IVD CE

COVID-19 IgM/IgG Rapid Test Kit

Product #: C50001

Document number：RB/CE-05 rev.1.4

1. Precaution

a) This kit is designed for COVID-19 IgG & IgM antibody detection in serum/plasma/blood; make sure you are fully aware of the intended use. It is intended as a supplement tool of RT-PCR for COVID-19 testing.

b) Check the kit package carefully and read this instruction through to confirm the validity of the kit, and the appearance of the package. Only valid kit can be used.

c) If any damage or leakage were found, please contact your vendor for replacement. Do not use in test unless otherwise agreed by the vendor.

d) All samples collected may be contagious, please handle carefully according to local laws and regulations. Used test kit and tested sample shall be handle carefully to avoid further contamination.

e) The test cassette and the buffer shall be used within 5min after opening the foil package. Do not open it without planned experiment.

f) Do not use component from other sources, otherwise the result is not valid.

g) The kit is designed for one single use, do not use repeatedly.

h) This kit is for professional use only, not for home or self-testing.

2. Principle

The kit is based on immunochromatographic assay, to detect COVID-19 IgG & IgM antibody in serum / plasma / blood, which is rapid, accurate and easy-to-operate. During the beginning of infection, IgM is the main antibody that the body produces, while IgG will be produced after a period of infection. Positive result of IgM indicates a recent infection while positive result of IgG will indicate the infection of COVID-19 has occurred for certain period.

3. Application

This kit is designed to detect COVID-19 IgG & IgM antibody in serum / plasma / blood. It is a supplement for RT-PCR diagnosis of COVID-19.

4. Kit Components

a) Test Cassette (test card), 50 pcs

b) Sample buffer, 5ml/vial, 2 pcs

c) Disposable pipette, 50 pcs

d) Kit instruction, 1 pc

5. Specimen collection and preparation

Use new pipet or micropipette tips for different samples. All samples are contagious, please handle carefully or according to local regulations. Please prepare samples according to local regulations or COVID-19 guidelines from local CDC or WHO.

5.1 Serum

- Collect blood sample into a tube, then let the blood clot, centrifuge to let serum separate.
- Carefully take the separated serum with micropipette to run the test.

5.2 Plasma

- Collect blood sample into a tube (with EDTA or citrate as anticoagulants), then centrifuge to separate the plasma.
- Carefully take the separated plasma with micropipette to run the test.

5.3 Fingertip blood

- Wash the hand before collecting blood.
- Use an alcohol pad to sanitize the skin and then use lancet to puncture the skin, and carefully take the blood with the micropipette for testing.

Caution: Lancet is disposable, do not use repeatedly.

6. Test Procedure

a) The test will take **10-15min**. Schedule your time before test.

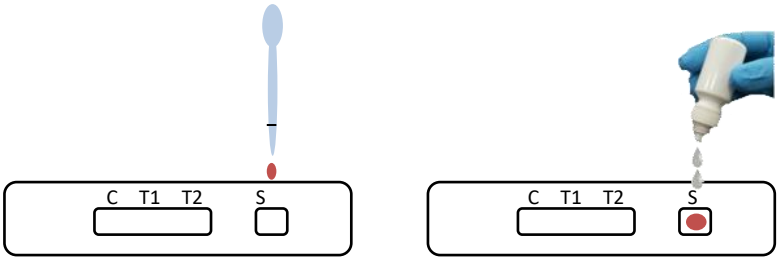
b) Take out the sample, and bring it to room temperature if it is refrigerated. For example, take the sample and keep at room temperature for 30min.

c) Take the needed test cassette, plastic pipette (100ul micropipette can also be used).

d) Open the foil pack, and take sample with micropipette, take **whole blood sample 20µl** (OR **10µl for serum / plasma sample**) into the sample well on the test card.

e) Add 2-3 drops of sample buffer drop by drop into the sample well on the test card, and observe the result from 10min after adding the buffer into sample well on the card.

Note: Strong positive result will be observed in 10min, while weak positive, negative result will be slower and will be observed in less than 15min. Result over 15min will be invalid.



7. Test Result interpretation

There are 3 lines on the cassette, Control Line (Line C) and Test Line (Line IgM, Line IgG). Line C is used for quality control. If Line C is invisible after testing, the result will be invalid, please run the test again with new cassette.

NEGATIVE

Only Line C is visible, **Line IgG and Line IgM** are **not visible.**

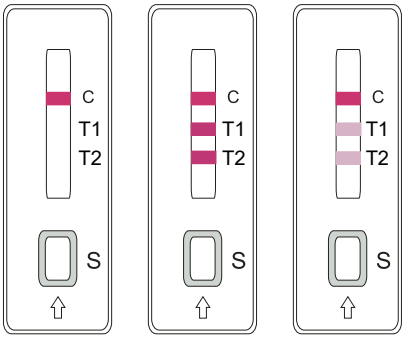
POSITIVE

Line C is visible. **Line T1 (Line IgG) is visible** indicates **IgG positive.**

Line C is visible. **Line T2 (Line IgM) is visible** indicates **IgM positive.**

Stronger (Darker) Line T indicates **Strong Positive (++)**

Weak (Lighter) Line T indicates **Weak Positive (+)**



********** Explanation of result **********

According to Guidelines of COVID-19 Diagnosis and Treatment from China Ministry of Health, IgM will arise 3-5 days after infection. Thus positive of IgM will indicate an early stage of infection.

After certain period of time or treatment or at recovery stage, IgG will rise very high level, the result will be positive.

- **In case of IgM positive and IgG positive result, indicating the infection is ongoing.**
- **In case of IgG positive while IgM negative, indicating the infection has occurred for certain time.**
- **In case of IgG negative and IgM negative, indicating a negative result.**

For clinical diagnosis, please combining with clinical symptoms and RT-PCR, as well as CT scanning. The current rapid test kit is only served as aiding tool for supplement of conventional method.

Caution **Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.**

8. Performance Characteristics

8.1 Sensitivity and specificity

The clinical performance was established based on a trial of 132 clinical samples collected from Sars-Cov-2 infected patients who were confirmed infected / negative previously by RT-PCR. The results were listed as below tables:

IgM comparison	Result	**PCR**		Total Result
		Positive	**Negative**	
COVID-19	Positive	42	2	44
Rapid Test Kit	Negative	5	83	88
Total Result		47	85	132

Relative sensitivity: 89.36% (95% CI: 76.11% - 96.02%),
Relative specificity: 97.65% (95% CI: 90.96% - 99.59%),
Total accuracy: 94.70% (95% CI: 86.64% - 97.89%).

IgG comparison	Result	**PCR**		Total Result
		Positive	**Negative**	
COVID-19	Positive	46	2	48
Rapid Test Kit	Negative	1	83	84
Total Result		47	85	132

Relative sensitivity: 97.87% (95% CI: 87.28% - 99.89%),
Relative specificity: 97.65% (95% CI: 90.96% - 99.59%),
Total accuracy: 97.73% (95% CI: 92.63% - 99.94%).

8.2 Cross-reactivity

This test kit was tested with anti-Influenza A & B, anti-HCV & anti-HBV, anti-Respiratory Syncytial Virus and anti-Rhinovirus, which demonstrated all negative results and no cross reactions had been found.

However, due to the recombinant N protein antigen is used in the kit, this kit may cross react with other coronavirus antibodies, such as HKU1, NL63, OC43, or 229E. Patients with previous exposure to these virus may get false positive results.

8.3 Potentially Endogenous Interfering Substances

Samples spiked with the following interfering substances were tested and no interference were observed.
Penicillin: 100mg/L,
Ascorbic Acid: 20mg/dL
Hemoglobin: 500mg/dL
Bilirubin: 50mg/dL
Total cholesterol: 6mmol/L
Human IgG: 5 mg/mL
Human IgM: 1 mg/mL

9. Limitation of the procedure

- This test has not been reviewed by the FDA.
- 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.
- 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.
- 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.
- The kit is for aiding diagnosis purpose and on-site testing. Positive result shall be further confirmed by RT-PCR and/or clinical syndromes or CT scanning. Diagnosis of COVID-19 infection shall be determined by the doctor, considering both clinical symptom and laboratory test.
- The Color of Line T is related to COVID-19 antibody contained in the sample. If the antibody concentration is at very high level, Line T may appear and then be lighter, in this case, please further dilute the sample solution with DD water and run the test again to see a stable Line T.

10. Storage and period of validity

The kit will be valid for 12 months when stored at 2-30°C in dry and dark place. Do not freeze. Avoid direct sunlight. Production date and expiry information are printed on the package.

11. Explanation of symbols

CE	CE Mark		Keep dry
	Consult instruction for use	LOT	Batch number
	For single use	IVD	IVD product
2 30°C	Store between 2-30°C		Date of manufacture
	Manufacturer		Do not use if package is damaged
EC REP	European union representative		Expire date

Ring Biotechnology Co., Ltd
Building 3, Zhongtongtai TechnoPark,
No 11, Kechuang 14th St, Beijing
Business Development Area, Beijing
100176, P.R. China
Telephone +86-10-56267496
Website http://www.ringbio.com
Email info@ringbio.com

EC REP **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany