



Proven Medical Testing[®]

Quality Testing, Proven Results

RSV Antigen Rapid Test

Instruction for Use

A rapid test for the qualitative detection of Respiratory Syncytial Virus nucleocapsid antigens in anterior nasal swab specimens. For professional in vitro diagnostic use only. Please read the package insert carefully before using.

INTENDED USE

The RSV Antigen Rapid Test is an in vitro diagnostic test for the qualitative detection of Respiratory Syncytial Virus antigens(viral fusion protein) in nasal swab, throat swab or nasopharyngeal swab, using rapid immuno-chromatographic method. It is intended to aid in the rapid differential diagnosis of Respiratory Syncytial Virus viral infections

SUMMARY

Respiratory Syncytial Virus 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 surfaces or objects. The RSV Antigen Rapid Test utilizes specific monoclonal antibodies to qualitatively detect RSV antigen in anterior nasal swab specimens. The test can be performed without cumbersome laboratory equipment, and the results are available at 15-30 minutes.

PRINCIPLE

The RSV Antigen Rapid Test is an immuno- chromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the RSV viral fusion protein antigen in nasal swab, nasopharyngeal swab samples. The test is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The RSV Antigen Rapid Test contains the anti-RSV antibody conjugated with colloidal-gold particles and the anti-RSV antibody coated on the test line regions. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored lines in the test regions. The presence of this colored line in the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

MATERIALS SUPPLIED

- 20 X Test device, each cassette is Individual sealed in a foil pouch with a package of desiccant.
- 20 X Swab
- 20 X Extraction Tube with buffer
- 1 X Package Insert

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-38°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Do not use after expiration date
3. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
4. Do not use it if the tube/pouch is damaged or broken.
5. Test is for single use only. Do not re-use under any circumstances.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
7. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
8. Humidity and temperature can adversely affect results.

SAMPLE COLLECTION AND PREPARATION

It is applicable to the diagnosis of the Respiratory Syncytial Virus from the samples of nasal swab, throat swab or nasopharyngeal swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

1. Nasal swab Specimen: Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, blow your nose before sampling. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually 1/2 to 1 inch (1.5 to 2.5cm) inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal mucosa for approximately 15 seconds to collect the sample. Do not touch the nostril with the swab. Do not touch the tip of the swab to the skin. Do not touch the tip of the swab to the eye. Do not touch the tip of the swab to the mouth. Do not touch the tip of the swab to the nose. Do not touch the tip of the swab to the face. Do not touch the tip of the swab to the hair. Do not touch the tip of the swab to the clothing. Do not touch the tip of the swab to the patient. Do not touch the tip of the swab to the environment. Do not touch the tip of the swab to anything else. Do not touch the tip of the swab to the patient's face. Do not touch the tip of the swab to the patient's hair. Do not touch the tip of the swab to the patient's clothing. Do not touch the tip of the swab to the patient's environment. Do not touch the tip of the swab to anything else. Do not touch the tip of the swab to the patient's face. Do not touch the tip of the swab to the patient's hair. Do not touch the tip of the swab to the patient's clothing. Do not touch the tip of the swab to the patient's environment. Do not touch the tip of the swab to anything else.
2. Throat swab Specimen: Insert a sterilized swab into pharynx and collect mucous membrane mainly wiping the posterior pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.
3. Nasopharyngeal swab Specimen: Insert swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

TEST PREPARATION

Before testing, open the package and equilibrate the test cassette, extraction solution and specimens to room temperature, and shake the extraction solution gently before use. The most suitable temperature condition to perform

the test is room temperature (15~30 °C). If the test kit is stored at room temperature, it can be opened and used immediately.

TEST PROCEDURES

1. Tear off the sealing film of the extraction solution tube.
2. Place the swab in the extraction solution tube, rotate the swab for about 10 times and no less than 15 seconds, and press the swab tip against the tube wall to release the antigen in the swab.
3. Squeeze the swab over the swab tip to withdraw the swab so as to extract as much liquid as possible from the swab. Dispose of used swabs according to biohazard waste disposal method and local regulations.
4. Install the dripper of the tube and shake well the tube.
5. Take out the test card from sealed foil pouch and place on a dry, clean and level surface. Add two drops of extracted specimen to each of the specimen well(s) on the test card, and start the timer.

Notes: Applying sufficient amount of extracted specimen is essential for a valid test result. If migration (the wicking of membrane) is not observed in the test window after one minute, add one more drop to specimen well.

6. Read the results at 10 minutes, and the result after 20 minutes is no longer valid.

INTERPRETATION OF RESULTS

*Read results of each test individually.

Negative: Only one red colored band appears on the control region.

Positive: In addition to the control band, a distinct colored band also appears on the test region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

PERFORMANCE

1. Detection Limit: The minimum detection limit of this reagent is as follows:
Subtype A, Strain: RSV (long), TCID₅₀/mL: 3.67×10^4
Subtype B, Strain: RSV (wild-type), TCID₅₀/mL: 1.12×10^4
2. Reaction with Various Serotype of Respiratory Syncytial Virus: The current test kit is able to detect the following serotype of the Respiratory Syncytial Virus: Subtype A (A2, long) Subtype B (9320, wild-type)
3. Cross Reaction: No cross reaction has been confirmed of the Respiratory Syncytial Virus Test Cassette with the following pathogens:
[Bacteria]
Acinetobacter baumannii, *Bordetella pertussis*, *Branhamella catarrhalis*, *Candida albicans*, *Candida glabrata*, *Cardiobacterium hominis*, *Eikenella corrodens*, *Enterococcus faecalis*, *Enterococcus gallinarum*, *Escherichia coli*, Group C streptococcus, Group G streptococcus, *Haemophilus aphrophilus*, *Haemophilus influenzae*, *Haemophilus paraphrophilus*, *Klebsiella pneumoniae*, *Neisseria gonorrhoeae*, *Peptococcus asaccharolyticus*, *Peptostreptococcus anaerobius*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas*

aruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae (group B), Streptococcus mutants, Streptococcus pneumoniae, Streptococcus pyogenes (group A), Villanelle parva.

[Virus]

Influenza A, Influenza B, Adenovirus Type 1~8,11,19,37, Coxsackie virus Type A16, B1 ~ 5, Cytomegalovirus, Echovirus Type 3,6,9,11, 14,18,30, Enterovirus Type 71, Mumps virus, Type I simple herpes virus Parainfluenza virus Type 1 ~ 3, Poliovirus Type 1 ~ 3, Respiratorysyncytial virus, Rhinovirus Type 1A, 13,14

[Mycoplasma etc]

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae.

4. Clinical Performance: To evaluate the clinical performance of the RSV Antigen Rapid Test, directly collected anterior nasal swab specimens which were confirmed with reference RT-PCR assay were tested, including 430 confirmed RSV specimens (130 positive nasal swab specimens, 300 negative nasal swab specimens). The positive percent agreement and negative percent agreement are presented as follows.

Clinical performance compared to reference RT-PCR Assay: RSV

- **RSV Antigen Rapid Test vs Reference RT-PCR Assay**
 - **RSV Positive**
 - Positive: 121
 - Negative: 3
 - Total: 124
 - **RSV Negative**
 - Positive: 9
 - Negative: 297
 - Total: 306
 - **Total**
 - Positive: 130
 - Negative: 300
 - Total: 430
- **Performance Metrics**
 - **Sensitivity (Positive Percent Agreement):** 93.07% (95% CI: 87.37%–96.32%)
 - **Specificity (Negative Percent Agreement):** 99.00% (95% CI: 97.10%–99.66%)
 - **Accuracy (Overall Percent Agreement):** 97.20% (95% CI: 95.19%–98.40%)