OSOM®

RSV/Adeno Test

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OSOM® RSV/Adeno Test

Catalog number 197E

FOR EXPORT USE ONLY. NOT FOR SALE IN THE U.S.
FOR LABORATORY AND PROFESSIONAL USE ONLY.

INTENDED USE

The OSOM® RSV/Adeno test is a rapid chromatographic immunoassay for the qualitative detection of Respiratory Syncytial Virus (RSV) and/or Adenovirus antigens directly from nasopharyngeal samples (nasal swabs and nasal washes/aspirates) in patients suspected of having a viral respiratory infection. Throat swabs are also an acceptable sample type for the detection of Adenovirus antigens. This test is intended for use as an aid in the diagnosis of RSV and/or Adenovirus infections in symptomatic patients. It is recommended that negative test results be confirmed by viral culture. Negative results should not be used as the sole basis for treatment.

SUMMARY AND EXPLANATION OF TEST

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] It is said that approximately 50% and nearly 100% of children suffer from infection with these viruses by 1 and 2 years of age, respectively. 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.

Adenovirus causes respiratory tract infections, such as pharyngitis/tonsillitis, pharyngo-conjunctival fever, and pneumonia, but also diarrhea, epidemic keratoconjunctivitis, and other diseases. Pharyngoconjunctival fever is epidemic in summer, while other adenovirus infections are nearly perennial. The incidence of adenovirus respiratory tract infections is higher in children. These viruses account for up to 10% of such infections in children, and the infections sometimes become severe.[3,4,5]

Accurate diagnosis can also help reduce the inappropriate use of antibiotics and gives the physician the opportunity to prescribe an appropriate therapy. The OSOM RSV/Adeno Test can provide rapid detection of RSV and/or Adenovirus antigens from symptomatic patients.

PRINCIPLE OF THE TEST

The OSOM RSV/Adeno Test consists of a test stick that specifically detects RSV and/or Adenovirus antigens. The test procedure requires the solubilization of the antigen from a nasal swab or wash/aspirate sample, by mixing with Extraction Buffer. For adenovirus, throat swabs are also acceptable, The test stick is then placed in the sample mixture, which migrates along the membrane surface.

If RSV antigens are present in the sample, it will form a complex with gold colloidal-labeled mouse monoclonal IgG antibodies to RSV. The resulting complex will then be bound by another mouse anti-RSV antibody coated on the nitrocellulose membrane to form a red/purple line in the presence of RSV antigen.

If adenovirus antigens are present in the sample, it will form a complex with gold colloidal-labeled mouse monoclonal IgG antibodies to adenovirus. The resulting complex will then be bound by another mouse anti-adenovirus antibody coated on the nitrocellulose membrane to form a red/purple line in the presence of adenovirus antigen.

A black control line must appear in the control region of the stick for results to be valid. The appearance of red/purple lines of any intensity in the test line region indicates a positive result

REAGENTS AND MATERIALS PROVIDED

25 Test Sticks
25 Test Tubes
25 Sterile Nasal Swabs
1 Extraction Buffer vial
- 0.6 mL – phosphate buffered salt solution (pH7.6), and 0.09% sodium azide (as a preservative)

1 Extraction buffer dropper top
1 Directional Insert
1 Workstation

MATERIALS REQUIRED BUT NOT PROVIDED

A timer or watch
Throat swabs for Adenovirus detection only
Nasal suction collection container

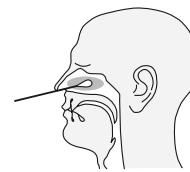
WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Follow your clinical and/or laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens.[6]
- Swabs, tubes and test sticks are for single use only.
- The extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
- Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.

• Do not interchange or mix components from different kit lots.

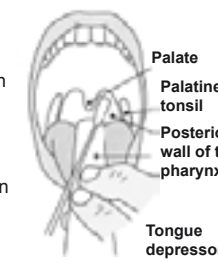
STORAGE CONDITIONS
• Store Test Sticks and Extraction Buffer tightly capped refrigerated or at room temperature (2°-30°C/36°-86°F).
• Do not freeze any of the test kit components.
• Do not use test sticks and reagents after expiration date.
• Recap the desiccated container immediately after removing a test stick.

SPECIMEN COLLECTION AND PREPARATION
Methods of sample collection
1) Nasal swabs
Insert swab (included in kit) into nostril until resistance is felt. Rub the swab along the nasal membrane several times.



2) Nasal suction fluid
Attach a suction catheter with mucus trap to the suction apparatus. Insert one end of the catheter into the nasal cavity, and suck out the nasal fluid. Collect a sample by immersing a swab included with kit into the nasal fluid collected in the trap.

3) Throat swabs (Adenovirus only)
While the mouth is open wide, depress the tongue with a tongue depressor. Collect a sample carefully by strongly rubbing the palate, tonsil, and posterior wall of the pharynx with a separately sold swab (for the collection of throat samples). Caution should be exercised to prevent contact between the swab and the inside of the buccal cavity/tongue/teeth.



• Use only the nasal swab or nasal suction method for detection of RSV antigens.
• Throat swab specimens may be used for the detection of adenovirus antigens. These are not provided with the kit and should be sourced separately.
• The swabs provided with the kit are intended for use as nasal swabs only. Do not use these swabs to collect throat samples.
• Test the sample as soon as possible after collecting the specimen. If samples cannot be processed immediately, specimens may be held at 2°-8°C (36°-46°F) for up to 24 hours.
• To transport patient nasal swabs, place swab in a clean, dry container such as a plastic or glass tube.
• **A separate swab must be collected if culture is desired.**
• The test performance depends on the quality of the sample obtained, and the handling and transport of the sample. Training in specimen collection is recommended because of the importance of specimen quality. False negative results may occur from inadequate specimen collection and/or handling.

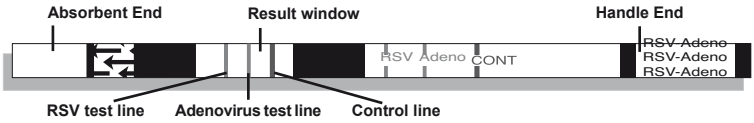
QUALITY CONTROL (QC)
The OSOM RSV/Adeno test provides two types of controls: Procedural internal controls to aid in determining test validity and external controls.

Internal Procedural Controls
Several controls are incorporated into each test stick for routine quality checks.

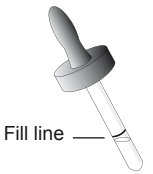
1. The appearance of the black control line in the results window is an internal procedural control:
   • **Test System:** The appearance of the black control line assures that adequate test volume was present and that adequate capillary migration of the extracted sample has occurred. It also verifies proper assembly of the Test Stick.
   • **Operator:** The appearance of the control line indicates that adequate test volume was present for capillary flow to occur. If the control line does not appear at the end of read time, the test is invalid.

2. The clearing of the background in the results area may also be documented as an internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid.

TEST PROCEDURE

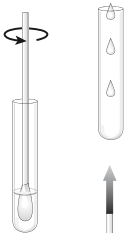


STEP 1: ADD EXTRACTION BUFFER
Using the supplied dropper top, add 0.3 mL of Extraction buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube.

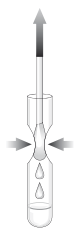


Note: Add Extraction buffer to the test tube before putting in the specimen swab to prevent contaminating the Extraction Buffer vial.

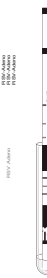
STEP 2: MIX SWAB IN BUFFER
Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.



STEP 3: SQUEEZE LIQUID FROM SWAB
Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. Discard the swab in a suitable biohazardous waste container.



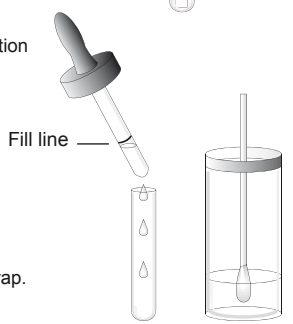
STEP 4: ADD TEST STICK
Remove a Test Stick from the canister. Recap the canister immediately. Place the test stick (arrows pointing downward) into the tube with the extraction buffer solution. Set a timer for 10 minutes.



STEP 5: READ RESULTS
At 10 minutes read results by removing stick from the tube and holding against a white background.Some positive results may be seen and reported earlier. See interpretation of results section. Test is invalid beyond the stated read time. Discard used test tubes and Test Sticks in suitable biohazardous waste container.

TEST PROCEDURE, NASAL SUCTION FLUID

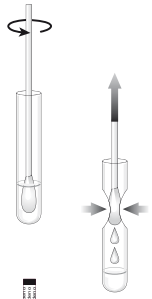
STEP 1: ADD EXTRACTION BUFFER
Using the supplied dropper top, add 0.3 mL of Extraction buffer to each test tube. Fill the dropper to the line indicated on the barrel of the dropper top and expel entire contents into tube.



Note: Add Extraction buffer to the test tube before putting in the specimen swab to prevent contaminating the Extraction Buffer vial.

STEP 2: COLLECT SAMPLE
To obtain sample from suction fluid, immerse a swab, included with kit, into the nasal fluid collected in the trap.

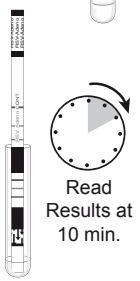
STEP 3: MIX SWAB IN BUFFER
Put the specimen swab into the tube. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least ten times (while submerged). Best results are obtained when the specimen is vigorously mixed in the solution.



STEP 4: SQUEEZE LIQUID FROM SWAB
Squeeze out as much liquid as possible from the swab by pinching the side of the flexible test tube as the swab is removed. Discard the swab in a suitable biohazardous waste container.

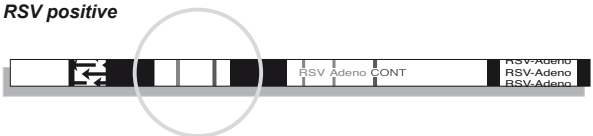
STEP 5: ADD TEST STICK
Remove a Test Stick from the canister. Recap the canister immediately. Place the test stick (arrows pointing downward) into the tube with the extraction buffer solution. Set a timer for 10 minutes.

STEP 6: READ RESULTS
At 10 minutes read the results by removing stick from the tube and holding against a white background. The Reading Guide may be used for this purpose. Some positive results may be seen and reported earlier. See interpretation of results section. Test is invalid beyond the stated read time. Discard used test tubes and Test Sticks in suitable biohazardous waste container.



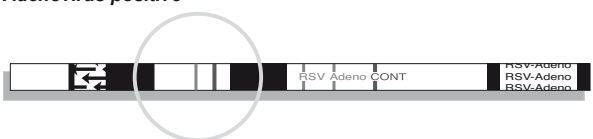
INTERPRETATION OF TEST RESULTS
The appearance of a black Control Line, with or without a red/purple Test Line(s), indicates a valid result. A black or red/purple line that appears uneven in color shading is still considered a valid line. In cases of moderate or high positive specimens, some color behind the Test Line may be seen. As long as the Test Line and the Control Line are visible, the results are valid.

RSV positive



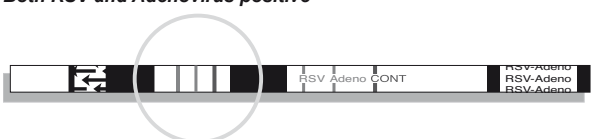
One black line in the control position and one pink/purple line in the RSV test line position.

Adenovirus positive



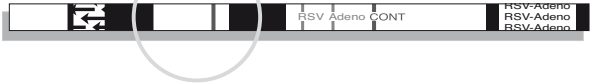
One black line in the control position and one pink/purple line in the Adeno test line position.

Both RSV and Adenovirus positive



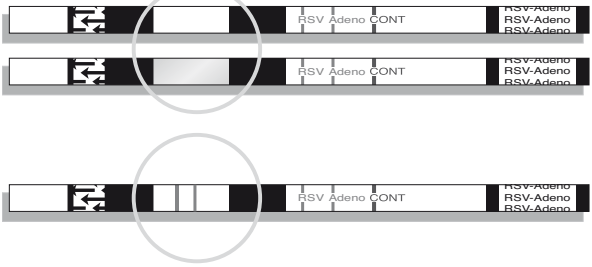
One black line in the control position and a pink/purple line at both the RSV and the Adeno test line positions.
Note that the red and black lines can be any shade of that color. The lines can be lighter or darker than the lines in the picture. Any visible red/purple line should be considered positive.

Negative



A black Control Line but no red/purple Test Line is a presumptive negative result. A negative result means that no RSV or adenovirus antigen was present or the level of the antigen in the sample is below the detection limit of the assay.

Invalid



If no black Control Line appears or background color makes reading the black Control Line impossible, the result is invalid. If this occurs, repeat the test using a new Test Stick.

REPORTING RESULTS

- Report negative test results when only the black control line is observed which indicates that RSV viral antigen and adenoviral antigen is not detected. Infection due to RSV or adenovirus cannot be ruled out since the antigens may be present in the specimen below the detection limit of the test. Negative tests are presumptive and should be confirmed by culture.
- Report positive test results when both the black control line and any shade of red line are observed which indicates the presence of RSV and/ or adenovirus antigen. This result does not rule out co-infections with other pathogens or identify any specific viral subtype.
- If result is considered invalid, repeat the test using a new sample and a new test dipstick.

LIMITATIONS

- The OSOM RSV/Adeno Test is for the qualitative detection of RSV viral and/or adenovirus antigens. The test performance depends on antigen load and may not correlate with viral culture performed on the same specimen. Negative test results are not intended to rule out other viral infections.
- Sensitivity can differ with various strains of RSV and/or adenovirus due to difference in antigen expression.
- This test detects both viable and non-viable RSV and/or adenovirus, and may yield a positive result in the absence of living organisms.
- 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 specimen collection and/or handling.
- As with all diagnostic assays, the results obtained with this test kit yield data that must be used only as an adjunct to other information available to the physician.
- High levels of blood on specimen swabs might cause an intense red background on the test strip that could interfere with the test interpretation. Avoid samples that have been heavily contaminated with whole blood.
- Positive and negative predictive values of these diagnostic assays are highly dependent on prevalence or current level of RSV and/or adenovirus activity. During peak RSV/Adenovirus activity in a season, positive predictive values are higher, with false positives less likely; and negative predictive values are lower, with false negatives more likely. Conversely, during low RSV/Adenovirus activity (e.g., off-season or beginning of a season), negative predictive values are higher and positive predictive values lower, with false positive test results more likely.

EXPECTED RESULTS
RSV/Adenovirus viruses can cause epidemics which typically occur during the winter months.

PERFORMANCE CHARACTERISTICS

Comparison of OSOM RSV/Adeno Test to In Vitro Diagnostic Agent (Immunochromatography):

NASOPHARYNGEAL SAMPLES FOR RSV

	In Vitro Diagnostic Agent (Immunochromatography)		
		+	-	total
OSOM RSV/Adeno Test	+	178	3	181
	-	2	216	218
	total	180	219	399

Clinical sensitivity: 98.9% (178/180)
Clinical specificity: 98.6% (216/219)

THROAT SWABS FOR ADENOVIRUS

	In Vitro Diagnostic Agent (Immunochromatography)		
		+	-	total
OSOM RSV/Adeno Test	+	79	5	84
	-	7	190	197
	total	86	195	281

Clinical sensitivity: 91.9% (79/86)
Clinical specificity: 97.4% (190/195)

Comparison of OSOM RSV/Adeno Test to PCR:

NASOPHARYNGEAL SAMPLES FOR RSV

	PCR		
		+	-	total
OSOM RSV/Adeno Test	+	179	2	181
	-	19	199	218
	total	198	201	399

Clinical sensitivity: 90.4% (179/198)
Clinical specificity: 99.0% (199/201)

THROAT SWABS FOR ADENOVIRUS

	PCR		
		+	-	total
OSOM RSV/Adeno Test	+	75	9	84
	-	7	190	197
	total	82	199	281

Clinical sensitivity: 91.5% (75/82)
Clinical specificity: 95.5% (190/199)

NASOPHARYNGEAL SAMPLES FOR ADENOVIRUS

		PCR		
		+	-	total
OSOM RSV/Adeno Test	+	96	8	104
	-	17	500	517
	total	113	508	621

Clinical sensitivity: 85.0% (96/113)
Clinical specificity: 98.4% (500/508)

Assay Reproducibility
Accuracy
(1) Perform the test using a negative control for accuracy assessment as the sample: the test is negative.
(2) Perform the test using a strongly positive RSV control for accuracy assessment (RS virus titer: 5.5 x 10^5 - 6.5 x 10^5 $TCID_{50}$/mL) and a moderately positive RSV control for accuracy assessment (RS virus titer: 5.5 x 10^4 - 6.5 x 10^4 $TCID_{50}$/mL) as the samples: the test is only positive for RS virus.
(3) Perform the test using a strongly positive adenovirus control for accuracy assessment (adenovirus titer: 7.5 x 10^5 - 8.5 x 10^5 $TCID_{50}$/mL) and a moderately positive adenovirus control for accuracy assessment (adenovirus titer: 7.5 x 10^4 - 8.5 x 10^4 $TCID_{50}$/mL) as the samples: the test is only positive for adenovirus.

Within-run reproducibility
(1) Use a negative control for within-run reproducibility assessment as the sample and repeat the test 5 times: the test is negative every time.
(2) Use a strongly positive RSV control for within-run reproducibility assessment (RS virus titer: 5.5 x 10^5 - 6.5 x 10^5 $TCID_{50}$/mL*) as the sample and repeat the test 5 times: the test is only positive for RS virus every time.
(3) Use a strongly positive adenovirus control for within-run reproducibility assessment (adenovirus titer: 7.5 x 10^5 - 8.5 x 10^5 $TCID_{50}$/mL*) as the sample and repeat the test 5 times: the test is only positive for adenovirus every time.

((1)-(3): tested by the in-house methods of Sekisui Medical)

Analytical Sensitivity
RS virus antigen: 2.5 x 10^4 $TCID_{50}$/mL
Adenovirus antigen: 3.5 x 10^4 $TCID_{50}$/mL

Analytical Specificity and Cross-reactivity
The OSOM RSV/Adeno Test was evaluated with 48 bacterial and viral isolates. Bacterial isolates were tested at a concentration of approximately >1 x 10^7 cfu/mL. All of the bacteria listed gave negative responses. Viral isolates were tested at approximately >1 x10^6 $TCID_{50}$/mL. All of the viruses listed produced negative responses.

Bacterial Panel
Acinetobacter calcoaceticus
Bordetella pertussis
Candida albicans
Corynebacterium diptheriae
Enterococcus faecalis
Enterococcus gallinarum
Escherichia coli
Haemophilus influenza
Klebsiella pneumoniae
Moraxella catarrhalis
Mycobacterium avium
Neisseria meningiditis
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus epidermidis
Streptococcus Group A
Streptococcus Group B
Streptococcus mutans
Streptococcus pneumoniae
Torulopsis glabrata (Candida glabrata)

Viral Panel

Echovirus Type 3
Echovirus Type 6
Echovirus Type 9
Echovirus Type 11
Echovirus Type 14
Echovirus Type 18
Echovirus Type 25
Echovirus Type 30
Coxsackievirus Type B1
Coxsackievirus Type B2
Coxsackievirus Type B3
Coxsackievirus Type B4
Coxsackievirus Type B5
Herpes simplex virus Type 1
Influenza virus Type A/New Caledonia/20/99 (H1N1)
Influenza virus Type A/Hiroshima/52/2005 (H3N2)
Influenza virus Type B/Shanghai/361/2002 (Yamagata lineage)
Influenza virus Type B/Malaysia/2506/2004 (Victoria lineage)
Influenza virus Type C/JJ/50
Influenza virus Type C/Yamagata/3/96
Parainfluenza virus Type 1
Parainfluenza virus Type 2
Parainfluenza virus Type 3
Mumpus virus
Rubella virus
Measles virus

RSV Panel testing

This kit produces a positive reaction with the following RS virus strains.

Respiratory Syncytial Virus Type A/Long
Respiratory Syncytial Virus Type A/A-2
Respiratory Syncytial Virus Type B/Washington/18537/62
Respiratory Syncytial Virus Type B/WV/14617/'85[B-1 wild type]
Respiratory Syncytial Virus Type B/9320

Adenovirus Panel testing

This kit produces a positive reaction with the following adenovirus strains.

Adenovirus Type 1
Adenovirus Type 2
Adenovirus Type 3
Adenovirus Type 4
Adenovirus Type 5
Adenovirus Type 6
Adenovirus Type 7
Adenovirus Type 8
Adenovirus Type 11
Adenovirus Type 18
Adenovirus Type 19
Adenovirus Type 37
Adenovirus Type 41

REORDER