SARS-CoV-2 IgM / IgG Antibody Detection Kit（Fluorescence immunoassay)

User manual

【Product name】

SARS-CoV-2 IgM / IgG Antibody Rapid Test Kit（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

This kit is used for the qualitative detection of SARS-CoV-2 IgM and IgG antibodies in human serum, plasma, and whole blood samples in vitro. It is only used as a supplementary detection indicator for suspected cases of negative SARS-CoV-2 nucleic acid detection or for SARS-CoV-2 nucleic acid detection in suspected case diagnosis. The combined use of the tests cannot be used as a basis for the diagnosis and exclusion of pneumonitis caused by SARS-CoV-2 infection, and it is not suitable for screening in the general population.

【Inspection principle】

This kit is used to detect SARS-CoV-2 IgM and IgG antibodies in human serum, plasma or whole blood, based on the principle of fluorescent immunochromatography. If the sample tested contains SARS-CoV-2 IgM or IgG antibody, the antibodies will bind to the antigens conjugated fluorescent nanoparticles, and then captured by the secondary antibodies in detection zone 1 (T1) or detection zone 2 (T2) to form one or two red Lines which can be recognized by a fluorescent reader, indicating positive results. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	The test card consists of SARS-CoV-2 IgM / IgG antibody test strip and plastic card case; the test strip consists of nitrocellulose membrane, sample pad, fluorescent nanoparticle pad, absorbent paper, and PVC board
Sample diluent	1（3mL）	Phosphate buffer
lancet	25	/
Sampling tube	25	/
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】

Nir-1000 dry fluorescent immunoassay analyzer produced by WWHS Biotech. Inc.

【Sample requirements】

1. Serum, plasma, and whole blood samples can be used for testing.
2. Serum / plasma sample collection: Serum and plasma should be separated as soon as possible after blood collection to avoid hemolysis. The separated serum and plasma should be tested quickly. If they cannot be used in a timely manner, they should be stored at 2- 8℃. After 3 days, they should be stored frozen at -20 ℃. Please make the sample recover to room temperature before testing. It is not recommended to use severe hemolytic and heat extinguishing samples.
3. Whole blood collection: use an anticoagulation tube to collect blood, or add an anticoagulant in the blood collection tube (heparin, EDTA salt, sodium citrate lamp anticoagulant are recommended), add the collected blood sample and shake it for later use. If it cannot be tested immediately, it can be stored at 2-8℃ for 7 days. Intravenous samples over 7 days are not suitable for this kt.

【Test procedure】

(1) Start NIR-1000 dry fluoroimmunoassay analyser according to the instruction manual of the instrument, and carry out quality control verification according to the instruction manual of the instrument（Note: the reagent has been calibrated in advance, and the calibration curve parameters of each batch of reagent have been stored in the information card. The information card is inserted before use, so it is not necessary to calibrate again, and the test can be carried out only after the quality control is passed. Otherwise, the cause should be found out before testing.)

(2) Transfer 20 μL of whole blood or 10 μL of serum or plasma specimen to the sample well, followed by adding 4 drops (100 μL）of sample diluent to the sample well.

(3) Insert the test card into NIR-1000 dry fluoroimmunoassay analyser, read and record the results at 15 minutes after addition of samples, then dispose of used test appropriately.

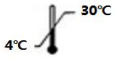
【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with SARS-CoV-2 Nucleocapsid proteins concentration lower than1ng/ml and higher than 500ng/ml, the detection results are reported as "< 1ng/ml" and "> 500ng /ml", respectively.

【Note】

- For in vitro diagnostic use.
- This test has been authorized only for the detection of SARS-CoV-2 IgM and IgG antibodies, not for any other viruses or pathogens.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- Proper sample collection, storage and transport are essential for correct results.
- Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots.
- Do not reuse the used test card.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Do not store specimens in viral transport media for specimen storage.
- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
- Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of SARS-COV-2.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

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【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc
Address: 505, building 1, Shenzhen Biomedical Innovation Industrial Park, 14 Jinhui Road, Kengzi street, Pingshan New District, Shenzhen
Contact: 0755-84235529
Name of after sales service unit: WWHS Biotech. Inc
Contact: 0755-84235529
Production address: 505, building 1, Shenzhen Biomedical Innovation Industrial Park, 14 Jinhui Road, Kengzi street, Pingshan New District, Shenzhen
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