Novel Coronavirus
(2019-nCoV) IgM/IgG Test Kit
(Colloidal Gold Immunochromatography) Instruction

Product Name

Novel Coronavirus (2019-nCoV) IgM/IgG Test Kit (Colloidal Gold Immunochromatography)

Package Specification

50 T/Box (Non-Sterile)

Intended Use

This test kit is used for the *in-vitro* qualitative test of 2019-nCoV IgM and IgG antibody in human samples (serum, plasma and whole blood).

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Test Principle

This test kit use indirect method to detect the 2019-nCoV IgM/IgG antibody.

After a sample containing the materials under test has been applied on the sample pad, the sample flows through the binding pad and nitrocellulose membrane via siphon forming a solid phase of 2019-nCoV antigen, 2019-nCoV IgM/IgG and Mouse Anti-Human IgM/IgG labeled with colloidal gold on the testing line, and another solid phase of Goat Anti-Mouse IgG, Mouse Anti-Human IgM/IgG, labeled with colloidal gold on the control line. When the testing is complete, observe the chromogenic reaction of the colloidal gold on the detection and control lines to determine the testing result of the2019-nCoV IgM/IgG in human samples (serum, plasma and whole blood).

Components

The test kit is composed of a standard component and an optional component.

Standard components: test reagent card, sample diluent and instructions.

Optional ingredients: blood lancet and capillary.

Materials and Components

Test Reagent Card: Nitrocellulose membrane (main raw material for T line: recombinant antigen; main raw material for C line: Goat Anti-Mouse IgG), binding pad (main raw material: Mouse Anti-Human IgM/IgG labeled with colloidal gold), sample pad, water absorbing pad and plastic shell.

Sample diluent: phosphate buffer, containing 1% bovine serum albumin.

Storage and Expiration Date

The test kit should be stored at 2~30°C and is valid within 18 months tentatively. Opened test reagent card should be used within 1 hour, and immediate use is recommended.

Specimen Requirements

1. Blood should be drawn following <Guide of 2019-nCoV Laboratory Test Technique> (Second Edition).

2. Whole blood samples: anticoagulant blood collection tubes containing EDTA are available. Detection should be done within half an hour after the blood is collected. The blood should be stored at 2-8 °C less than 12 hours.

3. EDTA blood collection tubes are available for plasma, and separating gel blood collection tubes with yellow stopper are available for serum. Serum and plasma should be separated as soon as the samples are collected, and avoid hemolysis.

4. The separated serum and plasma samples should be detected within 4 hours at room temperature. If the detection can not be done immediately, the serum and plasma samples can be stored for 24 hours at 2-8 °C. Stored at -20 °C and lower for long-term storage. This test kit prefers serum samples.

5. Before detection, restore the samples to room temperature and mix completely. Frozen samples should be thawed completely before being used. Repeating thawing and freezing should be avoided, as this may cause deterioration. Severe chyle and hemolysis should be avoided.

Procedures

Read the kit instructions carefully before using and follow the kit instructions carefully:

1. Preparation

Take out the test card and the sample under test, and allow them to restore to room temperature; Mix all the liquid components thoroughly; Open the aluminium foil bag of the test card.

2. Sample Determination

(1) For serum/plasma samples: add 10 μL of samples into the sample diluent, and mix thoroughly; add 80 μL of the mixture into the loading hole of the test card vertically.

(2) For whole blood samples: add 20 μL of samples into the sample diluent, and mix thoroughly; add 80 μL of the mixture into the loading hole of the test card vertically.

3. Detection

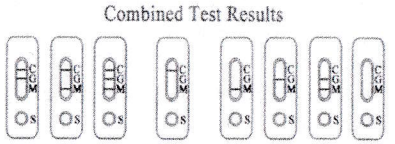
Place the test card at room temperature for 10 minutes and then observe the testing result. The observation is invalid if the time exceeds 20 minutes.

Test Results Interpretation

1. Positive: Two or three color bands appear in the observation window. That is two or three red or purplish red line appears on the control line and testing line, respectively, indicating that the 2019-nCoV IgM/IgG testing of the sample under test is positive .

2. Negative: A red or purplish red line appears on the control line in the observation window, and nothing appears on the testing line (M line and G line) , indicating that the 2019-nCoV IgM/IgG testing of the sample under test is negative, or the concentration is lower than the lower limit of detection.

3. Invalid: No line appears on the control line in the observation window, indicating that the testing is invalid, and a new sample should be taken for testing.



Display (Right)

Limitation of the Test Method

1. This kit is for qualitative testing and for *In-Vitro* Diagnostic use only.

2. Specimens can not be used for detection if obvious microbial contamination occurs.

3. The test results of the samples are related to the collection, preparation, transportation and quality of preservation of the samples. Any error may cause the test results inaccurate; if the cross-contamination is not controlled well during the preparation of the samples, false positive may occur.

4. A window period of the production of antibodies exists after human is infected with 2019-nCoV. Thus, the results of negative should be further determined with clinical symptoms and other 2019-nCoV auxiliary detection index.

Product Performance Index

1. Positive consistency rate: Test 3 positive reference materials (P1-P3), and the results should all be positive.

2. Negative consistency rate: Test 3 negative reference materials (N1-N3), the results should all be negative.

3. The lower limit of detection: Test 3 reference materials of sensitivity (L1, L2, L3), and repeat the testing 3 times for each materials. The results of L1 should all be positive; the results of L2 should all be negative or positive and the results of L3 should all be negative.

4. Repeatability: take out 10 test reagents from the same batch and test the reference materials of repeatability (R). The test results should all be the same which is positive, and the color rendering of the testing lines should be uniform as well.

Important Note

1. This kit is for *in vitro* qualitative test only. Please read this instruction carefully before use, and follow the procedures strictly. Please do not mix reagents from different batch numbers.

2. The collection, storage and test of the samples should strictly comply with "Guide of Novel Coronavirus Pneumonia Laboratory Test Technique (Second Edition)" and "Guide of Novel Coronavirus Laboratory Bio-safety (Second Edition)".

3. The waste or remaining samples during the test are suggested to be treated with diethyl ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid and chloroform to inactivate the virus.

4. Immediate use of the test card is recommended, and the test card is non-reusable.

5. Test results of the test kit are only for clinical reference. The clinical diagnosis of the disease should be considered with it's symptoms, signs, medical history, test of other laboratory and response of treatment.

6. Due to the methodology or specificity of the antibodies and other reasons, the results may differ among reagents from different manufacturers.

7. Inspectors should carefully protect any incision, abrasion and other skin damage, and prevent autoinoculation. All operations should comply with "Bio-safety General Requirement in Laboratory". The waste produced should take environment-friendly and harmless treatment based on relevant regulations to ensure the safety of contacts and environment during the process.

References

1. "Diagnosis and Treatment Scheme for Pneumonia Infected by New Coronavirus (Trial Version 5)", National Health Office Medical Letter [2020] No. 103, 2020.02.05. China.

2. "Guidelines for Bio safety of Novel Coronavirus Laboratories (Second Edition)", Science and Education Letter of National Health Office No. 2020 No. 70, 2020.01.23. China.

3. "Technical Guidelines for Laboratory Testing of Pneumonia Infected by New Coronavirus (Second Edition)", CDC, 2020.01.22. China.

4. "Guidelines for Bio safety Protection in Clinical Laboratory Testing of New Coronavirus Pneumonia (Trial Version)", Inspection Branch of Chinese Medical Association, 2020.01.30. China.

5. "Guiding Principles for the Preparation of In vitro Diagnostic Reagent Instructions" ([2014] No. 17). China.

6. The Ministry of Health of the People's Republic of China. The fourth edition of the "National Clinical Laboratory Operating Regulations." China.

Basic Information

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CONSUMER INFORMATION [Warranty Terms and Conditions] This product is guaranteed against manufacturing defects to its specifications, provided that it is within the shelf life and that the care in handling, storage indicated on the label and in these product storage instructions have been followed correctly.

Medical Device Production License Number No. 20170032 of Chongqing Food and Drug Administration

Date of Production / Date of Expiration On packaging

Date of Approval and Amendment of IFU 05.20.2020

Symbol Instruction

SYMBOL	MEANING	SYMBOL	MEANING
IVD	In vitro diagnostic medical device		Temperature limitation
	Manufacture	EC REP	Authorized representative in the European community
	Date of manufacture		Use by date
	Do not reuse		Consult instructions for use
LOT	Batch code	CE	Meet the council directive 98/79 / EEC requirements
	Caution		Do not use if package is damaged
ISO	International organization for standardization 13485		