SAMPLE PROCEDURE

This “Sample Procedure” is not intended as a substitute for your facility’s Procedure Manual or reagent labeling, but rather as a model for your use in customizing for your laboratory’s needs.

Space has been provided within the document to allow you to update this template with information specific to your facility. It is suggested that a current version of the manufacturer’s directional insert be maintained as a supplement.

PROCEDURE

Title: Sekisui Diagnostics Acucy™ Influenza A&B Test
Procedure #:

Institution: _____

Prepared by: _____ Date:_____

Title: _____

Accepted by: _____ Date adopted: _____

Title: _____

Reviewed by:_____ Date:_____

_____ _____

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Discontinued by:_____ Date:_____

I. TEST NAME

Acucy™ Influenza A&B Test
For use with the Acucy™ Reader
This is a CLIA Waived Test

For facilities in the US: A CLIA 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 you state health department.

II. 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]

III. SUMMARY AND EXPLANATION OF TEST

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.

IV. PRINCIPLES OF TEST

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

V. REAGENTS / MATERIALS

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

VI. 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.

VII. STORAGE AND STABILITY

- Store the Acucy Influenza A&B Test at room temperature, 15°-30°C (59°-86°F), 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 foils pouch is opened the Test Cassette must be used within 30 minutes or discarded.**

At this facility, kits are stored: _____.

_____

VIII. QUALITY CONTROL & ASSURANCE

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.
5. The Reader will read the information from the 2D barcode on the CAL-Device automatically.
6. 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.
7. When the calibration is complete in approximately 10 seconds, the Reader displays CALIBRATION RESULTS.
8. The results will be displayed as PASSED or FAILED.
9. Select NEXT on the screen.
10. Open the drawer and remove the CAL-Device. Return the CAL-Device to the storage case.
11. 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

QC Testing Frequency and Documentation

For this facility, External QC is run: _____

_____

Results of External QC and action(s) taken when control results are unacceptable are documented:

_____

_____

IX. PATIENT PREPARATION, SPECIMEN COLLECTION & STORAGE

This facility's procedure for patient preparation is: _____.

_____.

This facility's procedure for sample labeling is: _____.

_____.

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 the 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 turbinate (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.

This facility's procedure for transporting specimens is: _____.

_____.

This facility's procedure for rejected specimens is: _____.

_____.

X. TEST PROCEDURE

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.

The Reader may be set to two different modes (WALK AWAY/NORMAL and READ NOW). Refer to the Acucy System Manual to set up modes for your workflow.

This facility's test mode is set to: _____

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. From the SELECT TEST TO RUN screen, select FLU A&B.
8. 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.

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.

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.
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.
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.
    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.
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

For this facility, sample swabs, used tubes and Test Cassettes are disposed:

_____

_____

XI. INTERPRETATION OF TEST 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- 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- 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- 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- 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- Invalid results
Note: If invalid results are obtained, repeat the test using a new patient sample, reagent and Test Cassette.

In the event this test becomes inoperable, this facility's course of action for patient samples is:

_____

_____

_____

XII. RESULT REPORTING

This facility's procedure for patient result reporting is:

_____

_____

_____.

XIII. 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.

XIV. 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 clinical study was conducted during the 2017-2018 influenza season. (Refer to Instructions for Use- Acucy™ Influenza A& B Test)

XV. PERFORMANCE CHARACTERSITICS

Refer to Instructions for Use- Acucy™ Influenza A& B Test

XVI. CROSS REACTIVITY

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	

XVII. INTERFERING SUBSTANCES

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

XVIII. REFERENCES

Refer to Instructions for Use- Acucy™ Influenza A& B Test

XIX. ASSISTANCE

For assistance contact Sekisui Diagnostics Technical Assistance at (800) 332-1042.