ScheBo® • SARS - CoV-2 Quick™
IgM/IgG

（Colloidal Gold Method）

Instruction for use

CE

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

CONTENT

1. INTENDED USE

ScheBo® SARS-CoV-2 Quick™ IgM/IgG Test（Colloidal Gold Method）is intended for the in vitro qualitative detection of SARS-CoV-2 IgM and IgG antibodies from human serum, plasma and whole blood samples.

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.

2. TEST PRINCIPLE

The SARS-CoV-2 IgM/IgG Quick test is based on the immunochromatographic method. The SARS-CoV-2 IgM/IgG is detected by SARS-CoV-2 recombinant antigen and mouse anti human IgM/IgG antibody. SARS-CoV-2 IgM/IgG in the sample reacts with SARS-CoV-2 recombinant antigen bound to gold particles. This complex migrates along the membrane and reaches the IgM/IgG test line（T）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/IgG test line（T）and a purplish red color develops. When the result is negative, the sample does not contain any SARS-CoV-2 recombinant antigen-antibody complex that can bind to the IgM/IgG test line（T）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. KIT COMPONENTS

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

4. WARNINGS AND PRECAUTIONS

Samples for human serum plasma or whole blood, should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and take other appropriate safety precautions to avoid or reduce the risk of infection.

5. STORAGE CONDITIONS AND SHELF LIFE

The test card is stored at 2℃-30℃, 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. APPLICABLE INSTRUMENTS

None.

7. SAMPLE REQUIREMENTS

7.1. Applicable to human serum, plasma or whole blood samples.

7.2. For whole blood sampling, it is recommended to 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 capillary tube or pipette allow a large drop of blood to form, position the device horizontally, and lightly touch the drop of blood (avoid touching the skin); allow the blood drop to be drawn into the collection vessel by capillary action (avoid air bubbles).

7.3. For serum and plasma samples, The samples shall be tested immediately after collection. Serum and plasma samples can be stored for 5 days at 2-8℃, anticoagulant whole blood samples should not be stored for more than 24 hours at room temperature, and should not be stored for more than 7 days at 2-8℃. If long-term storage is required, it should be stored at -20℃. Avoid repeated freezing and thawing of samples.

7.4. 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.

7.5. 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.

8. MATERIALS REQUIRED BUT NOT PROVIDED

Sample vortex mixer

10-100μl pipette and tips

Test tubes

Sample collection tubes

Timer

9. TEST PROCEDURES

Step 1: Take out the sample to be tested and let it reaches room temperature. Mix the sample well before testing.

Step 2: Open the aluminium foil bag, take out the detection 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 with the pipette and add 80μL（or 4

drops, note: large dropper） 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 (please take photos of the results).

10. INTERPRETATION OF THE RESULTS

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

10.2. Positive:

10.2.1 If both the C-line and the M-line appear, it means that the IgM antibody against SARS-CoV-2 is detected, and the result is that the IgM antibody is positive:

10.2.2 If both the C-line and the G-line appear, it means that the IgG antibody against SARS-CoV-2 is detected, and the result is that the IgG antibody is positive：

10.2.3 If the C-line, M-line and G-line are all present, it means that SARS-CoV-2 IgG and IgM antibody are detected, and the result is that IgG and IgM antibody are positive:

10.3. 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:

11. LIMITATION OF THE PROCEDURES

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

11.2. This product can only be used for the determination of serum, plasma and whole blood samples.

11.3. Affected by the minimum detection limit of the product, the negative result may be caused by the antibody concentration in the tested sample is lower than the minimum detection limit.

12. PERFORMANCE CHARACTERISTICS

Compliance rate of positive references

Three positive references P1-P3 of SARS-CoV-2 antibody were tested, the results are

positive.

Compliance rate of negative reference

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

Minimum detection limit

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

Repeatability

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

Clinical Evaluation

Methods: a retrospective study was carried out with 226 samples from the First Affiliated Hospital of Anhui Medical University, including 78 samples of other respiratory tract infections, 108 samples of normal people and 40 samples of SARS-CoV-2 patients. All samples were tested with ScheBo® SARS-CoV-2 Quick™ IgM/IgG(Colloidal Gold Method). 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
colloidal gold method IgM	Results	Positive	Negative	
	Positive	39	1	40
	Negative	1	185	186
Total Results		40	186	226

Method		Clinical diagnosis results		Total Results
colloidal gold method IgG	Results	Positive	Negative	
	Positive	39	0	39
	Negative	1	186	187
Total Results		40	186	226

Serial number	Reference method	Sensitivity	Specificity
SARS-CoV-2 IgM	COVID-19 clinical diagnosis results	97.5%	99.5%
SARS-CoV-2 IgG	COVID-19 clinical diagnosis results	97.5%	100%

13. PROCEDURAL NOTES

13.1. Read this manual carefully before using this test.

13.2. It needs 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.

13.3. Protect the product from moisture.

13.4. All reagents and samples should reach room temperature (15-30℃) before use.

13.5. Do not use lipid samples.

13.6. Do not use hemolytic samples.

13.7. Do not use turbid contaminated samples.

13.8. Do not dilute the sample for testing.

13.9. Do not store this kit in frozen condition.

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

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

13.12. 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.

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

14. DATE OF ISSUE

ScheBo®•SARS-CoV-2 Quick™ IgM/IgG Test insert.

Version 01, 22th March, 2020

15. EXPLANATION OF THE SYMBOLS USED

IVD	For in vitro diagnostic use
REF	Catalogue number
LOT	Batch code
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community
	Use by
	Do not use if package is damaged
	Consult instruction for use
	Temperature limit at 2°C~30°C.
	Contents sufficient for 20 tests.
	Contents sufficient for 25 tests
	Contents sufficient for 50 tests
	Contents sufficient for 100 tests

	Do not re-use
	Caution
	Keep dry

16. REFERENCES

17. GENERAL INFORMATION