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™ RSV Test (Cat. No. 1030)
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™ RSV Test
For use with the Silaris Dock
CLIA Waived: For use with Nasal Swabs

II. INTENDED USE

The Silaris™ RSV Test performed on the Silaris™ Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of respiratory syncytial virus (RSV) viral RNA. The Silaris RSV Test uses a nasal swab specimen collected from patients with signs and symptoms of respiratory infection. The Silaris RSV Test is intended as an aid in the diagnosis of RSV infection in children and adults in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude RSV virus infection and should not be used as the sole basis for treatment or other patient management decisions.

III. SUMMARY AND EXPLANATION

RSV is an RNA virus that is responsible for outbreaks of respiratory tract infections. RSV infections can occur throughout the year, but typically peak during the winter months.[1] RSV viruses not only cause upper respiratory tract infections but also bronchiolitis of the lower respiratory tract, which often becomes severe in infants and toddlers with underlying diseases.[2] Children who were born premature, or who have pre-existing lung, heart or immune dysfunctions have the greatest risk of developing RSV associated infections. Diagnosis of RSV is difficult because the initial symptoms can be similar to those caused by other infectious agents. Considering that the RSV virus is highly contagious, accurate diagnosis and prompt treatment of patients can have a positive effect on public health.[1]

In the United States, RSV is estimated to be responsible for 73,400 to 126,300 hospitalizations annually for bronchiolitis and pneumonia alone among children younger than 1 year.[3] In an analysis of U.S. viral surveillance and mortality data, respiratory syncytial virus (RSV) was reported as the most common viral cause of death in children younger than 5 years when compared to influenza A (H1N1), influenza A (H3N2), and influenza B.[4]

IV. PRINCIPLE OF THE TEST

The Silaris RSV Test is a point of care Nucleic Acid Amplification Test (NAAT) for detection of RSV virus in patients with signs and symptoms of respiratory infection 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 a Silaris RSV 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 RSV 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 RSV TEST CONTENTS:

Each Silaris RSV 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 RSV Test Cassette (25): Single-use, foil-pouched with desiccant and Test Cassette containing lyophilized reagents for the targeted amplification and detection of RSV viral RNA.
- RSV Positive Control swab (1): Positive for RSV (green shaft). Contains inactivated RSV virus dried onto a swab.
- RSV Negative Control swab (1): Negative for RSV (pink shaft). Contains buffer solution dried onto a swab.
- Instructions For Use (IFU) (1)
- Quick Reference Guide QRG (1)

  NOTE: Extra Transfer Pipettes provided for your convenience.

MATERIALS PROVIDED SEPERATELY

Silaris Dock (Catalog #1026)

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

Silaris RSV Control Kit (Catalog #1029)

STORAGE AND HANDLING

- Store reagents at room temperature (15°C - 30°C, 59°F - 86°F). Do not refrigerate or freeze.
- Do not reuse kit 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 (within 5 minutes).
- Do not use kit or kit contents 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. Wear the appropriate personal protective equipment.
- Inactivated viruses are used to make the positive control swab. However, Control Swabs, patient samples and used Test Cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Dispose of kit contents 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 RSV or Silaris Flu A/Flu 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 (within 5 minutes) 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 regard all precautions in the Silaris RSV Test Kit 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 RSV 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.
- Use the Results Interpretation table in Silaris RSV Test Kit Instructions For Use to interpret results accurately.

VII. QUALITY CONTROL

Process Controls

Each Silaris RSV 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-RSV nucleic acid probe is used as a negative control for false positive results due to nonspecific binding.

Refer to the Interpretation of Results section of the Silaris RSV Test Kit Instructions For Use 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 RSV Test is working properly. The Silaris RSV Test kit contains two Control Swabs:

- 1 RSV Positive Control Swab (green shaft)
- 1 RSV Negative Control Swab (pink shaft)

Sekisui Diagnostics recommends that an RSV Positive and RSV Negative control be run:

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

Additional Silaris RSV Control Swabs may be purchased from Sekisui Diagnostics (Catalog # 1029). Run control swabs using the same procedure as for a patient specimen.

If External QC testing fails, repeat the testing using the prepared Nasal Swab Buffer (if within one hour of preparation) and a new 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 (36°F to 46 °F) and tested within 24 hours from the time of collection.
- **Do not freeze the prepared sample prior to testing.**
- The nasal swab buffer is the same in both the Silaris Flu A/Flu B and Silaris RSV kits, you may use the buffer from either kit to perform the test.
- 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: “RSV 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 test takes approximately 30 minutes to complete. 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 then interpret and record the results according to the Interpretation of Results section below.
Note: *Results should be interpreted within 1 hour of test completion.*

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
RSV = Respiratory Syncytial Virus
NC = Internal Negative Process Control

Note: *The appearance of any shade of Blue Test Line at the "RSV" position is a valid result that is interpreted as positive for the RSV viral RNA target. A negative result will only contain a Blue Test Line at the "C" position.*

Take time to look at test lines very carefully.

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

- **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 RSV position indicates a negative result for the presence of RSV.

- **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, RSV, 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 "RSV" position means that the RSV viral RNA target was amplified and detected as a valid result. This can occur due to the overabundance of RSV 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 RSV Test was determined using the procedures provided in this instructions for use. Failure to follow these procedures may alter test performance.
- The Silaris RSV 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 RSV 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 2017-2018 RSV 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 RSV 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.

- 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 respiratory syncytial virus (RSV) varies from year to year, with outbreaks occurring during the fall and winter months. The RSV positivity rate is dependent upon many factors, including specimen collection, test method, and geographic location. Prevalence varies throughout the RSV season and from location to location.

The Silaris RSV prospective clinical study was conducted during the 2017-2018 RSV season. (Refer to Instructions for Use – Silaris™ RSV Test)

XIV. PERFORMANCE CHARACTERISTICS

Refer to Instructions for Use – Silaris™ RSV Test

XV. CROSS-REACTIVITY

Cross-reactivity was performed by testing 41 potentially cross-reacting organisms with the Silaris RSV Test. Each organism was diluted in a pooled clinical matrix and tested in triplicate. The organisms, concentrations, and test results are shown in the table below. All organisms gave negative results at the concentrations tested.

Test Results of Possible Cross-Reactive Organisms

Organism Key #	Organism Name	Test Level	Test Results (# of RSV Pos / 3
1	Adenovirus Type 1	5.10E+05 TCID50/mL	0/3
2	Adenovirus Type 7	3.31E+04 TCID50/mL	0/3
3	Coronavirus	1.10E+04 TCID50/mL	0/3
4	Coronavirus	2.95E+05 TCID50/mL	0/3
5	Cytomegalovirus	1.10E+04 TCID50/mL	0/3
6	Cytomegalovirus	1.90E+04 TCID50/mL	0/3
7	Cytomegalovirus	2.52E+04 TCID50/mL	0/3
8	Echovirus	2.95E+05 TCID50/mL	0/3
9	Enterovirus	1.04E+04 TCID50/mL	0/3
10	Human Metapneumovirus	1.01E+04 TCID50/mL	0/3
11	Measles virus	2.95E+05 TCID50/mL	0/3
12	Mumps virus	9.75E+04 TCID50/mL	0/3
13	Parainfluenza Type 1	2.52E+04 TCID50/mL	0/3*
14	Parainfluenza Type 2	1.10E+04 TCID50/mL	0/3
15	Parainfluenza Type 3	1.18E+04 TCID50/mL	0/3

16	Rhinovirus	3.31E+04 TCID50/mL	0/3
17	Rhinovirus	3.31E+04 TCID50/mL	0/3
18	Rhinovirus	3.02E+04 TCID50/mL	0/3
19	Epstein-Barr virus	3.98E+07 cp/mL	0/3
20	*Bordetella pertussis*	4.22E+06 cfu/mL	0/3
21	*Candida albicans*	9.80E+05 cfu/mL	0/3
22	*Escherichia coli*	1.92E+07 cfu/mL	0/3
23	*Haemophilus influenzae*	1.20E+06 cfu/mL	0/3
24	*Klebsiella pneumoniae*	4.15E+07 cfu/mL	0/3
25	*Lactobacillus sp.*	3.00E+06 cfu/mL	0/3
26	*Legionella longbeachae*	9.65E+06 cfu/mL	0/3
27	*Moraxella catarrhalis*	1.99E+05 cfu/mL	0/3
28	*Mycobacterium tuberculosis*	3.62E+06 cfu/mL	0/3
29	*Neisseria gonorrhoeae*	6.30E+06 cfu/mL	0/3
30	*Neisseria meningitidis*	1.28E+06 cfu/mL	0/3
31	*Neisseria subflava*	7.30E+06 cfu/mL	0/3
32	*Proteus vulgaris*	2.07E+07 cfu/mL	0/3
33	*Pseudomonas aeruginosa*	6.05E+05 cfu/mL	0/3
34	*Staphylococcus aureus*	6.95E+07 cfu/mL	0/3
35	*Staphylococcus epidermidis*	3.24E+07 cfu/mL	0/3
36	*Streptococcus pneumonia*	2.09E+06 cfu/mL	0/3
37	*Streptococcus pyogenes*	2.72E+07 cfu/mL	0/3
38	*Streptococcus salivarius*	2.32E+06 cfu/mL	0/3
39	*Mycoplasma pneumoniae*	2.81E+05 CCU/ml	0/3
40	Influenza A/California/07/2009	2.15E+04 TCID50/mL	0/3
41	Influenza B/Massachusetts/2/2012	5.00E+05 TCID50/mL	0/3

**Replicate 3 of Organism # 13 Parainfluenza Type 1 was repeated due to an invalid result.*

XVI. INTERFERING SUBSTANCES

To assess substances with the potential to interfere with the performance of the Silaris RSV Test, two (2) RSV strains were tested in replicates of three (3) with each interfering substance at the “worst case” concentration. For each sample, virus was diluted into a pooled negative clinical matrix to achieve a 1.5X LoD concentration. Each RSV strain was tested with an 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. Potential interferents, their concentrations, samples tested, and test results are summarized in the table below. The Silaris RSV Test performance is not negatively affected by the potentially interfering substances tested.

Interfering Substances: Agreement of Observed/Expected			
Potential Interferent	Interferent Concentration for Making Contrived Swab	Sample Tested	% Agreement with Expected Results
Controls	NA	Negative	100% (2/2)
	NA	RSV A2 at 450 TCID50/ml	100% (3/3)
	NA	RSV B1 at 15 TCID50/mL	100% (3/3)
Blood (Human)	1% (v/v)	Negative	100% (3/3)
	1% (v/v)	RSV A2 at 450 TCID50/ml	100% (3/3)
	1% (v/v)	RSV B1 at 15 TCID50/mL	100% (3/3)
Phenylephrine nasal spray	Neat	Negative	100% (3/3)
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3)
Oxymetazoline nasal spray	Neat	Negative	100% (3/3)
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3)
Ocean Saline Nasal Spray	Neat	Negative	100% (3/3)
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3)
Chloraseptic Max	Neat	Negative	100% (3/3)
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3)
Nasacort (Triamcinolone, nasal corticosteroid)	Neat	Negative	100% (3/3)
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3)
Zicam (Nasal gel, homeopathic allergy relief medicine)	Neat	Negative	100% (3/3) *
	Neat	RSV A2 at 450 TCID50/ml	100% (3/3)
	Neat	RSV B1 at 15 TCID50/mL	100% (3/3) **
Cepacol (throat lozenge)	1 lozenge/5mL	Negative	100% (3/3)
	1 lozenge/5mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	1 lozenge/5mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Mucin, Type II	5 mg/mL	Negative	100% (3/3)
	5 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	5 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Beclomethasone	1.6 mg/mL	Negative	100% (3/3)
	1.6 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	1.6 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Budesonide	3.2 mg/mL	Negative	100% (3/3)
	3.2 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	3.2 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Dexamethasone	30 mg/mL	Negative	100% (3/3)
	30 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	30 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3) *
Flunisolide	1.6 mg/mL	Negative	100% (3/3)
	1.6 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	1.6 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Fluticasone Propionate	0.25 mg/mL	Negative	100% (3/3)
	0.25 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)

Interfering Substances: Agreement of Observed/Expected			
Potential Interferent	Interferent Concentration for Making Contrived Swab	Sample Tested	% Agreement with Expected Results
Fluticasone Propionate	0.25 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Mometasone furoate	1 mg/mL	Negative	100% (3/3)
	1 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	1 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Mupirocin (antibiotic)	20 mg/mL	Negative	100% (3/3)
	20 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	20 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Tobramycin (antibacterial)	75 mg/mL	Negative	100% (3/3)
	75 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	75 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Triamcinolone	0.05 mg/mL	Negative	100% (3/3)
	0.05 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3) *
	0.05 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)
Zanamivir (anti-viral drug)	50 mg/mL	Negative	100% (3/3) *
	50 mg/mL	RSV A2 at 450 TCID50/ml	100% (3/3)
	50 mg/mL	RSV B1 at 15 TCID50/mL	100% (3/3)

**One replicate was repeated due to an invalid result*
*** Two replicates were repeated due to invalid results*

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™ RSV Test

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