Influenza A Virus /Influenza B Virus Antigen Combined Rapid Test Kit (Latex)

【Product name】

Influenza A Virus /Influenza B Virus Antigen Combined Rapid Test Kit (Latex)

【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 influenza A virus antigen / influenza B 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 (IAV-line) was coated with mouse anti- Influenza A Virus monoclonal antibody 2 (IAV-Ab2), and IBV-line was coated with mouse anti- Influenza B Virus monoclonal antibody 2(IBV-Ab2), the quality control region (C-line) was coated with goat anti-mouse IgG polyclonal antibody and latex labeled mouse anti-Influenza A Virus monoclonal antibody 1 (IAV-Ab1) and mouse anti- Influenza B Virus monoclonal antibody 1(IBV-Ab1) on the gold-labeled pad. During the detection of the sample, the human anti-influenza A virus antigen (IAV-Ag) in the sample combined with latex (Lm) labeled mouse anti-influenza A virus monoclonal antibody 1 to form (Lm- mouse anti-influenza A virus monoclonal antibody 1-[IAV-Ag]) immune complex, which moved forward in the nitrocellulose membrane. The (Lm IAV-Ab1-[IAV-Ag]-IAV-Ab2) is formed and agglutination by binding to the mouse anti-influenza A virus monoclonal antibody 2 coated in the IAV line through the detection zone, if the sample contains human anti-influenza B virus antigen (IBV-Ag). During detection, it binds with Lm-labeled mouse anti-influenza B virus monoclonal antibody 1 (Lm-mouse anti-influenza B virus monoclonal antibody 1-[IBV- Ag]) to form an immune complex. Through the detection zone, it binds with mouse anti-influenza A virus monoclonal antibody 2 coated in IBV line to form "(Lm-IBV- Ab1- [IBV- Ag]-IBV-Ab2)" to form agglutination. The remaining latex labeled mouse anti-influenza virus monoclonal antibody 1 and mouse anti-influenza B virus 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 influenza A virus antigen, the detection area cannot form immune complexes, only the quality control area will form immune complexes and develop color.

【Main components】

Normal type：

SPEC / Component	10 tests/ Box	25 tests/ Box	40tests/ Box	Main components
IAV/IBV Rapid test kit	10 tests	25 tests	40 tests	It is composed of absorbent paper, nitrocellulose film, gold pad and sample pad. Goat anti-mouse IgG polyclonal antibody was coated on the quality control line of nitrocellulose membrane, mouse anti-influenza A virus monoclonal antibody 2 was coated on detection area IAV, mouse anti-influenza B virus monoclonal antibody 2 was coated on gold label pad, mouse anti-influenza A virus monoclonal antibody 1 and mouse anti-influenza B virus monoclonal antibody 1 were coated with latex.
Sample extract buffer	6mL×1 Bottle	7mL×2 Bottles	8mL×3 Bottles	20mM PBS 0.3% TritonX-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
IAV/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. Goat anti-mouse IgG polyclonal antibody was coated on the quality control line of nitrocellulose membrane, mouse anti-influenza A virus monoclonal antibody 2 was coated on detection area IAV, mouse anti-influenza B virus monoclonal antibody 2 was coated on gold label pad, mouse anti-influenza A virus monoclonal antibody 1 and mouse anti-influenza B virus monoclonal antibody 1 were coated with latex.
Sample extract buffer	0.5mL×1 Bottle	0.5mL×10 Bottles	0.5mL×25 Bottles	0.5mL×40 Bottles	20mM PBS 0.3% TritonX-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.

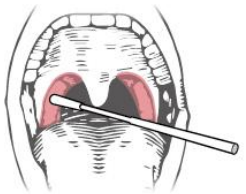
【Sample requirements】

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. Nasopharyngeal 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.

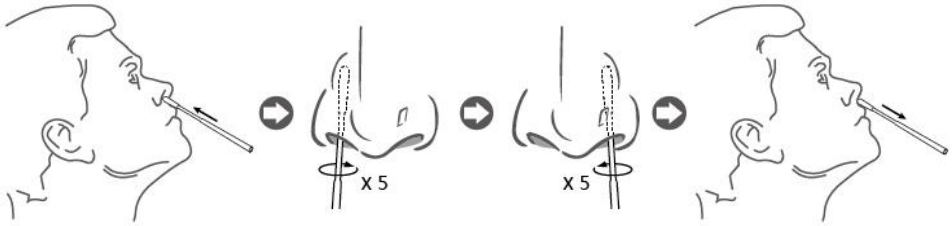
3. Nasal cavity secretions collection

a) Insert the swab provided in the kit into one nostril of the patient. The swab tip should be inserted up to 2～4cm until resistance is met.

b) Roll the swab 5times along the mucosa inside the nostril to ensure that both mucus and cells are collected.

c) Using the same swab, repeat this process for the other nostril to ensure that adequate sample is collected from both nasal cavities.

d) Withdraw the swab from the nasal cavity.



4. The samples should be treated with the sample extraction solution 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.

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

6. 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. Specimen extraction

1.1 Normal type product testing method (fig1)

a) Add 0.5mL (about 10 drops) of the sample extraction buffer into the sample extract tube.

b) Insert the swab into the sample extract tube which contains 0.5mL of the extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the simple extract tube.

c) Leave the swab in the sample extract tube for 1 minute

d) Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

e) Fit the dropper tip with filter on top of the extraction tube tightly.

1.2 Simple type product testing method (fig2)

a) Open the sample processing tube containing the sample extract

b) Open the sample extract tube containing the sample extract, Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.

c) Leave the swab in the extraction tube for 1 minute.

d) Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

e) Fit the dropper tip with filter on top of the extraction tube tightly.

2. Detection operations:

a) Open a pouch containing a test cassette. Place the test cassette on a dry, horizontal work surface.

b) Add 2-3 drops (about 60-100μl) of sample solution extract to the sample well of the test cassette.

c) Observe the results showed within 10-15 minutes, and the results showed after 15 minutes have no clinical significance.

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

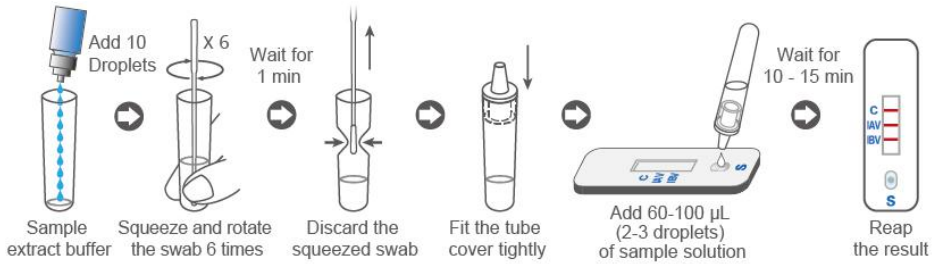
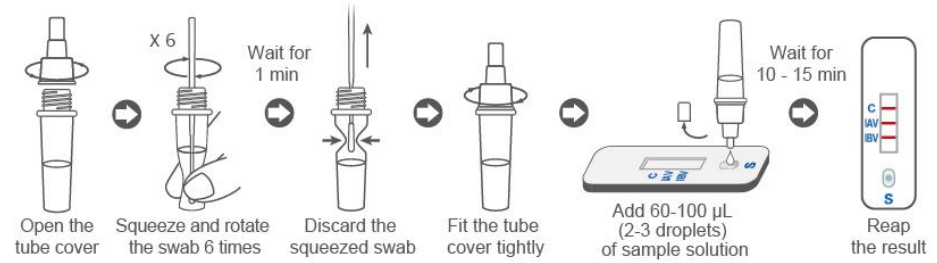


Fig 2. Schematic diagram of Simple type product test procedure:



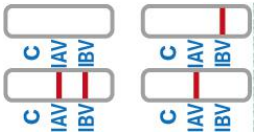
【Interpretation of assay result】

1. Positive: Test line of IAV and quality control line develop colors. It is suggested that the Influenza A virus antigen is positive

2. Positive: Test line of IBV and quality control line develop color. It is suggested that the Influenza B virus antigen is positive

3. Positive: Test line of IAV, IBV line and quality control line develop color, It is suggested that the Influenza A and B virus antigen are positives.

4. Negative: Only the quality control line is colored in the test window. It is suggested that the concentration of Influenza A and B virus antigen does not reach the detection level.



5. Invalid result: There are no red stripes in the quality control line. 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 influenza A virus or influenza B virus antigen in human nasopharyngeal secretions and throat secretions collection.
3. The positive results only showed that there was N protein antigen of influenza A virus / influenza B virus, which could not be used as the only criterion for judging influenza A / B virus infection. The clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests (especially etiological detection), treatment response and epidemiology.
4. The negative results can not completely rule out the possibility of influenza A virus / B influenza virus infection. It may be that the antigen level of influenza A virus / B influenza virus 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 8 to 8.
2. The coincidence rate of negative reference samples: the coincidence rate of negative reference samples should be 10 to 10.
3. Lowest detectable limit： The lowest detectable limit for quality control products of IAV, IVB are not less than 1:8.
4. Repeatability: The repetitive controls of IAV and IBV 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 tract adenovirus, respiratory syncytial virus, EB virus, measles virus, cytomegalovirus, enterovirus 71 and other positive samples.

5.2. The negative samples were tested for mucin, blood, HAMA and biotin, and the results were all negative.

5.3. When all the interference was added 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 detection of influenza A virus / influenza B virus antigen by the kit.

6. Statistics of 307human serum were statistically analyzed. The IAV positive rate detection was 93.94%, 95% confidence interval was [80.39%-98.32%], negative detection coincidence rate was 98.18%, 95% confidence interval was [95.80%-99.22%],Total coincidence rate was 97.72%, 95% confidence interval was [95.37%-98.89%].The IBV positive rate detection was 96.30%, 95% confidence interval was [81.72%-99.34%], negative detection coincidence rate was 97.86%, 95% confidence interval was [95.40%-99.01%],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 15minutes.
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.

Beijing Zhongjian Antai Diagnostic Technology Co., Ltd.

No.29 Qingfeng Road, Daxing Bio-pharmaceutical Industry Base, Zhongguancun Science & Technology Park, Daxing District, Beijing, 102629, P.R.China

Index of Symbol

	Do not reuse		For in vitro diagnostic use only
	Store between 4-30℃		Consult instructions for use
	Use by		Lot number
	Do not use if package is damaged		Contains sufficient for <n> tests


Keep away from sunlight


Keep dry


Manufacturing date


Manufacturer

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

Effective Date: January 22, 2022