【Reference】

[1] Shi Shaorui, Niebin etc, *Detection of viral nucleic acid in multiple biological samples of new coronavirus pneumonia cases*

[2] Ying-Hui Jinetl, *A rapid advice guideline for the diagnosis and treatment of 2019 novel coronavirus(2019-nCoV) infected pneumonia(standard version)*

The COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT

（Colloidal gold immunochromatography）

Instruction Manual

【Product Name】

Common name: The COVID-19 IgG/IgM ANTIBODY RAPID TEST KIT（Colloidal gold immunochromatography）

【Packaging Specification】

25 T/box, 1 T/box

【Intended Use】

This kit is used to qualitatively detect the IgG/IgM antibody of the COVID-19 in human Serum /plasma/whole blood. The COVID-19 is the newly discovered seventh coronavirus that can infect human beings. This virus causes an immune response in the lungs, leading to pneumonia, which is life-threatening in severe cases. The COVID-19 is extremely contagious and can be transmitted through channels such as body fluids, air droplets, and feces, etc. Therefore, early diagnosis of the COVID-19 can effectively treat patients, and also effectively isolate patients to avoid further infection.

【Detection Principle】

According to the principle of double antibody sandwich method, the kit uses immunochromatographic technology to detect the IgG/IgM antibody of COVID-19 in human serum/ plasma/whole blood. The COVID-19 characteristic protein RBD protein antibody in the sample binds to the colloidal gold labeled RBD protein, and the mixture is chromatographed to the kit T1 line and T2 line combining to the mouse anti-human IgG/IgM antibody respectively to form a visible detection line.

【Major Components】

Number	Component Name	Major Components And Concentrations	Specification / Quantity	
			25T/box,	1T/box
1	Test cassette	The test cassette consists of a test strip and a plastic cassette. The test strip is supported by a plastic backing, and successively pasted with a water absorbing material, a nitrocellulose film and a glass fiber sample pad. It is packed in a suitable size plastic case and then separately packed in a reagent bag. The specific position on the nitrocellulose membrane (NC membrane) was streaked and coated with 0.5 mg/ml mouse anti-human IgG antibody, mouse anti-human IgM antibody and 0.5mg / ml goat anti-rabbit IgG antibody; the sample pad has RBD protein and rabbit IgG antibody.	25 bags/ box	1 bags/ box
2	Diluent	0.01M phosphate （PBS）buffer solution （pH 7.4±0.2）	0.3mL/ bottle 25bottles/box	0.3mL/ bottle 1 bottle/box
3	Dropper tip	/	25	1
4	Alcohol Pad	/	25	1
5	Instruction manual	/	1 sheet	1 sheet

【Storage Conditions And Validity】

The reagent should be stored at 4 ℃ ~ 30 ℃, the validity period is 12 months, and cannot be frozen. The test cassette shall be used as soon as possible within 30 minutes after opening the independent packaging and sealing.

Note: The production date and expiration date are shown on the label.

【Specimen Requirements】

1. Collect whole blood, serum or plasma samples in accordance with routine clinical laboratory procedures, and all stored at 2-8℃.

2. Samples should not be left at room temperature for a long time after collection. It is best to test the samples within 2 days after collection.

3. Whole blood samples should not be frozen. Blood should be collected using anti-coagulation tubes, and the storage time should not exceed 1 week.

4. Place the sample at room temperature to restore before testing.

【Detection operation】

Read the instruction manual completely before testing. Leave the reagents and samples at room temperature(20-30 ° C) for 30 minutes before use. Do not open the inner packaging until it is ready. After opening the inner packaging, use within 30 minutes at room temperature (20-30 ℃), humidity< 60% ; humidity above 60% must be used immediately after opening.

1. Whole blood specimen

1) Open the box and take out the test cassette, diluent, and put them at room temperature for 15-30 minutes.

2) Add 20ul of whole blood to the sample well by using dropper.

3) Add 2 drops of diluent to the sample well.

4) Observe the results after 15 minutes, and the results showed after 20 minutes have no significance.

2. Serum/plasma specimen

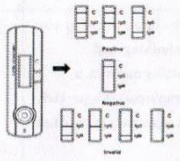
1) Open the box and take out the test cassette and put it at room temperature for 15-30 minutes.

2) Add 20ul of Serum or plasma to the sample well by using dropper.

3) Add 4 drops of diluent to the sample well.

4) Observe the results after 15 minutes, and the results showed after 20 minutes have no significance.

【Reference Interval】



POSTIVE (+):

COVID-2019 IgG Postive:

One red line appears in the region G and the other line appears in the region C.

COVID-2019 IgM Postive:

One red line appears in the region M and the other line appears in the region C.

COVID-2019IgG& IgM Postive:

One red line appears in the region G , One red line appears in the region M, and the other line appears in the region C.

The positive results showed that the COVID-2019 antibody was present in the samples.

NEGATIVE (-):

The display window only shows the quality control line (C line). The negative results showed that the samples did not contain COVID-2019 antibody, or the content was lower than the detection level of this product.

Nucleic acid testing is recommended for samples with negative results.

INVALID:

The display window does not show the quality control line (C line), indicating incorrect operation process or deterioration of reagent. In this case, read the instructions carefully again and retest with new reagents. If the problem persists, discontinue use of the batch immediately and contact your local supplier.

【Interpretation Of Test Results】

1. The test results of this reagent are only for clinical reference. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment response.

2. Clinicians need confirmation tests when they have doubts about the test results or when the test results are obviously abnormal.

3. Operation errors, sample factors, environment, etc, may affect the test results.

【Limitations Of Test Methods】

1. Try to use fresh samples within 2 days for the kit.

2. The accuracy of the test depends on the sample collection process. Improper sample collection, improper storage of samples, unfresh samples, or repeated freeze-thaw cycles of samples will affect the test results.

3. The test cassette only provides qualitative detection of the COVID-19 antibody in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.

4. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment responses.

5. Due to the limitation of the methodology of immunological detection reagents, its analytical sensitivity is generally lower than that of nucleic acid reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.

6. Analysis of the possibility of false negative results:

①Unreasonable sample collection, transportation and processing may lead to false negative results.

②Genetic variations of virus can cause changes in antibody determinants, which can lead to false negative results.

③The optimal sample type and sampling time after infection have not been verified, so collecting samples at different times on the same patient may avoid false negative results.

【Matters Needing Attention】

1. This kit is only used for in vitro diagnosis.

2. Do not swallow the reagents or expose reagents to the skin, eyes and mucous membrane. Once in contact, rinse the contaminated areas with water immediately.

3. The detection temperature is 15 ℃ ~ 30 ℃, and the best humidity is 40% ~ 60%.

4. After the reagent card is taken out of the aluminum foil bag, the experiment should be carried out as soon as possible to avoid the humidity caused by too long time in the air.

5. All samples of patients should be treated as potential sources of infection.

6. If the reagent has expired, it cannot be used again.

【Interpretations Of Identification】

IVD	In vitro diagnostic medical device	EC REP	Authorized representative in the European Community	LOT	Production batch code
CE	CE Mark		Consult instructions for use		Temperature limit
	Manufacturer		Do not re-use		Use-by date