COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit(Colloidal Gold Method)

Instructions For Professional Use

[Product Name]

COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit (Colloidal Gold Method)

[Packing Specifications]

1 Test/box;2 Test/box;5 Test/box;25 Test/box

[Intended Use]

The kit is an in vitro immunochromatographic assay for the qualitative detection of Covid-19, Influenza A and Influenza B virus antigens in human nasopharyngeal, oropharyngeal swab, and salvia samples.

Covid-19 is an acute respiratory infectious disease that humans are easily infected with. According to current epidemiological investigations, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms are: fever, fatigue, dry cough, in a few cases can appear nasal congestion, sore throat, myalgia and diarrhea.

Influenza, often called "the flu," is caused by the influenza virus. It is a highly contagious viral infection of the respiratory tract that can be spread by coughing or sneezing. Influenza outbreaks occur every fall and winter. There are influenza A, B and C viruses. Influenza A viruses are more prevalent than influenza B and Cand causes more severe illness.

Covid-19 infection and Influenza virus infection have similar symptoms, such as fever, cough, etc. This kit can simultaneously detect the antigens of the three viruses and provides an easy workflow, short turnaround time, and rapid diagnosis of Covid-19, Influenza A and influenza B virus infections using nasopharyngeal, oropharyngeal swab or salvia samples.

[Detection Principle]

The kit is an immunochromatographic assay,based on double antibody sandwich method to detect Covid-19 and Influenza A/B virus antigens. This method does not require expensive medical instruments and consumables. After adding the extracted specimen to the sample well on the test cassette, Covid-19, Influenza A/B virus antigens in the sample will interact with the colloidal gold-labeled anti-SARS-CoV-2 and Influenza A/B antibodies on the conjugate pads. Then the conjugate pad will release re-solubilized conjugate onto the nitrocellulose membrane. The nitrocellulose membrane (NC membrane) diffuses it forward.

As the sample moves along the device binding reagents situated on the nitrocellulose membrane bind to the target at the test line. If the sample contains a COVID-19 antigen, it will bind to the colloidal goldanti-SARS-CoV-2 Np monoclonal antibody, diffuse forward, and then react with the anti-SARS-CoV-2 Np monoclonal antibody immobilized on the NC membrane detection line (COVID-19 Test line). Similarly, if the specimen contains Influenza A/Influenza B antigens, the antigens will react with antibody-coated particles, the conjugate migrate laterally forward, and cause a colored lines (A, B linesrespectively).

On the contrary, if there is no Covid-19, Influenza A/B virus antigen in the sample or the concentration of the antigens is below the minimum detection limit, there is no colored lines in the test area and the result is considered to be negative.

As a procedure control, there is a quality control line (C line), this line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred, otherwise the test result is invalid.

[Main components]

Components	Quantity	Description
Test Cassettes	1 / 2 / 5 / 25 tests	Each test cassette consisted of a nitrocellulose membrane (NC membrane) coated with anti-SARS-CoV-2 Np monoclonal antibody,anti-Influenza A and anti-Influenza B monoclonal antibodies, goat anti-mouse IgG antibody, and a conjugation pad pretreated with anti-SARS-CoV-2 Np monoclonal antibody, anti-Influenza A and anti-Influenza B monoclonal antibodies.
Extraction tube	1/2/5/25pcs	Each tube contains 0.5ml of virus lysis solution.
Throat swab	1/2/5/25pcs	/
Paper bag	1/2/5/25pcs	/
Quantitative dropper	1/2/5/25pcs	/
Instructions for use	1/1/1/1pcs	/

[Storage Conditions and Validity]

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed foul bags. The test must remain in the sealed pouch until use. Test should be used as soon as possible within 30 minutes after unsealing the aluminum foil bag.

DO NOT FREEZE. Do not use beyond the expiration date.

[Sample Collection and Preparation]

Pharyngeal swab collection method:

1. Slightly tilt the patient's head;
2. Instruct the patient to open his mouth as wide as possible to expose the pharyngeal tonsils on both sides;
3. Swab over the patient's tongue base with a cotton swab;
4. Vigorously swab tonsillar area and posterior oropharynxusing the swab. Rotate the swab several times.
5. Hold the extraction tube by hand. Insert the swab head into the extraction tube which contains virus lysis solution to dissolve the sample in the liquid as much as possible;identifying the scoreline,break the swab shaft against the side of the tube, discard the tail of the swab, cover the tube tightly and shake for 5 seconds, test the sample as soon as possible

Nasopharyngeal swab collection method:

1. Carefully insert a sterile swab into the nostril of the patient, reaching the surface of the posteriornasopharynx;
2. Rotate the swab 5 times or more against the nasal wall;
3. Slowly withdraw the swab from the nasal cavity.
4. Hold the extraction tube by hand. Insert the swab head into the extraction tube which contains virus lysis solution to dissolve the sample in the liquid as much as possible;identifying the scoreline,break the swab shaft against the side of the tube, discard the tail of the swab, cover the tube tightly and shake for 5 seconds, test the sample as soon as possible.

Saliva sample collection method:

1. Patients should clean their mouth 30 minutes before saliva collection, and avoid eating, smoking or chewing gum;
2. Instruct the patient to gently spit into the paper bag(about 3-4 times) until the volume of saliva reaches 1/5 of the volume of the paper bag, and avoid foam formation as much as possible during the process. If the amount of saliva is insufficient, the patient can be instructed to increase the secretion of saliva by pressing the tongue against the palate or the lower jaw;
3. The paper bag with collected saliva should be placed at room temperature for 20 minutes to burst the foam on salvia, so as to avoid the problem of inaccurate sampling amount.
4. Take an extraction tube, unscrew the cover, use the quantitative dropper to suck 80ul saliva from the paper bag, add into the extraction tube, mix well, close the cover of the tube, shake for 5 seconds, and test the sample as soon as possible;

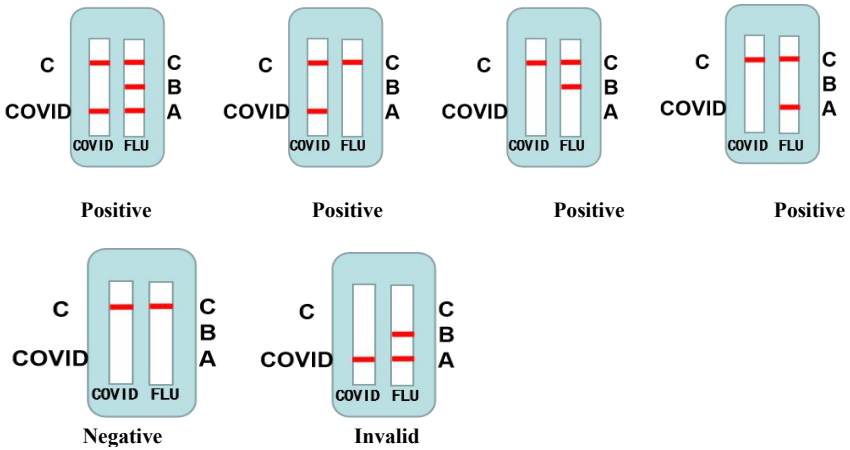
[Test Method]

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (20-25°C) prior to testing. 1.Remove the test cassette from the sealed foil pouch and use it within 30 minutes. Best results will be obtained if the test is performed immediately after opening the foil pouch.

2. Invert the specimen extraction tube and add 2-3 drops of extracted specimen (approx.60µl) to each of the specimen well(S) respectively and then start the timer.

3.Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

[Interpretation of Test Results]



POSITIVE COVID-19:* Two distinct colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of COVID-19 antigens in the sample.

POSITIVE Influenza A:* Two distinct colored lines appear in the right window.One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Inflenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B:* Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear in the right window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE**: The intensity of the color in the test line region (T) will vary based on the amount of COVID-19 antigen, Flu A and/or B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/B/A).

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[Limitations of the test method]

1. This kit is immunochromatography kit, and is only used for auxiliaryin vitro diagnosis.
2. False negatives may result from improper sampling, transportation, handling and low virus content in samples.
3. For doubtful test results, the user should combine the patient's symptoms and perform further tests, such as nucleic acid tests.
4. The test results of this reagent are to be used only for clinical reference and should not be considered as the sole basis for clinical diagnosis and treatment.

[Product performance indicators]

1. The COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit was used to detect 60 RT-PCR COVID-19 positive samples with a sensitivity of 93%. detect 170 negative specimens,168 were negative, with a specificity of 98.82%.
2. The COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit was used to detect 60 RT-PCR FluA positive cases with a sensitivity of 96.62%.detect 170 negative specimens, 168 were negative, with a specificity of 99.41%.
3. The COVID-19/ FluA/ FluB Antigen Combo Rapid Test Kit was used to detect 89RT-PCR FluB positive cases with a sensitivity of 97.75%.detect 170 negative specimens, 170 were negative, with a specificity of 100%.

[Precautions]

1. This product is for in vitro diagnostic only.
2. Please ensure that appropriate amount of specimens are used for testing. Excessive or too small amount of specimens may lead to deviation of results.
3. As this product is visually read, in order to ensure the correct interpretation of the results, do not read the results in the dim light.
4. The reagent should be used up within 30 minutes after the aluminum foil bag is unsealed, and it should be used as soon as possible.
5. In the interpretation, as long as the red line appears in the quality control area, if the red line appears in the test area, the test can be determined as positive.

[Symbol on the Labeling]

	For single use only		Storage Temperature
IVD	In vitro diagnostic use	LOT	Batch Code
	Caution		Consult Instructions for Use
CE	Comply with the European		Manufacturer
	Use-by Date	EC REP	Authorized Representative

[Contact Info.]

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