SARS-CoV-2/Flu A/B-Antigen Combined Rapid Test Kit (Colloidal Gold)

【Product name】

Common name: SARS-CoV-2/Flu A/B-Antigen Combined Rapid Test Kit (Colloidal Gold)

【Packing specification】

1 test/box, 20 tests/box, 40 tests/box.

【Intended use】

This product is used for in vitro qualitative detection of SARS-CoV-2 antigen and influenza A/B virus antigen in human Nasal secretions swabs.

【Test principle】

SARS-CoV-2 Antigen test principle: the nitrocellulose membrane detection line (T-line) is coated with SARS-CoV-2 monoclonal antibody, the quality control line (c-line) is coated with Goat anti mouse IgG polyclonal antibody, and the gold label pad is coated with colloidal gold to label SARS-CoV-2 monoclonal antibody. When the positive samples were detected, the SARS-CoV-2n antigen in the samples combined with the colloidal gold (AU) labeled SARS-CoV-2 monoclonal antibody to form an immune complex (Au-[SARS-CoV-2 Ab]-[SARS-CoV-2Ag]). The complex moved forward in the nitrocellulose membrane by chromatography. After arriving at the detection line, the complex binds with the coated SARS-CoV-2 monoclonal antibody to form "(Au-[SARS-CoV-2 Ab] - [SARS-CoV-2 Ag] - [SARS-CoV-2 Ab]", which appears agglutination color. The remaining colloidal gold forms the labeled SARS-CoV-2 monoclonal antibody on the quality control line and binds to the Goat anti mouse IgG polyclonal antibody, which produces color after agglutination. In the negative samples, there was no SARS-CoV-2 antigen in the samples, no immune complex was formed, only C-line was used.

Influenza A /B Virus Antigen test principle: The detection area of nitrocellulose membrane (A-line) is coated with mouse anti-Influenza A Virus monoclonal antibody 2 (IAV-Ab2), and B-line is coated with mouse anti- Influenza B Virus monoclonal antibody 2(IBV-Ab2), the quality control region (C-line) is coated with goat anti-mouse IgG polyclonal antibody and colloidal gold 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 colloidal gold (Au) labeled mouse anti-influenza A virus monoclonal antibody 1 to form (Au- mouse anti-influenza A virus monoclonal antibody 1-[IAV-Ag]) immune complex, which moved forward in the nitrocellulose membrane. The (Au-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 A-line through the detection zone, if the sample contains human anti-influenza B virus antigen (IBV-Ag). During detection, it binds with colloidal gold-labeled mouse anti-influenza B virus monoclonal antibody 1 to form (Au-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 B virus monoclonal antibody 2 coated in B-line to form "(Au-IBV- Ab1- [IBV- Ag]-IBV-Ab2)" to form agglutination. The remaining colloidal gold labeled mouse anti-influenza A 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】

SPEC / Component	1 test /Box	20 tests/ Box	40 tests/ Box	Main components
Antigen Combined Rapid Test Kit	1 test	10 tests	40 tests	SARS-CoV--2 test kit: It is composed of absorbent paper, nitrocellulose film, gold-labeled pad and sample pad. Goat anti-mouse IgG polyclonal antibody is coated on the quality control line (C-line) of nitrocellulose membrane, SARS-CoV-2 monoclonal antibody is coated on detection area T-line, SARS-CoV-2 monoclonal antibody is coated on gold label pad. Influenza A /B Virus Antigen test kit: It is composed of absorbent paper, nitrocellulose film, gold-labeled pad and sample pad. Goat anti-mouse IgG polyclonal antibody is coated on the quality control line of nitrocellulose membrane, mouse anti-influenza A virus monoclonal antibody 2 is coated on detection area A-line, mouse anti-influenza B virus monoclonal antibody 2 is coated on detection area B-line, mouse anti-influenza A virus monoclonal antibody 1 and mouse anti-influenza B virus monoclonal antibody 1 are coated on gold label pad.

Sample diluent	0.5mL×1 Bottle	0.5mL×10 Bottles	0.5mL×40 Bottles	NaCl、TritonX-100、20mM Phosphate buffer solution（pH 7.4）.
Sample collection swab	1 each	20 each	40 each	polypropylene fiber head/synthetic flocking head plastic rod

【Storage conditions and expiry date】

4~30℃, valid for 24 months.

18～30℃, 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. The sample types of this kit are nasal swabs. Obtaining nasal l swabs using standard clinical laboratory methods: polypropylene fiber head / synthetic pile head plastic rod swabs are recommended for sample collection.

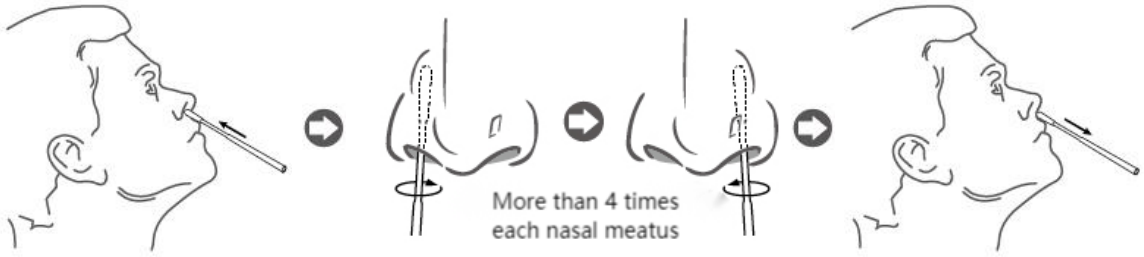
2.2 Nasal secretions collection:

a）When collecting samples, blow your nose with toilet paper and carefully unpack the swab to avoid hand contact with the top of swab.

b）Then the head is raised slightly. Insert the swab into one nostril, slowly deep 1-1.5 cm along the bottom of the inferior nasal meatus (for age 2-14 years old, 1 cm deep), then rotate at least 4 times (the residence time is not less than 15 seconds).

c）Then repeat the same procedure for another nasal cavity with the same swab.

d) Immerse the top of swab in the sample processing tube of the kit or in the virus preservation solution.



Note: The standardization of sampling will have an impact on the test results, and it is suggested that the samplers should be professionals, or personnel who have been guided and trained by professionals. Disposable sampling swabs can only be used with the sample preservation solution of the same person, and can only be used to collect samples of the same person, mixed use is prohibited. The contamination of the sampling swab should be avoided during the sampling process and should be detected immediately after sampling.

2.3 After the sample is collected, the sample should be treated with the sample treatment solution as soon as possible and tested. The samples that can be detected within 24 hours with virus preservation solution can be stored at 2-8 ℃, while the samples that can not be detected within 24 hours should be stored at-80 ℃ or below for 4 months.

2.4 Please do not use specimens that bacteria, place for too long or freeze-thaw repeatedly to avoid sample contamination or non-specific reactions caused by bacteria.

2.5 The sample must be restored to room temperature before testing.

【Inspection method】

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

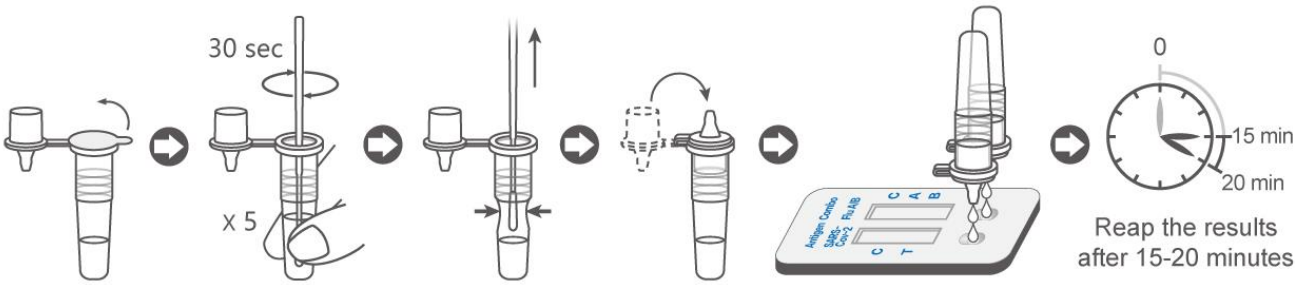
2. Sample preparation without virus collection solution

a) Open the sample treatment tube containing the sample treatment solution;

b) The swab is inserted into the sample treatment tube containing the sample treatment solution. At the same time, squeeze the top of swab by hand across the outer wall of the sample processing tube at least 10 times, and the top of swab should be rotated and mixed in the preservation solution for at least 30 seconds to ensure that the sample is fully remain in the sampling tube.

c) The top of swab liquid is squeezed dry by hand across the outer wall of the sample handling tube, the swab is discarded. After the cover of the sample processing tube is covered, and the tip is vertically downward to squeeze the tube wall. Extrude 2-3 drops of

sample into the reagent card sample hole.



3. The results are read within 15 to 20 minutes, and the test results are invalid after 20 minutes. Please interpret the results within the specified time, less than or more than that time may lead to wrong results.

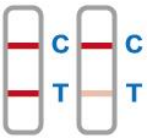
4. If too little solution is added to the test card, false negative or invalid results may occur.

5. Do not read in dim light

6. Wastes such as reagents and samples after use should be disposed of properly.

【Interpretation of test results】

1. SARS-CoV-2 Antigen



2.1 Positive: the T-line and the C-line can be colored at the same time, and the color of the T-line can be deep or light, all of which are positive results, indicating that SARS-CoV-2 antigen is detected in the sample and SARS-CoV-2 infection is suspected. Please report immediately and isolate and see a doctor according to the prevention and control regulations.

2.2 Negative: there is only one red C-line in the test window. It is suggested that SARS-CoV-2 Antigen is not detected in the sample, but the possibility of infection could not be completely ruled out by the negative result. Follow-up treatment should be carried out in accordance with the local epidemic prevention and control policy, and further examination in the hospital should be recommended if necessary.

2.3 Invalid result: no red C-line appears in the window. The invalid results should be retested, and the retest should be carried out in strict accordance with the instructions.

2.

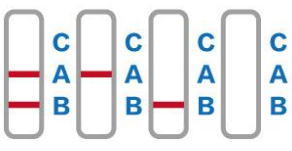
Influenza A / B virus antigen

1.1 Positive: A-line and C-line are colored, indicating that influenza A virus antigen is positive.

1.2 Positive: B-line and C-line are colored, indicating that influenza B virus antigen is positive.

1.3 Positive: A-line,B-line and C-line are colored, indicating that influenza A virus antigen are positive.

1.4 Negative: only one red C-line appeared in the test window, indicating that the concentration of influenza A and B virus antigens in the samples do not reach the detection level.



1.5 Invalid result: no red C-line appears in the window. The invalid results should be retested,

and the retest should be carried out in strict accordance with the instructions.

【Limitations of testing methods】

1. This reagent is a qualitative in vitro diagnostic reagent for auxiliary diagnosis. This reagent is a qualitative in vitro diagnostic reagent for auxiliary diagnosis. The test results are only used for clinical auxiliary diagnosis, which is not the only basis for clinical diagnosis. It should be judged comprehensively according to clinical symptoms and other detection indexes.

2. This product is only used for qualitative detection of SARS-CoV-2 antigen and influenza A / B virus Nasal swabs.

3. The test results of this kit are only for clinical reference, and the clinical diagnosis and treatment of patients should be considered in the light of their symptoms / signs, medical history, other laboratory examinations and treatment responses.

2. The positive results only showed the existence of SARS-CoV-2 antigen and influenza A / B virus which could not be used as the only criterion. 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.

3.Negative results can not completely rule out the possibility of virus infection, may be SARS-CoV-2 antigen, influenza A / B virus level is too low can not be detected by this kit. Or the detection of mutants that may exist in the virus may lead to negative results. In addition, because the best sample type of the product and the disease cycle where the peak concentration of the virus is located have not been verified, sampling samples from different stages and different parts of the same patient may avoid false negative.

4. It may be due to improper technical or step operation, as well as contamination of samples and the presence of other drugs that may interfere with the detection and lead to inconsistent or incorrect results.

5. Possibility analysis of false positive results: if the samples are cross-contaminated in the process of transportation and treatment, it may lead to false positive results; if the consumables and equipment used in the test are contaminated, it may lead to false positive results.

6. Possibility analysis of false negative results: unreasonable sample collection, transport, storage and processing, low content of pathogens in samples may lead to false negative results; mutation of the pathogen may lead to false negative results.

【Product performance index】

1. Appearance: the appearance is smooth, the material is firmly attached, the content is complete, the package is intact, the mark is clearly discernible, and there are no visible impurities in the sample treatment solution.

2. Strip width: strip width ≥ 3mm.

3. Move speed: the liquid migration speed should not be lower than 10mm/min.

4. SARS-CoV-2 antigen

4.1 Compliance rate of positive quality control products: the positive internal quality control compliance rate should be 5/5.

4.2 Compliance rate of negative quality control products: the negative internal quality control compliance rate should be 10/10.

4.3 Limit of detection: The test results should meet the requirements of detection limit quality control.

4.4 Repeatability: test 1 internal repeatability quality control products, each test for 10 times, results should be positive.

4.5 The sensitivity was 93.63% and specificity was 98.20% respectively after evaluation

4.6 Analysis specificity

4.6.1 Cross reaction: This product is no cross reaction occurred in the positive samples of influenza A virus , influenza B virus, pneumonia mycoplasma, chlamydia, adenovirus, respiratory, hepatitis C virus, treponema pallidum, human immunodeficiency virus, EB virus, measles virus, cytomegalovirus, enterovirus type 71, varicella-zoster virus.

4.6.2 Mucin, Blood, HAMA and Biotin to the negative samples, and the test results were negative. And add all the interference to the weak positive samples, and the test results of weak positive samples were all positive, indicating that the above endogenous interfering substance had no obvious interference on the detection of the SARS-CoV-2 antigen by the kit.

5. Influenza A / B virus antigen

5.1. Coincidence rate of positive reference samples: The coincidence rate of positive reference samples should be 8 to 8.

5.2. The coincidence rate of negative reference samples: the coincidence rate of negative reference samples should be 10 to 10;

5.3. LOD: The LOD for IAV and IBV quality control products is not less than 1:8.

5.4 Repeatability: IAV and IBV repetitive nature controls are tested for 10 times each, and the results should be positive.

5.5 After analysis and evaluation, the sensitivity and specificity of the product were 93.63% and 98.20%, respectively.

5.6.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.

5.7. The negative samples are detected by mucin, blood, HAMA and biotin, the results are all negative. When all the interference is

added to the weak positive samples, the test results of the weak positive samples are all positive, indicating that the above endogenous interfering substances has no obvious interference with the test of influenza A virus / influenza B virus antigen by the kit.

【Caution】

1.For in vitro diagnosis only, please read this manual carefully before the test.

2.This kit is a disposable in vitro diagnostic reagent. Please do not reuse it.

3.This reagent must be used within the validity period.

4.In the kit and samples have not returned to room temperature conditions, can not be operated, so as not to affect the accuracy of the results.

5.The test kit should be tested as soon as possible after it is taken out of the package to avoid being kept in the air for too long and causing moisture.

6.The operation should be carried out strictly according to the instructions, and do not mix different Lots of test cards and sample preservation solution, etc.

7.Operation errors or too small sample size may lead to deviations in the test results.

8.If the plastic bag of the test card is damaged, please do not use this product. The test results of these reagents are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment.

9.Waste samples and reagents should be disposed of according to potential infectious substances.

10. If it is suspected that the sample is contaminated, it should be re-sampled and tested.

11. Do not inhale the sample preservation solution.

12. There is desiccant in the aluminum foil bag and should not eat.

13. The reagents in the sample preservation solution contain small amounts of preservatives that may irritate the skin and eyes. If the solution comes into contact with the skin or eyes, wash it with a lot of water. If skin irritation or rash occurs, you should see a doctor in time.

14. During operation, you should pay attention to safety measures, wash or disinfect hands before and after use.

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	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

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Version Number : 1.0
Effective Date: April 12, 2022