2019-nCoV IgG/IgM Detection Kit (Colloidal Gold) Product Insert

Product Name

Generic name: 2019-Novel Coronavirus (2019-nCoV) IgG/IgM Detection Kit (Colloidal Gold)

Packaging Specifications

50 Tests /box

Intended Use

The kit is intended for the qualitative detection of 2019-nCoV IgG/IgM antibodies in human serum, plasma, and whole blood. The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR). The kit is not intended for finger prick testing.

Summary of the test

2019-nCoV is a Betacoronavirus, with enveloped particles of round or oval shape, often pleomorphic, and a diameter of 60-140 nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current studies show that 2019-nCoV shares > 85% genome identity to bat SARS-like coronavirus (bat-SL-CoVZC45), which was identified in Wuhan viral pneumonia cases in 2019. On January 12, 2020, the WHO officially named this virus as Novel Coronavirus (2019-nCoV), and renamed to SARS-CoV-2 on February 11 2020. The disease caused by SARS-CoV-2 is COVID-19.

The common signs of a person with COVID-19 include fever and fatigue. The respiratory symptoms are mainly dry cough with gradually worsening dyspnea. Severe cases are characterized by acute respiratory distress syndrome, septic shock, irreversible metabolic acidosis and coagulation dysfunction. Some patients have mild onset symptoms without fever. Majority of patients have good prognosis, with a few patients developing serious illness and death.

The human body produces IgM and IgG antibodies after virus infection. IgM antibody levels normally start rising within 1 week and reach peak titer within 2-3 weeks after initial infection. IgG antibody appears later than IgM antibody. It usually appears at day 14 after infection, reaches peak titer in the 5th week after infection, and lasts for 6 months or even several years. When IgG titer in the convalescence period of a patient increases or decreases 4 times or more compared with that in the acute period, it has clinical diagnostic significance for virus infection.

Principle

The detection kit uses the principle of solid-phase immunochromatography: the separation of components in a blood sample through a medium by capillary force.

2019-nCoV specific IgM and IgG antibodies in blood samples bind to colloidal gold-labeled viral antigen.

Each cassette is a dry medium that has been coated with a recombinant 2019-nCoV antigen (conjugate pad), mouse anti-human IgM antibody (“IgM” test line), mouse anti-human IgG antibody (“IgG” test line) as well as a reference protein (“C” control line) (Figure 1).

Once the diluted serum/plasma/whole blood is loaded into the sample well, it diffuses upward via capillary force. When it passes through the conjugate pads, the colloidal gold-labeled 2019-nCoV antigens will bind to 2019-nCoV IgM and IgG, forming colloidal gold-labeled antigen-IgM and/or IgG complexes. The complexes continue to flow along the nitrocellulose membrane by capillary force. If 2019 nCoV IgM antibody is present in the sample, the IgM test line will be bound by the mIgM-IgM- colloidal gold-labeled antigen complex thereby generating a red colored line (red IgM line). If there is no 2019 nCoV IgM antibody present in the sample, no colored line is generated. The unbound immune complexes and antibodies continue to flow to the IgG test line, where mouse anti-human IgG antibody binds with 2019 nCoV IgG antibody to form mIgG-IgG- colloidal gold-labeled antigen complex and generating a red colored line (red IgG line). The unbound colloidal gold conjugates continue to flow and are bound by line C (Control line), indicating the reaction is completed.

Main Components

Component Name	Composition
Test Cassette	Aluminum foil bag, desiccant, test strip and PVC plate. The test strip consists of absorbent pad, nitrocellulose membrane, sample pad, colloidal gold marker pad and PVC plate. The nitrocellulose membrane IgM line (IgM Test line) is coated with about 1.0 mg/mL mouse anti-human IgM antibody, the nitrocellulose membrane IgG line (IgG Test line) is coated with about 1.0 mg/mL mouse anti-human IgG antibody, the C line (Control line) is coated with about 1.0 mg/mL reference protein C, and the conjugate pad contains about 40 OD recombinant 2019-nCoV antigen colloidal gold conjugate.
Sample Diluent	HEPES buffer containing casein (0.1 M), 5 mL/bottle.
Pipette Dropper	50 pcs/bag

Note: The components in the kit with different lots cannot be used interchangeably.

Storage Conditions and Validity Period

The kit should be stored at 4-30 °C in its sealed aluminum foil packaging. The validity is for 6 months from the date of manufacturing (refer to packaging for expiration information). Once the individual test cassette is opened (4-30 °C with < 65% humidity), it should be used within 1 hour. Opened Sample Diluent bottle should be used within 1 month.

Specimen Collection and Handling

1. The kit is intended for testing of human serum, plasma, or whole blood specimens.

2. Specimens should be collected by standard protocols.

3. Hemolyzed, or hyperlipidemic blood samples should not be tested.

4. Collect plasma samples using a heparin sodium or EDTA anticoagulant blood tube. Samples should be run on the same day as collection. If not, serum/plasma samples can be stored at 2-8°C for 7 days, or at -20 °C or lower for 24 days. Avoid repeated freezing and thawing of samples. Whole blood samples should be tested immediately.

5. Bring the sample to room temperature (18 °C -28 °C) before processing. Frozen samples should be completely thawed, and mixed well before testing. Avoid repeated freezing and thawing. Specimens containing visible particulate matter should be clarified by centrifugation at 3,000g x 10 min before testing.

Test Procedure

Please read instructions carefully before use.

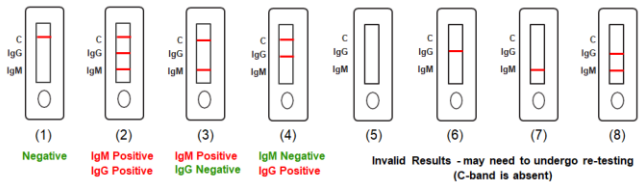
1. Bring the Test Cassette, Sample Diluent, and Sample to room temperature before testing. Conduct test at room temperature.

2. For human serum, plasma or whole blood specimens, add one drop (20 uL) of sample to the sample well of the cassette using a dropper, followed by adding 3 drops of diluent into the same well after opening the yellow cap of the dropper bottle.

3. Read results after 10 minutes. Results read after 15 minutes are invalid.

Interpretation of Test Results

The test results are to be interpreted as the following (Figure 1):



1. Negative for 2019-nCoV: The test lines (IgM and IgG) do not appear, but the quality control line (C) is colored.

2. IgM Positive and IgG Positive for 2019-nCoV: All lines including two test lines (IgM and IgG) and Control line (C) are colored.

3. IgM Positive and IgG Negative for 2019-nCoV: Both the IgM test line and Control line (C) are colored, while IgG test line does not appear.

4. IgM Negative and IgG Positive for 2019-nCoV: Both the IgG test line and Control line (C) are colored, while IgM test line does not appear.

5-8. Invalid: There is no colored Control line (C) that appears. The results are invalid regardless of whether red colored lines appear on either or both of the test lines (IgM and/or IgG); repeat testing is required.

Limitations of Test Methods

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of 2019-nCoV specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.

2. The product test results are for clinical reference only and should not be the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with clinical symptoms/signs, medical history, other laboratory detection, treatment responses, epidemiology and etc. Suspected samples are recommended to be retested at intervals.

3. The accuracy of the test may be affected by sample collection and storage. High temperature and direct sunlight should be avoided.

4. The product provides qualitative, not quantitative detection of 2019-nCoV IgM and IgG antibody. The intensity of the test line does not necessarily correlate to 2019-nCoV antibody titer in the specimen.

5. The product has not been tested with samples positive for SARS-CoV and MERS-CoV antibodies.

6. A negative or non-reactive result can occur if the quantity of antibodies for the 2019-nCoV present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.

7. If symptoms persist and the result from the 2019-nCoV Detection Kit is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.

8. This test should not be used for screening of donated blood.

Product Performance Index

1. Coincidence rate of negative reference controls: The negative reference samples were tested, and the results identify all as negative for 2019-nCoV IgG/IgM antibody with 100% coincidence rate.

2. Coincidence rate of positive reference samples: The positive reference controls were tested. PC01-PC05 were 2019-nCoV IgG/IgM-positive, with a coincidence rate of 100%; PC06-PC10 were 2019-nCoV IgG-negative and IgM-positive, with a coincidence rate 100%; and PC11-PC15 were 2019-nCoV IgG -positive and IgM-negative, with a coincidence rate of 100%.

3. Precision:
Within batch precision: The reproducible reference controls were tested, CV1 and CV2 were 2019-nCoV IgG-positive and IgM-negative; and CV3 and CV4 were 2019-nCoV IgG-negative and IgM-positive. Uniform color was observed.

Batch to batch precision: The reproducibility reference controls were tested, and the results from three different manufacturing lots were compared. CV1 and CV2 were 2019-nCoV IgG-positive and IgM-negative; and CV3 and CV4 were 2019-nCoV IgG-negative and IgM-positive. Uniform color was observed.

4. Clinical performance characteristics:

		Clinical Diagnosis		Total
		Confirmed	Negative	
2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	Positive (+)	184	11	**195**
	Negative (-)	17	358	**375**
Total		**201**	**369**	**570**

This comparison gave the following results:

Sensitivity: 91.54% [95%CI: 86.87%, 94.65%]

Specificity: 97.02% [95%CI: 94.74%, 98.33%]

Total Coincidence Rate: 95.09% [95%CI: 92.99%, 96.58%]

Precautions

1. This product is for *in vitro* diagnosis only.

2. Professionally trained operators are required to carry out the test. Before using the kit, please read the instructions carefully and perform the test in accordance.

3. It is essential to ensure that test laboratories adhere to appropriate biosafety practices.

4. National guidelines on the laboratory biosafety should be followed in all circumstances.

5. Compliance with the Instructions is crucial to the proper operation and usage of this product. Biolidics shall not be liable for any claims in the event that there is any damage or loss caused by the operation or use of the product outside of the Instructions, or which is not due to an act or omission or fault of Biolidics.

References

1. Hui, D. S., I Azhar, E., et al. (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China [J]. International Journal of Infectious Diseases, 91, 264–266.

2. Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4 [J]. Journal of clinical microbiology 42(4): 1564-1569.

3. Smith, A.B., Mock, V., et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

Basic Information

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Medical Device Registration Certificate No. /Product Technical Requirement No.

2019-nCoV IgG/IgM Detection Kit (Colloidal Gold) has received Provisional Authorisation from the Health Sciences Authority in Singapore.

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Production Date and Expiration Date

See the label.

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