Medakit CE

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

REF 303002 1 Test/25 Tests/40 Tests

Intended Use

The Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) developed by Medakit is intended for the qualitative detection of the antibodies of IgM/IgG against novel coronavirus in serum, plasma or whole blood from patients with clinical suspicion of 2019-nCoV infection. The kit is **for *in vitro diagnostic use.***

Introduction

In late 2019, there was an outbreak of 2019-nCoV which was characterized via genome sequencing. The latent period of the the virus infection is from 1 to 14 days, and the average is about 5 days. Some of people who have been affected show no specific symptoms. However, they could be the sources of transmission of the disease to others. Therefore, it is very important to conduct a test early for the infection of the 2019-nCoV.

Polymerase chain reaction (PCR) assays have been developed and used for determining the infection for suspicious patients. PCR has been well accepted and is in widespread use for the detection of the microbiological infection. Unfortunately, the rate of positive is somehow only 30% to 50% in cases with the 2019-nCoV infection. Therefore, the IgM/IgG immunoassay could be a better alternative testing tool.

The antibody of IgM aganist the 2019-nCoV starts to be detectable in about 3-4 days in blood of an infected patient who has a symptom, and the level reaches peaks in 10 - 14 days. The level of the IgM persists but rapidly diminishes over the next 12 weeks before it is no longer clinically detectable. The antibody of IgG starts detectable in 10-14 days after infection, and increases rapidly for the next 7 to 30 days, and decreases slowly for almost a year. The presence of IgM in a single specimen suggests that the patient has currently experienced a 2019-nCoV infection. In most cases the infection probably occurred within the preceding month. The specific IgM might have been producing for a period of 3 months.

Principle of the Assay

The immune colloidal gold technique is used in the assay to detect antibodies of IgM/IgG against the 2019-nCoV. The reagent binding pad is coated with recombinated proteins of the 2019-nCoV and rabbit IgG antibodies labeled with colloidal gold, respectively. A nitrocellulose membrane in test area of a strip is coated with rabbit anti-human IgM and IgG monoclonal antibodies. The quality control area within the nitrocellulose membrane is coated with goat anti-rabbit IgG antibodies. When testing, the antigene protein of the virus forms immuno-complexes with the specific IgM or IgG antibodies against 2019-nCoV in the specimen to be tested. As a result of chromatography, immuno-complexes move along the membrane and will be captured by the mouse anti-human IgM or IgG coated in the test area to form a visible line with red color (T line). The free colloidal gold marker or immune complexes continue to move forward and specifically bind to the goat anti-rabbit antibody coated in the quality control area to form a visible line (C line). If the specimen does not contain the anti-virus antibodies, no test line will show, only quality control line(C line) will appear.

Kit Presentation

Materials Supplied

Test device: There are two different packages with 25 or 40 test cards containing immobilized novel coronavirus antigen proteins and mouse IgG labeled with colloidal gold, respectively, and goat anti-rabbit IgG antibodies as a control. Sample version includes only 1 test card.
Transfer pipet: There are 25 or 40 pieces, respectively.1 in the sample
Specimen diluent buffer: The kit contains 1.5mL x 2 bottles or 3ml x 1 bottle for 25 test package; and 1.5mL x 3 bottles or 4.5mL x 1 bottle for 40 test package. Or 1ml x 1 bottle for the sample version.
Note: The Specimen diluent buffer cannot be used with a mixed lot.

Materials Required But Not Provided

1. Timer
2. Specimen collection container

Storage and Stability

1. Store in a dry place at 2-30 ℃, protected from light. The validity is 18 months.
2. In general, the kit shall be used within 30 minutes after the aluminum foil bag is opened. If the temperature is higher than 30 ℃ or the humidity of the environment is higher than 70%, the kit shall be used as soon as possible after opening of the aluminum foil bag.
3. The date for the manufacturing and the expiration date are printed on the outside of the package.

Precautions

- This test is designed for *in vitro* diagnostic use only.
- For professional use only.
- Material should not be pipetted by mouth.
- Treat all materials as if they were infectious and dispose of all material in complying with local regulation. Liquid waste should be treated with 1% sodium hypochlorite before disposed or treated in complying with the requirements for disposal of infectious materials by local law .
- Liquid solutions in this kit contain sodium azide at a concentration of less than 0.1%, these solutions should be handled with care and when disposed down the drain they should be flushed thoroughly with fresh water.
- Do not use the kit beyond the expiration date.
- The test card is sealed in a protective foil pouch. Do not use if pouch is damaged or open. Remove test card from pouch just prior to use. Do not touch the reaction area of test card.
- Do not use damaged cards. Do not mix components from different lots of the kit.
- Use the disposable pipette, tube and card provided for each specimen testing.
- Do not re-use.

Specimen Collection and Storage

1. Handle all blood and serum as if they are capable of transmitting infectious agents.

2. Optimal performance of the kit depends upon the use of fresh plasma, serum or whole blood samples (clear, non-hemolyzed, non-lipemic, non-icteric). The amount of specimen with a minimum volume of 50 μL is recommended in case of a repeat testing is required. Specimens should be collected aseptically with a venipuncture.

3. Specimens should be stored in a temperature of between 2 ℃ and 8 ℃. if testing will take place within two days. If specimens are to be kept for a longer period, they should be stored at -20 ℃ or colder (except for whole blood). The whole blood specimen is recommended to be tested within 3 days, if it is stored at 2 - 8 ℃ and it should not be frozen. Do not use a frost-free freezer because it may allow the specimens to go through freeze-thaw cycles that will degrade the antibodies within the specimens. Specimens that are improperly stored or are subjected to multiple freeze-thaw cycles may yield erroneous results.

4. The National Committee for Clinical Laboratory Standards (NCCLS) provides recommendations for storing blood specimens (Approved Standard Procedures for the Handling and Processing of Blood Specimens, H18-A. 1990).15. This rule should be followed.

Quality Control

A built-in control for the procedure on the card ensures that the test has been performed correctly. This pink/red colored line should always appear above the printed C line on the card. If a line does not appear in the control region, discard the card as this is an invalid test, and perform the test again.

It is recommended that the positive and negative controls should be run for each new lot of the kit or as required by your laboratory for QA standard operating procedures (SOP). If the controls do not read as expected, repeat the test. Contact your local technical support if the QC results continue to be invalid.

Test Procedure

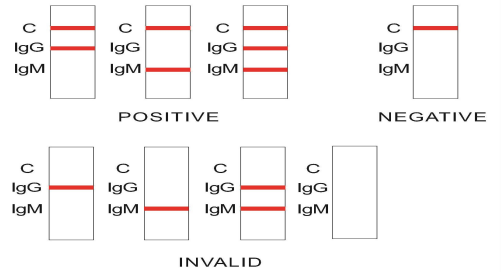
1. Preparing

a) The specimens to be tested and the required reagents shall be removed from the storage condition and be balanced to room temperature;
b) The kit shall be removed from the packaging bag and placed flat on a dry bench.

2. Testing

a) Add specimen
Serum/Plasma: The volume of one drop of the specimen dripping from the dropper we supplied is 10 μL. Take 10 μL of serum or plasma into sample well (S), and then add vertically 2 drops (about 100 μL) of specimen diluent.
Whole blood: The volume of one drop of the specimen dripping from the dropper we supplied is 10 μL. Take 20 μL of whole blood to sample well(S), and then add vertically 2 drops (about 100 μL) of specimen diluent.
b) The positive specimens can be detected within 10 minutes after sample addition. Relevant verification shows that the observation of the test results will be affected if the reaction time were exceed 15 minutes (record time after sample addition), so it is recommended to read and record the test results within 10 minutes.

Interpretation of Results



1. **IgG POSITIVE**: It is positive for IgG antibodies against the 2019-nCoV if two lines appear. One colored line should be in the control line region (C), and another one appears in the IgG test line region.

2. **IgM POSITIVE**: It is positive for IgM antibodies against the 2019-nCoV if two lines appear. One colored line should be in the control line region (C), and another one appears in the IgM test line region.

3. **IgG and IgM POSITIVE**: It is positive for both IgG and IgM antibodies against the 2019-nCoV if three lines appear. One colored line should be in the control line region (C), and another two should appear in IgG test line region and IgM test line region.

NOTE: The intensity of the color in the test line regions will vary depending on the antibodies against the 2019-nCoV presented in the specimen. Therefore, any shade of color in the test line region should be considered positive.

4. **NEGATIVE**: One colored line appears in the control region (C). No apparent colored line appears in the IgG or IgM test region (T).

5. **INVALID**: Control line fails to appear. Insufficient sample volumes or incorrect procedures are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test card. If the problem persists, the test kit should be discontinued of using immediately and your local distributor should be contacted.

Limitations

1. This product is only used for testing of individual serum, plasma or whole blood samples.
2. A negative result does not rule out the possibility of 2019-nCoV infection.
3. A positive result does not mean a current infection with 2019-nCoV, since the IgM could present in the blood for as long as 3 months, and the IgG should appear in the blood for at least 1 year no matter the patient is cured or not.
4. The test results of this product are for clinical reference only and shall not be taken as the sole basis for clinical diagnosis and treatment. The clinical management of patients shall be considered in combination with their symptoms, signs, medical history, other laboratory tests (especially pathogen detection), response to treatment , epidemiology and other information.
5. Serological antibody testing is of limited reference value in patients with impaired immune function or receiving immunosuppressive therapy.
6. Positive IgM antibodies occurs in the blood of patients with not only primary infection but also in secondary infection.
7. The target detection object of this product is the IgM/IgG antibodies aganist the 2019-nCoV. The positive results do not directly reflect the presence of 2019-nCoV in the specimen of the patient.

Performance Characteristics

Sensitivity and Specificity

In order to test the sensitivity and specificity of the Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold), blood samples were collected from COVID-19 patients from four hospitals. The tests were done separately in each site. A total of 753 specimens were tested: 331 positive clinically confirmed patients and 422 negative (non-SARS-CoV-2 infected) patients. For the test, 10 samples were tested negative out of 331 confirmed samples, resulting in sensitivity of 96.98% (95% CI is 94.51% to 98.54%). 3 samples were tested positive out of 442 negative samples, generating a specificity of 99.29% (95% CI is 97.94% to 99.85%). Those results indicate that there is a high consistency between the clinical diagnosis and the test results of novel coronavirus (2019-ncov) IgM/IgG antibody combo test kit (colloidal gold), which is suitable for the diagnosis of novel coronavirus infection.

Cross-reactivity

A series of 63 serum specimens confirmed positive for the different antinuclear antibodies (ANA), rheumatoid factor (RF), and other common viruses, such as Influenza (H1N1, H3N2, H5N1, H7N9, Yamagata, Victoria), RSV, RUB, CMV, HSV, VZV, HIV, EBV, adenovirus, rotavirus, mumps, enterovirus, and measles) , and Legionella were obtained from outside clinical laboratories. All of the specimens were negative for 2019-nCoV antibodies. These specimens were then run in the Medakit IgM/IgG Test Kit for Novel Coronavirus Antibody. The results of this study indicate that the Medakit IgM/IgG Test Kit for Novel Coronavirus (2019-nCoV) Antibody contains no cross-reacting proteins to other common viruses, Legionella, ANA or rheumatoid factor.

References

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6. The seventh edition of Guidance for Diagnosis and Treatment for Novel Coronavirus Pneumonia by National Health Commission of People's Republic of China
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Ordering Information

Catalogue No. 303002

Item: Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)

Specimen: Whole blood/Serum/Plasma

Format: Device

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EC REP

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Guide to Symbols

Caution	Keep away from sunlight
Manufacturer	Batch Code
Consult instructions for use	Do not reuse
Keep Dry	Temperature Limitation (2-30°C)
Catalogue number	In vitro diagnostic medical device
Do not use if package is damaged	Use-by date
European Conformity	Authorised Representative in the European Community
Date when the medical device was manufactured	