

HIGHTOP

SARS-CoV-2 IgM/IgG Antibody Rapid Test (Immunochromatography)

IVD FOR PROFESSIONAL USE ONLY

PRODUCT NAME

SARS-CoV-2 IgM/IgG Antibody Rapid Test (Immunochromatography)

INTENDED USE

The kit is used to detect the IgM and IgG antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human serum, plasma or whole blood sample qualitatively. It is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

TEST PRINCIPLE

This kit is an immunochromatographic assay, using capture method for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgM/IgG antibody in human serum, plasma or whole blood sample.

When the sample contains the SARS-CoV-2 IgM antibody, it forms a complex with the gold label antigen (SARS-CoV-2 recombinant antigen). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgM monoclonal antibody) at the T2 line to form a complex and develop color (T2 line), which indicates a positive result. When the sample does not contain the SARS-CoV-2 IgM antibody, no complex can be formed at the T2 line, and no red band appears, which indicates a negative result.

When the sample contains the SARS-CoV-2 IgG antibody, it forms a complex with the gold label antigen (SARS-CoV-2 recombinant antigen). The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgG monoclonal antibody) at the T1 line to form a complex and develop color (T1 line), which indicates a positive result. When the sample does not contain the SARS-CoV-2 IgG antibody, no complex can be formed at the T1 line, and no red band appears, which indicates a negative result.

Regardless of whether the SARS-CoV-2 IgM and/or IgG antibody is contained in the sample, the gold label quality control antibody (Biotinylated BSA) will bind with the coated antibody at the C line to form a complex and develop color (C line).

MAIN COMPONENTS

T1-line coated with mouse anti-human IgG monoclonal antibody, T2-line coated with mouse anti-human IgM monoclonal antibody, gold label pad solid phase SARS-CoV-2 recombinant antigen, Biotinylated BSA, C-line coated with streptavidin-conjugated IgG.

Sample dilution: composed of 20 mM phosphate buffer solution (PBS)

Disposable plastic straws are optional.

MATERIAL NEEDED BUT NOT PROVIDED

1. Specimen Collection Containers
2. Centrifuge (for serum/plasma sample)
3. Timer
4. Personal protective equipment, such as a protective gloves, medical mask, goggles and lab coat.

5. Appropriate biohazard waste container and disinfectants.

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity ≤ 60%, Temp: 20°C-30°C). Please use immediately when the humidity > 60%.

SAMPLE REQUIREMENT

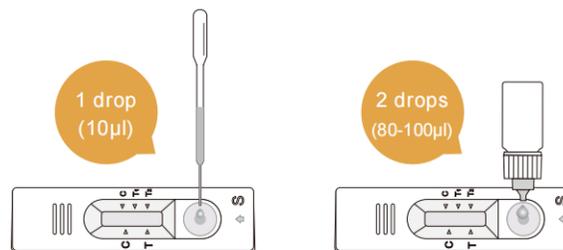
1. The reagent can be used for the serum, plasma and whole blood samples.
2. A serum / plasma / whole blood sample must be collected in a clean and dry container. EDTA, sodium citrate, heparin can be used as anticoagulants in plasma / whole blood samples. Detect immediately after collecting blood.
3. Serum and plasma samples may be stored at 2-8°C for 7 days prior to assay. If testing is delayed more than 7 days, the sample should be frozen (-20°C or colder). Repeat freeze and thaw for no more than 3 times. Whole blood samples with anticoagulant can be stored at 2-8°C for 3 days, and should not be frozen; whole blood samples without anticoagulant should be used immediately (if the sample has agglutination, it can be detected by serum).

TEST METHODS

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity ≤ 60%, Temp: 20°C-30°C). Please use immediately when the humidity > 60%.

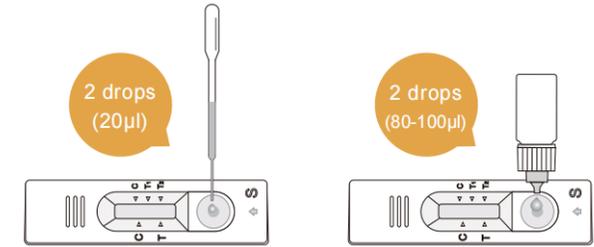
For Serum/Plasma

1. Remove the test device from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add one (1) full drop of serum or plasma (10µl) vertically into the sample well.
3. Add two (2) drops (80-100µl) of sample buffer into the sample well
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



For Whole Blood

1. Remove the test cassette from the sealed pouch, place it on a clean and level surface with the sample well up.
2. Add two (2) full drops of whole blood (20µl) vertically into the sample well.
3. Add two (2) drops (80-100µl) of sample buffer into the sample well.
4. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



INTERPRETATION OF RESULTS

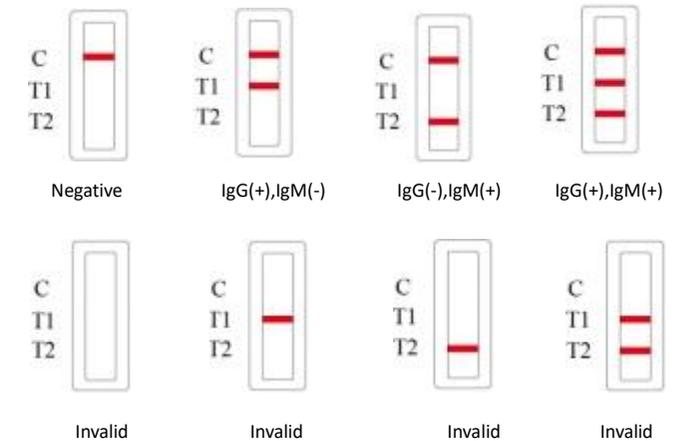
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T1 test region (T1), indicating the IgG positive.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T2 test region (T2), indicating the IgM positive.

POSITIVE: Three distinct red lines appear. One line should be in the control region (C), the T1 test region (T1) and the T2 test region (T2), indicating the IgG and IgM positive.

NEGATIVE: One red line appears in the control region (C). No red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of SARS-CoV-2 IgM/IgG antibody cannot be determined by this qualitative test. The depth of the T-line color is not necessarily related to the concentration of the antibody in the sample.
2. The results of the reagent are only for clinical reference, which is not the only

basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

To estimate the positive percent agreement (PPA), between the assessment reagent and the PCR comparator, 205 serum were collected from subjects who tested positive for SARS-CoV-2 by a polymerase chain reaction (PCR) method and who also presented with COVID-19 symptoms. Each specimen was tested using the assessment reagent and PCR reagent.

To estimate the negative percent agreement (NPA), 645 serum specimens from subjects assumed to be negative for SARS-CoV-2 were tested. Of the 645 specimens, 300 specimens were collected prior to October 2019 (pre-COVID-19 outbreak) and an additional 345 specimens were collected in 2020 from subjects who were exhibiting signs of respiratory illness but tested negative for SARS-CoV-2 by a PCR method. All 645 specimens were tested using the SARS-CoV-2 IgM/IgG assay.

The results are shown below:

Positive Agreement

Sample type	# PCR Positive at any time	Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test		
		#Positive Results	PPA	95%CI
Serum	205	193	94.15%	90.05%-96.62%

Negative Agreement by Category

Category	n	Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test		
		#Negative Results	NPA	95%CI
Pre-COVID-19 Outbreak	300	298	99.33%	97.60%~99.82%
Other Respiratory Illness	345	324	93.91%	90.87%~95.98%
Total	645	622	96.43%	94.71%~97.61%

2. Cross-reactivity

Specimens which tested positive with following various agents from patients were investigated with SARS-CoV-2 IgM/IgG Antibody Rapid Test. The results showed no cross reactivity.

Name	Results
Human coronavirus 229E	Negative
Human coronavirus OC43	Negative
Human coronavirus HKU1	Negative
Human coronavirus NL63	Negative
MERS-coronavirus	Negative
Adenovirus IgM Ab	Negative
Adenovirus IgG Ab	Negative
Human Metapneumovirus(hMPV)	Negative
Parainfluenza virus IgG	Negative
Parainfluenza virus IgM	Negative
Influenza A IgM Ab	Negative
Influenza B IgM Ab	Negative

Haemophilus influenzae	Negative
Rhinovirus	Negative
Respiratory Syncytial virus IgM Ab	Negative
Respiratory Syncytial virus IgG Ab	Negative
Epstein-Barr virus IgM Ab (infectious mononucleosis)	Negative
Epstein-Barr virus IgG Ab	Negative
Human Immunodeficiency virus(HIV)	Negative
Plasmodium falciparum	Negative
Plasmodium ovale	Negative
Dengue virus (type 1-4)	Negative
Mycoplasma pneumoniae IgM Ab	Negative
Mycoplasma pneumoniae IgG Ab	Negative
Chlamydia pneumoniae IgM Ab	Negative
Chlamydia pneumoniae IgG Ab	Negative
Parainfluenza IgM Ab	Negative
Parainfluenza IgG Ab	Negative
Enterovirus IgM Ab	Negative
Enterovirus IgG Ab	Negative
Legionella pneumophila IgM Ab	Negative
Mycobacterium tuberculosis IgG Ab	Negative
Streptococcus pneumoniae	Negative
Streptococcus pyrogenes	Negative
Bordetella pertussis IgM Ab	Negative
Bordetella pertussis IgG Ab	Negative
Pneumocystis jirovecii (PJP)	Negative

3. Interferences

The test result of SARS-CoV-2 IgM/IgG Antibody Rapid Test do not be interfered with the substance at the following concentration:

Name	Concentration	Results
Haemoglobin	≤ 10g/L	Negative
Bilirubin Conjugated	≤ 1000μmol/L	Negative
Bilirubin Unconjugated	≤ 1000μmol/L	Negative
Human Serum Albumin	≤ 10g/dL	Negative
Triglycerides	≤ 6mmol/L	Negative
Cholesterol	≤ 10mmol/L	Negative
Antibodies against E. coli	/	Negative
Human anti-mouse antibody (HAMA)	/	Negative
Rheumatoid Factor	/	Negative
ANA anti-nuclear antibodies	/	Negative
Anti-mitochondrial antibody	/	Negative

4. Hook Effect

No hook effect was observed in high concentration SARS-CoV-2 IgG samples with dilution of 1:1024.

No hook effect was observed in high concentration SARS-CoV-2 IgM samples

with dilution of 1:256.

ATTENTIONS

1. For IN VITRO diagnostic use only.
2. Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.
3. The test device should remain in the sealed pouches until use. If sealing problem happens, do not test. Don't use after the expiration date.
4. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

BIBLIOGRAPHY

- [1] Yinghui Jin, Lin Cai, Zhenshun Cheng, et al. A rapid advice guideline for the diagnosis and treatment of 2019 novel coronavirus (2019-nCoV) infected pneumonia (standard version). Med J Chin PLA, 2020, (1), 1-20.
- [2] Chen Wang, Peter W Horby, Frederick G Hayden, George F Gao. (2020). A novel coronavirus outbreak of global health concern. The Lancet, 395(10223), 470-473.
- [3] Na Zhu, Ph.D., Dingyu Zhang, M.D., Wenling Wang, Ph.D., et al. (2020). A Novel Coronavirus from Patients with Pneumonia in China, 2019. The New England Journal of Medicine.
- [4] World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020.

MANUFACTURER / POST-SALE SERVICE UNIT

Qingdao Hightop Biotech Co., Ltd.

Add.: No.369 Hedong Road, Hi-tech Industrial Development Zone, Qingdao, Shandong, 266112, China

Tel: 0086-532-58710705

Fax: 0086-532-58710706

Web: www.hightopbio.com

E-mail: sales@hightopbio.com

EUROPEAN REPRESENTATIVE

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany



INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
	Temperature limit		Batch code
	For single use		In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date		Contains sufficient for <n> tests
	European representative		Keep away from sunlight

IFU- SARS-CoV-2 IgM/IgG, 2021-05, A/2, English