

IMMUVIEW[®]

RSV ANTIGEN TEST



ENGLISH (UK)

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) 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.

Description

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 or throat swab specimens.

Principle

ImmuView® RSV Antigen Test is a rapid lateral flow test for detection of RSV.

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 provided

- 1 tube with 22 test strips
- Freezedried positive control for RSV
- Negative control for RSV
- 6.5 mL running buffer
- 1 tweezer
- 22 transfer pipettes
- 22 test tubes
- 1 cardboard test tube holder
- Scorecard

Quick guide can be found on the inside of the box and on page 11.

Materials Required but not Provided

- Timer.
- Sterile standard transport media, swabs, and collection containers/
transport tubes.

Storage and Stability

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

Sample Collection and Storage

Please follow your local procedure for nasal wash or swab collection (throat or nasopharyngeal). Transport media that have been validated can be found on page 20.

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 μ L) 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.
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 test(s) 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 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.
The positive control will show a full control line and a blue RSV line.
The negative control will show a full control line.

Quick Guide for control testing

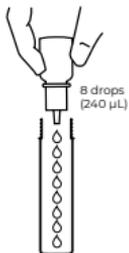
1. The control



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

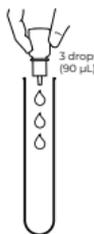
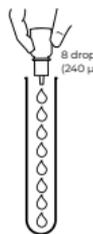
Procedure for nasal wash/transport media

1. Bring the patient sample(s) to room temperature.
2. Add 3 drops (90 μ L) of running buffer (RB) to each of the test tubes (hold the buffer bottle vertically).
3. Fill a separate transfer pipette with sample material and add 3 drops (120 μ L) of the sample to the test tube (hold the pipette vertically).
4. Mix the sample(s) and buffer by swirling the test tube gently.
5. Open the test container and take out the number of test strips needed and close the top firmly afterward.
6. Insert one test strip into each test tube.
7. Incubate the tests for 15 minutes at room temperature.
8. 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.
9. 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.
2. Add 8 drops (240 μ L) 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.

Quick Guide

Nasal Wash		Nasopharyngeal / Throat Swab		
1A Add running buffer	2A Add sample and whirl gently	1B Add running buffer	2B Add swab with sample material and whirl for 1 minute	3 Add test and wait 15 minutes
 <p>3 drops (90 µL)</p>	 <p>3 drops (120 µL)</p>	 <p>8 drops (240 µL)</p>	 <p>1 minute</p>	 <p>15 minutes</p>
OR				
Result Interpretation				
A: Control B: RSV * Look closely. The intensity of the line B may vary from very clear to faint.	 <p>A B</p>	 <p>A B*</p>	 <p>A B</p>	<p>1</p> <p>RSV positive</p>
	 <p>A B</p>	 <p>A B</p>	 <p>A B</p>	<p>2</p> <p>RSV positive*</p>
	 <p>A B</p>	 <p>A B</p>	 <p>A B</p>	<p>3</p> <p>Negative</p>
Invalid test				
 <p>A B</p>	 <p>A B</p>	 <p>A B</p>	<p>4</p> <p>No control - retest sample</p>	
 <p>A B</p>	 <p>A B</p>	 <p>A B</p>	<p>5</p> <p>No control - retest sample</p>	
<p>A B</p>	<p>A B</p>	<p>A B</p>	<p>6</p> <p>Incomplete line - retest sample</p>	

Interpretation of results

RSV positive will appear as a blue test line in the bottom of the test. The control test line in the top will appear blue.

If no control line is observed and/or incomplete test lines are present the test is invalid and the sample should be retested (see test results number 4, 5, and 6, page 11)..

A **positive sample for RSV** will show a blue line for RSV positive, and at the top of the test a blue control test line will appear (see test result number 1 and 2, page 11).

Look closely. Even if there is a very faint line for RSV the test result is positive (see test result number 2, page 11). The enclosed “Scorecard” can help to determine if the test result is positive or negative.

A **negative sample** will show a single blue control line in the top of the test (see test result number 3, page 11).

Limitations

- A negative test result does not exclude infection with RSV nor is it intended to rule out other microbial-caused respiratory infections.
- 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 performed 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 newstrains of RSV.
- ImmuView® RSV Antigen test has been validated on nasal wash and throat or nasopharyngeal swabs. Other specimens have not been validated and can cause incorrect results

Clinical data for the IFU

149 retrospective samples from children younger than 6 years were tested using a comparator RSV antigen test (Comparator) and the ImmuView® RSV Antigen Test (ImmuView®). 126 samples were calculated as positive agreement at 93% (13/14) between comparator and ImmuView® and a negative agreement at 99% (112/113).

Swab (nasopharyngeal and throat) < 6 years			
	Comparator		
ImmuView®	Positive	Negative	Total
Positive	13	1*	14
Negative	0	112	112
Total	13	113	126

*PCR positive for RSV

Swab (nasopharyngeal and throat) < 6 years	
Positive agreement	93% (13/14; CL: 69-99%)
Negative agreement	99% (112/113; CL: 95-100%)

23 samples were wash material with a positive and negative agreement at 100% (12/12) between the comparator and ImmuView®.

Nasal wash or nasopharynx secretion < 6 years			
	Comparator		
ImmuView®	Positive	Negative	Total
Positive	12	0	12
Negative	0	11	11
Total	12	11	23

Nasal wash or nasopharynx secretion < 6 years	
Positive agreement	100% (12/12; CL: 76-100%)
Negative agreement	100% (11/11; CL: 74-100%)

152 retrospective samples from adults older than 18 years were tested using the comparator and the ImmuView® test. 134 samples were swab material. The positive agreement between the comparator and ImmuView® was 86% (6/7) and the negative agreement was 99% (126/127).

Swab (nasopharyngeal and throat) >18 years			
	Comparator		
ImmuView®	Positive	Negative	Total
Positive	6	1*	7
Negative	1*	126	127
Total	7	127	134

*PCR positive for RSV

Swab (nasopharyngeal and throat) >18 years	
Positive agreement	86% (6/7; CL: 49-97%)
Negative agreement	99% (126/127; CL: 95-100%)

18 samples were wash material. 50% (1/2) was in positive agreement and 94% (16/17) were in negative agreement between the comparator and ImmuView®.

Nasal wash or nasopharynx secretion >18 years			
	Comparator		
ImmuView®	Positive	Negative	Total
Positive	1	0	1
Negative	1	16	17
Total	2	16	18

Nasal wash or nasopharynx secretion >18 years	
Positive agreement	50% (1/2; CL: N/A)
Negative agreement	94% (16/17; CL: 73-99%)

Analytical studies

Limit of detection

ImmuView® RSV antigen test has limit of detection (LOD) at 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 Test 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 the table one (1) cross-reacted with the ImmuView® RSV Antigen Test. The bacteria was tested at a concentration of 10^7 CFU/mL. The virus were tested between 10^3 - 10^6 TCID50.

Organisms tested for interference	
<i>Corynebacterium pseudodiphtheriticum</i>	<i>Neisseria lactamica</i>
<i>Enterococcus faecalis</i>	<i>Proteus vulgaris</i>
<i>Escherichia coli</i>	<i>Pneumococcus</i> type 1
<i>Gardnerella vaginalis</i>	<i>Pseudomonas aeruginosa</i>
<i>Hemophilus influenzae</i>	<i>Staphylococcus aureus</i> (Cowan)
<i>Klebsiella pneumoniae</i>	<i>Serratia marcescens</i>
<i>Lactobacillus casei</i>	<i>Streptococcus mutans</i> (Type A)
<i>Legionella philadeelphia</i>	<i>Streptococcus pneumoniae</i>
<i>Listeria monocytogenes</i>	<i>Streptococcus pyogenes</i> (Grp A)
<i>Moraxella osloensis</i>	<i>Streptococcus</i> Grp B
<i>Mycobacterium tuberculosis</i>	<i>Streptococcus</i> Grp C
<i>Mycoplasma pneumoniae</i>	<i>Streptococcus</i> Grp F
<i>Neisseria gonorrhoeae</i>	<i>Streptococcus</i> Grp G
<i>Neisseria meningitidis</i>	<i>Streptococcus sanguis</i>

Organisms tested for interference	
Adenovirus 2	Parainfluenza virus type 3
Adenovirus 5	Herpes simplex type 1
Adenovirus 10	Herpes simplex type 2
Adenovirus 18	Influenza A (H1N1)
Cytomegalovirus	Influenza A (H3N2)
Echovirus 2	Influenza B (Hong Kong)
Echovirus 3	Rhinovirus 18
Enterovirus D68	Rhinovirus 2
Mumps (Enders)	Rhinovirus B
Parainfluenza virus type 1	Rhinovirus 16

Interfering substances

None of the substances 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.

Agent	Concentration	Agent	Concentration
4-acetamidophenol	10 mg/mL	Erythromycin	0.067 mg/mL
Acetylsalicylic acid	0.1 mg/mL	Glucose	20 mg/mL
Albumin	10 mg/mL	Glucose	10 mg/mL
Albumin	5 mg/mL	Glucose	3 mg/mL
Albumin	0.6 mg/mL	Guaicol glycerol ether	20 mg/mL
Albumin/Glucose/pH 7	10 mg/mL/20 mg/mL/pH 7	Ibuprofen	0.1 mg/mL
Albumin/Glucose/pH 9	10 mg/mL/20 mg/mL/pH 9	Mouth spray	25 %
Albumin/Glucose/pH 7	5 mg/mL/10 mg/mL/pH 7	Mouthwash	25 %
Albumin/Glucose/pH 9	5 mg/mL/10 mg/mL/pH 9	Nasal spray - Otrivin	25 %
Albumin/Glucose/pH 7	0.6 mg/mL/3 mg/mL/pH 7	Oseltamivir (Tamiflu)	0.03 mg/mL
Albumin/Glucose/pH 9	0.6 mg/mL/3 mg/mL/pH 9	pH (basic)	9
Antihistamine	0.22 mg/mL	pH (neutral)	7
Ascorbic acid (c-vitamin)	1 mg/mL	Red blood cells washed 10%	1%
Bilirubin	0.2 mg/mL	Red blood cells washed 10%	0.1 %
Bromhexin/cough syrup	0.22 mg/mL	Spinach (chloryfyllin)	0.1 mg/mL
Caffeine	15 mg/mL	Spinach (chloryfyllin)	0.01 mg/mL
Chlorpheniramine	5 mg/mL	Vancomycin	0.1 mg/mL
Corticosterone	0.015 mg/mL		

Transport Media

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

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

Quality Certificate

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



Quality System
DS/EN
ISO 13485



Information and Ordering

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