

HIGHTOP

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

FOR PROFESSIONAL USE ONLY

PRODUCT NAME

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

INTENDED USE

The kit is used to detect the IgM antibody 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.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

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 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 T line to form a complex and develop color (T line), which is a positive result. When the sample does not contain the SARS-CoV-2 IgM antibody, no complex can be formed at the T line, and no red band appears, which is a negative result.

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

MAIN COMPONENTS

Cassette: T-line coated with mouse anti-human IgM monoclonal antibody, gold label pad solid phase SARS-CoV-2 recombinant antigen, rabbit IgG antibody, C-line coated with goat anti-rabbit IgG antibody.

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

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 12 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.

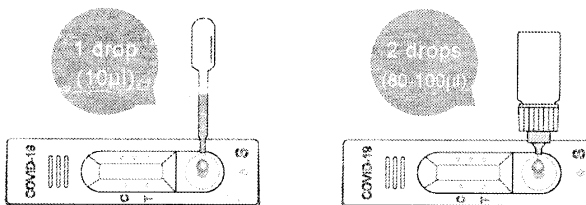
3. Serum and plasma samples may be stored at 2-8°C for 3 days prior to assay. If testing is delayed more than 3 days, the sample should be frozen (-20°C or colder). Repeat freeze and thaw for no more than 3 times. Whole blood samples with anticoagulant can be stored at 2-8°C for 3 days, and should not 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%.

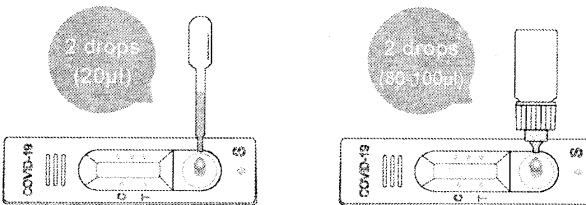
For Serum/Plasma

1. Remove the test cassette 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.



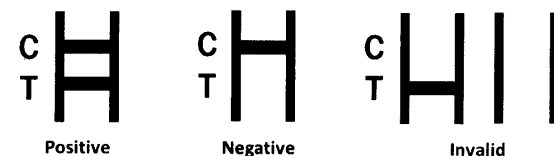
INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. One line should be in the control

region (C) and the other line should be in the test region (T).

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.



LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of SARS-CoV-2 IgM 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

SARS-CoV-2 IgM Ab Rapid Test	PCR Test		Total
	Positive	Negative	
Positive	246	40	286
Negative	54	960	1014
Total	300	1000	1300

Analysis of coincidence rate of SARS-CoV-2 IgM Ab rapid test and PCR test in serum samples:

Positive coincidence rate = $246 / (246 + 54) \times 100\% = 82\%$,

Negative coincidence rate = $960 / (40 + 960) \times 100\% = 96\%$,

Total coincidence rate = $(246 + 960) / (246 + 54 + 40 + 960) \times 100\% = 92.8\%$.

2. Cross-reactivity

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

Mycoplasma pneumoniae IgM Ab
Influenza A IgM Ab
Influenza B IgM Ab
Parainfluenza IgM Ab
Respiratory Syncytial virus IgM Ab
Adenovirus IgM Ab
Chlamydia pneumoniae IgM Ab

3. Interferences

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

Substance	Concentration
Hemoglobin	≤ 10g/L
Triglyceride	≤ 6mmol/L
Bilirubin	≤ 1000μmol/L
No interference from rheumatoid factors, antinuclear antibodies and antimitochondrial antibodies.	

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

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- [3] 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.
- [4] 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.
- [5] World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020.

MANUFACTURER

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INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between		Batch number
	For single use		In vitro diagnostic medical device
	Manufacturer		Date of manufacture

	Expire date		Contains sufficient for <n> tests
	European representative		CE Mark

2020-03

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