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 Silaris™ 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

Silaris™ Influenza A&B Test
For use with the Silaris Dock
CLIA Waived: For use with Nasal Swabs

II. INTENDED USE

The Silaris™ Influenza A&B Test performed on the Silaris Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technology for the qualitative, visual detection and differentiation of influenza A and influenza B viral RNA. The Silaris Influenza A&B Test uses a nasal swab specimen collected from patients with signs and symptoms of respiratory infection. Silaris Influenza A&B assay is intended as an aid in the diagnosis of influenza infections in conjunction with clinical and epidemiological risk factors. The assay is not intended to detect the presence of influenza C virus.

Negative results do not preclude influenza virus 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 2016-2017 influenza season. 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.

III. SUMMARY AND EXPLANATION

Along with the common cold, influenza is one of the most common acute respiratory infections. It produces symptoms such as headache, chills, dry cough, body aches and fever. It produces symptoms such as headache, chills, dry cough, body aches and fever. It affects 10% – 20% of the United States population annually, resulting in more than 110,000 hospitalizations and 10,000 to 40,000 deaths.[1]

The influenza A virus is typically more prevalent and is associated with more serious influenza epidemics.[2] Influenza B infections usually present with milder symptoms.[3] Diagnosis of influenza and differentiation from other respiratory infections is difficult because the initial symptoms can be similar. Since the influenza virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health. Rapid diagnosis of viral infection can also help reduce the inappropriate use of antibiotics. Initiation of antiviral therapy for influenza within 48 hours of symptom onset is recommended for quick improvement of symptoms and reduction in viral shedding. [4] The Silaris Influenza A&B Test is a Nucleic Acid Amplification Test (NAAT). It is designed to be run at point of care locations and rapidly report detection of influenza viruses A and/or B from patients.

IV. PRINCIPLE OF THE TEST

The Silaris Influenza A&B Test is a point of care Nucleic Acid Amplification Test (NAAT) for detection of influenza A virus and/or influenza B virus in patients with flu-like symptoms in approximately 30 minutes. To perform the test, nasal swab specimens are added to the Nasal Swab Buffer to solubilize the sample. An aliquot of the Nasal Swab Buffer is then dispensed into an Silaris Influenza A&B Test Cassette. The Test Cassette contains internal process positive and negative controls, enzymes, OscAR™ reagents, and a detection strip necessary for the 4 steps in the assay. These 4 steps are lysis of the virus, reverse transcription of viral RNA to cDNA, nucleic acid amplification, and detection. The Silaris Dock controls reaction temperatures, timing, and fluid movements within the Test Cassette resulting in a fast and automated influenza A and influenza B assay. After approximately 30 minutes, the test results are interpreted by the visualization of Blue Test Lines on the detection strip in the Test Cassette. A blue process control line at the control (C) area is used to ensure proper reagent and Silaris™ Dock function and to confirm a valid negative test result.

V. REAGENTS AND MATERIALS

SILARIS INFLUENZA A&B TEST CONTENTS:

Each Silaris Influenza A&B Test kit contains enough reagents and materials for 25 tests. The following components are included in a kit.

- Rayon Swab (25): Sterile swab for nasal sample collection
- Nasal Swab Buffer (25): Single-use vial of solution containing 5mL of buffer with dimethyl sulfoxide and < 0.01% sodium azide.
- Transfer Pipette (25): Single-use, fixed volume Pipette used to transfer sample from the Nasal Swab Buffer vial into the Test Cassette. **NOTE: Supplied within the Test Cassette Pouch**
- Silaris Influenza A&B Test Cassette (25): Single-use, foil-pouched with desiccant and Test Cassette containing lyophilized reagents for the targeted amplification and detection of influenza A and B viral RNA.
- Control swab (1): Positive for Influenza A and negative for Influenza B (yellow shaft). Contains inactivated influenza A virus dried onto a swab.
- Control swab (1): Positive for Influenza B and negative for Influenza A (blue shaft). Contains inactivated influenza B virus dried onto a swab.
- Instructions For Use (IFU) (1)
- Quick Reference Guide QRG (1)

MATERIALS PROVIDED SEPERATELY

Silaris Dock (Catalog #1026)

Note: *Refer to Silaris Dock Operator Manual for specific dock information and cleaning procedure.*

Silaris Influenza A&B Control Kit (Catalog #1024)

STORAGE AND HANDLING

- All kit components must be stored at room temperature (15°C - 30°C, 59°F - 86°F)
- Store reagents at room temperature (15° – 30°C, 59°F – 86°F). Do not refrigerate or freeze.
- Do not reuse kits contents: Rayon Swabs, Test Cassettes, Transfer Pipettes, Control swabs, or Nasal Swab Buffer.
- Do not remove the Test Cassette from the foil pouch until immediately before use.
- Do not use kit or reagents past the expiration date.

At this facility, kits are stored:

_____

_____

VI. PRECAUTIONS

- For in vitro diagnostic use.
- Federal Law restricts sale of this device to or on the order of a licensed practitioner.
- To be used in conjunction with the Silaris Dock.
- Follow universal precautions when handling patient samples. All patient samples should be treated as if potentially infectious. Follow standard BSL-2 guidelines when working with patient samples. Put on the appropriate personal protective equipment.
- Inactivated and lypohilized viruses are used to make the control swabs. However, control swabs, patient samples and used cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Dispose of kit reagents and patient samples according to all local, state and federal regulations.
- Do not use Swabs or Nasal Swab Buffer other than those provided with the Silaris Influenza A&B Test kit.
- Do not write on the Test Cassette except in the indicated area on the Test Cassette label for recording sample identification and test date.
- Do not remove the foil tab from the Test Cassette until immediately before use. Once the tab is removed, add sample immediately and start testing.
- Once sample is added and the Dock lid is closed, the test has started. Do not move the Dock, open the lid, or unplug the Dock until the Dock indicates the test has completed.
- Do not use any damaged kit contents.
- Do not use kit components after their expiration date.
- Sample collection and handling procedures require specific training and guidance.
- All test kit components are single use items. Do not use with multiple specimens.
- To help obtain accurate results, follow all instructions and heed all precautions in this Instructions For Use.
- Inadequate or inappropriate sample collection, handling, processing, and/or storage can yield inaccurate results.
- Use only the fixed volume Transfer Pipette provided in the kit to transfer the patient sample from the Silaris Nasal Swab Buffer tube into the Test Cassette port. Do not pour the patient sample from the Silaris Nasal Swab Buffer vial into the Test Cassette sample port.
- Do not use visually bloody or overly viscous samples.

- When transferring the prepared patient sample, avoid drawing up large particulates, which may clog the Transfer Pipette.
- Due to the high sensitivity of the Silaris Influenza A&B Test, contamination of the work area with previous samples may cause false positive results. Clean the Silaris Dock and surrounding surfaces as described in the procedure in the Silaris Dock Operators Guide.
- Do not attempt to open a used Test Cassette or a Test Cassette with closed sample port.
- Do not touch the heads of the Control Swabs. Cross contamination may occur due to the high sensitivity of the test.
- If infection with a novel influenza A virus is suspected, samples should be collected with appropriate infection control precautions for novel virulent influenza viruses. Follow the current clinical and epidemiological screening criteria recommended by public health authorities on whether to send the sample to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL-3+ facility is available to receive and culture the samples.
- Use the Results Interpretation table in this Instructions For Use to interpret results accurately.

VII. QUALITY CONTROL

Process Controls

Each Silaris Influenza A&B Test Cassette contains two internal process controls: an internal positive control (labeled 'C' on the Test Cassette) and negative control (labeled 'NC' on the Test Cassette). The positive process control is a non-infectious RNA bacteriophage in the Test Cassette and is used as the positive process control to verify all assay steps (RNA extraction, reverse transcription, amplification and detection) were executed properly. A non-influenza nucleic acid target is used as a negative control for false positive results due to nonspecific binding.

Refer to the Interpretation of Results section of this package insert for instructions on interpreting the results for the Process Controls.

External Positive and Negative Controls:

External controls may be used to show that the Silaris Influenza A&B Test is working properly.
The Silaris Influenza A&B Test kit contains two Control Swabs:

- 1 FLU A Positive/FLU B Negative swab (yellow shaft)
- 1 FLU B Positive/FLU A Negative swab (blue shaft)

Sekisui Diagnostics recommends that an Influenza A positive/Flu B negative and an Influenza B positive/Flu A negative control be run:

- Once for each new lot or shipment of kits received
- Once for each new operator
- As deemed additionally necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

Additional Silaris Influenza A&B Control Swabs may be purchased from Sekisui Diagnostics (Catalog #1024). Run control swabs using the same procedure as for a patient specimen.

If External QC testing fails, repeat the test using a new Control swab, reagent and test cassette or contact Sekisui Diagnostics Technical Support for assistance at 800-332-1042 (U.S. Only) or 781-652-7800 (outside the US), before testing 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:

_____

_____

VIII. SPECIMEN COLLECTION AND HANDLING

Proper sample collection is an important step for an accurate test result. Carefully follow the instructions below.

This facility's procedure for patient preparation is:_____

_____

This facility's procedure for sample labeling is: _____

_____

_____

Nasal Swab Sample

NOTE: Use only the Rayon Swabs supplied with the kit

To collect the nasal swab sample, insert the Rayon Swab into the nostril exhibiting the most secretions. Carefully insert the swab approximately 1 inch into the patient's nostril. Gently rotate the swab several times against the nasal wall.

SAMPLE STORAGE AND SAMPLE EXTRACTION

- For best results, direct nasal swabs should be tested immediately after collection. If immediate testing is not possible, a direct nasal swab can be stored in its original packaging at room temperature (15° C to 30°C, 59°F to 86°F) for up to 2 hours prior to testing. If a direct nasal swab cannot be tested within 2 hours, it can be refrigerated at 2°C - 8°C and tested within 24 hours from the time of collection.
- **Do not freeze the prepared sample prior to testing.**
- The prepared sample may be stored at room temperature (15° C to 30°C, 59°F to 86°F) for up to 1 hour.
- Patient nasal swabs previously stored in viral transport media are not recommended and will

invalidate the test.

Remove the cap from the Nasal Swab Buffer vial and set it aside.

Insert the nasal swab specimen into the Nasal Swab Buffer and rotate it 5 times rubbing it against the wall of the vial.

Remove the patient nasal swab from the Nasal Swab Buffer vial and discard it into a biohazardous waste container.

Replace the cap on the Nasal Swab Buffer vial.

Write the patient identification (ID) information and testing date onto the Nasal Swab Buffer vial label in the area provided.

If immediate testing is not possible, recap the nasal Swab Buffer vial. The prepared sample may be stored at room temperature (15°C - 30°C, 59°F - 86°F) for up to 1 hour.

This facility's procedure for transporting specimens is: _____

_____

_____

This facility's procedure for rejected specimens is: _____

_____

_____

IX. TEST PROCEDURE

All clinical samples must be at room temperature before beginning the assay.

Check expiration date on each individual Test Cassette foil pouch or outer box before using. Do not use any Test after the expiration date on the label.

Place Dock on a flat surface.

Connect the AC Adapter to the Power Cord.

Insert round end of the power cord into the Dock. Plug the AC end of the power cord into an electrical outlet.

Open the Dock by depressing the black button located on the top left.

Verify the Dock screen displays: "DOCK READY INSERT CASSETTE".

Do not open the foil pouch until the sample is ready for testing. The Test must be initiated within 30 minutes of opening the foil package.

Remove a Test Cassette and Transfer Pipette from the foil package (these items are packaged together).

Write the patient identification (ID) information and testing date on the Test Cassette label in the area provided.

NOTE: *The foil pouch also contains a desiccant pack. This can be discarded with the foil pouch after Test Cassette and Transfer Pipette are removed.*

Insert the Test Cassette into the Dock, leaving the lid open. Press the Test Cassette down firmly to seat it in the Dock.

NOTE: *Do **NOT** remove the foil tab covering the sample port until immediately before testing.*

Once the test cassette is placed into the Dock, you have 5 minutes to add the sample into the cassette.

Do not close Dock lid until sample has been added to the Test Cassette.

Verify the Dock screen displays: “FLU A/FLU B CASS. INSERTED”

The Dock screen will then display: “ADD SAMPLE THEN CLOSE LID”

Invert Nasal Swab Buffer Vial to mix

Remove the cap from the prepared patient sample in the Nasal Swab Buffer and set it aside.

Firmly squeeze the **TOP** bulb of the pipette.

While continuing to squeeze the top bulb firmly, place the pipette tip well below the surface of the liquid in the Nasal Swab Buffer vial.

Keep the pipette tip well below the surface of the liquid of the vial containing the prepared patient sample in Nasal Swab vial.

Slowly release the top bulb to completely fill the pipette stem with sample.
Some liquid may also be in the overflow reservoir.

Note: *Although excess liquid will enter the pipette’s overflow chamber, only the liquid in the pipette stem will be dispensed.*

Completely remove the foil tab covering the sample port on the Test Cassette. Discard the foil tab.

Note: *Once the tab is removed from the sample port, sample must be added immediately (within 5 minutes).*

Insert the tip of the Transfer Pipette containing the sample into the sample port of the Test Cassette.

Squeeze the **TOP** bulb of the pipette firmly to dispense all of the sample from pipette stem into the Test Cassette.

NOTE: *A small amount of sample may remain in the overflow chamber (lower bulb). This is normal.*

Dispose of the Pipette in a biohazardous waste container.

The Dock screen will then read: “SAMPLE LOADED CLOSE LID”.

Close the lid of the Dock immediately to automatically begin the test program.

Verify the Dock screen displays: “SAMPLE LOADED LID CLOSED”.

Verify the Dock screen displays: “CASSETTE SEALED TEST STARTED”.

Verify the Dock screen displays: “TEST RUNNING REMAINING XX:XX”.

Note: *The screen will continue to display “TEST RUNNING” until complete. The Dock will beep at the end of test processing.*

Do not re-open the Dock lid until the display indicates the test is complete. Opening the lid will abort the test. Do not move or unplug the Dock while the test is processing.

Verify the Dock screen displays: “TEST COMPLETE READ RESULTS”.

Open the lid of the Dock.

Remove the Test Cassette and interpret the results according to the Interpretation of Results section below.

Dispose of the Test Cassette in the biohazardous waste container.

For this facility, sample swabs, used pipettes, used nasal swab buffers, and used cassettes test devices are disposed: _____

_____

_____

X. INTERPRETATION OF RESULTS

C = Internal Positive Process Control
FLU A = Influenza A
FLU B = Influenza B
NC = Internal Negative Process Control

Note: *The appearance of any shade of Blue Test Line at the FLU A and/or FLU B positions is a valid result that is interpreted as positive for the influenza A and/or influenza B viral RNA target. A negative result will only contain a Blue Test Line at the C position.*

The appearance of **ANY** shade of a Blue Test Line at the Flu A position indicates a positive result for the presence of Flu A.

- **WITH OR WITHOUT** the appearance of a blue process control line at the C position
- **AND** the absence of a negative process control line at the NC position

The appearance of **ANY** shade of a Blue Test Line at the Flu B position indicates a positive result for the presence of Flu B.

- **WITH OR WITHOUT** the appearance of a blue process control line at the C position

- **AND** the absence of a negative process control line at the NC position

The appearance of **ANY** shade of a Blue Test Line at both the Flu A and Flu B position indicates a positive result for the presence of Flu A and Flu B.

- **WITH OR WITHOUT** the appearance of a blue process control line at the C position
- **AND** the absence of a negative process control line at the NC position

The absence of **ANY** shade of a Blue Test Line at both the Flu A and Flu B position indicates a negative result for the presence of Flu A and Flu B.

- **AND** the appearance of a blue process line at the C position
- **AND** the absence of a negative process control line at the NC position

The appearance of **ANY** shade of a negative process control line at the NC position, indicates an invalid test.

The appearance of **ALL** or **NO** lines at the C, FLU A, FLU B, and NC position, indicates an invalid test.

***If an invalid result is obtained, the sample may be rerun with a fresh Test Cassette only if the prepared sample has been stored for less than 1 hour at room temperature. (15°C -30°C or 59°F -86°F).**

NOTE: The absence of a Blue Test Line at the "C" position in conjunction with a Blue Test Line at the "Influenza A" and/or "Influenza B" position means that the Influenza A and/or Influenza B viral RNA target was amplified and detected as a valid result. This can occur due to the overabundance of "Influenza A" and/or "Influenza B" target that competes with the Control target.

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

_____

_____

XI. RESULT REPORTING

This facility's procedure for patient result reporting is: _____

_____

_____

XII. LIMITATIONS

- The performance of the Silaris Influenza A&B Test was determined using the procedures provided in this instructions for use. Failure to follow these procedures may alter test performance.

- The Silaris Influenza A&B Test is for use with nasal swab specimens only.

- Improper collection, storage or transport of specimens may lead to false negative results.
- Test results should be interpreted in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests performed.
- As with other tests, negative results do not rule out Flu A or Flu B infections and should not be used as the sole basis for patient management decisions.
- This is a qualitative test. Test line intensity is not indicative of the quantity of virus in the sample.
- Positive and negative predictive values are dependent upon prevalence. Test performance was established for the 2016-2017 influenza season. Performance may vary depending on the prevalence and population tested.
- False negative results may occur if viruses are present at levels below the test's limit of detection.
- False negative results may occur if mutations are present in the regions targeted by the test.
- Test performance has not been evaluated for patients without signs and symptoms of influenza infection.
- Cross-reactivity with respiratory tract organisms other than those listed in the Analytical Specificity Study may lead to erroneous results.
- Test performance has not been evaluated for the purpose of monitoring antiviral treatment.
- Test performance has not been evaluated in immunocompromised patients.
- Test performance has not been evaluated in patients who received inhaled influenza vaccine.
- This test cannot rule out diseases caused by other viral or bacterial agents.
- Analyte targets (viral nucleic acid) may persist in vivo, independent of virus viability. Detection of analyte targets does not imply that the corresponding viruses are infectious or are the causative agents for clinical symptoms.
- The presence of inhibitors in the sample can lead to invalid results.

XIII. EXPECTED VALUES

The prevalence of influenza varies from year to year, with outbreaks occurring during the fall and winter months. The influenza positivity rate is dependent upon many factors, including specimen collection, test

method, and geographic location. Prevalence varies throughout the flu season and from location to location.

The clinical study was conducted during the 2016-2017 influenza season. (Refer to Instructions for Use – Silaris™ Influenza A&B Test)

XIV. PERFORMANCE CHARACTERISTICS

Refer to Instructions for Use – Silaris™ Influenza A&B Test

XV. CROSS-REACTIVITY

The analytical specificity was evaluated with a panel of common organisms when tested on the Silaris Influenza A&B Test. Thirty-three (33) organisms were obtained from Zeptometrix Corporation except for Chlamydia pneumonia and Corynebacterium glycinophilum (were obtained from ATCC). These potentially cross-reacting non-influenza organisms were tested in replicates of three (3) in this study. The organisms were diluted into a Pooled Negative Nasal Sample (PNNS) matrix to create samples at the concentration in the table below for testing.

Analytical Exclusivity – Organisms Tested, Concentrations and Test Results

Organism Key #	Organism Name	Stock Concentration	Test Level	Flu A Test Result (# of Flu A Positive /3)	Flu B Test Result (# of Flu B Positive /3)
1	Adenovirus Type 1	1.02E+08 TCID50/mL	5.10E+05 TCID50/mL	0/3	0/3
2	Adenovirus Type 7	6.61E+06 TCID50/mL	3.31E+04 TCID50/mL	0/3	0/3
3	Human herpesvirus 5 (Cytomegalovirus)	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3
4	Human coronavirus 229E	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3
5	Human coronavirus OC43	5.89E+07 TCID50/mL	2.95E+05 TCID50/mL	0/3	0/3
6	Human Enterovirus 71 (HEV-71)	4.17E+05 TCID50/mL	1.04E+04 TCID50/mL	0/3	0/3
7	Epstein-Barr virus	7.95E+09 cp/mL	3.98E+07 cp/mL	0/3	0/3
8	Human parainfluenza virus 1	1.26E+06 TCID50/mL	1.26E+04 TCID50/mL	0/3	0/3
9	Human parainfluenza virus 2	2.19E+06 TCID50/mL	1.10E+04 TCID50/mL	0/3	0/3
10	Human parainfluenza virus 3	5.89E+05 TCID50/mL	1.18E+04 TCID50/mL	0/3	0/3
11	Measles virus	5.89E+07 TCID50/mL	2.95E+05 TCID50/mL	0/3	0/3
12	Human metapneumovirus	3.55E+05 TCID50/mL	1.01E+04 TCID50/mL	0/3	0/3
13	Mumps virus	1.95E+07 TCID50/mL	9.75E+04 TCID50/mL	0/3	0/3
14	Respiratory syncytial virus	3.16E+06 TCID50/mL	1.58E+04 TCID50/mL	0/3	0/3
15	Human rhinovirus 17	6.61E+06 TCID50/mL	3.31E+04 TCID50/mL	0/3	0/3

16	Bordetella pertussis	8.43E+08 cfu/mL	4.22E+06 cfu/mL	0/3	0/3
17	Chlamydia pneumoniae	≥ 5E+03 IFU/mL*	≥ 1.67E+04 IFU/mL	0/3	0/3
18	Corynebacterium glycinophilum	≥ 5.56E+07 IFU/mL**	≥ 1.59E+06 IFU/mL	0/3	0/3
19	Escherichia coli	3.83E+09 cfu/mL	1.92E+07 cfu/mL	0/3	0/3
20	Haemophilus influenzae	2.40E+08 cfu/mL	1.20E+06 cfu/mL	0/3	0/3
21	Lactobacillus sp.	6.00E+08 cfu/mL	3.00E+06 cfu/mL	0/3	0/3
22	Legionella longbeachae	1.93E+09 cfu/mL	9.65E+06 cfu/mL	0/3	0/3
23	Moraxella catarrhalis	3.97E+07 cfu/ml	1.99E+05 cfu/ml	0/3	0/3
24	Mycobacterium tuberculosis	7.23E+08 cfu/mL	3.62E+06 cfu/mL	0/3	0/3
25	Mycoplasma pneumoniae	5.62E+07 CCU/mL	2.81E+05 CCU/mL	0/3	0/3
26	Neisseria meningitidis	2.55E+08 cfu/mL	1.28E+06 cfu/mL	0/3	0/3
27	Neisseria subflava	1.46E+09 cfu/mL	7.30E+06 cfu/mL	0/3	0/3
28	Pseudomonas aeruginosa	1.21E+08 cfu/mL	6.05E+05 cfu/mL	0/3	0/3
29	Staphylococcus aureus	1.39E+10 cfu/mL	6.95E+07 cfu/mL	0/3	0/3
30	Staphylococcus epidermidis	6.47E+09 cfu/mL	3.24E+07 cfu/mL	0/3	0/3
31	Streptococcus pneumonia	4.17E+08 cfu/mL	2.09E+06 cfu/mL	0/3	0/3
32	Streptococcus pyogenes	5.43E+09 cfu/mL	2.72E+07 cfu/mL	0/3	0/3
33	Streptococcus salivarius	4.63E+08 cfu/mL	2.32E+06 cfu/mL	0/3	0/3

All 33 exclusivity organisms were negative at the concentrations tested. Exclusivity is verified for the strains tested.

XVI. INTERFERING SUBSTANCES

To assess substances with the potential to interfere with the performance of the Silaris Influenza A&B Test, four (4) influenza strains were tested in replicates of three (3) with each interfering substance at the "worst case" concentration. The influenza strains selected for testing include a 2009 pandemic swine-like H1N1 influenza A strain, an H3N2 influenza A strain, and two influenza 8 strains representing Victoria and Yamagata lineages. Virus was serially diluted into a pooled clinical matrix to achieve a 1.5X LOD concentration.

Each influenza strain was tested with the "worst case" interferent concentration, representing the highest concentration likely to be found in a respiratory sample. Additionally, each strain was tested without the interfering substance as a control.

The results are shown in the table. The Silaris Influenza A&B Test performance is not negatively affected by the potentially interfering substances under "worst case" concentration conditions.

Interfering Substances: Agreement of Observed/Expected		
Interferent Description, Concentration	Target	% Agreement with Expected Results
Mucin, 20 µg Mucin/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Blood (Human)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)

1% (v/v)	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Neo-Synephrine (phenylephrine nasal spray)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Afrin (Oxymetazoline nasal spray)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Nasacort (Triamcinolone, nasal corticosteroid	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
No Interferent	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Zicam (Nasal gel, homeopathic allergy relief medicine)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Cepacol (throat lozenge)	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Zanamivir (anti-viral drug) 10mg/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Mupirocin (antibiotic) 12 mg/mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)
Tobramycin (antibacterial) 2.43 mg /mL	Negative	100% (3/3)
	FluA/Cali	100% (3/3)
	FluA/Texas	100% (3/3)
	FluB/Nevada	100% (3/3)
	FluB/Mass	100% (3/3)

XVII. ASSITANCE AND CONTACT INFORMATION

For technical questions or assistance, please contact Sekisui Diagnostics Technical Support at (800)-332-1042. (U.S. Only) or 1-781-652-7800 (Outside U.S.)

XVII. REFERENCES

Refer to Instructions for Use – Silaris™ Influenza A&B Test