SSI DIAGNOSTICA

IMMUVIEW®

RSV ANTIGEN TEST

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Lateral flow test for qualitative detection of respiratory syncytial virus (RSV) in nasal wash, nasopharyngeal swab and throat swab 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. The ImmuView® RSV Antigen Test can be read visually.

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 becomelife-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.

ImmuView® RSV Antigen Test is for use by laboratory professionals and/or healthcare professionals only.

Principle

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

Precautions

- Ensure that the running buffer is added to all the test tubes. False positive results can occur if no running buffer is added to the test tubes.
- The presence of partial lines and dots represents invalid test results. The sample should be re-tested.
- Test results should be read within the recommended reading frame of 5 minutes after incubation.
- Let the kit components equilibrate to room temperature before testing.
- Do not mix the components of the kit with components from different kit lots.
- Do not use the ImmuView® RSV Antigen Test after the expiry date.
- Inspect the tests and vials before use to ensure they are intact. Any damaged vials/tests should be discarded.

Materials provided

- 1 tube with 22 tests
- Freeze-dried 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

A quick guide can be found on the inside of the box and on page 9.

Materials required but not provided

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

Storage and stability

Please find the information on the box and labels. This product does not require any additional storage conditions. Do not freeze the product.

Preservatives

It is not known that any preservatives interfere with the result.

Sample collection and storage

Please follow your local procedure for nasal wash or swab collection (throat or nasopharyngeal).

Transport media which have been validated are listed in the section “Transport media”.

Quality control

The positive and negative controls provided with ImmuView®RSV Antigen Test function as the kit’s quality control. The positive and negative controls should follow the same procedure as nasopharyngeal/throat swab. The positive control should be visible at the control test line and the RSV test line.

The negative control should only be visible at the control line.

Before use check the vials to ensure there is no damage and/or leak. In case of damage or leak discard the vial.

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. Follow your local or state requirements for frequency of quality control testing.

Procedure for nasal wash/transport media

1. Bring the patient sample(s) to room temperature.

2. Add 3 drops (90 µL) of running buffer 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 µL) 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 tests needed and close the top firmly afterwards.

6. Insert one test into each test tube.

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

8. Lift each of the tests 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.**

9. Discard the tests, 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 µL) of running buffer 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 tests needed and close the top firmly afterwards.

5. Insert one test into each test tube.

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

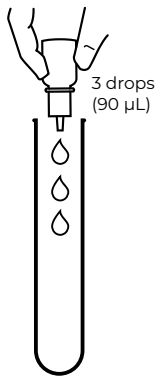
7. Lift each of the tests out of the test tubes separately and place horizontally on a clean white paper or bench and read and **interpret the results within 5 minutes after incubation.**

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

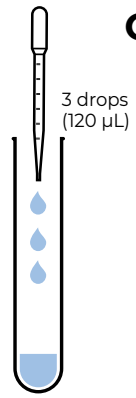
Quick guide

Nasal Wash

1A
Add running buffer



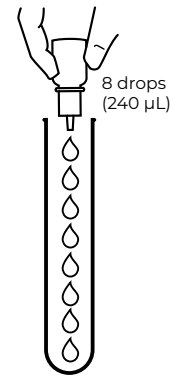
2A
Add sample and whirl gently



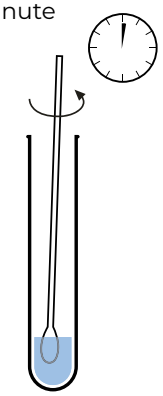
OR

Nasopharyngeal / Throat Swab

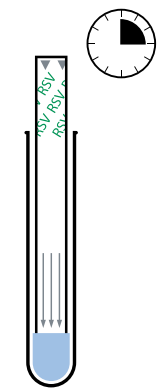
1B
Add running buffer



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



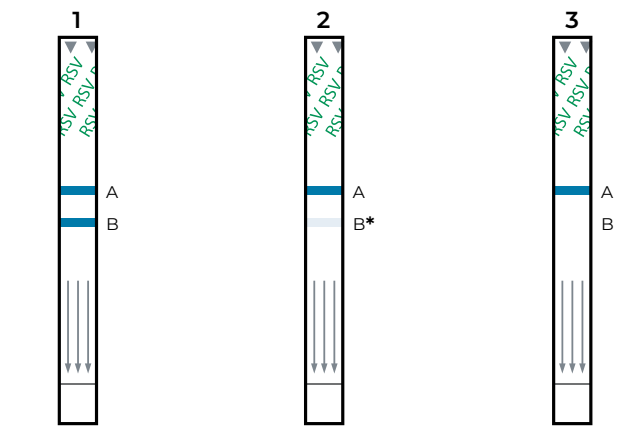
3
Add test and wait 15 minutes



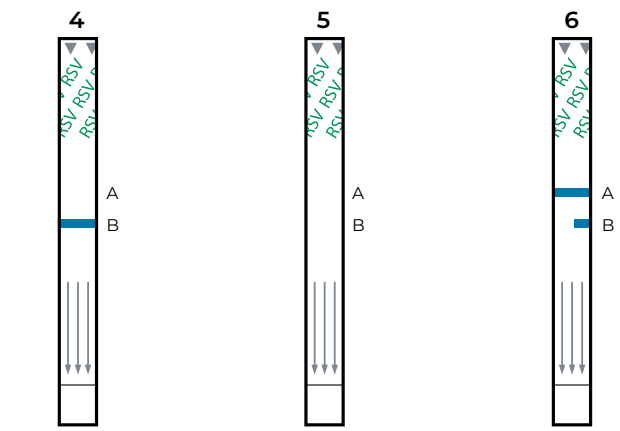
A: Control
B: RSV

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

Result interpretation



Invalid test



Interpretation of results

A positive sample for RSV

A blue line for RSV positive, and a blue control line (see test result number 1 and 2, page 9).

Look closely. Even if there is a very faint line for RSV the test result is positive (see test result number 2, page 9).

A negative sample

A single blue control line in the top of the test (see test result number 3, page 9).

Invalid sample

If no control line is observed the test is invalid and the sample should be retested (see test results number 4 and 5, page 9).

Only a full line indicates a positive result - dots and half lines do not indicate a positive result (see test result number 6, page 9).

Disposal

Follow local procedures and/or guidelines from national authorities for disposal of biological materials.

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 new strains 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.

- The ImmuView® RSV Antigen Test has only been validated with the transport media listed in the section “Transport Media”.

Clinical data

Based on retrospective samples:

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%)

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%)

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%)

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 a limit of detection (LOD) at 1.77 µg/mL (antigen level). For inactivated native RSV strain A, it is $1.25x10^5$ $TCID_{50}$/mL.

Interference (cross-reactivity)

The bacteria were tested at a concentration of 10^7 CFU/mL. The viruses were tested between 10^3-10^6 $TCID_{50}$.

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

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 following substances interfered with the ImmuView® RSV Antigen Test.

Agent	Concentration	Agent	Concentration
4-acetamidophenol	10 mg/mL	Erythromycin	0.067 mg/mL
Acetylsalicyclic 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	Guaiacol 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		

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.

Transport media

The 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

Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Quality certificate

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

Presafe Denmark A/S

Quality System
DS/EN
ISO 13485

REF
99110

IVD

CE

Information and ordering

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IFU's in other languages

https://ssidiagnostica.com/ifu/immuview-rsv/

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