



Dynamiker Biotechnology (Tianjin) Co., Ltd.

2019-nCoV IgG/IgM Rapid Test

Catalogue No.: DNK-1419-1

User Manual / 40 tests

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1. INTENDED USE

The 2019-nCoV IgG/IgM Rapid Test is based on rapid immunochromatographic test. It is used for the detection of 2019 Novel Coronavirus (2019-Ncov) IgG and IgM antibody in human whole blood/serum/plasma, offering a diagnostic reference for COVID-19. The kit is intended for professional use only.

2. INTRODUCTION

Coronavirus is a type of single-stranded positive-stranded RNA virus with an envelope. It has a diameter of about 60 to 220 nm and is widely present between humans and other mammals. Most coronavirus infections are mild infections, but there are still two coronavirus outbreaks that have caused serious consequences: severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) [1, 2]. Specifically, the above two coronaviruses have caused more than 10,000 cases in the past two decades; among them, the lethal rate of SARS-CoV is about 10% and the lethal rate of MERS-CoV is about 37% [3, 4].

In December 2019, a series of unexplained pneumonia cases appeared in Wuhan, Hubei, with clinical manifestations very similar to viral pneumonia. On January 7, 2020, the whole genome sequence of the lower respiratory tract sample showed that the pathogen showed a typical coronavirus morphology, and was different from the six coronaviruses (including SARS-CoV and MERS-CoV) previously found. A new coronavirus. Therefore, it was named the new coronavirus 2019 (2019-nCoV) [5]. On February 8, 2020, pneumonia infected with the new coronavirus was temporarily named as new coronavirus pneumonia (referred to as new coronary pneumonia, NCP). As of 24:00 on February 9, 2020, there were 35,982 confirmed cases across the country, a cumulative report of 40,171 confirmed cases, a total of 908 deaths, and 23,589 suspected cases [6]. The virus can be transmitted through respiratory droplets, contact, etc., and has strong human-to-human transmission ability. Its basic regeneration number R_0 is about 2.2 (90% high-density interval 1.4-3.8) [7]. So far, in addition to China, some imported confirmed cases have been found in other countries in Asia, Europe, and the Americas, and reports have been transmitted from person to person. The most common symptoms of the virus infection were fever, cough, myalgia, or fatigue. All patients had pneumonia, and chest CT examinations revealed abnormalities. Some patients have dyspnea after one week, and the disease progresses rapidly in severe cases. Within a few days, acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, and coagulation dysfunction can occur. Overall, severe respiratory diseases caused by the new coronavirus, similar to SARS, have the potential to cause high mortality.



At present, the clinical detection method of new coronary pneumonia is mainly the real-time fluorescent RT-PCR method, but this method still suffers from the problems of low positive rate and high detection environment requirements, and it cannot achieve large-scale screening. Therefore, the "Technical Guide for Laboratory Testing of New Coronavirus Pneumonia (Fourth Edition)" emphasizes the use of nucleic acid testing and serum antibody testing of respiratory samples for the screening and diagnosis of suspected patients with new crowns. At the same time, serum antibody testing has lower laboratory requirements, is convenient and fast, and is suitable for large-scale screening in primary hospitals.

The 2019-nCoV IgG/IgM Rapid Test is a prescription-use laboratory assay that provides aid to the diagnosis of COVID-19.

3. PRINCIPLE

This product uses capture colloidal gold immunochromatography to detect 2019-nCoV protein-specific IgG antibodies and IgM antibodies in human serum/plasma samples. Colloidal gold labeling was used to mark nucleocapsid protein and rabbit IgG antibody. The nucleocapsid protein-colloidal gold complex and rabbit IgG antibody-colloidal gold complex was coated on a colloidal gold pad. The detection line (G line), the detection line (M line) and quality control line (C line) were coated with mouse anti-human IgG (G line), mouse anti-human IgM (M line) and goat anti-rabbit IgG antibody (C line), respectively. If the test sample is positive for the IgG antibody, the 2019- nCoV protein-specific IgG antibody combines with the colloidal gold-labeled nucleocapsid protein to form a complex. The complex moves forward along the strip under the chromatographic action and passes the detection line (G line) and will react with pre-coated mouse anti-human IgG antibody, an immune complex is formed to show a red band. Colloidal gold-labeled rabbit IgG antibody shows a red band in combination with goat anti-rabbit IgG antibody at the control line (C line). If the test sample is positive for IgM antibody, the 2019- nCoV protein-specific IgM antibody combines with colloidal gold-labeled nucleocapsid protein to form a complex, and the complex moves forward along the paper strip under the action of chromatography, passing the detection line (M line) and will react with pre-coated mouse anti-human IgM antibody, an immune complex is formed to show a red band. Colloidal gold-labeled rabbit IgG antibody shows a red band in combination with goat anti-rabbit IgG antibody at the quality control line (C line). If both IgG antibody and IgM antibody are positive in the test sample, the immune complexes will form and red bands will appear when passing through the test line (G line) and test line (M line). The quality control line (C line) should show red band when testing the sample. The red band shown on the quality control line (C) is the standard for judging whether the chromatographic process is normal, and it also serves as the internal control standard for the reagent.

Samples are added into sample pad and test can be achieved within 5-10 minutes.



4. COMPONENTS

Components	Components	Quantity
Test Cassette	Test line (G): coated with mouse anti-human IgG antibodies with proper concentration; Test line (M): coated with mouse anti-human IgM antibodies with proper concentration; Control line (C): coated with goat anti-rabbit IgG antibodies with proper concentration; Conjugate pad: coated with Nucleocapsid protein-colloidal gold complex and rabbit IgG antibody-colloidal gold complex with proper concentration	1 Test cassette/bag, 40 bags/kit
Desiccant	SiO ₂	1 piece/bag, 40 bags/kit
Dilution solution	Protein-containing phosphate buffer	1 × 4mL
Instruction for use	N/A	1 piece

5. STORAGE and EXPIRATION DATE

1. Test should be stored at 2-30°C in dark and dry place for 18 months. DO NOT freeze the test.
2. Test cassette is recommended to be used within 0.5 hour after opening the bag.
3. Refer to the labels to check the production date and expiry date of the kit.

6. MATERIALS NEEDED but NOT SUPPLIED

1. Pipette (10-100uL,)
2. Pipette tips (10-100µL)
3. Timer



7. SAMPLE COLLECTION and PREPARATION

1. Collect samples according to standard laboratory procedures. Avoid cross-contamination among samples. Sample labeling should be clear and correct without mistake.

2. Samples volume should no less than 100µL. Fingertip blood is available.

3. Sample stability and storage

3.1 Sample transportation

Sample transportation should comply with biosafety requirements.

3.2 Sample storage

Samples can be stored at 2-8°C for up to 5 days. For longer storage, store the samples at -20°C for up to 12 months. Maximum 5 repeated freezing and thawing are allowed.

8. TEST PROCEDURE

8.1 Carefully refer to the instruction for use prior to performing the test.

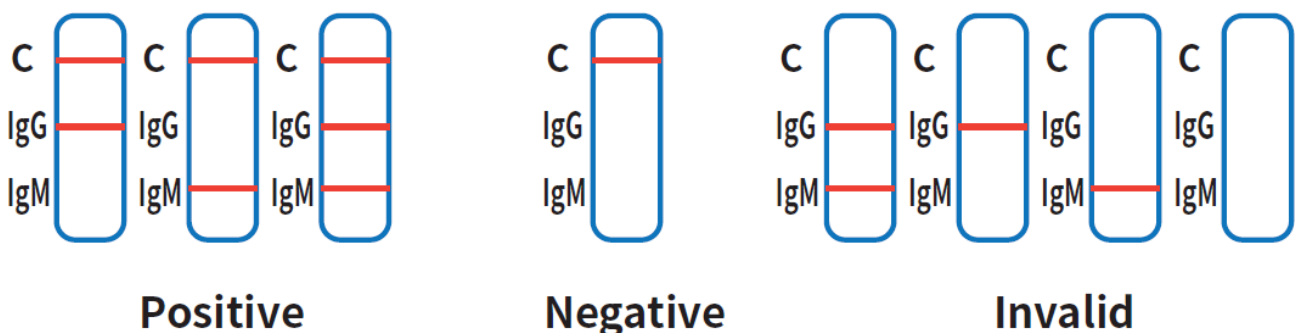
8.2 Take out the kits 30 mins before test, ensure that tests and samples are at room temperature.

8.3 Place test cassettes on flat and clean bench; dispense 10µL of sample and slowly add into sample pad. For whole blood, take 20µL.

8.4 Add 60µL Dilution solution into sample pad.

8.5 Read and record the results after 10 minutes (No longer than 20 minutes). Abnormal results may occur after 20 minutes.

9. INTERPRETATION of RESULTS





IgG Positive (+):	Presence of two red lines, test line (G) and control line (C), indicates 2019-nCOV IgG antibodies present in samples.
IgM Positive (+):	Presence of two red lines, test line (M) and control line (C), indicates 2019-nCOV IgM antibodies present in samples.
IgG+IgM Positive (+):	Presence of three red lines, test line (M), test line (G) and control line (C), indicates 2019-nCOV IgM and IgG antibodies present in samples.
Negative (-):	Appearance of single control line (C), no red test line (G) and no red test line (M), indicates the absence of 2019-nCOV IgM and IgG antibodies present in samples.
Invalid:	No red control line (C) appears. Invalid results may due to incorrect operation or loss of efficacy in tests. Repeat test firstly, if problem remains, stop using products in same lot number and contact with local distributor for support.

10. Clinical performance

A multiple clinical study enrolled 162 positive serum samples from proven COVID-19 patients, and 300 negative samples. Using this kit, 151 cases out of 162 proven samples were positive, with the sensitivity of 93.20%, 286 cases out of 300 clinical excluded samples were negative, with specificity of 95.33%.

11. LIMITATIONS of METHODOLOGY

1. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms / signs, medical history, other laboratory tests, and treatment response.
2. Improper sample collection, transfer, storage, and processing may cause erroneous test results.

12. PRECAUTIONS

1. The product is only for in vitro diagnosis.
2. Inspection of product packing and sealing as well as expiration date is necessary prior to performing the test.
3. Please re-collect samples for test if samples are in severe hemolysis.
4. Tests can be stored at room temperature. Ensure that tests are kept from moisture. Tests stored at low temperature (DO NOT FREEZE) should bring to room temperature



before testing.

5. Test should be performed as quickly as possible. Long-time exposure of test to air and moisture will cause invalid results.

6. Overload of samples may result in unexpected results, such as false positives.

7. Accuracy of test can be affected by environment temperature (<math><10^{\circ}\text{C}</math> or $>40^{\circ}\text{C}$) and relative humidity (>80%).

13. REFERENCE

[1] Thomas G Ksiazek, Dean Erdman, Cynthia S Goldsmith, Sherif R Zaki, Teresa Peret, Shannon Emery, Suxiang Tong, Carlo Urbani, James A Comer, Wilina Lim. A novel coronavirus associated with severe acute respiratory syndrome[J]. New England journal of medicine, 2003,348(20): 1953-1966.

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[6] National Health Committee of the People's Republic of China, Prevention and Control of New Coronavirus Pneumonia Epidemic.

[7] Riou J, Althaus C L. Pattern of early human-to-human transmission of Wuhan 2019-nCoV[J]. bioRxiv, 2020.

13. MANUFACTURER

Company: Dynamiker Biotechnology (Tianjin) Co., Ltd

Address: No. 101-2, 14th Building, Ecological Science Park No. 2018 Zhongtian Avenue, Eco-City TEDA, Tianjin 300467, P. R. China

Post code: 300467

Tel: +86-022-25264212

Fax: +86-022-25264212

Website: www.dynamiker.com











[EC REP]

Company Name: Wellkang Ltd.

Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK

[SYMBOLS USED]

Symbol	Description
	Use By
	Batch Code
	Manufacturer
	Keep Away from Sunlight
	Temperature Limitation
	In Vitro Diagnostic Medical Device
	Authorized Representative in the European Community
	CE Mark