Dynamiker Biotechnology (Tianjin) Co., Ltd.

2019-nCoV IgG/IgM Rapid Test

Catalogue No: DNK-1419-1

User Manual / 40 tests

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 an adjunctive 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. Coronaviruses cause diseases with symptoms ranging from those of a mild common cold to more severe ones such as Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

The incubation period for COVID-19 ranges from 2 – 14 days following exposure, with most cases showing symptoms approximately 4 – 5 days after exposure. The most common symptoms of the virus infection were fever, cough, myalgia, or fatigue.

Definitive COVID-19 diagnosis entails direct SARS-CoV-2 detection by nucleic acid amplification technology (NAAT). Serological assays can contribute to the identification of individuals exposed to the virus and assess the extent of exposure of a population, and might thereby help to decide on application, enforcement, or relaxation of containment measures.

3. PRINCIPLE

This product uses capture colloidal gold immunochromatography to detect 2019-nCoV protein-specific IgG antibodies and IgM antibodies in human whole blood, serum and plasma samples. Colloidal gold labeling was used to mark nucleocapsid protein, spike protein and rabbit IgG antibody. The antigen-colloidal gold complex and rabbit IgG antibody-colloidal gold complex was coated on a colloidal gold pad. The detection line (IgG), the detection line (IgM) and control line (C) were coated with mouse anti-human IgG (IgG), mouse anti-human IgM (IgM) and goat anti-rabbit IgG antibody (IgG), respectively. If the test sample is positive for the IgG antibody, the 2019-nCoV protein-specific IgG antibody combines with the colloidal gold-labeled antigen to form a complex. The complex moves forward along the strip under the chromatographic action and passes the detection line (IgG) 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). If the test sample is positive for IgM antibody, the 2019-nCoV protein-specific IgM antibody combines with colloidal gold-labeled antigen to form a complex, and the complex moves forward along the paper strip under the action of chromatography, passing the detection line (IgM) 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 control line (C). 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 (IgG) and test line (IgM). The control line (C) should show red band when testing the sample. The red band shown on the 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.

4. COMPONENTS

Components	Components	Quantity
Test Cassette	Test line (IgG): coated with mouse anti-human IgG antibodies with proper concentration; Test line (IgM): 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 antigen-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

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

6. MATERIALS NEEDED but NOT SUPPLIED

- Pipette (10-100μL)
- Pipette tips (10-100μL)
- Timer

7. SAMPLE COLLECTION and PREPARATION

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

7.2 Serum/plasma needs 10μL, whole blood needs 20μL.

7.3 Sample stability and storage.

7.3.1 Sample transportation.

Sample transportation should comply with biosafety requirements.

7.3.2 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;

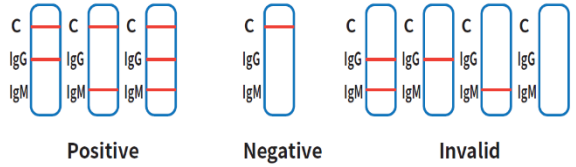
8.2 Take out the kits 30 mins before test, ensure that tests and samples are at room temperature;

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

8.4 Add 60μL (Two drops) 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 (IgG) and control line (C), indicates 2019-nCoV IgG antibodies present in samples.

IgM Positive (+): Presence of two red lines, test line (IgM) and control line (C), indicates 2019-nCoV IgM antibodies present in samples.

IgG+IgM Positive (+): Presence of three red lines, test line (IgM), test line (IgG) 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 (IgG) and no red test line (IgM), indicates the absence of 2019-nCoV IgM and IgG antibodies present in samples.

Invalid: No red control line (C) appears. Invalid results may be 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.Product Performance

10.1 Conformance rate of negative reference

For testing 15 negative reference products in the internal reference products of the enterprise, the coincidence rate should be 15/15.

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10.2 Conformance rate of positive reference

For testing 10 positive reference products in the internal reference products of the enterprise, the coincidence rate should be 10/10.

10.3 Minimum detection limit

Detect the 4 minimum detection limit reference products L1-L4 among the internal reference products of the enterprise, L1 should be negative, L2, L3 and L4 should be positive.

10.4 Repeatability

Take the same batch of reagents and repeat the determination of the repeatable reference products S1, S2, S3, and S4 in the company's internal reference products 10 times each. S1, S2, and S3 are positive and the color rendering is uniform, and S4 is negative.

10.5 Difference between batches

Take three batches of reagents and repeat the determination of the repetitive reference products in the internal reference products of the enterprise for 10 times each, all of them should be positive, and the color rendering is uniform.

10.6 Analysis specificity

a.The following samples were tested and exhibited no cross-reactivity: endemic human coronavirus (HKU1, OC43, NL63 and 229E), influenza virus (new type A H1N1, seasonal H1N1, H3N2, H5N1, H7N9), influenza B virus (Yamagata, Victoria), rhinovirus A, B, C), human cytomegalovirus, norovirus, mumps virus, varicella-zoster virus, measles virus (MAE), enterovirus (group A, B, C, D), respiratory syncytial Virus, Epstein-Barr virus, adenovirus (types 1, 2, 3, 4, 5, 7, 55), rotavirus, measles virus, Mycoplasma pneumoniae antibody, high concentration of novel coronavirus IgM antibody and high concentration of novel coronavirus IgG antibody samples.

b.Cross-reactivity to SARS virus antibodies has not been verified. The N protein sequence identity of SARS-CoV and 2019-nCoV is as high as 94%, which may cross-react with SARS virus antibodies.

c.Hemoglobin (≤7mg/mL), bilirubin (≤300mg/L), triglyceride (≤7.5mmoL/L) did not interfere with the test results.

d.Rheumatoid factor, antinuclear antibody, anti-double-stranded DNA antibody, anti-mitochondrial antibody, HAMA positive, high-concentration novel coronavirus IgM antibody samples and high-concentration novel coronavirus IgG antibodies, human total IgG antibodies (≤50 g/L) Human total IgM antibody (≤10 g/L) did not interfere with the test results.

e.Alpha-interferon, zanamivir, ribavirin, oseltamivir, paramivir, lopinavir, ritonavir, abidor, levofloxacin, azithromycin, ceftriaxone, Meropenem, tobramycin, and histamine hydrochloride did not interfere with the test results.

10.7 Clinical performance

By using clinically confirmed and excluded samples, the clinical sensitivity and specificity of 2019-nCoV IgG/IgM Rapid Test were analyzed. From the clinical evaluation results, the clinical sensitivity of this product for IgG antibody detection is 89.19%, the clinical specificity is 96.26%, and the total accuracy rate is 93.37%. The clinical sensitivity for IgM antibody detection was 87.83%, the clinical specificity was 95.32%, and the overall accuracy rate was 92.26%. The clinical sensitivity of the combined detection of IgG / IgM antibody was 93.24%, the clinical specificity was 94.39%, and the overall accuracy rate was 93.92%. After preliminary evaluation, it is basically confirmed that the clinical performance of this product can meet the needs of the epidemic.

11.LIMITATIONS of METHODOLOGY

- 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.
- Improper sample collection, transfer, storage, and processing may cause erroneous test results.

12.PRECAUTIONS

- The product is only for in vitro diagnosis.
- Please strictly follow the instructions for the intended use and operation for testing, otherwise it may produce unexpected results, and the manufacturer does not take related responsibilities.
- Inspection of product packing and sealing as well as expiration date is necessary prior to performing the test.
- Please re-collect samples for test if samples are in severe hemolysis.
- 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.
- Test should be performed as quickly as possible. Long-time exposure of test to air and moisture will cause invalid results.
- Overload of samples may result in unexpected results, such as false positives.
- Accuracy of test can be affected by environment temperature (<10°C or >40°C) and relative humidity (>80%).

13.MANUFACTURER

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[SYMBOLS USED]

Symbol	Description
	Expiry
LOT	Lot Number
	Manufacture Date
	Manufacturer
	Keep Away from Sunlight
2°C 30°C	Temperature Limitation
IVD	In Vitro Diagnostic Medical Device
	Do not Re-use
EC REP	Authorized Representative in the European Community
CE	CE Mark

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