Salocor

COVID-19 (SARS-CoV-2)
IgM/IgG Rapid Test Cassette
(Whole Blood/Serum/Plasma)

Instruction for use

CE

For professional in vitro diagnostic use only
Store at 2℃ - 30℃

CONTENT

1. INTENDED USE

SARS-CoV-2 IgM/IgG antibody test kit is intended for the in vitro qualitative detection of SARS-CoV-2 IgM and IgG antibodies from human serum, plasma and whole blood samples.

1.1. Summary

SARS-CoV-2 was discovered in pneumonia caused by novel coronavirus (Corona Virus Disease 2019) in 2019 and was officially named "SARS-CoV-2" by WHO on February 11, 2020. SARS-CoV-2 is a new strain of coronavirus that has never been found in human body before. The common signs of people infected with coronavirus are respiratory symptoms, fever, cough, shortness of breath and dyspnea. In more serious cases, infection can lead to pneumonia, severe acute respiratory syndrome, renal failure, and even death. This product is intended for the auxiliary diagnosis of SARS-CoV-2 infection.

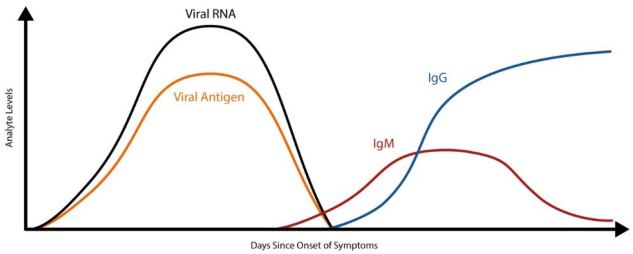
1.2. Abbreviations

SARS-CoV-2: novel coronavirus

COVID-19: novel coronavirus pneumonia

1.3. Sensitivity and specificity in acute phase/early stage (1~14 days)

Patients may only make antibodies to COVID-19 infection a week to 12 days after they first become sick. If doctors rely on these COVID-19 IgG/IgM rapid tests early in the disease, their diagnosis could be wrong. Furthermore, elderly or immunocompromised patients may never (or only much later) develop anti-SARS-COV-2 antibodies. Reliable detection of IgM antibodies early in infection is also problematic due to cross-reactions resulting in false-positive results. Most importantly from a public health perspective, COVID-positive patients are infectious to other people early in infection when the COVID-19 IgG/IgM tests are giving false-negative results[6].



Estimate of general biomarker levels during the typical timecourse of COVID-19/SARS-CoV-2 infection. Data from Liu et al. and Li et al. Please note that this is purely illustrative and should not be used as a primary reference.

https://thenativeantigencompany.com/why-we-need-antigen-and-antibody-tests-for-covid-19/

The sensitivity and specificity of the SARS-CoV-2 IgM/IgG rapid test in acute phase/ early phase is outlined in sections 12 and 13.

2. PRINCIPLE

The SARS-CoV-2 IgM/IgG rapid test is based on the immunochromatographic method. The SARS-CoV-2 specific IgM/IgG antibodies are detected by SARS-CoV-2 recombinant antigen and mouse anti human IgM/IgG antibodies. SARS-CoV-2 specific IgM/IgG antibodies in the sample react with SARS-CoV-2 recombinant antigen bound to gold particles. This complex migrates along the membrane and reaches the IgM (M) / IgG (G) test line which has mouse anti human IgM/IgG antibody against SARS-CoV-2 IgM/IgG complex.

When the result is positive, the gold-labelled SARS-CoV-2 recombinant antigen - antibody complex binds to the IgM (M) / IgG (G) test line and a purplish red color develops. When the result is negative, the sample does not contain any SARS-CoV-2 specific antibodies and SARS-CoV-2 recombinant antigen-antibody complex does not occur, which could bind to the IgM (M) / IgG (G) test line so no color becomes visible. Development of a purplish red control line (C) guarantees that sample application and migration have taken place correctly and that the test was properly performed.

3. REAGENTS

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

4. PRECAUTIONS

4.1. The interpretation of the test results must be carried out in strict accordance with this manual.

4.2. For single in-vitro diagnostic use only.

4.3. For professional use only.

4.4. Samples need to be tested in a laboratory with proper testing conditions. All samples and materials in the testing process shall be handled according to the operation specifications of infectious diseases laboratory.

4.5. Do not open the pouch until you are ready to perform the test. Humidity can adversely affect the test performance.

4.6. All reagents and samples should reach room temperature (15-30°C) before use.

4.7. Do not use lipid samples.

4.8. Do not use hemolytic samples.

4.9. Do not use turbid samples.

4.10. Do not dilute the samples to be tested before testing.

4.11. Do not store this kit in frozen condition.

4.12. Do not use the product if package is damaged.

4.13. Do not use the product after expiration date.

4.14. Do not re-use the product.

4.15. Use only the buffer solution provided with the kit.

4.16. Read and interpret the results within 15 minutes.

4.17. Avoid cross-contamination of samples by using a new specimen collection container for each sample.

4.18. All patient samples should be treated as if capable of transmitting disease. Adequate handling and disposal methods should be established. It is recommended to wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested. Do not eat, drink or smoke in the area where specimens or kits are handled.

4.19. This kit is limited to qualitative detection of SARS-CoV-2 antibody in human serum, plasma or whole blood.

4.20. False negative results will be caused when the antibody titer in the sample is lower than the minimum detection limit of the test or the antibody does not appear at the time of sample collection.

4.21. Samples with high titers of heterophilic antibodies or rheumatoid factors may affect the results.

5. STORAGE AND STABILITY

The test card is stored at 2°C-30°C, and the shelf life is 12 months. The test card sealed inside the aluminium foil bag shall be used within 1 hour after opening.

6. SPECIMEN COLLECTION AND PREPARATION

6.1. Applicable to human serum, plasma (K2EDTA, Heparin and Citrate) or whole blood samples.

6.2. For whole blood sampling, it is recommended to use a safety lancet to make a finger prick. After puncturing the skin, use clean gauze to wipe away the first drop of blood to avoid specimen dilution with interstitial fluid. With the patient's hand pointing downward, firmly grasp the finger towards the base with your thumb placed along the length of the patient's finger. Gently massage along the length of the finger towards the tip, using a light squeeze-and-release motion to allow large droplets of blood to form and encourage continuous blood flow. If using a pipette, allow a large drop of blood to form, position the device horizontally, and lightly touch the drop of blood (avoid touching the skin).

6.3. Whole blood samples shall be tested immediately after collection. Serum and plasma samples can be stored for 5 days at 2-8°C. Anticoagulant whole blood samples should not be stored for more than 6 hours at room temperature. If long-term storage is required for serum and plasma samples, they should be stored at -20°C. Avoid repeated freezing and thawing of samples.

6.4. If stored samples are used, let the samples reach room temperature and mix well before testing. When there are visible particles in the sample, it should be centrifuged before the test to remove the precipitate.

6.5. If there is a lot of lipid, hemolysis or turbidity in the sample, please do not use the sample to avoid affecting the result interpretation.

7. MATERIALS

7.1. Materials Provided

Serial number	Content	Number
1	Instruction for use	1 piece
2	Test Card	25 cassettes
3	Sample diluent	1 dropper vial
4	Small dropper	25 droppers

7.2. Material Required But Not Provided

- Sample vortex mixer
- 10-100μl pipette and tips
- Sample collection tubes
- Timer

8. DIRECTION FOR USE

Step 1: If stored samples are used, take out the sample to be tested and let it reach room temperature. Mix the sample well before testing.

Step 2: Open the aluminium foil bag, take out the test card and place it on the horizontal desktop.

Step 3: Mark the sample number on the test card.

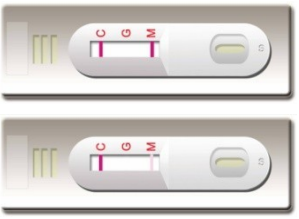
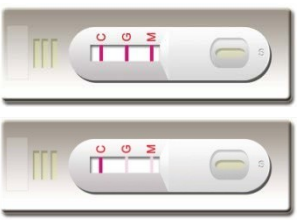
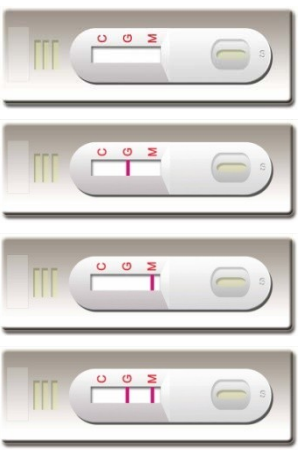
Step 4: Take 10μL (or 1 drop, note: small dropper) of the sample to be tested (serum, plasma or whole blood sample) from the sample tube or direct finger prick with the provided pipette by gently squeezing the bulb and add it into the sample well on the test cassette.

Add 80μL (or 2 drops, note dropper vial) of sample diluent into the sample hole on the test card immediately, and ensure that there is no bubble during the operation.

Step 5: Read and interpret the results within 15 minutes.

9. INTERPRETATION OF THE RESULTS

9.1	**Negative:** If only C-line appears, indicating that SARS-CoV-2 antibody is not detected, and the result is negative:	

9.2	**Positive**	
9.2.1	If both the C-line and the M-line appear, indicating that the IgM antibody against SARS-CoV-2 is detected, and the result is that the IgM antibody is positive:	
9.2.2	If both the C-line and the G-line appear, indicating that the IgG antibody against SARS-CoV-2 is detected, and the result is that the IgG antibody is positive	
9.2.3	If the C-line, M-line and G-line are all present, indicating that SARS-CoV-2 IgG and IgM antibody are detected, and the result is that IgG and IgM antibody are positive:	
9.3	**Invalid result:** if C- line is not observed, it is invalid whether there is a detection line or not, and the detection shall be carried out again:	

10. QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

11. LIMITATIONS

11.1. The results of this test are only intended to be used to assist the clinical diagnosis.

11.2. The SARS-CoV-2 IgM/IgG antibody test kit 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 the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.

11.3. The SARS-CoV-2 IgM/IgG antibody test kit will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.

11.4. At an early stage, at the onset of the first symptoms, anti-SARS-COV-2 IgM concentrations may be below detectable levels.

11.5. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

11.6. Results from immunosuppressed patients should be interpreted with caution.

11.7. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

11.8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

11.9. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

11.10. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS- CoV-2 infection or to inform infection status.

11.11. Not for the screening of donated blood.

12. EXPECTED VALUES

Primary SARS-COV-2 infection is characterized by the presence of detectable IgM antibodies 3-14 days after the onset of infection. Secondary SARS-COV-2 infection is characterized by the elevation of SARS-COV-2-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.

13. PERFORMANCE CHARACTERISTICS

- **Compliance rate of positive references**

Three positive reference samples P1-P3 of SARS-CoV-2 antibody were tested, the results were positive.

- **Compliance rate of negative reference**

Six negative reference samples N1-N6 of SARS-CoV-2 antibody were tested, and the results were negative.

- **Minimum detection limit**

Three samples of references L1-L3 with the lowest detection limit of SARS-CoV-2 antibody were tested, and the results were all positive.

- **Repeatability**

One SARS-CoV-2 antibody positive repetitive reference sample was tested 10 times, the results were all positive.

- **Clinical Evaluation in the recovery period**

Methods: a retrospective study was carried out with 1555 samples from the First Affiliated Hospital of Anhui Medical University, Fuyang City CDC and Anhui Province CDC including 617 samples of other respiratory tract infections, 416 samples of pregnant women, 252 samples of nonrespiratory tract infections, 112 physical examination samples and 158 samples of SARS-CoV-2 patients in the recovery period (>14 days). All samples were tested with SARS-CoV-2 IgM/IgG antibody test kit. The results of detection and clinical diagnosis of SARS-CoV-2 IgM and IgG antibody were statistically analyzed by kappa consistency analysis:

Method		Clinical diagnosis results		Total Results
SARS-CoV-2 IgM	Results	Positive	Negative	
	Positive	150	11	161
	Negative	8	1386	1394
Total Results		158	1397	1555

Method		Clinical diagnosis results		Total Results
SARS-CoV-2 IgG	Results	Positive	Negative	
	Positive	148	1	149
	Negative	10	1396	1406
Total Results		158	1397	1555

Serial number	Reference method	Sensitivity	Specificity
SARS-CoV-2 IgM	COVID-19 clinical diagnosis results	94.9%	99.2%
SARS-CoV-2 IgG	COVID-19 clinical diagnosis results	93,7%	99.9%
SARS-CoV-2 IgG/IGM	COVID-19 clinical diagnosis results	94,9%	99,2%

- **Clinical Evaluation in acute phase**

Methods: a retrospective study was carried out with 294 PCR confirmed acute phase (1-14 days) samples from the First Affiliated Hospital of Anhui Medical University, Fuyang City CDC and Anhui Province CDC. The sensitivity was calculated using SARS-CoV-2 IgM and IgG antibody test results.

Method		Clinical diagnosis results in acute phase		
SARS-CoV-2 IgM/IgG	Results	IgM	IgG	IgM/IgG
	Positive	133	103	134
	Negative	161	191	160
Total Results		294	294	294
Sensitivity		45,2%	35,0%	45,6%

14. CROSS REACTIVITY

The SARS-CoV-2 IgM/IgG antibody test kit has been tested to detect IgM and IgG in positive antibodies of Human coronavirus 229E, Human coronavirus OC43, Human coronavirus HKU1, Human coronavirus NL63, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1-4, Influenza A virus, Influenza B virus, Haemophilus influenzae, Rhinovirus, Respiratory syncytial virus, Epstein-Barr virus, Enterovirus, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Pneumocystis jirovecii. The results showed no crossreactivity.

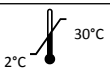
15. INTERFERING SUBSTANCES

The following potentially interfering substances were added to COVID-19 negative and positive serum, plasma and whole blood samples.

Substance	**Concentration**	**Substance**	**Concentration**
Bilirubin Conjugated	192.4 µmol/L	Hemoglobin	2.25 g/L
Bilirubin Conjugated	384.75 µmol/L	Human Serum Albumin	22.5 g/L
Bilirubin Unconjugated	141.75 µmol/L	Human Serum Albumin	45 g/L
Bilirubin Unconjugated	70.9 µmol/L	Rheumatoid factor	16.9 IU/mL
Cholesterol	16.9 mmol/L	Rheumatoid factor	33.75 IU/mL
Cholesterol	8.45 mmol/L	Triglyceride	20.8 mmol/L
HAMA	14.1 mg/mL	Triglyceride	41.6 mmol/L
HAMA	28.2 mg/mL	ANA anti-nuclear antibodies	1 : 270
Hemoglobin	1.1 g/L	ANA anti-nuclear antibodies	1 : 135

None of the substances at the concentration tested interfered in the assay.

16. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
	Use by
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2°C - 30°C.
	Contents sufficient for 25 tests
	Do not re-use
	Caution
	Keep dry
	Protect from direct sunlight
CE	CE Mark

17. REFERENCES

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[3] Phelan A L, Katz R, Gostin L O. The Novel Coronavirus Originating in Wuhan, China: Challenges for Global Health Governance. JAMA. 2020; 323(8):709-710. DOI:10.1001/jama.2020.1097

[4] Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. NEJM. 2020, 382(8):727-733. DOI: 10.1056/NEJMoa2001017.

[5] Li Jin, Ye Guangming, Chen Liangjun, etc. al., Novel coronavirus (2019-nCoV) nucleic acid detection false negative results analysis and Countermeasures. Chinese Journal of laboratory medicine. DOI: 10.3760/cma.j.issn.1009-9158.2010.0006.

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[7] WHO. Coronavirus disease 2019 (COVID-19) Situation Report – 94 2020. Available from: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200419-sitrep-90-covid-19.pdf?sfvrsn=551d47fd_2

[8] Liu L, Liu W et al. A preliminary study on serological assay for severe acute 2 respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 3 admitted hospital patients. Available from: https://www.medrxiv.org/content/10.1101/2020.03.06.20031856v1.full.pdf

18. DATE OF ISSUE

Salocor COVID-19 (SARS-CoV-2) IgM/IgG antibody test kit insert.

Version 05, June 10th, 2020

19. GENERAL INFORMATION

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