TEST RÁPIDO CORONAVIRUS COVID-19 MANUAL Y PROCEDIMIENTO

SARS-CoV-2 IgM/IgG Antibody Test Kit

Instruction For Use

[Product Name]
SARS-CoV-2 IgM/IgG Antibody Test Kit

[Packing Specification]

20 tests/kit, 40 tests/kit

[Intended Use]
This kit is used for the qualitative detection of 2019-nCoV IgM/IgG antibody in human serum, plasma or whole blood in vitro.

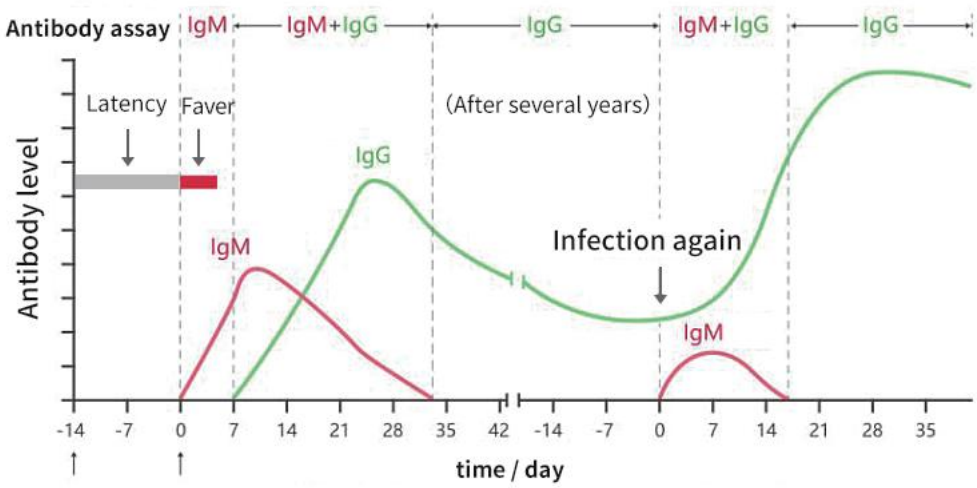
Coronavirus belongs the genus Coronavirus of the familyCoronaviridaein systematic classification. It is enveloped positive-sense single-stranded RNA virus, with a diameter of about 80-120nm. Its genetic material is the largest among all RNA viruses, and it only infects human, rats, pigs, cats, dogs and bird vertebrates. A variant of Coronavirus is the pathogen that causes SARS and belongs to RNA viruses.

Among them, 2019 Novel Coronavirus, i.e., 2019-nCoV, was discovered in virus pneumonia cases in Wuhan in 2019 and was named by the World Health Organization on January 12, 2020. People infected with 2019-nCoV will experience symptoms to varying degrees, some with fever or a mild cough, some with pneumonia, and some with more severe symptoms or even death. The fatality rate of the virus is about 2%~4%. However, this is an early percentage and may change as more information becomes available. Meanwhile, this does not mean that it is not serious, and it just means that not everyone infected with this virus will face the worst consequences.

When the human body comes in contact with foreign antigens, the earliest antibody produced is IgM, which is directly secreted by B cell receptor. B cellsproducing IgM enter the lymph nodes and are stimulated by T cells and antigenpresenting cells at the generative center. Then, they grown and differentiate into plasma cells and producea large amount of IgM.

IgM is generally produced in 3~7 days after infection. Therefore, IgM can be used for reflecting whether the body is in an acute infection state as a main indicator of early diagnosis.

IgM antibody can be detected 0-7 days in advance



Wuhan Easydiagnosis Biomedicine Co.,Ltd

EC REP MedNet GmbH
Borkstrasse 10, 48163 Münster, Germany

[Test Principle]

This kit applies the principle of GICA to qualitatively detect the 2019-nCoV IgM and IgG antibody in human serum, plasma or whole blood. Take the test specimen and add it to the specimen well of the test paper, and then add 2 drops of specimen diluent. The IgM/IgG antibody in the specimen binds to the colloidal gold-labeled recombined 2019-nCoV antigen on the binding pad to form a complex, which diffuses forward along the nitrocellulose membrane (NC membrane) under chromatography. Then, it binds to an anti-human IgM/IgG antibody fixed on the NC membrane test line (M/G line) to form a purple-red band, showing the 2019-nCoV IgM/IgG antibody. The deeper the color of the band on the M/G line, the higher the concentration of the 2019-nCoV IgM/IgG antibody in the specimen will be. To monitor the effectiveness of the test card, a quality control line (C line) is set. Regardless of whether there is a M/G line, the C line shall show color development, or the test result will be judged as invalid.

[Main Components]

Spec. / Components	20tests/kit	40 tests/kit	Main Components
IgM/IgG Antibody test strip	20 strips	40 strips	Plastic card, NC membrane (coated with anti-human IgM/IgG antibody and C line antibody), binding pad (with colloidal gold-labeled recombined 2019-nCoV antigen), absorbent paper and PVC board
Specimen diluent	1 tube	1 tube	
Instruction for use	1 piece	1 piece	

[Storage Conditions and Validity]

The kit shall be stored at 2~30℃ and is valid for 18 months. After unpacking the aluminum foil bag, please use it as soon as possible.

[Specimen Requirements]

1. It is suitable for specimens of human serum, plasma and whole blood; EDTA, heparin sodium and sodium citrate anticoagulant are recommended for plasma/whole blood.

2. Specimens shall be used as soon as possible after collection; if not used immediately, serum/plasma specimens can be stored at 2-8°C for 5 days; if long-term storage is required, they shall be stored at -20°C; and whole blood specimens shall be stored at 2-8°C to avoid hemolysis.

3. Do not use the specimen that contains a large amount of lipids, or any hemolytic or turbid, or the result determination may be affected.

[Test Steps]

Please read the Instructions for the kit carefully before use.

1. Take the test specimen and required reagents out of the storage environment and equilibrate them to room temperature;

2. Unpack the aluminum foil bag, take out the test card, and place it on a horizontal table;

3. 10μL serum,plasma samples or 15μL whole blood samples, add it vertically to the specimen well of the test card, and immediately add 2 drops (about 60μL) or add 60μL of specimen diluent with a pipette;

4. Start timing, and determine the result within 15min.

[Interpretation of Test Results]

1.**Negative result:** if only the C line appears and if the M line and the G line both do not show color development, it means that no 2019-nCoV IgM/IgG antibody is detected and that the result is determined to be negative (as shown in the Figure below).

2. **Positive result:**

a)if both the C line and the M line show color development, it means that a 2019-nCoV IgM antibody is detected and that the result is determined to be IgM positive (as shown in the Figure below).

b) if both the C line and the G line show color development, it means that a 2019-nCoV IgG antibody is detected and that the result is determined to be IgG positive (as shown in the Figure below).

c) if the C line， the M line and the G line all show color development, it means that 2019-nCoV IgM and IgG antibody are both detected and that the result is determined to be IgM positive and IgG positive (as shown in the Figure below).

3. **Invalid result:** if the C line does not appear no matter whether the M/G line shows color development, it means that the test is invalid (as shown in the Figure below).

At this moment, it indicates incorrect operation or deterioration or damage of the test card. Please read the Instructions carefully again and conduct the test again with a new test card. If the problem persists, immediately stop using that batch of products and contact the supplier.

[Limitations of the Test Method]

The test resultshall be determined within 15min after the specimenis added, or the result will be invalid.

[Precautions]

1. This kit is intended for in vitro diagnosis use only.

2.Before use, please equilibrate the specimens and related reagents at room temperature. To prevent the test card from being affected with damp, please use it within 30min after unpacked.

3.Do not use any specimen diluent not matched with this reagent.

4. When adding the specimen with a dropper, discard the first dropor two drops of the specimensolution, and then add the specimen vertically to avoid air bubbles at thespecimen adding end.

2 °C 30°C	Temperature Limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	In vitro diagnostic medical device
	Manufacturer	REF	Catalogue number
Σ n	Contains sufficient for <N> tests		Consult instruction for use
	Do not reuse	CE	

[Contact Information]

Wuhan EasyDiagnosis Biomedicine Co., Ltd
Address: No.A8 2-2 Building, Optics Valley Biomedical Industry Park Phase II, No.858 Gaoxin Road, Wuhan East Lake Hi-tech Development Zone, 430074 Wuhan, China
Tel: +86(0)27-87808955
Fax: +86(0)27-87808005
WEB: www.mdeasydiagnosis.com
Email: easydiagnosis@gmail.com

EC REP **MedNet GmbH**
Borkstrasse 10, 48163 Münster, Germany