AG-RSV Ag RAPID TEST KIT

INTENDED USE

AstraGene's RSV Ag Rapid Test Kit is a rapid and convenient immunochromatographic assay for the qualitative detection of Respiratory Syncytial Virus antigens (viral fusion protein) from nasal swab or nasopharyngeal swab obtained from patient with signs and symptoms of respiratory infection. The device is designed to aid in the rapid differential diagnosis of Respiratory Syncytial Virus infection.
This assay provides only a preliminary result. Negative results should be confirmed by cell culture or DFA; they do not preclude Respiratory Syncytial Virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

PRINCIPLE

Respiratory syncytial virus is a single-stranded RNA virus of the Paramyxoviridae family. It is a common cause of upper and lower respiratory tract infections and the major cause of bronchiolitis and pneumonia in infants and children .nearly half of all children became infected by their first year of life.
AstraGene's RSV Ag Rapid Test Kit is an antigen-capture immunochromatographic assay, detecting presence of RSV viral fusion protein antigen in nasal swab, nasopharyngeal swab samples. This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen RSV Monoclonal antibodies specifically against RSV antigen are conjugated with colloidal gold and deposited on the conjugate pad, and immobilized on the Test Zone on the nitrocellulose membrane. When a sample is added, the gold-antibody conjugate is rehydrated and the RSV antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of positive results. If RSV antigen are absent in the sample, no pink line will appear in the Test Zone (T).
To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

Description	**10 tests**	**1 test**
Test Cassette and Desiccant	10 Cassette	Cassette
Reagent Solution Bottle	1 No	1 No.
Reagent tube with dropper	10 Nos	1 No.
Sterile Nasal Swab	10 Nos	1 No.
Instruction for use	1 No	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/RSVAg/22/01	AG/RTK/RSVAg/22/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

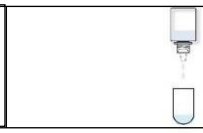
SPECIMEN COLLECTION & PREPARATION

Nasal Swab Sample (for optimal test performance with a Nasal Swab specimen, use the Swabs supplied in the kit)
It is important to obtain as much secretion as possible. Therefore, to collect a Nasal Swab sample, insert the sterile Swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the Swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the Swab a few times against the nasal wall.
Nasopharyngeal Swab Sample:
It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal Swab sample, carefully insert the sterile Swab into the nostril that presents the most secretions under visual inspection. Keep the Swab near the septum floor of the nose while gently pushing the Swab into the posterior nasopharynx. Rotate the Swab several times.
Note:
Specimens should be tested as soon as possible after collection. However, if transport of Swab samples is required, minimal dilution of the sample is recommended, as this may result in decreased test sensitivity. Nasal wash/aspirate specimens may be stored frozen (-70°C or lower) for up to 1 month. All clinical specimens must be at room temperature before beginning the assay.

PROCEDURE FOR POSITIVE OR NEGATIVE SAMPLE

- Add 300ul reagent solution (approximately 9 drops) into the reagent tube.
- Add positive control swab or negative control swab to the tube with reagent solution.
- Vigorously rotate and twist the swab against the side of the tube at least 10 times.
- Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.
- Hold the sample dropper vertically. Add 5 drops (about 120 µl) of the specimen without air bubbles into the sample well.
- Please follow the results interpretation procedure to verify the validity of the device.

PROCEDURE

A) Add 300ul reagent solution (approximately 9 drops) into the reagent tube.	

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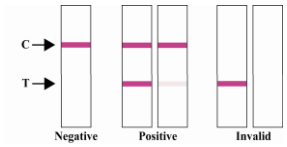
B) Add Nasal/Nasopharyngeal swab to the tubewith reagent solution.	
C) Vigorously rotate and twist the swab againstthe side of the tube at least 10 times.	
D) Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly. Then place the filter tip onto reagent tube tightly.	
E} Hold the reagent tube vertically with the filtertip pointing downward. Add 7 drops (about 150 µl) of the specimen without air bubbles into thesample well. *Note: Read results at 20 minutes.	**Note:** 1. For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply one to two more drops of reagent solution to help the sample migrate on the membrane. 2. Do not interpret results after 30 minutes

RESULT INTERPRETATION

Positive

A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result.



Negative:

A pink colored band appears only at the control region (C), indicating a negative result

Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number

PERFORMANCE CHARACTERISTICS

When compared to PCR test Relative Sensitivity: 97.56%; Relative Sp ecificity:99.44%; Overall agreement: 99.09%

LIMITATION OF THE PROCEDURE

- The contents of this kit are to be used for the qualitative detection of RSV antigen from nasal swab, nasopharyngeal swab, nasal wash and nasal aspirate specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
- Test Results must be evaluated in conjunction with other clinical data available to the physician.
- Negative test results do not rule-out possible other non-RSV viral infections.
- Positive test results do not rule out co-infections with other pathogens.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only.
- Do not reuse.
- Do not use it if the product seal or its packaging is compromised.
- Do not use it after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.

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- Wash your hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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