SSI DIAGNOSTICA

IMMUVIEW®

RSV ANTIGEN TEST

ENGLISH

Lateral flow test for qualitative detection of respiratory syncytial virus (RSV) in nasal wash, nasopharyngeal swap and throat swap specimens.

IMMUVIEW® RSV ANTIGEN TEST

For *in vitro* diagnostic use

Intended use

The ImmuView® RSV Antigen Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) fusion protein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of respiratory syncytial virus (RSV) infections. Negative test results should be confirmed by cell culture or other methods.

Explanation of the Test

Respiratory syncytial virus is a virus that causes infections of the lungs and respiratory tract. RSV is most common among infants and children under the age of 1 but can also occur among adults. In healthy children and adults, RSV symptoms are mostly mild and can resemble a common cold. However, the RSV can cause severe infection especially in premature babies which can lead to additional clinical diseases such as bronchiolitis or pneumonia, which can become life-threatening.

Rapid identification and diagnosis of RSV has become more important due to the availability of effective anti-microbial therapy. Rapid identification can lead to reduced hospital stays, reduction in anti-microbial use and reduction in the cost of hospital care.

ImmuView® RSV Antigen Test provides a simple, rapid method for the diagnosis of RSV using nasal wash and nasopharyngeal swab specimens.

Principle of procedure

ImmuView® RSV Antigen Test is a rapid lateral flow test for detection of RSV. The test strip is a capture test line, with monoclonal RSV antibodies.

Eight (8) or three (3) large free-falling drops of buffer reagent are mixed with either swabs from patients or nasal wash, respectively. The test strips are introduced into each tube containing test material. The strip contains a colored bead conjugate that contains; blue beads conjugated to anti-RSV monoclonal antibodies. After fifteen (15) minutes of incubation, remove, read and interpret the results. The colored beads bind to the captured antigens, causing development of a blue line. When there are no antigens present in the samples, no blue line will develop on the strip. The sample continues to migrate through the membrane and a blue/grey line develops in the control (C) area. This built-in procedural control provides evidence that the test was performed properly, and the sample and reagents have migrated through the device strip. If the control line does not appear, the test is invalid.

Precautions

The presence of partial lines and dots represent INVALID test results. The sample should in that case be re-tested.

Ensure that the tests running buffer (RB) is added to all the test tubes first and verified as present, prior to adding patient samples or controls.

Test results should be read within the recommended readingframe of 15 minutes after incubation.

Do not use the test after the kit's expiry date.

Do not mix the components of the kit with components from different kit lots.

Let the kit components equilibrate to room temperature before testing.

Materials Required but not Provided

Clock, timer or stopwatch. Sterile standard transport media, swabs and collection containers/transport tubes.

Quality Control

The positive and negative controls provided with ImmuView® RSV Antigen Test, function as the kit's quality control.

Before using a new lot, or a new shipment of the same lot or by a new operator, please perform quality control testing before testing clinical samples.

Control Procedure

1. Bring the positive and negative controls (found in the kit) to room temperature. Mix thoroughly prior to testing.

2. Add 8 drops (240 µL) of running buffer to each control tube (hold the buffer bottle vertically before dispensing). THIS IS VERY IMPORTANT.

3. Mix the sample(s) and buffer by swirling the control tube gently and the lyophilized positive control will dissolve. The negative control is running buffer added an empty vial.

4. Open the test container and take out the number of test strips needed and close the top firmly afterward.

5. Insert one test strip into each control tube.

6. Incubate the tests for 15 minutes at room temperature.

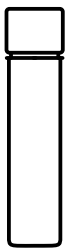
7. Lift each of the test strips out of the control tubes separately and place horizontally on a clean white paper or bench and read and interpret the results.
   DO NOT READ the test strips more than 15 minutes after the incubation step as the results may be inaccurate.

8. Discard the test strips after interpretation.
   The positive control will show a full control line and a blue RSV line.
   The negative control will show a full control line.

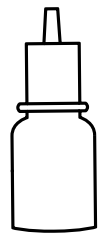
If these criteria are not met, do not proceed using the kit on clinical samples. Please contact SSI Diagnostica A/S.

Quick Guide for control testing

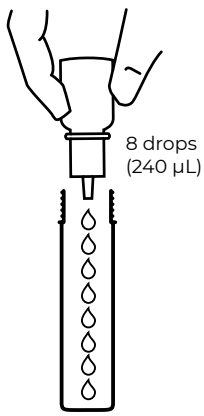
1. The control



2. The running-buffer

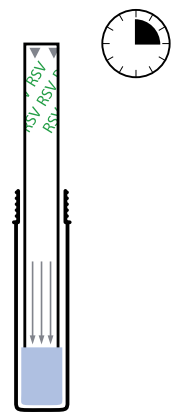


3. Add 8 drops of running buffer to the control vial



(Make sure that the positive control is completely dissolved)

4. Add the test to the vial with the dissolved control and wait 15 minutes



5. Read the test

A: Control
B: RSV

Positive control

Negative control

If any other result occur when performing a control test, please contact SSI Diagnostica A/S

Procedure for nasal wash/transport media

1. Bring the patient sample(s) to room temperature. Mix thoroughly prior to testing.

2. Place a separate test tube in the cardboard holder for each sample. Label either the test tubes or the strips with the sample ID number using an indelible marker.

3. Add 3 drops (90 µL) of running buffer (RB) to each of the test tubes (hold the buffer bottle vertically).

4. Fill a separate transfer pipette with sample material and add 3 drops (120 µL) of the sample to the test tube (hold the pipette vertically).

5. Mix the sample(s) and buffer by swirling the test tube gently.

6. Open the test container and take out the number of test strips needed and close the top firmly afterward.

7. Insert one test strip into each test tube.

8. Incubate the tests for 15 minutes at room temperature.

9. Lift each of the test strips out of the test tubes separately and place horizontally on a clean white paper or bench and read and interpret the results.
   DO NOT READ the test strips more than 15 minutes after the incubation step as the results may be inaccurate.

10. Discard the test strips after interpretation and recording of the test results into the appropriate biohazard container.

Procedure for nasopharyngeal/throat swab

1. Place a separate test tube in the cardboard holder for each sample. Label the test tubes with the sample ID number using an indelible marker.

2. Add 8 drops (240 µL) of running buffer (RB) to each of the test tubes (hold the buffer bottle vertically).

3. Place the swab containing the material and whirl for one (1) minute.

4. Open the test container and take out the number of test strips needed and close the top firmly afterward.

5. Insert one test strip into each test tube.

6. Incubate the tests for 15 minutes at room temperature.

7. Lift each of the test strips out of the test tubes separately and place horizontally on a clean white paper or bench and read and **interpret the results within 5 minutes after incubation.**
   DO NOT READ the test strips more than 15 minutes after the incubation step as the results may be inaccurate.

8. Discard the test strips after interpretation and recording of the test results into the appropriate biohazard container.

Interpretation of results

The Control test line at the top will appear blue. Only a full line indicates a valid result - **dots do not indicate a valid result.**

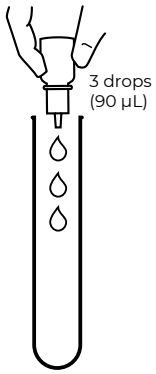
A **positive sample for RSV** will show a blue line in the middle of the strip.
Note: Two grey/purple test lines do not indicate a positive result. This result is invalid and needs to be re-tested.

If no Control line is observed the test is **invalid** and the sample should be retested.

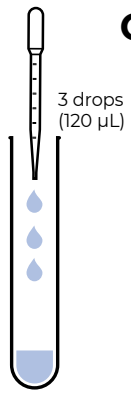
Quick Guide

Nasal Wash

1A
Add running buffer

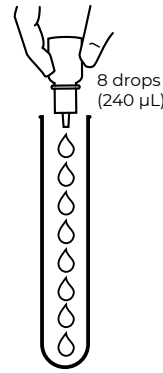


2A
Add sample and whirl gently

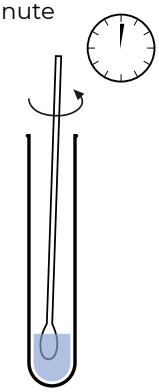


Nasopharyngeal / Throat Swab

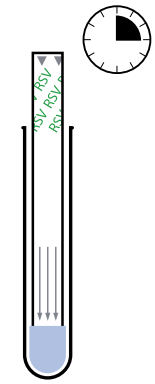
1B
Add running buffer



2B
Add swab with sample material and whirl for 1 minute



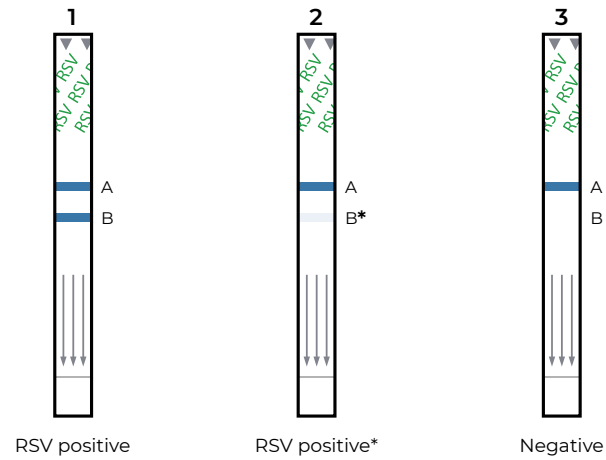
3
Add test and wait 15 minutes



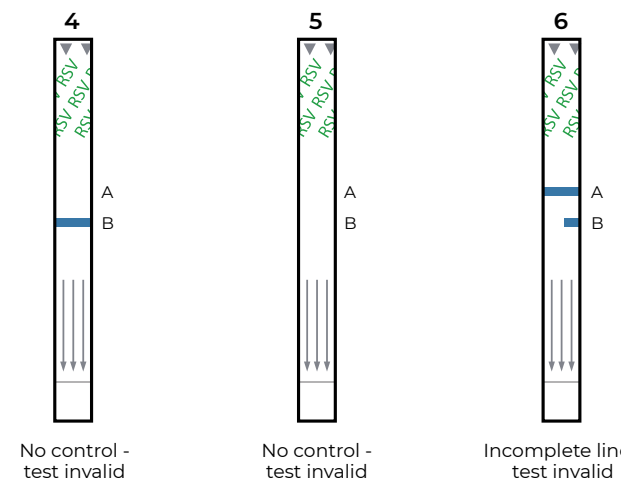
A: Control
B: RSV

*** Look closely.**
The intensity of the line B may vary from very clear to faint.

Valid test



Invalid test → retest



Limitations

A negative test result does not exclude infection with RSV nor is it intended to rule out other microbial-caused respiratory infections. Therefore, the results obtained with the ImmuView® RSV Antigen Test should be used in conjunction with clinical findings to make an accurate diagnosis.

The ImmuView® RSV Antigen Test detects both viable and non-viable RSV. Test performance depends on antigen load in the specimen and may not correlate with cell culture or PCR perfomed on the same specimen.

Inadequate specimen collection or low levels of virus shedding may result in sub-optimal performance and may yield false negative results.

The potential for interference from anti-microbials and interferon has not been established. Monoclonal antibodies may not detect all antigenic variants or new strains of RSV.

Analytical data

Limit of detection

ImmuView® Respiratory syncytial virus (RSV) antigen test has an acceptable limit of detection (LOD) on 1.77 µg/mL (antigen level). For inactivated native RSV strain A it is $1.25*10^5$ TCID50/mL.

Interference (Cross-reactivity)

Different virus and bacteria were tested with ImmuView® RSV Antigen in triplicates. The organism was both tested in normal saline (negative samples) and in saline spiked with native RSV. None of the mentioned organisms in table one (1) cross-reacted with the ImmuView® RSV Antigen Test.

Table 1: Organisms tested for cross-reactivity

Bacteria:	**CFU/mL**
Corynebakterium pseudodiphteriticum	1.0 x 10^7
Enterococcus faecalis	1.0 x 10^7
Escherichia coli	1.0 x 10^7
Gardnerella vaginalis	1.0 x 10^7
Hemophilus influenzae	1.0 x 10^7
Klebsiella pneumoniae	1.0 x 10^7
Lactobacillus casei	1.0 x 10^7
Legionella philadeelphia	1.0 x 10^7
Listeria monocytogenes	1.0 x 10^7
Moraxella osloensis	1.0 x 10^7
Mycobacterium tuberculosis	1.0 x 10^7
Mycoplasma pneumoniae (BIORAD nr. 6000-2504)	1.0 x 10^7
Neisseria gonorrhoeae	1.0 x 10^7
Neisseria meningiditis	1.0 x 10^7
Neisseria lactamica	1.0 x 10^7
Proteus vulgaris	1.0 x 10^7
Pneumococcus type 1	1.0 x 10^7
Pseudomonas aeruginosa	1.0 x 10^7
Staphylococcus aureus (Cowan)	1.0 x 10^7
Serratia marcescens	1.0 x 10^7
Streptococcus mutans (Type A)	1.0 x 10^7
Streptococcus pneumoniae	1.0 x 10^7
Streptococcus pyogenes (Grp A)	1.0 x 10^7
Streptococcus Grp B	1.0 x 10^7
Streptococcus Grp C	1.0 x 10^7

Bacteria:	CFU/mL
Streptococcus Grp F	1.0 x 10^7
Streptocuccus Grp G	1.0 x 10^7
Streptococcus sanguis	1.0 x 10^7

Virus:	TCID50
Adenovirus 2	1.0 x 10^5
Adenovirus 5	1.0 x 10^3
Adenovirus 10	1.0 x 10^3
Adenovirus 18	1.0 x 10^3
Cytomegalovirus	1.0 x 10^5
Echovirus 2	1.0 x 10^3
Echovirus 3	1.0 x 10^3
Enterovirus D68	2.0 x 10^4
Mumps (Enders)	1.0 x 10^3
Parainfluenza virus type 1	1.0 x 10^5
Parainfluenza virus type 3	1.0 x 10^5
Herpes simplex type 1	1*10^5
Herpes simplex type 2	1.0 x 10^6
Influenza A (H1N1)	1*10^5
Influenza A (H3N2)	1*10^5
Influenza B (Hong Kong)	1.0 x 10^6
Rhinovirus 18	unknown
Rhinovirus 2	1.0 x 10^3
Rhinovirus B	1.0 x 10^3
Rhinovirus 16	1.0 x 10^3

Interfering substances

None of the substances in table 2 interfered with the ImmuView® RSV Antigen Test. However, high doses of acetylsalicylic acid (5 mg/mL), Ciprofloxacin (0.22 mg/mL), diphenhydramine (5 mg/mL), oxymetazoline (10 mg/mL), phenylephrine (100 mg/mL) and phenylpropanolamine (20 mg/mL) may cause false weak positive results. Another interfering factor is pH 4 which also can cause interference.

Table 2: Interfering agents and concentrations herein

Agent	Concentration
4-acetamidophenol	10 mg/mL
Acetylsalicyclic acid	0.1 mg/mL
Albumin	10 mg/mL
Albumin	5 mg/mL
Albumin	0,6 mg/mL
Albumin/Glucose/pH 7	10 mg/mL/20 mg/mL/pH 7
Albumin/Glucose/pH 9	10 mg/mL/20 mg/mL/pH 9
Albumin/Glucose/pH 7	5 mg/mL/10 mg/mL/pH 7
Albumin/Glucose/pH 9	5 mg/mL/10 mg/mL/pH 9
Albumin/Glucose/pH 7	0,6 mg/mL/3 mg/mL/pH 7
Albumin/Glucose/pH 9	0,6 mg/mL/3 mg/mL/pH 9
Antihistamine	0.22 mg/mL
Ascorbic acid (c-vitamin)	1 mg/mL
Bilirubin	0.2 mg/mL
Bromhexin/cough syrup	0.22 mg/mL
Caffeine	15 mg/mL
Chlorpheniramine	5 mg/mL

Agent	Concentration
Corticosterone	0.015 mg/mL
Erythromycin	0.067 mg/mL
Glucose (H)	20 mg/mL
Glucose (L)	10 mg/mL
Glucose (M)	3 mg/mL
Guaiacol glycerol ether	20 mg/mL
Ibuprofen	0.1 mg/mL
Mouth spray - Strefzap	25 %
Mouthwash - Apotekets klorhexidin	25 %
Mouthwash - Vioflour	25 %
Nasal spray - Otrivin	25 %
Oseltamivir (Tamiflu)	0.03 mg/mL
pH (basic)	9
pH (neutral)	7
Red blood cells washed 10%	1 %
Red blood cells washed 10%	0,1 %
Spinach (chloryfyllin)	0,1 mg/mL
Spinach (chloryfyllin)	0,01 mg/mL
Vancomycin	0.1 mg/mL

Transport Media

Following transport media did not interfere with the ImmuView® RSV Antigen Test.

Table 3: Transport Media

Amies Media
M4 Media
Saline
Tryptose Phosphate Broth
Veal Infusion Broth
Brain Heart Infusion
M4 RT Media
PBS pH 7,4
Stuart's Media
UTM-RT Media
Dukbecco medium

Clinical studies

Retrospective studies

The following results were obtained in against another RSV lateral flow test (Other RSV test).

Table 4: Performance

< 6 years; Swab (Nasopharyngeal & Throat)			
ImmuView	**Other RSV test**		
	Positive	Negative	Total
Positive	13	1*	14
Negative	0	112	112
Total	13	113	126

Positive agreement 93% (13/14; CL:69-99%)

Negative agreement 99% (112/113; 95-100%)

*** PCR positive**

< 6 years; Nasal Wash or nasopharynx secretion			
ImmuView	**Other RSV test**		
	Positive	Negative	Total
Positive	12	0	12
Negative	0	11	11
Total	12	11	23

Positive agreement 100% (12/12; CL:76-100%)

Negative agreement 100% (11/11; 74-100%)

Adults Swab (Nasopharyngeal & Throat)			
ImmuView	**Other RSV test**		
	Positive	Negative	Total
Positive	6	1*	7
Negative	1*	126	127
Total	7	127	134

Positive agreement 86% (6/7; CL:49-97%)

Negative agreement 99% (126/127; 95-100%)

*** PCR positive**

Adults Nasal Wash or nasopharynx secretion			
ImmuView	**Other RSV test**		
	Positive	Negative	Total
Positive	3	0	3
Negative	1	21	22
Total	4	21	25

Positive agreement 75% (3/4 NA)

Negative agreement 100% (21/21; 85-100%)

Storage and Shelf Life

Store at room temperature. Expiry date is printed on the package.

Quality Certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485.

Article number

99110

Information and Ordering

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark
T +45 4829 9100
F +45 4829 9179
info@ssidiagnostica.com
ssidiagnostica.com

Quality System DS/EN ISO 13485

REF 99110

1st edition • January 2019 • 96098

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark

ssidiagnostica.com

EXPERIENCE MATTERS