SARS-COV-2 (COVID-19) IgG&IgM Antibody Detection Kit (FIA)

【Product name】

Diagnostic Kit for Quantitative Determination of SARS-COV-2 (COVID-19) IgG&IgM Antibody by Fluorescence Lateral Flow Immunoassay

【Package specification】

Specification	Diluent	IC Card
20 pcs/Kit	1ml×20	1pc

【Intend use】

This product is used with FIT-1000 fluorescence analyzer to determine the content of SARS-COV-2 (COVID-19) IgG&IgM Antibody in human serum, plasma and whole blood only for medical institutions asr auxiliary diagnosis.It is only used as a supplementary detection index for suspected cases with negative detection of novel coronavirus nucleic acid or used in conjunction with nucleic acid detection in the diagnosis of suspected cases.

There are currently 7 human coronaviruses (HCoV) that can cause human respiratory diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HcoV-HKU1, MERS-CoV and new coronavirus (2019-nCoV) Is an important pathogen of human respiratory infections. Among them, the new coronavirus (2019-nCoV) clinical manifestations are systemic symptoms such as fever and fatigue, with dry cough, dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organs Functional failure, severe acid-base metabolism disorders, and even life-threatening.

When the human body is infected with the new coronavirus, the earliest antibody produced is the IgM antibody, which is usually produced 3-7 days after the infection, and is replaced by a large amount of IgG antibodies produced after about two weeks, so the new coronavirus specific antibodies IgM and IgG can be used as suspected patients. Auxiliary means of diagnosis.

【Test Principle】

This kit uses immunochromatography, the detection card contains: 1. Recombinant novel coronavirus antigen labeled with fluorescent microspheres and IgY antibody labeled with fluorescent microspheres; 2) Two detection lines are fixed (G line is coated with anti-human IgG antibody and M line are coated with anti-human IgM antibody) and a quality control line (C line) nitrocellulose membrane, used to detect new coronavirus specific antibodies IgM and IgG; C line is fixed with anti-IgY antibody.

When an appropriate amount of sample to be tested is added to the sample well of the detection card, the sample will move forward along the detection card under capillary action. If the sample contains IgM antibody, the antibody will label the new coronavirus antigen with fluorescent microspheres In combination, the immune complex will be captured by the anti-human IgM antibody immobilized on the membrane, and the measurement of the fluorescence analyzer shows that the value of the new coronavirus IgM antibody is higher than the normal human Cutoff value, which means that the antibody is positive. If the sample contains IgG antibody, the antibody will bind to the fluorescent microsphere-labeled new coronavirus antigen, the immune complex will be captured by the reagent fixed on the membrane, and the measurement value of the new coronavirus IgG antibody will be displayed by the fluorescence analyzer. Higher than the Cutoff value of normal people, it means antibody positive. If measured by the instrument, the measured values of the detection lines G and M are lower than the Cutoff value of the normal person, showing a negative result.

【Main Components】

1. Detection card. The detection card is composed of a plastic plate card, nitrocellulose membrane, absorbent paper, sample pad and carrier pad; it contains recombinant coronavirus antigen, mouse anti-human IgM monoclonal antibody, mouse anti-human IgG monoclonal antibody, IgY and anti- IgY antibody.
2. IC card: 1 piece;
3. Sample diluent: 1mL × 20 bottles;
4. Instruction manual.

【Storage & Expiry】

1. Store in a dry place at 2-30 ° C, protected from light.
2. After opening the inner package, the test card will be invalid due to moisture absorption, please use it within 1 hour.
3. The validity period is 12 months.

[Applicable instrument]

Time-resolved fluorescence analyzer FIT-1000 (hereinafter referred to as fluorescence analyzer).

[Sample requirement]

1. Suitable for human serum, plasma or whole blood samples, including plasma or whole blood samples prepared by clinically commonly used anticoagulants (EDTA, heparin, sodium citrate).
2. After the samples are collected, they should be

tested immediately. If it cannot be detected immediately, the serum and plasma samples to be tested can be stored at 2-8 ° C for 5 days. If long-term storage is required, it should be placed at -20 ℃ to avoid repeated freeze-thaw samples. Anticoagulated whole blood samples should not be stored for more than 72 hours at room temperature; not more than 7 days at 2-8 ° C.

3. Before testing, slowly return the refrigerated or frozen samples to room temperature and mix them carefully. When there is clearly visible particulate matter in the sample, it should be centrifuged before the test to remove the precipitate.

4. If the sample contains a lot of lipids, hemolysis or turbidity, please do not use it, so as not to affect the result judgment.

【Test procedure】

1. The test samples, test reagents and other test materials are balanced to room temperature and tested under room temperature.

2. Check if the batch numbers of the IC card and the kit are the same. The new batch of detection reagents must enter the IC card information into the instrument.

3. Open the aluminum foil bag from the tear, take out the detection card, and lay it flat on a horizontal table.

4. After thoroughly mixing the sample, take 10 μL of the sample dilution solution and mix it thoroughly; take 100 μL of the mixture into the reaction well of the detection card.

5. According to the sample type, select the "serum / plasma" type or "whole blood" type on the instrument.

6. Select the manual mode: place the test card for 10 minutes and read immediately; select the automatic mode: add the test card directly to the instrument after adding the sample, and the instrument will automatically measure and read after 10 minutes.

7. Calibration instructions: The calibration curve of each batch of reagents is recorded in the IC card, and the IC cards of different batches of reagents cannot be mixed.

【Cutoff Value】

The cutoff value of the new coronavirus (2019-nCoV) specific antibody IgG is 7 RU / mL.

The cutoff value of the new coronavirus (2019-nCoV) specific antibody IgM is 6.4 RU / mL.

The Cutoff value is determined according to the 95% distribution interval of normal people.

[Explanation of test results]

1. When the CoV-G test result is less than 7 RU / mL, the result is interpreted as negative for IgG antibodies.

2. When the CoV-G test result is greater than or equal to 7 RU / mL, the result is interpreted as IgG antibody positive.

3. When the test result of CoV-M is less than 6.4 RU / mL, the result is interpreted as negative for IgM antibody.

4. When the CoV-M test result is greater than or equal to 6.4 RU / mL, the result is interpreted as antibody IgM positive.

5. When the test result of CoV-G or CoV-M shows 0.000 RU / mL, it indicates that the concentration of IgG or IgM antibody in the sample is very low, which does not affect the detection, and the result is interpreted as negative.

6. In the early stage of infection, the lack of specific antibodies of the new coronavirus (2019-nCoV) IgG and IgM or low titers will lead to negative results, and should be reviewed within 7-14 days. The re-examination should be parallel detection of the last collected Samples to confirm whether there is a turning sun or a significant increase in titer.

7. IgM antibody positive occurs not only in the primary infection, but also in the secondary infection. IgM reaction can also be seen; IgG positive indicates that there is a previous infection or a secondary infection.

8. Confirm the infection of the new coronavirus should be combined with the clinical manifestations of the patient or further combined with other methods.

【Limitation】

1. The accuracy of the results depends on the control of the measured temperature and the measurement time;

2. After the sample and sample diluent are diluted and mixed, mixture should be added to the reaction well in time.

【Performance index】

1. Accuracy: positive test result with positive reference products of the enterprise.

2. Specificity: The test result is negative with the enterprise negative reference.

3. Precision: Use enterprise precision reference products S1 and S2 for testing, repeatability CV≤15%; use J2 for testing, the difference between batches CV≤15%.

4. Minimum detection limit: use the enterprise's minimum detection limit reference products to meet the requirements.

【Precautions】

1. For in vitro diagnosis only;

2. Please use within the validity period, do not mix reagent components of different batches;

3. This product is a one-time use in vitro diagnostic

reagent, please do not reuse;

4. It is forbidden to use the test card that does not match the IC card batch number.

5. The test card can be stored at room temperature, beware of moisture, and the test card stored at low temperature should be balanced to room temperature before use.

6. Single-test operation is appropriate for first time use;

7. The determination results are only used as a clinical auxiliary diagnosis basis for various diseases;

8. When using this kit, the precautions for each laboratory operation must be observed. All waste must be disposed in accordance with the relevant regulations.