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 qualitative detection of 2019 Novel Coronavirus (also known as SARS-CoV-2) IgG and IgM antibody in human whole blood (Sodium citrate, EDTA, Sodium heparin) /serum/plasma (Sodium citrate, EDTA, Sodium heparin). The 2019-nCoV IgG/IgM Rapid Test is intended for use as an aid in identifying individuals with antibodies against SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist after infection and if the presence of antibodies confers protective immunity. The 2019-nCoV IgG/IgM Rapid Test should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to trained laboratory professionals use.

Results are for the detection of SARS-CoV-2 antibodies. The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies present post-infection is not well characterized.

The sensitivity of 2019-nCoV IgG/IgM Rapid Test early after infection is unknown. Negative results do not exclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for 2019-nCoV IgG/IgM Rapid Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay.

2. INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

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 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 nucleocapsid + spike protein mixture 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;

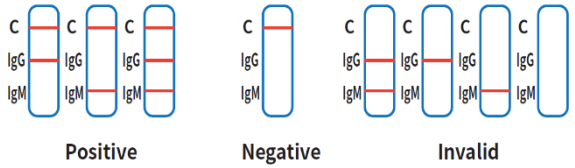
8.2 Take out the kits 30 mins before test, ensure that tests and samples are at room temperature;

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 Cross-reactivity

Cross-reactivity of the Dynamiker 2019n-CoV IgM/IgG Rapid Test was evaluated in two studies using a total of 130 serum or plasma samples which contain antibodies to the pathogens listed below. All 130 specimens were negative by the Dynamiker 2019n-CoV IgM/IgG Rapid Test. The data are summarized in the following table:

Sample Category	Number of samples	Dynamiker 2019-nCoV IgM/IgG Rapid Test Result					
		IgM			IgG		
		Pos	Neg	%CR	Pos	Neg	%CR
Anti-Flu A (IgG and IgM)	5	0	5	0%	0	5	0%
Anti-Flu B (IgG and IgM)	5	0	5	0%	0	5	0%
Anti-HCV (IgG and IgM)	5	0	5	0%	0	5	0%
Anti-HBV (IgG and IgM)	5	0	5	0%	0	5	0%
ANA	5	0	5	0%	0	5	0%
Anti-respiratory syncytial virus (IgG and IgM)	5	0	5	0%	0	5	0%
Anti-rhinovirus (IgG and IgM)	5	0	5	0%	0	5	0%
Anti-Haemophilus influenzae (IgG and IgM)	5	0	5	0%	0	5	0%

Anti-OC43 (beta coronavirus)	5	0	5	0%	0	5	0%

Type of specimens (positive)	Number of samples	Dynamiker 2019-nCoV IgM/IgG Rapid Test Result	
		Total IgM Negative	Total IgG Negative
Human Coronavirus HKU1	5	5	5
Human Coronavirus OC43	5	5	5
Human Coronavirus NL63	5	5	5
Human Coronavirus 229E	5	5	5
Influenza A virus	5	5	5
Influenza B virus	5	5	5
PIV	5	5	5
RhV	5	5	5
hMPV	5	5	5
Haemophilus influenzae	5	5	5
RSV	5	5	5
EBV	5	5	5
Adenovirus	5	5	5
Dengue virus	5	5	5
HIV	5	5	5
Plasmodium falciparum	5	5	5
Plasmodium ovale	5	5	5

10.2 Clinical performance

One hundred thirty-four serum specimens were evaluated by the 2019-nCOV IgG/IgM Rapid Test in Institute for Allergy and Asthma (IAA) Clinical Laboratory (Maryland, USA). Among these, 60 were from COVID-19 patients with positive real-time PCR diagnosis for SARS-CoV-2 viral infection, and 26 were from subjects with negative real-time PCR results. The 48 subjects without PCR testing had no obvious clinical presentations of COVID-19.

Summary of clinical evaluation results

Cases		PCR Comparator Method/Clinical Truth	
		Positive	Negative
2019-nCOV IgG/IgM Rapid Test	Positive	54	0
	Negative	6	74

Summary of clinical performance

Performance	Results	95% CI
PPA	90%	82.4%-97.6%
NPA	100%	100%-100%

PPA: Positive Percent Agreement

NPA: Negative Percent Agreement

Independent Clinical Validation

The 2019-nCOV IgG/IgM Rapid Test was validated in Clinical Department of Laboratory Medicine and National Reference Centre for Respiratory Pathogens, University Hospitals Leuven, Leuven, Belgium. A total of 153 PCR positive samples and 103 PCR negative samples were evaluated with this kit.

Summary of clinical performance

Days from onset of symptoms	**Samples numbers**	**Dynamiker-IgM (95% CI)**	**Dynamiker-IgG (95% CI)**	**Dynamiker-IgG or IgM (95% CI)**	**Dynamiker-IgG and IgM (95% CI)**
PPA	153	69.3% (61.6%-76.1%)	61.4% (53.5%-68.8%)	69.3% (61.6%-76.1%)	61.4% (53.5%-68.8%)
Day 0-6	37	46.0% (31.0%-61.6%)	27.0% (15.2%-43.1%)	46.0% (31.0%-61.6%)	27.0% (15.2%-43.1%)
Day 7-13	78	66.7% (55.6%-76.2%)	61.5% (50.4%-71.6%)	66.7% (55.6%-76.2%)	61.5% (50.4%-71.6%)
Day 14-25	38	97.4% (85.3%-100%)	94.7% (81.8%-99.5%)	97.4% (85.3%-100%)	94.7% (81.8%-99.5%)
NPA	103	95.1% (88.9%-98.2%)	99.0% (94.2%-100%)	95.2% (88.9%-98.2%)	99.0% (94.2%-100%)

11.LIMITATIONS of METHODOLOGY

- The 2019-nCOV IgG/IgM Rapid Test will only indicate the presence of SARS-CoV-2 antibodies in the specimen and should not be used for the diagnosis of SARS-CoV-2.
- In the early onset of symptom, anti-SARS-Cov-2 IgM and IgG antibody concentrations may be below detectable levels.
- A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Results from antibody testing should not be used to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Use of the 2019-nCOV IgG/IgM Rapid Test is limited to laboratory personnel who have been trained. Not for home use.
- The 2019-nCOV IgG/IgM Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antibodies in whole blood, serum or plasma specimens only. Neither quantitative value nor the rate of increase in SARS-CoV-2 antibody concentration can be determined by this qualitative test.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

12.PRECAUTIONS

- The product is only for in vitro diagnosis.
- Please strictly follow the instructions for the intended use and operation for testing.
- 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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EC REP

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[SYMBOLS USED]

Symbol	Description
	Use-by date
LOT	Lot Number
	Manufacture Date
	Manufacturer
	Keep Away from Sunlight
2℃ 30℃	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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