2019-nCoV IgG/IgM Rapid Test

Rapid immunochromatographic test

for detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimens.

For professional in vitro diagnostic use only.

Cat. no. **1-363-K025** cassettes: 25 pcs

CE

INTENDED USE

The 2019-nCoV IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimen.

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 novel coronavirus. Therefore, it was named the 2019 nCoV [5]. On February 8, 2020, pneumonia caused by the novel coronavirus was temporarily named as 2019 nCoV pneumonia (referred to as novel coronavirus coronary pneumonia, NCP). As of 24:00 on February 9, 2020, there were 35,982 confirmed cases across the country, 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 R0 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 human to human transmission. 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 2019 nCoV, similar to SARS, have the potential to cause high mortality.

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 (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 nucleocapsid protein 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 nucleocapsid protein 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.

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

REAGENTS

The test contains mouse anti-human IgM, mouse anti-human IgG antibodies and Nucleocapsid protein colloidal gold complex and rabbit IgG antibody colloidal gold complex. A goat anti-rabbit IgG is employed in the control line system.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
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 (<10°C or >40°C) and relative humidity (>80%).

STORAGE AND STABILITY

- Test should be stored at 2-30°C in dark and dry place for 18 months.

BioMaxima S.A., ul. Vetterów 5, 20-277 Lublin, Poland
tel.: +48 81 745 51 40; fax: +48 81 744 29 15; e-mail: info@biomaxima.com

1-363-K/ENG/2020-04-23

DO NOT freeze the test;

- Test cassette is recommended to be used within 0.5 hour after opening the bag;
- Refer to the labels to check the production date and expiry date of the kit.

SPECIMEN COLLECTION AND PREPARATION

The 2019-nCoV IgG/IgM Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

Fingerstick Whole Blood Specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:Touch the end of the capillary tube to the blood until filled to approximately 20µL. Avoid air bubbles.
- Testing should be performed immediately.

Venipuncture Whole Blood Specimens:

- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

Serum or Plasma Specimens:

- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 5 days, for long term storage, serum/plasma specimens should be kept below -20°C for up to 12 months. Maximum 5 repeated freezing and thawing are allowed.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

• If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
• Heparin, EDTA, sodium citrate can be used as the anticoagulant for collecting the specimen.

MATERIALS PROVIDED:

- Test cassettes
- Droppers/ Capillary tubes
- Package insert
- Buffer

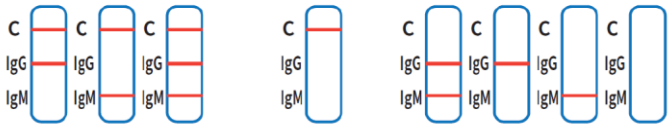
MATERIALS REQUIRED BUT NOT PROVIDED:

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

TEST PROCEDURE

1. Carefully refer to the instruction for use prior to performing the test;
2. Take out the kits 30 mins before test, ensure that tests and samples are at room temperature;
3. Place test cassettes on flat and clean bench; dispense 10µL of serum/plasma sample and slowly add into sample pad. For whole blood and fingerstick blood, take 20µL (One drop);
4. Add 60µL (Two drops) Dilution solution into sample pad;
5. Read and record the results after 10 minutes (No longer than 20 minutes). Abnormal results may occur after 20 minutes.

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 (IgM) and control line (C), indicates 2019-nCOV IgM antibodies present in samples.
IgG and 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 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.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

By using clinically confirmed and excluded samples, the diagnostic sensitivity and diagnostic specificity of 2019-nCOV IgG / IgM Rapid Test

BioMaxima S.A., ul. Vetterów 5, 20-277 Lublin, Poland
tel.: +48 81 745 51 40; fax: +48 81 744 29 15; e-mail: info@biomaxima.com

1-363-K/ENG/2020-04-23

were analyzed.

Comparative analysis of IgG antibody test results and clinical diagnosis results:

Method		Clinical diagnosis results		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	66 (A)	4 (B)	70
	Negative	8 (C)	103 (D)	111
Total Result		74	107	181

Diagnostic sensitivity (positive coincidence rate)
A/(A+C)×100% ＝89,19%
Diagnostic specificity (negative coincidence rate)
D/(B+D) 96,26 %
Total coincidence rate
(A+D)/(A+B+C+D) 93,37%

Comparative analysis of IgM antibody test results and clinical diagnosis results:

Method		Clinical diagnosis results		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	**Positive**	**Negative**	
	Positive	65 (A)	5 (B)	70
	Negative	9 (C)	102 (D)	111
Total Result		74	107	181

Diagnostic sensitivity (positive coincidence rate)
A/(A+C)×100% ＝87,83%
Diagnostic specificity (negative coincidence rate)
D/(B+D) 95,32 %
Total coincidence rate
(A+D)/(A+B+C+D) 92,26%

Cross-reactivity

The 2019-nCoV IgG/IgM Rapid Test has been tested:
a. For 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 reaction;
b. Cross reaction 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;
The results showed no cross-reactivity.

BIBLIOGRAPHY

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.
2. Raoul J de Groot, Susan C Baker, Ralph S Baric, Caroline S Brown, Christian Drosten, Luis Enjuanes, Ron AM Fouchier, Monica Galiano, Alexander E Gorbalenya, Ziad A Memish. Middle East Respiratory Syndrome Coronavirus (MERS CoV): Announcement of the Coronavirus Study Group[J]. Journal of Virology, 2013,87(14): 7790 7792.
3. WHO. Summary of probable SARS cases with onset of illness from 1 November 2002 to 31 July 2003. Dec 31, 2003.
4. WHO. Middle East respiratory syndrome coronavirus (MERS CoV). November, 2019.
5. Chaolin Huang, Yeming Wang, Xingwang Li, Lili Ren, Jianping Zhao, Yi Hu, Li Zhang, Guohui Fan, Jiuyang Xu, Xiaoying Gu, Zhenshun Cheng, Ting Yu, Jiaan Xia, Yuan Wei, Wenjuan Wu, Xuelei Xie, Wen Yin, Hui Li, Min Liu, Yan Xiao, Hong Gao, Li Guo, Jungang Xie, Guangfa Wang, Rongmeng Jiang, Zhancheng Gao, Qi Jin, Jianwei Wang, Bin Cao. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China[J]. The Lancet, 2020.
6. National Health Committee of the People's Republic of China, Prevention and Control of Novel Coronavirus Pneumonia Epidemic.
7. Riou J, Althaus C L. Pattern of early human to human transmission of Wuhan 2019 nCoV[J]. bioRxiv, 2020.

GRAPHICAL SYMBOLS USED:

IVD	For in vitro diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by	2	Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog number
	Manufacturer		Consult Instructions For Use		Keep away from sunlight

BioMaxima S.A., ul. Vetterów 5, 20-277 Lublin, Poland
tel.: +48 81 745 51 40; fax: +48 81 744 29 15; e-mail: info@biomaxima.com

1-363-K/ENG/2020-04-23