SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold)

Instructions for Use

1. Intended Use

The SARS-CoV-2 IgM/IgG Test Kit (Colloidal Gold) is intended for in vitro qualitative detection of IgM and IgG antibodies in human serum, plasma or whole blood from individuals suspected of COVID-19 by their healthcare point of care provider.

This test is only provided for use by clinical laboratories or to health care workers for point of care testing, and not for at home testing.

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. The diagnosis should be confirmed in combination with clinical symptoms or other conventional testing methods.

2. Summary and Explanation of the Test

The novel coronaviruses belong to the β genus.COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection;asymptomatic infected people can also be an infectious source.Based on the current epidemiological investigation,the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough.Nasal congestion,runny nose, sore throat, myalgia and diarrhea are found in a few cases.

This antibody test kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, the virus that causes COVID-19, indicating recent or prior infection, by detecting antibodies to SARS-CoV-2 in human blood specimens. Although not everyone who is infected will develop an antibody response, appropriately validated serology tests, when used broadly, can be useful in understanding how many people have developed an adaptive immune response to the virus and how far the pandemic has progressed.

3. Principles of the Test

This kit adopts colloidal gold-immunochromatography assay (GICA).

The test card contains:

1. Colloidal gold-labeled antigen and quality control antibody complex.
2. Nitrocellulose membranes immobilized with two test lines (M line and G line) and one quality control line (C line).

When an appropriate amount of sample is added to the sample well of the test card, the sample will move forward along the test card under capillary action.

If the sample contains an IgM/IgG antibody of SARS-CoV-2, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen, and the immune complex will be captured by the monoclonal anti-human IgM antibody or monoclonal IgG antibody immobilized on the nitrocellulose membrane to form a purple/red M line or G line, showing that the sample is positive for IgM or IgG antibody.

4.REAGENTS

The nominal formula for each medium is as follows:

Diluent		**Test Card**
Water	90-98%	Chloroauric acid
Sodium chloride	0.1-1%	Antigen
Tris (hydroxymethyl) aminomethane	0.1-1%	Anti-RBC
Tween-20	0.1-1%	Anti-body IgG
Sucrose	0.1-1%	Anti-body IgM
Bovine serum albumin	0.1-1%	Goat anti-rabbit IgG
Trehalose	0.1-1%	Rabbit IgM
Proclin-300	0.01-1%	
Sodium Casein	0.01-1%	
PEG 20000	0.01-1%	
Disodium phosphate	0.001-1%	
Sodium dihydrogen phosphate	0.0001-1%	

5. Kit Reagents and Components

Materials Provided:

Component Name	1T/box	20T/box	25T/box	50T/box
Disposable Dropper	1	20	25	50
Sample Diluent	0.5ml	4ml	5ml	10ml
Desiccant	1	20	25	50
Disposable Test Card	1	20	25	50
Instruction Manual	1	1	1	1

6. Warnings and Precautions

1. This kit is limited to the qualitative detection of new coronavirus antibodies in human serum, plasma or whole blood.
2. For emergency and use by medical or health professionals only at designated point of care facilities.
3. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
4. Handle specimens as if they contain infectious agents in accordance to standardized procedures, and OSHA standards on blood-borne pathogens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not use it if the tube/pouch is damaged or broken.
7. Test is for single use only. Do not re-use under any circumstances.
8. Humidity and temperature can adversely affect results.
9. Do not use product after indicated expiration date.
10. Follow storage recommendations listed on the product labels. Storage and handling outside of these conditions may adversely affect product.
11. The personnel who performed the testing were blinded to the identity / code of the sample and the expected results.
12. Dispose of all samples and used test components in appropriately approved and labeled biohazard waste containers.
13. This kit will have a negative result under the following conditions: when the titer of the novel coronavirus antibody in the sample is lower than the minimum detection limit of this kit, or the novel coronavirus antibody has not yet appeared at the time of sample collection.
14. Samples containing higher titers of heterophilic antibodies or rheumatoid factors may affect the expected results.

7. Shelf Life and Storage

1. Store in a dry place at 2～30°C away from light.
2. Transport at2-37℃ for 20days
3. After opening the inner packaging, the test card will become invalid due to moisture absorption, please use it within 1 hour.
4. The shelf life of the test kit is 12 months from date of manufacture.

8. Sample Collection and Preparation

1. This test can be performed using either human serum, plasma or whole blood samples, including peripheral blood, plasma prepared from clinically used anticoagulants (EDTA, heparin, sodium citrate), etc.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis.
3. Serum and plasma samples may be stored at 2-8°C for up to 5 days if not tested immediately. For long-term storage, it should be stored at -20°C. Avoid multiple freeze-thaw cycles. Anticoagulated whole blood samples should not be stored for more than 72 hours at room temperature; not more than7 days at 2～8°C.
4. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.
5. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

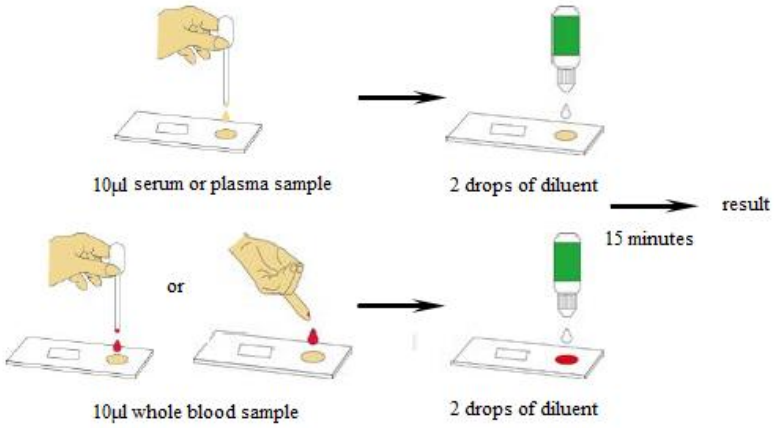
9. Test Procedure

Step1: Allow the test device, buffer, specimen to equilibrate to room temperature (15-30℃) prior to testing.
Step2: Remove the test device from the sealed pouch. Place the test device on a clean, flat surface.
Step3: Label the device with specimen number.
Step4: Using a Disposable Dropper, transfer serum, plasma or whole blood. Hold the dropper vertically and transfer 1 drop of specimen

(approximately 10μ l) to the specimen well(S) of the test device, and immediately add 2 drops of test buffer (approximately 70-100μ l). Make sure there are no air bubbles.

Step5: Set up a timer. Read the results in 15 minutes.

Do not interpret the result after 20 minutes. To avoid confusion, discard the test device after interpreting the result. If you need to store it for a long time, please take a photo of the result.



10.Test Quality Control

1. A procedural control is included in the test. A red line appearing in the control region is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

2. Control standards are not provided with this kit. It is recommended to follow good laboratory practice including adding positive and negative controls in order to verify proper test performance.

11. Interpretation of Results

NEGATIVE:

If only the quality control line C appears, and the test lines M and G are not purple/red, it indicates that no antibody is detected, and the result is negative.

POSITIVE:

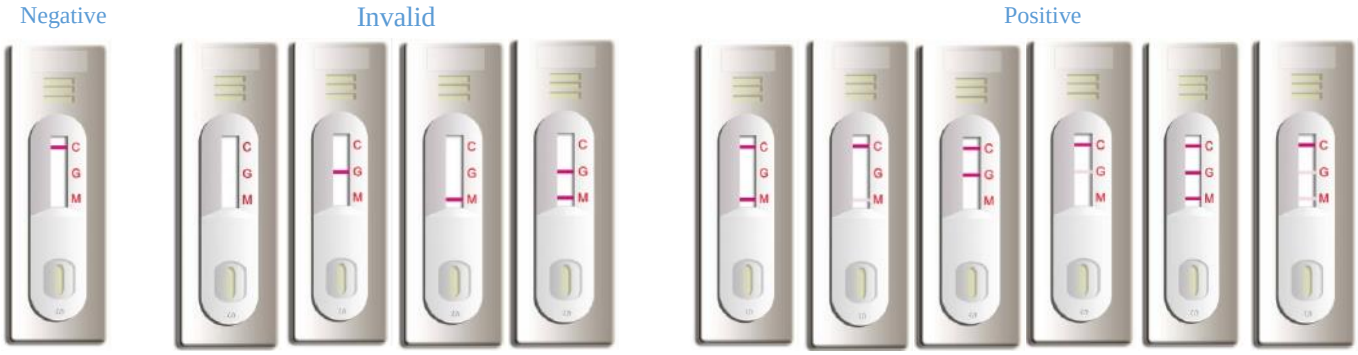
IgM positive: If both the quality control line C and the test line M appear purple/red, it indicates that the Ig M antibody is detected, and the result is positive for Ig M antibody.

IgG positive: If both the quality control line C and the test line G appear purple/red, it indicates that the Ig G antibody is detected, and the result is positive for Ig G antibody.

IgM and IgG positive: If the quality control line C and the test lines M and G all appear purple/red, it indicates that the Ig M and Ig G antibodies are detected, and the result is positive for both IgM and IgG antibodies.

INVALID:

If the quality control line C is not displayed, the test result is invalid regardless of whether there is a purple/red test line, and it should be tested again.



12.Performance Characteristics

Cross-reactivity

The SARS-CoV-2 IgM/IgG Test Kit (Colloidal gold) has been tested for anti-influenza A virus, anti-influenza B virus, anti-Adenovirus, anti-Respiratory syncytial virus,anti-Mycoplasma,anti-Hepatitis B, anti-Helicobacter pylori and anti-Streptococcus pneumoniae. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the SARS-CoV-2 IgG/IgM Rapid Test Kit (Colloidal gold) and no interference was observed. Triglyceride:100mg/dL;Ascorbic Acid: 20mg/dL;Hemoglobin: 1000mg/dL;Bilirubin: 60mg/dL ,Total cholesterol: 6mmol/L

13.Limitations

1. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
2. This product is for qualitative assessment only. This test is only provided for use by clinical laboratories or to health care workers for point of care testing, and not for at home testing.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Negative results do not preclude SARS-Co V2 infection and should not be used as the sole basis for patient management decisions. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. Due to the limitation of detection sensitivity, negative results may be caused by antibody concentrations lower than the analytical sensitivity of the product.
6. Positive results may be due to past or present infection with non-SARS-Co V-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
7. This test will only indicate the presence of SARS-Co V-2 IgM and/or IgG antibodies in the specimen.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
9. Not for screening of donated blood.

14. References

1 Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

2 Chao, E.L.; Henshaw, J.L., Occupational Safety and Health Administration: Model Plans and Programs for the OSHA Bloodborne Pathogens and Hazard Communications Standards. OSHA 3186-06R, 2003.

15 Symbols

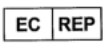
	Manufacturer		Date of manufacture
	Authorised Representative in the European community		Use by
	Caution		Batch code
	Do not reuse		Keep dry
	Do not use if package is damaged		Total number of tests
	instructions for use		in vitro diagnostic
	CE mark		Temperature limit

Name: JINAN BABIO BIOTECHNOLOGY CO., LTD.

Add: 303, Building 5 of SME Industrialization Base of Biomedical Park, 1777 Dazheng Road, High-tech Zone, Jinan City, 250101, Shandong Province, China

E-mail: zhou@jnbaibo.com

Tel: +86-(0)531-88697620/ +86-(0)531-88697602



Name: MedPath GmbH.

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel.: +49(0)89 189174474

FAX: +49(0)8954858884

E-mail:info@medpath.pro