
4. Approximately 2 minutes later add sample #2 to Test Cassette #2 and start a timer for 15 minutes.
5. Repeat step 3 for each sample to be tested (up to 7 samples per batch).
6. After the 15 minutes is up, input PATIENT ID, insert Test Cassette #1, and close the drawer. Test results will be displayed.
7. Press NEXT, then remove the Test Cassette from the drawer.
8. Press NEXT again to test the next sample.
9. Repeat Step 6-8 for each remaining sample.
10. Press FINISH once all batch testing is complete.

SET-UP READER TO READ NOW Mode (If needed, set Reader to READ NOW Mode.)

1. From the MAIN MENU screen, select SETTINGS.
2. Input SUPERVISOR PASSWORD, press ENTER.

3. Use the up ▲ and down ▼ arrow buttons to scroll through the SETTINGS MENU. Scroll to SETTING MENU 2/4, then select 5. READ NOW.
4. Confirm the READ NOW Mode is in the ON position (highlighted white). If not, press the ON button, which will highlight white and press ENTER to turn on the READ NOW Mode.

READ NOW MODE TEST PROCEDURE

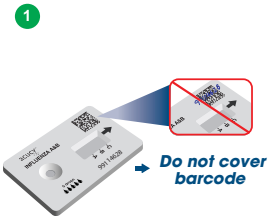
1. Open the Test Cassette foil pouch and label the Test Cassette with the PATIENT ID.

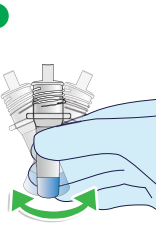
NOTE: Test cassette must be used within 30 minutes of opening or will need to be discarded.

NOTE: Do not cover barcode with PATIENT ID.

NOTE: Do not write on back of cassette.

2. Gently mix the Extraction Buffer vial to agitate sample.





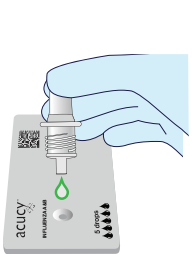
3. While Test Cassette is on a flat surface, invert the Extraction Buffer vial vertically above the Test Cassette so that the tip is approximately half an inch above the sample well.

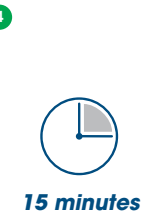
   Gently and carefully squeeze 5 drops into the sample well of the Test Cassette. DO NOT add sample to the result well of the Test Cassette.

NOTE: Allow for full drops to form and freely fall from dropper tip. Adding more than 5 drops of sample to the sample well of the Test Cassette may generate invalid or false results.

4. Start an external timer for 15 minutes.

NOTE: It is important to allow the Test Cassette to develop for the full 15 minutes before placing it into the Reader drawer.





5. From the MAIN MENU select RUN TEST

6. Select appropriate OPERATOR ID (Use the down ▼ arrow buttons to scroll, if needed)

7. The PATIENT ID screen will be displayed. Press BARCODE or KEYPAD.

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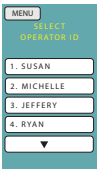

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8. If barcode is selected, scan patient's ID barcode using the Reader scanner and press ENTER.

OR

If KEYPAD is selected, use the keypad to enter PATIENT ID and press ENTER.

8

OR

9. **STOP:** Wait the full 15 minutes before continuing to the next step.

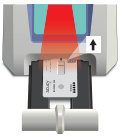
10. Once the 15 minutes is complete, select FLU A&B and then open the drawer until it clicks into place.

11. Insert Test Cassette with arrow facing the Reader.

9

10

11

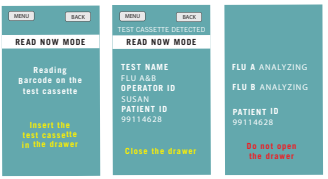


NOTE: The Reader will automatically scan the Test Cassette.

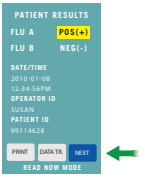
12. Once the beep is heard, the test is detected. Immediately close the drawer tightly. Reader will automatically display and print the test results.

13. Press the NEXT button.

12



13

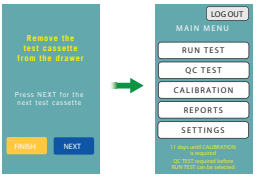


14. Open the drawer and remove the Test Cassette. Dispose of the Test Cassette in the proper biohazard container.

NOTE: If additional samples are being tested and need to be analyzed, press NEXT and follow the on-screen instructions or select FINISH to return to the MAIN MENU.

SEE INTERPRETATION OF RESULTS SECTION

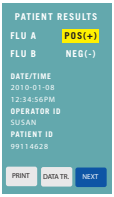
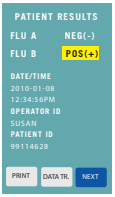
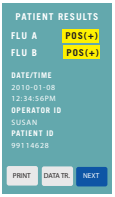
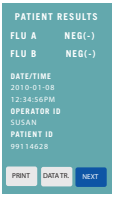
14



INTERPRETATION OF RESULTS

When the test is complete, the results will be displayed on the Reader screen. The results can also be printed by the printer (refer to the Acucy System Manual for further instructions).

The Reader will display results for FLU A&B separately. The results will be reported as POS (+), NEG (-), or INVALID. Any INVALID result should be re-tested with a new patient sample, reagent, and Test Cassette.

INFLUENZA A POSITIVE Screenshot showing a valid **positive result for influenza A and a negative result for influenza B.** **NOTE:** This positive result does not rule out co-infection with other pathogens.	
INFLUENZA B POSITIVE Screenshot showing a valid **positive result for influenza B and a negative result for influenza A.** **NOTE:** This positive result does not rule out co-infection with other pathogens.	
INFLUENZA A&B POSITIVE Screenshot showing a valid **positive result for both influenza A and influenza B.** **NOTE:** A dual positive result does not rule out co-infection with other pathogens or identify any specific influenza A or B virus subtypes **Note:** Co-infection with influenza A and B is rare. It is recommended that a dual positive sample (influenza A and influenza B positive) should be re-tested.	
NEGATIVE Screenshot showing valid **negative result for influenza A & influenza B**. **Note:** A negative result does not exclude influenza viral infection. Negative results should be confirmed by viral culture or an FDA-cleared influenza A and influenza B molecular assay.	
INVALID Screenshot showing invalid results. **Note:** If invalid results are obtained, repeat the test using a new patient sample, reagent and Test Cassette.	

LIMITATIONS

- The contents of this kit are to be used for the qualitative detection of influenza type A and B antigens from nasal and nasopharyngeal swab samples.
- This test detects both viable (live) and non-viable influenza A and B. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the TEST PROCEDURE may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific influenza A virus subtypes.
- Negative test results are not intended to rule in other non-influenza viral or bacterial infections.
- Children tend to shed virus more abundantly and for longer periods of time than adults. Therefore, testing samples from adults will often yield lower sensitivity than testing samples from children.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.
- Individuals who received nasally administered influenza A vaccine may have positive test results for up to 3 days after vaccination.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, influenza A viruses that have undergone minor amino acid changes in the target epitope region.
- If differentiation of specific influenza A subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Samples contaminated with whole blood >5% v/v or mucin >19 mg/mL v/v may interfere in the interpretation of the test. Visually bloody or overly viscous samples should not be used.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- The performance of this test has not been evaluated for monitoring antiviral treatment of influenza.

EXPECTED VALUES

The prevalence of influenza varies year to year, typically peaking in the winter months. The rate of positivity in influenza testing is impacted by many factors, including specimen collection and handling, test method used, patient age, time of year, geographic location and local disease prevalence. The overall positivity rate as determined by the Acucy Influenza A&B Test during the 2017-2018 U.S. clinical study, based on 1003 evaluable nasal or nasopharyngeal swab samples, was 24.6% for influenza A and 14.6% for influenza B. The observed results by age are:

Prospective Clinical Study during the 2017/2018 Influenza Season			
Age Group	**Number of Specimens**	**Number of Influenza A Positives**	**Influenza A Positivity Rate**
≤ 5 years of age	326	84	25.8%
6 to 21 years of age	406	130	32.0%
≥ 22 years of age	271	33	12.2%
Total	1003	247	24.6%

Prospective Clinical Study during the 2017/2018 Influenza Season			
Age Group	**Number of Specimens**	**Number of Influenza B Positives**	**Influenza B Positivity Rate**
≤ 5 years of age	326	36	11.0%
6 to 21 years of age	406	76	18.7%
≥ 22 years of age	271	34	12.5%
Total	1003	146	14.6%

PERFORMANCE CHARACTERISTICS

PROSPECTIVE CLINICAL STUDY

A prospective clinical study to establish the performance characteristics of the Acucy Influenza A&B Test in detecting influenza A and B antigens in nasal and nasopharyngeal swab specimens was conducted during the 2017 – 2018 flu season at 16 sites across the United States. Sites included family practice and pediatric offices, and clinics.

To be enrolled in the study, patient subjects had to present at the participating study centers with influenza-like symptoms as defined in the clinical study protocol and provide informed consent. Patient subjects were randomized to have either two nasal swabs or two nasopharyngeal swabs collected according to standard collection methods (i.e., even numbered subjects had two nasal swabs collected and odd numbered subjects had two nasopharyngeal swabs collected). The paired nasal swabs or nasopharyngeal swabs were obtained from each subject from the same nostril. The paired swabs were collected in no set order for testing under the clinical study protocol (i.e., one for Acucy Influenza A&B Test and the other for reference methods testing). Any swab specimens required for standard of care testing were collected prior to the specimens for this investigation; nasal washes/aspirates for standard of care testing excluded a patient from study participation.

One of the paired nasal or nasopharyngeal swabs was used for immediate testing with the Acucy Influenza A&B Test per the Instructions for Use. The other nasal or nasopharyngeal swab of the pair was rotated in 3.0 mL of viral transport media (VTM) for 10 seconds within one hour of specimen collection. The swab was subsequently removed and discarded. The sample eluted in VTM was stored at 2-8ºC until transport was made on the same day as specimen collection on ice-packs in an insulated container. The samples collected in VTM were tested by the reference methods within the allowable time frames of specimen collection per the standard reference laboratory cell culture procedure or the Instructions for Use for the FDA-cleared molecular tests.

Nasal or nasopharyngeal swab specimens were collected from 1053 subjects enrolled in the prospective clinical study. Of those, 41 swab samples were unevaluable due to patient eligibility and sample handling issues, or inconclusive reference testing results, leaving a total of 1012 prospectively collected swab samples to be included in the evaluation of the assay performance. There were an additional nine samples that generated an invalid result with the Acucy Influenza A&B Test, resulting in a total of 1003 evaluable samples. The subject age and gender distribution for all the 1003 prospective evaluable specimens is presented in table below.

Patient Demographics

Age Group	Number	Percentage of Patients
≤ 5 years	326	32.5%
6 to 21 years	406	40.5%
22 to 59 years	209	20.8%
≥ 60 years	62	6.2%
Total	1003	100%
Sex	**Number**	**Percentage of Patients**
Male	514	51.2%
Female	489	48.8%
Total	1003	100%

Performance of the Acucy Influenza A&B Test was compared to a composite reference, consisting of two FDA cleared molecular influenza A&B assays and cell culture to determine the Sensitivity and Specificity in nasal and nasopharyngeal swab specimens. A sample was considered positive for influenza A or influenza B by the composite reference if two or three of the comparative reference methods gave a positive result. A sample was considered negative for influenza A or influenza B by the composite reference if two or three of the comparative reference methods gave a negative result.

COMPARISON OF ACUCY INFLUENZA A&B TEST TO COMPOSITE REFERENCE: ALL NASAL AND NASOPHARENGEAL SWAB SAMPLES

Acucy Influenza A&B Test - Influenza A performance against a composite reference

Acucy Influenza A&B Influenza A	Composite Reference		
	Positive	Negative	Total
Positive	216	31	247
Negative	8	748	756
Total	224	779	1003
Sensitivity/Specificity	96.4%, 216/224 (95% CI 93.1% – 98.2%) / 96.0%, 748/779 (95% CI 94.4% – 97.2%)		

Acucy Influenza A&B Test - Influenza B performance against a composite reference

Acucy Influenza A&B Influenza B	Composite Reference		
	Positive	Negative	Total
Positive	130	16	146
Negative	28	829	857
Total	158	845	1003
Sensitivity/Specificity	82.3%, 130/158 (95% CI 75.6.% – 87.4%) / 98.1%, 829/845 (95% CI 96.9%% – 98.8%)		

COMPARISON OF ACUCY INFLUENZA A&B TEST TO A COMPOSITE REFERENCE: NASAL SWAB SAMPLES

Acucy Influenza A&B Test - Influenza A performance against a composite reference

Acucy Influenza A&B Influenza A	Composite Reference		
	Positive	Negative	Total
Positive	96	16	112
Negative	4	379	383
Total	100	395	495
Sensitivity	96.0%, 96/100 (95% CI 90.2% – 98.4%)		
Specificity	95.9%, 379/395 (95% CI 93.5% – 97.5%)		

Acucy Influenza A&B Test - Influenza B performance against a composite reference

Acucy Influenza A&B Influenza B	Composite Reference		
	Positive	Negative	Total
Positive	61	9	70
Negative	14	411	425
Total	75	420	495
Sensitivity	81.3%, 61/75 (95% CI 71.1% – 88.5%)		
Specificity	97.9%, 411/420 (95% CI 96.0% – 98.9%)		

COMPARISON OF ACUCY INFLUENZA A&B TEST TO A COMPOSITE REFERENCE: NASOPHARENGEAL SWAB SAMPLES

Acucy Influenza A&B Test - Influenza A performance against a composite reference

Acucy Influenza A&B Influenza A	Composite Reference		
	Positive	Negative	Total
Positive	120	15	135
Negative	4	369	373
Total	124	384	508
Sensitivity	96.8%, 120/124 (95% CI 92.0% – 98.7%)		
Specificity	96.1%, 369/384 (95% CI 93.7% – 97.6%)		

Acucy Influenza A&B Test - Influenza B performance against a composite reference

Acucy Influenza A&B Influenza B	Composite Reference		
	Positive	Negative	Total
Positive	69	7	76
Negative	14	418	432
Total	83	425	508
Sensitivity	83.1%, 69/83 (95% CI 73.7% – 89.7%)		
Specificity	98.4%, 418/425 (95% CI 96.6% – 99.2%)		

ANALYTICAL PERFROMANCE

REPRODUCIBILITY STUDIES

The reproducibility of the Acucy Influenza A&B Test was evaluated in testing performed at three point-of-care (POC) sites. A panel of swabs including negative (no virus), high negative (below the limit of detection), low positive (at or near the limit of detection) and moderate positive (at or near 2x the limit of detection) for influenza A and B were coded, randomized, and masked to the operators. The study was conducted with two operators per site over five non-consecutive days. As seen in the table below, the Acucy Influenza A&B Test produces reproducible results when tested by multiple intended users, at multiple sites, over multiple days.

Reproducibility Results by Site - Influenza A				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
Influenza A (H3N2) High Negative	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90)
Influenza A (H3N2) Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza A (H3N2) Moderate Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

Reproducibility Results by Site - Influenza B				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
Influenza B High Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza B Low Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
Influenza B Moderate Positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90)
Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

ANALYTICAL SENSITIVITY

The limit of detection (LoD) for the Acucy Influenza A&B Test was established in dilution studies performed with two influenza A strains and two influenza B strains on two lots of the Acucy Influenza A&B Test. The LoD represents the concentration of influenza virus that produces consistently positive results >95% of the time. The approximate LoD concentrations identified for each strain tested are listed in the table below.

Limit of Detection			
Strain	**Type**	**Subtype**	**LoD $TCID_{50}$/mL**
A/California/07/09 pdm	A	H1N1pdm09	$1.4x10^1$
A/Hong Kong/4801/14	A	H3N2	$7.1x10^1$
B/Brisbane/60/08	B	Victoria	$2.4x10^1$
B/Phuket/3073/13	B	Yamagata	$3.4x10^1$

ANALYTICAL REACTIVITY

A total of 28 influenza A and B strains were tested with the Acucy Influenza A&B Test, at levels at or near the assay LoD. All influenza A virus isolates gave positive A and negative B results. All influenza B virus isolates gave negative A and positive B results.

Analytical Reactivity				
Strain	**Concentration**	**Type**	**Subtype**	**Test Result**
A/NY/02/09	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1pdm09	Detected
A/Mexico/4108/09	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1pdm09	Detected
A/PR/8/34	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1	Detected
A/Singapore/63/04	$2.04x10^3$ $TCID_{50}$/mL	A	H1N1	Detected
A/Taiwan/42/06	$1.02x10^3$ $TCID_{50}$/mL	A	H1N1	Detected
A/Canada/6294/09	$2.12x10^3$ $TCID_{50}$/mL	A	H1N1pdm09	Detected
A/New Cal/20/99	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1	Detected
A/Solomon Islands/03/06	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1	Detected
A/NY/01/09	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1pdm09	Detected
A/NY/03/09	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1pdm09	Detected
A/Brisbane/59/07	$1.06x10^2$ $TCID_{50}$/mL	A	H1N1	Detected
A/Brisbane/10/07	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/Victoria/361/11	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/HK/8/68	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/Perth/16/09	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/Wisconsin/67/05	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/Rhode Island/01/2010	$5.00x10^5$ $TCID_{50}$/mL	A	H3N2	Detected
A/New York/55/2004	$2.00x10^5$ $TCID_{50}$/mL	A	H3N2	Detected
A/Florida/2/2006	$3.30x10^5$ $TCID_{50}$/mL	A	H3N2	Detected
A/Texas/50/2012	$1.06x10^2$ $TCID_{50}$/mL	A	H3N2	Detected
A/Texas/71/2007	$4.08x10^3$ $TCID_{50}$/mL	A	H3N2	Detected
A/Indiana/08/2011	$5.30x10^2$ $TCID_{50}$/mL	A	H3N2v	Detected
B/Malaysia/2506/04	$5.10x10^1$ $TCID_{50}$/mL	B	B	Detected
B/Massachusetts/2/12	$5.10x10^2$ $TCID_{50}$/mL	B	B	Detected
B/Wisconsin/1/10	$5.10x10^1$ $TCID_{50}$/mL	B	B	Detected
B/Texas/6/11	$7.24x10^2$ $TCID_{50}$/mL	B	B	Detected
B/Florida/07/04	$2.55x10^2$ $TCID_{50}$/mL	B	B	Detected
A/Anhui/1/2013	$1.00x10^8$ EID_{50}/mL	A	A (Avian)	Detected

ANALYTICAL SPECIFICITY: CROSS-REACTIVITY AND MICROBIAL INTERFERENCE

The Acucy Influenza A&B Test was evaluated with 41 organisms (bacterial, viral, fungal) and Human DNA. Bacterial isolates were tested at concentrations of approximately 10^6 colony forming units per mL (CFU/mL) or color changing units per mL (CCU/mL). Viral isolates were tested at approximately 10^5 plaque forming units per mL (PFU/mL), copies/mL or tissue culture infectious dose 50% per mL ($TCID_{50}$/mL). No cross-reactivity was observed at the concentrations tested as all of the microorganisms and Human genomic DNA was tested with the concentration of $1x10^4$ copies/mL. No interference toward the detection of influenza A analyte or influenza B analyte was observed from all microorganisms and human genomic DNA at the concentrations tested.

Potentially Cross-Reacting Bacterial and Fungal Isolates	Potentially Cross-Reacting Non-Influenza Virus Strain
Bordetella pertussis	Adenovirus type 1
Candida albicans	Adenovirus type 7A
Chlamydia pneumoniae	Human coronavirus
Escherichia coli	Enterovirus
Haemophilus influenzae	Coxsackie virus
Klebsiella pneumoniae	Cytomegalovirus
Lactobacillus acidophilus Z048	Epstein-Barr virus (EBV)
Legionella pneumoniae	Parainfluenza, Type 1
Moraxella catarrhalis	Parainfluenza, Type 2
Mycoplasma hominis	Parainfluenza, Type 3
Mycobacterium tuberculosis	Measles virus
Mycoplasma pneumoniae	Human metapneumovirus 3 type B1
Neisseria meningitidis	Human metapneumovirus 9 type A1
Neisseria gonorrhoeae	Human herpes virus 6 (HHV6), Z29
Pseudomonas aeruginosa	Human herpes virus 7 (HHV7), SB
Staphylococcus aureus MRSA	Mumps virus
Staphylococcus aureus MSSA	Respiratory syncytial virus type A2
Staphylococcus epidermidis MRSE	Respiratory syncytial virus type B
Streptococcus pneumoniae	Rhinovirus
Streptococcus pyogenes	
Streptococcus salivarius	Human genomic DNA
Corynebacterium ulcerans	

INTERFERING SUBSTANCES

The Acucy Influenza A&B Test was evaluated with potential interferents that may be encountered in respiratory specimens. The substances were tested at the concentrations listed in the table below. No interference was observed with the test for any of the substances at the concentrations tested.

Substance	Potential Interferent	Concentration
No substance control	Dry swab	N/A
Control	Viral transport media (VTM)	N/A
Mucus (Bovine)	Mucin protein	19 mg/mL
Whole blood	Whole blood with EDTA	5% v/v
Tylenol	Acetaminophen	0.1 mg/mL
NSAIDs	Aspirin	16.2 mg/mL
	Ibuprofen	40 mg/mL
	Naproxen	110 mg/mL
Nasal Corticosteroids	Dexamethasone (injection)	3 mg/mL
	Dexamthasone (oral)	0.5 mg/mL
	Fluticasone	50 µg/mL
	Mometasone furoate	2.5 µg/mL
	Budesonide	25 µg/mL
	Flunisolide	68.75 µg/mL
	Triamcinolone acetonide	5.5 µg/mL
	Beclomethasone	16 µg/mL
Nasal Sprays	Oxymetazoline	0.025% v/v
	Phenylephrine	0.5% v/v
	Sodium chloride	0.325% v/v
Nasal Gel	Galphima glauca, Luffa operculate	4x,4x
Antiviral	Oseltamivir	5 mg/mL
Antibacterial, systemic	Tobramycin	40.0 µg/mL
Throat Lozenges	Benzocaine	2.5% soln.
Antibiotic Nasal Ointment	Mupirocin	0.15 mg/mL
Allergy Medicine	Histaminum hydrochloricum	1% solution

COMPETITIVE INTERFERENCE

The performance of the Acucy Influenza A&B Test was evaluated in the presence of high levels of influenza A and influenza B. Contrived influenza A (H1N1pdm09 and H3N2) and B positive samples were prepared and applied to swabs. A high viral concentration of influenza A (at a concentration of 2 x 10^4 $TCID_{50}$/mL) was mixed with influenza B at near the LoD and applied to swabs. Similarly, a high viral concentration of influenza B (at a concentration of 2 x 10^4 $TCID_{50}$/mL) was mixed with influenza B at near the LoD and applied to swabs. No interference on test performance was observed.

CARRY-OVER CONTAMINATION

A cross contamination, carry-over, study was performed to demonstrate there is no carry-over or contamination from the previous test that would cause false positive results. Contrived influenza A and B positive samples at a concentration of 1 x 10^5 $TCID_{50}$/mL were prepared and applied to swabs. Positive and negative samples were tested 30 times in an alternating fashion. No false positive results were obtained.

CLIA WAIVER STUDIES

Clinical Performance by Intended Users

The performance of the Acucy Influenza A&B Test was evaluated at 16 intended use sites by non-laboratory personnel in a prospective clinical study during the 2017-2018 influenza season in the U.S. Nasal or nasopharyngeal swabs were collected from patients with flu-like symptoms and were tested with the Acucy Influenza A&B Test and the reference methods. Results were compared to a compostite reference, which was calculated from the results of three reference methods: two molecular methods and cell culture. Results for nasal and nasopharyngeal swabs combined are shown in the following tables.

Acucy™ Influenza A&B Test Influenza A Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu A	Composite Reference		
	Positive	Negative	Total
Positive	216	31	247
Negative	8	748	756
Total	224	779	1003
Sensitivity/ Specificity	96.4% (95% CI: 93.1% - 98.2%) 96.0% (95% CI: 94.4% - 97.2%)		

Acucy™ Influenza A&B Test Influenza B Performance Against the Composite Reference Nasal and Nasopharyngeal Swabs

Acucy™ Influenza A&B Test Flu B	Composite Reference		
	Positive	Negative	Total
Positive	130	16	146
Negative	28	829	857
Total	158	845	1003
Sensitivity/ Specificity	82.3% (95% CI: 75.6% - 87.4%) 98.1% (95% CI: 96.9% - 98.8%)		

Performance Near the Cut-off

Three CLIA-waived sites that participated in the prospective clinical study participtated in the Near Cut-off Study. The testing was performed by three untrained intended operators at each of the sites. This study was conducted to demonstrate that untrained intended users could perform the Acucy Influenza A&B Test and consistently detect samples at the limit of detection (LoD).

The test panel consisted of four contrived samples applied to nasal swabs: a Low Positve influenza A sample at 1X LoD, a High Negative influenza A sample at 0.1X LoD, a Low Positive influenza B sample at 1X LoD, and a High Negative influenza B sample at 0.25X LoD. Low Positive samples are expected to give a positive result, and High Negative samples are expected to give a negative result.

Samples were masked as subject samples and were presented to the intended use operators for testing throughout the course of a normal testing day. Testing took place over the course of two weeks on non-consecutive days. Each operator tested seven samples each testing day. Each site ultimately tested a panel of 84 samples.

The test results are summarized in the table below. The study demonstrates that untrained intended use operators are able to accurately perform and interpret the Acucy Influenza A&B Test at and below the level of the LoD for both influenza A and influenza B.

Near Cut-off Study Test Results: Percent Agreement of Observed/Expected Values

Site	Sample Type			
	Low Positive A	Low Positive B	High Negative A	High Negative B
1	21/21	20/21	21/21	20/21
2	21/21	20/21	21/21	21/21
3	21/21	21/21	21/21	21/21
Total	63/63	61/63	63/63	62/63
Agreement	100%	96.8%	100%	98.4%

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a problem with the Acucy System, please contact Sekisui Diagnostics Technical Support for assistance, at 800-332-1042 (U.S. Only) US) or 781-652-7800 (outside the U.S.).

Annual analytical reactivity testing results with CDC influenza panel can be found on our web site at:
https://www.sekisuidiagnostics.com/FluReactivity

REFERENCES

1 - U.S. Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.

2 - Montalto N, Byrd R. An Office-Based Approach to Influenza: Clinical Diagnosis and Laboratory Testing. American Family Physician. January 2003; 67:111-118.

3 - CLSI. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Fourth Edition. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards.

RE-ORDER

Acucy Influenza A&B Test (Catalog Number 1010)
Acucy Influenza A&B Control Kit (Catalog Number 1011)
Acucy System (Catalog Number 1039)

DEFINITIONS OF SYMBOLS

Instructions For Use	Temperature	Contains sufficient for "n" tests	Product Catalog Number
In Vitro Diagnostics	Manufacturer	Positive Control	Expiration dating
Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.	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.	Negative Control	
Product Batch Number		Single-use only. Do Not Reuse.	Authorized Representative

SEKISUI DIAGNOSTICS

Because every result matters™

Sekisui Diagnostics, LLC
6659 Top Gun Street
San Diego CA, 92121, U.S.A.
800-332-1042
www.sekisuidiagnostics.com

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