Respiratory syncytial virus Antigen Rapid Test Kit (Colloidal Gold)

【Product name】

Respiratory syncytial virus Antigen Rapid Test Kit (Colloidal Gold)

【Packing specification】

Normal type：10 tests/Box, 25 tests/Box, 40 tests/Box;

Simple type：1 test/Box, 10 tests/Box, 25 tests/Box, 40 tests/Box

【Intended use】

This product is used for in vitro qualitative detection of Respiratory syncytial virus Antigen in human pharyngeal secretions or nasopharyngeal secretions.

【Reactivity principle】

This kit adopts the principle of colloidal gold immunochromatography. The detection area of nitrocellulose membrane (T line) is coated with Mouse anti-respiratory syncytial virus monoclonal antibody 2, the quality control region (C-line) is coated with goat anti-mouse IgG polyclonal antibody and colloidal gold labeled Mouse anti-respiratory syncytial monoclonal antibody 1 (RSV -Ab1) on the gold-labeled pad. During the detection of the sample, the respiratory syncytial virus antigen （RSV-Ag） in the sample combined with colloidal gold (Au) labeled Mouse anti-respiratory syncytial monoclonal antibody 1 to form an (Au- Mouse anti-respiratory syncytial monoclonal antibody 1- [RSV-Ag]) immune complex, which flows forward in the nitrocellulose membrane. It combined with coated mouse anti-respiratory syncytial virus monoclonal antibody 2 to form agglutination “(Au RSV-Ab1-[RSV-Ag]-RSV-Ab2)” in the detection area (T-line) during the test. The remaining colloidal gold labeled Mouse anti-respiratory syncytial monoclonal antibody 1 combined with goat anti-mouse IgG polyclonal antibody coated on the quality control line to form agglutination and develop color. If the sample does not contain respiratory syncytial virus antigen, the detection area cannot form immune complex, only the quality control area will form immune complex and develop color.

【Main components】

Normal type：

SPEC / Component	10 tests/ Box	25 tests/ Box	40 tests/ Box	Main components
RSV-Ag Rapid test kit	10 tests	25 tests	40 tests	It is composed of absorbent paper, nitrocellulose film, gold-labeled pad and sample pad. The goat anti-mouse IgG polyclonal antibody is coated on the nitrocellulose membrane quality control line, the mouse anti-respiratory syncytial virus monoclonal antibody 2 is coated on the test line, and the colloidal gold labeled mouse anti-respiratory syncytial virus monoclonal antibody 1 is coated on the gold pad.
Sample extract buffer	6mL×1 Bottle	7mL×2 Bottles	8mL×3 Bottles	20mM PBS 0.3% Triton X 100
Sample extract tube	10 pcs	25 pcs	40 pcs	---

Simple type：

SPEC / Component	1 test/ Box	10 tests/ Box	25 tests/ Box	40 tests/ Box	Main components
RSV/IBV Rapid test kit	1 test	10 tests	25 tests	40 tests	It is composed of absorbent paper, nitrocellulose film, gold pad and sample pad. The goat anti-mouse IgG polyclonal antibody is coated on the nitrocellulose membrane quality control line, the mouse anti-respiratory syncytial virus monoclonal antibody 2 is coated on the test line, and the colloidal gold labeled mouse anti-respiratory syncytial virus monoclonal antibody 1 is coated on the gold pad.
Sample extract tube	0.5mL×1 Bottle	0.5mL×10 Bottles	0.5mL×25 Bottles	0.5mL×40 Bottles	20mM PBS 0.3% Triton X 100

【Storage conditions and expiry date】

- 4~30℃, valid for 24 months.
- When humidity is less than 60%, it should be used within 1 hour and when humidity is more than 60%, it should be used immediately.
- Expiration date and lot number are shown in the label.

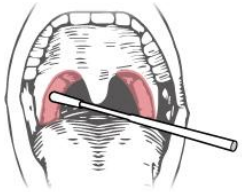
【Sample requirements】

1. Throat secretions collection:

a) Insert the swab provided in the kit completely from the mouth into the throat, centering on the red part of the throat wall and maxillary tonsils.

b) Rub the bilateral throat tonsils and throat wall moderately.。

c) Avoid touching the tongue and remove the swab.



2. Nasal secretions collection

a) Carefully insert the swab provided in the kit into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.

b) Swab over the surface of the posterior nasopharynx. Rotate the swab several times.

c) Withdraw the swab from the nasal cavity.

3. The samples should be treated with the Sample treatment solution A and B provided with this kit as soon as possible after collection. The collected extracts should be detected within1 day or stored at 2-8 ℃ after sealing and detected within 4 days.

4. Please do not use specimens with bacteria, too long storage time or repeated freezing and thawing to avoid sample contamination or non-specific reactions caused by growing bacteria

5. The sample should be restored to room temperature before testing. Avoid repeated freezing and thawing of samples.

【Test procedure】

This package insert must be read completely before performing the test. Please restore the reagent and sample to room temperature before inspection. Experimental humidity should be less than 60%, the experiment temperature is 18~30℃. The test procedure is as follows:

1. Sample processing

1.1 Normal type testing method (fig1)

a) Add 0.5ml (about 10 drops) sample extract buffer to the sample extract tube

b) Insert the swab into the sampling tube containing the 0.5ml sample extract. Rotate the swab at least 6 times while pressing the top of the swab on the bottom and side of the sample processing tube.

c) Put the swab into the Sample extract tube and let stand for 1 minute.

d) Squeeze the swab in the sample tube several times from outside the sample processing tube with your finger to obtain the liquid in the swab. Take off the cotton swab. The extracted solution will be used as the test sample.

e) Install the emitter and filter tightly on the top of the sample tube.

1.2 Testing method for easy-to-use products (fig2)

a) Open the sample extract tube containing the sample extract

b) insert the swab into the sampling tube containing the 0.5ml sample extract. Rotate the swab at least 6 times while pressing the top of the swab on the bottom and side of the sample processing tube.

c) Put the swab into the Sample extract tube and let stand for 1 minute.

d) Squeeze the swab in the sample tube several times from outside the sample extract tube with your finger to obtain the liquid in the swab. Take off the cotton swab. The extracted solution will be used as the test sample.

e) Install the emitter and filter tightly on the top of the sample tube.

2. Testing operation

a) Open the bag containing the test box. Put the kit on the horizontal working face where the link is dry.

b) Add 2-3 drops (about 60-100 μ L) sample solution to the sample hole of the kit.

c) The results showed that within 10-15 minutes, the results after 15 minutes had no clinical significance.

Fig 1. Schematic diagram of normal type product test procedure:

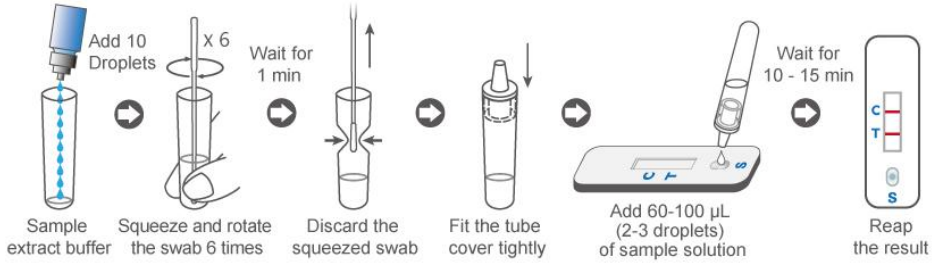
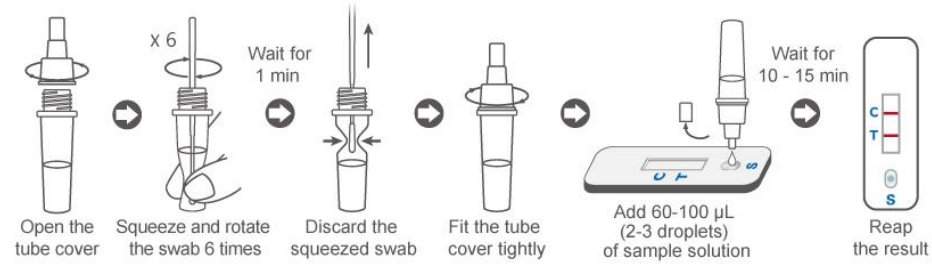


Fig 2. Schematic diagram of Simple type product test procedure:



【Interpretation of assay result】

1. Positive： Test-line and control line develop colors. It is suggested that respiratory syncytial virus antigen is positive.

2. Negative：Only the quality control line is colored in the test window. It is suggested that the concentration of respiratory syncytial virus antigen does not reach the detection level.

3. Invalid result: The quality control line has no red stripes. Invalid results should be re-tested and tested in strict accordance with the instructions. If the test results are still invalid, please contact the local supplier or our customer service for technical advice.

【Limitations of the test method】

1. This reagent is a qualitative test for auxiliary diagnosis.

2. This product is only used for qualitative detection of respiratory syncytial virus antigen in human nasal secretions and throat secretions collection.

3. The positive results only show the existence of respiratory syncytial virus, which cannot be used as the only criterion for judging respiratory syncytial virus infection. the clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests (especially etiological tests), treatment response and epidemiology.

4. The negative results can not completely rule out the possibility of respiratory syncytial virus infection. It may be that the level of respiratory syncytial virus antigen is too low to be detected by this kit, which may lead

to negative results. In addition, because the best sample type of the product and the disease cycle of the peak concentration of the virus have not been verified, the false negative results may be avoided by testing the samples collected at different stages and different parts of the same subject.

【Product performance indicator】

1. The coincidence rate of positive reference samples: the coincidence rate of positive reference samples should be 5 to 5.
2. The coincidence rate of negative reference samples: the coincidence rate of negative reference samples should be 10 to 10.
3. Limit of detection： The limit of detection for RSV quality control products is not less than 1:8.
4. Repeatability: RSV repetitive controls were tested for 10 times each, and the results should be positive.
5. Analysis specificity:

5.1. Cross reaction： This product has no cross reaction to mycoplasma pneumoniae, chlamydia pneumoniae, respiratory adenovirus, EB virus, measles virus, cytomegalovirus and other positive samples.

5.2. Results were all negative. Adding all the interference to the weak positive samples, the detection results of the weak positive samples were all positive, indicating that the above endogenous interfering substances had no obvious interference to the Respiratory syncytial virus Antigen Rapid Test Kit

6. Statistics of 307human serum were statistically analyzed. The positive rate detection was 94.59%, 95% confidence interval was [82.30%-98.50%], negative detection coincidence rate was 98.15%, 95% confidence interval was [95.74%-99.21%],Total coincidence rate was 97.72%, 95% confidence interval was [95.37%-98.89%].

【Cautions】

1. If the state of the kit and sample is not restored to 18~30 ℃, the operation should not be carried out, otherwise the accuracy of the results will be affected.
2. The positive samples obtained by rapid test should be confirmed by other methods.
3. The test reagent should be sealed and stored in a dry place. The test kit should be tested as soon as possible after it is removed from the package, so as not to stay in the air for too long and cause moisture.
4. The color of the test line is not necessarily related to the titer of the antigen in the sample, and the interpretation result is invalid after 15 minutes.
5. The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
6. Waste samples and test should be treated as potential infectious agents.
7. The time of occurrence of the quality control line should not be used as the time basis for judging the results of the test line. The color results should be observed and judged within 10-15 minutes.
8. The rapid test is only used for in vitro diagnosis.

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Do not reuse

IVD For in vitro diagnostic use only

Store between 4-30℃

Consult instructions for use

Use by

LOT Lot number

Do not use if package is damaged

Contains sufficient for <n> tests

Keep away from sunlight

Keep dry

Manufacturing date

Manufacturer

EC REP Authorized representative in the European Community

Riomavix S.L.
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain
E-mail: leis@riomavix.com
Tel.: +34 658 396 230

Version Number : 1.0

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