RSV Antigen Rapid Test Kit (Nasal Test)

Catalog Number: AU2036

For Research Use Only. Not for use in Diagnostic Procedures.

1. Intended Use

The Respiratory Syncytial Virus Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of RSV in human swab (Nasopharyngeal swabs and Anterior nasal swab). It is suitable for the auxiliary detection of Respiratory Syncytial virus infection.

2. Introduction

Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Illness begins most frequently with fever, runny nose, cough and sometimes wheezing. Severe lower respiratory tract disease may occur at any age, especially among the elderly or among those with compromised cardiac, pulmonary or immune systems. RSV is spread from respiratory secretions through close contact with infected persons or contact with contaminated surfaced or objects.

3. Principle

The Respiratory Syncytial Virus (RSV) Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of:

- A burgundy-colored conjugate pad containing recombinant antigen conjugated with colloid gold (monoclonal mouse anti Respiratory Syncytial Virus (RSV) antibody conjugates) and rabbit IgG-gold conjugates
- A nitrocellulose membrane strip containing test band (T bands) and a control band (C band).

The T band is pre-coated with monoclonal mouse anti- Respiratory Syncytial Virus (RSV) antibody for the detection of Respiratory Syncytial Virus (RSV) glycoprotein F antigen, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Respiratory Syncytial Virus (RSV) if present in the specimen will bind to the monoclonal mouse anti-Respiratory Syncytial Virus (RSV) antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-Respiratory Syncytial Virus (RSV) antibody, forming a burgundy-colored T band, indicating a Respiratory Syncytial Virus (RSV) antigen positive test result. Absence of test band (T) suggests a negative result. The test contains an internal control (C band) which should exhibit a

burgundy-colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

4. Kit Contents

Contents	Total Tests provided
Cassette Device	25 devices (each sealed foil pouch contains: 1 device, 1 desiccant)
Disposable Dropper	25 droppers
Sample Diluent	25 bottles
Collection Swaps	25 sterile single use specimen collection swaps
Instruction Manual	1 each

5. Storage and Stability

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

6. Precautions

- Read the entire procedure carefully prior to testing.
- The Sample Diluent contains a salt solution if the solution contacts the skin or eye, flush with copious amounts of water.
- Do not eat, drink, or smoke in the area where the specimens and kits are handled.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.

- Do not use test kit after expiration date.
- Do not mix Sample Diluent solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- For professional use only.
- For research use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease.
- Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

7. Sample Collection and Storage

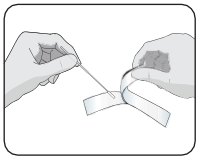
Prepare Materials

Open the package, take out the Respiratory Syncytial Virus (RSV) Antigen Assay cassette, the tube filled with the Sample Diluent and the swab. When you are ready to proceed with the test, open the foil pouch of the Respiratory Syncytial Virus (RSV) Antigen Assay cassette.

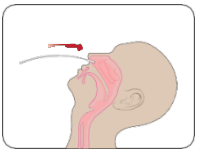
Note: Failure to swab properly may cause false negative results.

Nasopharyngeal Swab Collection Method:

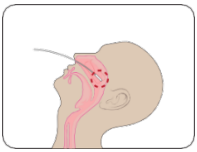
1. Remove the oropharyngeal swab from the pouch.



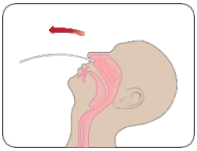
2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.

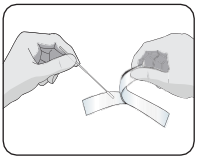


4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

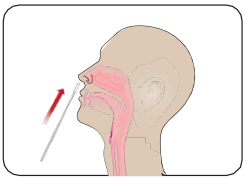


Anterior Nasal Swab Collection Method:

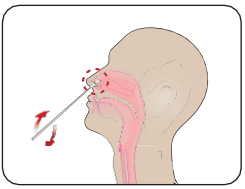
1. Remove the oropharyngeal swab from the pouch.



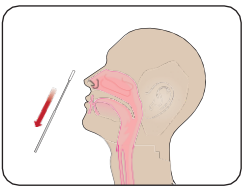
2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.



3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.



4. Slowly remove the swab from the nostril while rotating it.



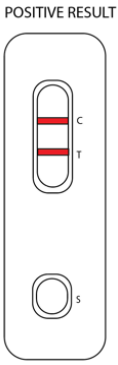
Sample Treatment:

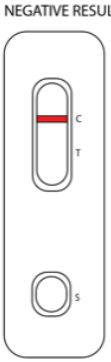
- Dip the swab after sample collection into the Sample Diluent solution tube, allow the solution to fully permeate the swab.
- Rotate and squeeze the swab against tube wall, then pull out the swab, and use the remained solution as the sample to be tested.

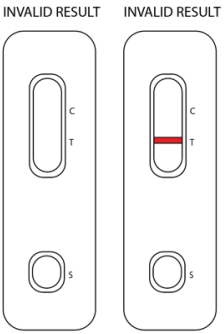
Assay Procedure:

- Apply 3 full drops of the Sample Diluent solution (300 μl) vertically into the sample well of the test cassette.
- The results are observed after 20 minutes.

8. Interpretation of Results

Positive	
	**Positive:** The colored line in the control line region (C) appears and a colored line appears in test line region (T). The result is positive for RSV antigen

Negative Results	
	**Negative:** The colored line in the control line region (C) appears. The absence of colored line in test line region (T) indicates that no RSV antigen is detected. The result is negative for RSV antigen.

Invalid Result	
	**Control line (C) fails to appear.** Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact Attogene at 512-333-1330.

9. Note

- The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level cannot be determined by this qualitative test.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

10. Quality Control

Internal Procedural Controls:

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.

External Control:

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

- New operator uses the kit, prior to performing testing of specimens.
- A new lot of test kit is used.
- A new shipment of kits is used.
- The temperature used during storage of the kit fall outside of 2°C -30°C.
- The temperature of the test area falls outside of 15°C -30°C.

11. Limitations of the Test

1. The Respiratory Syncytial Virus Antigen Rapid Test Kit (Nasal Test) is for in research use only. This test should be used for the detection of Respiratory Syncytial Virus antigens in human swab (Nasopharyngeal swabs and Anterior nasal swab) specimens.
2. The Respiratory Syncytial Virus Antigen Rapid Test Kit (Nasal Test) will only indicate the presence to Respiratory Syncytial Virus in the specimen.
3. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
4. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

12. Notice

1. Must strictly follow the instructions for operation and interpretation of the results.

2. The product is qualitatively tested, and the result cannot be used as a quantitative basis. should be tested using reagents within the validity period.

3. The Sample Diluent is for single person one-time use, cannot be reused.

4. Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antigen in the sample.

5. The samples stored at low temperature should be warmed up to room temperature and fully mixed before testing.

6. Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

Who we are

Attogene is a biotechnology company located in Austin, Texas. Our focus is to enhance health and wellness by offering and developing customer focused Life Science Products domestically and internationally.

Our mission is to:

- Enhance detection technologies
- Enable rapid responses
- Enable impactful research discoveries

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