

**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 instructions for use (IFU) be maintained as a supplement.

**PROCEDURE**

**Title: Sekisui Diagnostics OSOM RSV Test Cat. No. 1091**

**Procedure #:**

Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Prepared by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Accepted by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date adopted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| 1. **TEST NAME**
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OSOM® RSV Test

CLIA Complexity: WAIVED for use with anterior nasal swab

Certificate of Waiver is required to perform the test in a waived setting

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test

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| 1. **INTENDED USE**
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The OSOM® RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in anterior nasal swab specimens from patients with signs and symptoms of respiratory infections. This test is intended for in vitro diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients aged 6 months to 6 years old, and adults over 60 years of age.

Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as an FDA-cleared molecular assay.

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| 1. **SUMMARY AND EXPLANATION OF TEST**
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Respiratory syncytial virus is a prevalent respiratory virus that can cause a range of illnesses, varying from mild to severe, across all age groups. However, it poses a greater risk and severity in infants, young children, older adults, and individuals with weakened immune systems. RSV is the primary cause of acute lower respiratory tract infections in infants, with an estimated 33 million cases reported worldwide. Early diagnosis of RSV infection is of utmost importance, and several methods are available to detect it in respiratory samples. Swift and accurate detection of RSV is especially critical for implementing effective infection control measures and preventing hospitalizations, as RSV poses a significant risk, particularly in pediatric wards.

The OSOM RSV Test provides a simple, rapid method for the diagnosis of RSV using anterior nasal swab (ANS) specimens. Its user-friendly format and rapid results allow for quick diagnosis and aid in treatment and hospitalization decisions.

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| 1. **PRINCIPLE**
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The OSOM RSV Test is designed to detect the extracted nucleoprotein antigen-specific to RSV in anterior nasal swab specimens directly collected from patients exhibiting signs or symptoms of a respiratory infection.

When specimens are extracted and added to the sample well of the test device, RSV viral antigens present in the specimen bind to antibodies against RSV nucleoprotein conjugated to gold colloidal particles. The antigen-conjugate immunocomplexes migrate across the test strip and are captured at the test line of the nitrocellulose membrane. Test results are interpreted at 15-20 minutes visually.

An RSV positive result is indicated by the presence of two pinkish-red colored lines, one in the control line "C" and the other in the test line "T." Conversely, an RSV negative result is indicated by the presence of only one colored line in the control line "C." The presence of the control line "C" in the test window is crucial for self-validation. It should always appear at the designated position "C" in a valid test result. Any result without this control line is invalid.

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| 1. **REAGENTS AND MATERIALS**
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Provided

27\* - Test devices in sealed aluminum foil pouch with desiccant

27\* - Reagent tubes prefilled with extraction buffer (350 µL) and dropper tips

25 - Sample collection swabs (Anterior Nasal)

1 - Positive control swab (noninfectious RSV antigen)

1 - Negative control swab (noninfectious nasal clinical matrix)

1- Instructions for Use (IFU)

1- Quick Reference Guide (QRG)

\*NOTE: Two extra test devices have been included for external QC testing.

Required but not provided

• Timer

• Tube rack for specimens

• Any necessary personal protective equipment

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| 1. **STORAGE AND STABILITY**
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• The test kit should be stored at 2-30°C in the original sealed pouch. Do not freeze.

• Bring all test components to room temperature at least 30 minutes prior to use.

• The freshly collected anterior nasal swab specimen is recommended to be processed no later than one hour after specimen collection when kept at room temperature (15-30°C), or within 24 hours when stored at 2-8°C. Do not freeze swab specimens before testing.

• The test is stable until the expiration date printed on the outside of the box. Do not use after the expiration date.

At this facility, kits are stored: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| 1. **WARNINGS AND PRECAUTIONS**
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• For in vitro diagnostic use.

• For prescription use only.

• Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

 • For use with kit provided swabs. Use only swabs provided with the kit.

 • Do not use if any of the test kit contents or packaging is damaged.

• Do not use any test component after the expiration date which is printed on the outer packaging.

• Do not interchange kit contents from different lots.

• Test components are single-use. Do not re-use.

• Do not touch the swab tip.

• Once opened, the test card should be used within 90 minutes.

• Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.

• Ensure that testing and result interpretation are conducted in a well-lit space with sufficient lighting.

• Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.

• Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fails to give the expected results.

• As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

• Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit components.

• Nitrile or latex gloves should be worn when performing this test.

• Dispose of used contents as biohazardous waste in accordance with federal, state, and local requirements.

• Handle all specimens as though they contain infectious agents.

• Observe established precautions against microbiological hazards throughout the procedure.

• The Extraction Reagent contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: visit [https://www.poison.org/contact-us Or call 1-800-222-1222](https://www.poison.org/contact-us%20Or%20call%201-800-222-1222).

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| 1. **SPECIMEN COLLECTION**
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The acceptable specimen type for testing with the OSOM RSV Test is a direct anterior nasal swab specimen. It is essential that correct specimen collection must be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

Freshly collected specimens should be processed as soon as possible, but no later than one hour (when kept at room temperature) or up to 24 hours (when stored at 2-8°C) after specimen collection. Specimens in extraction buffer can be processed up to 30 minutes after collection when kept at room temperature.

To collect the anterior nasal swab sample, tilt the patient’s head back 70 degrees and insert the soft end of the swab into patient’s nostril no more than ¾ of an inch into the nose (no more than ½ inch if swabbing a child). Slowly rotate the swab, gently pressing against the inside of patient’s nostril at least 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Use the same end of the swab and repeat the same steps on the other nostril. Refer to Specimen Collection: Nose and Throat at

<https://elsevier.health/en-US/preview/specimen-collection-nose-and-throat>

This facility’s procedure for specimen collection is:

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| 1. **TEST PROCEDURE AND PROTOCOL**
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Collect specimens according to instructions in “Specimen Collection”. Test device and sample should be brought to room temperature (15-30°C) prior to testing. Conduct all testing on a level surface and ambient conditions.

1. Peel off the aluminum foil from the top of the Reagent Tube containing 350 µL of extraction buffer.
2. Insert the collected swab specimen into the Reagent Tube until the swab head touches the bottom of the tube.
3. Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least 10 times.
4. Remove the swab while squeezing the sides of the tube to release the maximum amount of liquid from the swab head. Properly discard the swab.

NOTE: Do Not freeze swab specimens before testing.

1. Firmly push on the provided Dropper tip to close the Reagent tube.

NOTE: Do NOT touch or grab the hole of the dropper tip.

Specimens in extraction buffer can be processed up to 30 minutes after collection when kept at room temperature.

1. Invert the processed Reagent Tube and hold it vertically above the sample well. Squeeze the tube gently and dispense two (2) drops of the sample into the sample well of the test device. NOTE: Too few drops can result in invalid results, and too many drops could produce incorrect results.
2. Read the results at 15 minutes visually. Do not read result more than 20 minutes after the sample application.

NOTE: False negative or false positive results can occur if read before or after 15-20 minutes.

For this facility, sample swabs, used extraction reagent capsules, and used test devices are disposed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| 1. **RESULT INTERPRETATION**
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**Positive**

If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink Test (T) line with a visible Control (C) line should be read as positive.

**Negative**

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes RSV was not detected in the sample.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

**Invalid**

If a Control (C) line is not visible, the test is not valid. Re-test with a new swab and a new test cassette. If the problem persists, please call +1-800-332-1042.

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

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| 1. **QUALITY CONTROL**
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**Internal Quality Control**

The presence of a pinkish-red colored band in the Control area of the window acts as an internal control to ensure adequate migration has occurred but does not determine if an adequate sample has been added. In the absence of this Control line, the test is invalid and must be repeated. If the control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new device is recommended.

If the internal procedural control line is still absent on the retest, please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

**External Quality Control**

Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as the clinical sample swab, and conduct the assay as described in the Test Procedure section. Controls should minimally be run before using each new lot or shipment of OSOM RSV Test kit, at regular intervals afterward, or any time when the validity of the test results is questioned. All users should follow local, state, and federal regulations regarding quality control procedures.

If the controls do not perform as expected, do not report patient results. Please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

***QC Testing Frequency and Documentation***

For this facility, External QC is run:

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

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| 1. **LIMITATIONS**
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• There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with RSV as compared to a molecular test, especially in samples with low viral load.

• Viral transport media (VTM) should not be used with this test.

• Negative test results are not intended to rule out other non-RSV viral or bacterial infections.

• Positive test results do not rule out co-infections with other bacterial or viral pathogens.

• All negative test results obtained with the OSOM RSV Test are presumptive and confirmation with a molecular assay may be necessary.

• This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

• Incorrect test results may occur if a specimen is incorrectly collected or handled.

• Results from testing with the OSOM RSV Test should not be used as the sole basis to diagnose or exclude RSV infection or to determine infection status.

• This test detects both viable (live) and non-viable RSV. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.

• Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

• The OSOM RSV Test is a qualitative test and does not provide information on the viral concentration present in the specimen.

• Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no RSV activity when disease prevalence is low. False-negative test results are more likely during peak RSV activity when the prevalence of disease is high.

• The OSOM RSV Test has been evaluated for use with human specimen material only.

• Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.

• The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.

• The validity of the OSOM RSV Test has not been proven for identification/ confirmation of tissue culture isolates and should not be used in this capacity.

• Therapeutic anti-RSV monoclonal antibodies may interfere with the OSOM RSV Test.

• Performance characteristics have not been established for use with patients aged 7 to 59 years or for immunocompromised patients.

• There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates). The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2023 and March 2024. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of RSV and their prevalence, which change over time.

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| 1. **EXPECTED VALUE**
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The rate of positivity as determined by the OSOM RSV Test during the 2023-2024 clinical study was 11.7% (96/818).

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| 1. **CLINICAL PERFORMANCE**
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Refer to Instructions for Use – OSOM RSV Test

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| 1. **CLIA WAIVER STUDY**
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The accuracy of the OSOM RSV Test was evaluated in a prospective clinical study during November 2023 to March 2024 at six intended-use CLIA-waived sites. The sites consisted of urgent care clinic, adult care center, and physicians’ offices. A total of nine (9) operators, representative of CLIA-waived site personnel (intended users) with no prior laboratory experience, participated in the study without any training on the use of the test. The results obtained from the OSOM RSV Test by the intended users were compared with those obtained using an FDA-cleared RT-PCR method. This study evaluated 818 prospectively collected specimens, of which 111 tested positive and 707 tested negative by the FDA-cleared RT-PCR method. The comparison of the OSOM RSV Test results with the comparator method results showed PPA of 83.8% (93/111) with a 95% CI of 75.8%-89.5%, NPA of 99.6% (704/707) with a 95% CI of 98.8% 99.9%. A summary of these results is presented in the Clinical Performance section.

A near-the-cutoff study was conducted to demonstrate the capability of untrained users to accurately test samples with concentrations near the assay cutoff. This study was conducted at three CLIA-waived intended-use sites using simulated swab samples as part of the reproducibility study. The samples were spiked with RSV virus targeting 1x LoD concentration (low positive ≈ 95% positivity) and high negative samples (0.1x LoD). The swabs were provided to the operators in blinded and randomized panels for testing with the OSOM RSV Test according to the test procedure. A total of seven (7) untrained operators participated, with each site having two or three operators. Each operator tested 15 low positive and 15 negative samples over five nonconsecutive days. The results of this study revealed a 100% agreement with expected results. A summary of these results is presented in the Reproducibility section.

Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test was not sensitive to the environmental stresses or potential user errors.

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| 1. **REFERENCES**
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1. You Li, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet 2022;399;2047-2064. https://doi.org/10.1016/S0140-6736(22)00478-0.

2. Kelly J. Henrickson, et al. Diagnostic assays for respiratory syncytial virus disease. Supplement. Pediatr Infect Dis J 2007;26: S36–S40.

3. Falsey AR, et al. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005;352(17):1748-1759.

4. Trinh TT Tien, et al. Development of a rapid fluorescent immuno-chromatographic test to detect respiratory syncytial virus. Int. J. Mol. Sci. 2018, 19, 3013; <https://doi.org/10.3390/ijms19103013>.

5. Kristine K. Macartney, et al. Nosocomial Respiratory Syncytial Virus Infections: The Cost-Effectiveness and Cost-Benefit of Infection Control. Pediatrics. 2000;106(3):520-526.

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| 1. **ASSISTANCE**
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For technical assistance contact Sekisui Diagnostics Technical Services at (800) 332 1042.

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