FREEDOM FOR ALL DIAGNOSTICS™

REF **1001**

IVD **In-Vitro Diagnostic**

SARS-CoV-2 IgM/IgG Antibody Assay Kit

For professional in-vitro diagnostic use only. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

PACKAGE SPECIFICATIONS

1 test/pack
25 tests/pack

INTENDED USE

SARS-CoV-2 IgM/IgG Antibody Assay Kit is a rapid chromatographic immunoassay intended for use in the qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma, or whole blood as an aid in the diagnosis of primary and secondary SARS-CoV-2 infections.

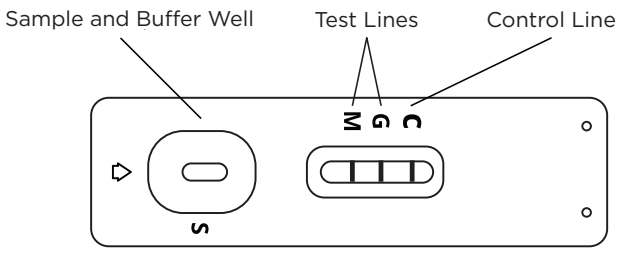
SUMMARY

COVID-19 is the infectious disease caused by the recently discovered novel coronavirus. The World Health Organization (WHO) has officially named the disease coronavirus disease 2019 (COVID-19), an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which is a virus closely related to the SARS virus. For use by trained professionals only*.

SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography) has completed the Section IV.D notification process under FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)," and can be used in U.S. laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests, for the detection of IgM and IgG antibodies to SARS-CoV-2 in serum, heparin- and sodium citrate-anticoagulated plasma, or EDTA-anticoagulated whole-blood samples from individuals with current or prior COVID-19 infection.

The test results of this product are only for clinical reference, and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, treatment response, epidemiology, and other information. In the early stage of infection, if the virus-specific IgM antibody is not produced or the titer is very low, it will lead to negative results. If a virus infection is suspected, the patient should be prompted to get checked again within 7 to 14 days.

TEST PRINCIPLE



This product adopts colloidal gold immune-technology, spraying colloidal gold-labeled recombinant novel coronavirus antigen and quality-control antibody gold marker on the binding pad; the nitrocellulose membrane is coated with two test lines (G and M) and a control line (C). The M line is coated with mouse anti-human IgM monoclonal antibody, which is used to detect novel coronavirus IgM antibodies. The G line is coated with mouse anti-human IgG monoclonal antibody, which is used to detect novel coronavirus IgG antibodies. The C line contains quality-control antibodies. When the novel coronavirus sample is added to the sample hole of the test card, the sample will move along the test card under the action of chromatography. If the sample contains the novel coronavirus IgM antibody, the antibody binds to the gold-labeled virus antigen.

The immune complex forms a sandwich complex with the coated anti-human IgM monoclonal antibody at the M line, showing a purplish red M line and indicating positive IgM antibody for the novel coronavirus. If the sample contains the novel coronavirus IgG antibody, it binds to the gold-labeled novel coronavirus antigen. The immune complex forms a sandwich complex at the G line with the enveloped murine anti-human IgG monoclonal antibody, showing a purplish red G line and indicating that the novel coronavirus IgG antibody is positive. If the test lines (G and M) do not produce color, the negative result is displayed. The card also contains a control line (C). The magenta control line should appear in every valid test, indicating that the test is properly performed and that reagents are functional as specified. If the control line does not appear, it means that the test result is invalid, and the sample should be tested again.

WARNINGS AND PRECAUTIONS

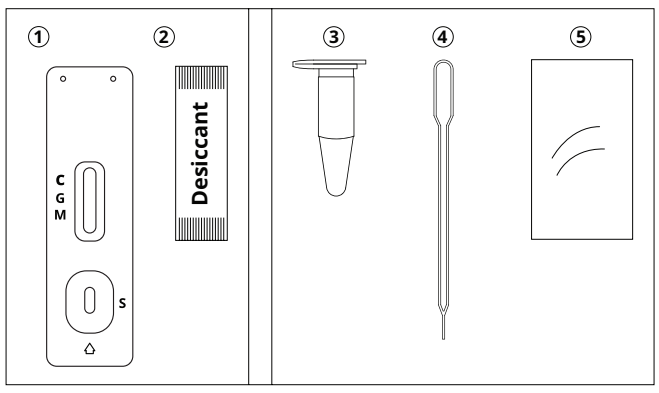
1. Equilibrate the sample diluent and test card to room temperature (for more than 30 minutes) before testing.
2. The test should be performed strictly in accordance with the instructions.
3. The result must be interpreted within 20 minutes.
4. Do not use repeated freeze-thaw, and highly hemolytic and lipidemic blood samples.
5. The test samples should be regarded as infectious agents, and they must be operated in accordance with the infectious-disease laboratory operation rules, and biological safety should be considered.
6. This product is a single-use in-vitro diagnostic reagent. Do not use expired products.
7. Do not use a kit with obvious damage and damaged test card in the package.
8. There is a desiccant in the aluminum-foil bag, do not swallow.
9. Humidity and temperature can adversely affect results.
10. Use of this product is limited to U.S. laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests.

Caution: After the test is completed, the used test cards, sample diluents, and pipettes, etc. are treated as biomedical waste. Users should take precautions to ensure their safety and that of others.

STORAGE AND STABILITY

Store the test kit at 2 °C to 30 °C, with a valid period of 6 months. Test strip should be used within 1 hour once the foil pouch is opened. The date of manufacture and expiry date are shown on the label.

REAGENTS AND MATERIALS



The white foil bag contains:
1. Test cassette
2. Desiccant

The clear plastic bag contains:
3. Ampoule of sample diluent (pH 6.5 to 8.0, phosphate buffer)
4. Disposable Pasteur pipette
5. Leaflet with instructions for use

Materials required but not provided: timer, prelabeled tube

SPECIMEN COLLECTION AND PREPARATION

Collect specimens in accordance with correct medical practices from the following sources:

a. Plasma
Collect the blood into the collection tube (containing heparin anticoagulant or sodium citrate anticoagulant) by venipuncture, and then centrifuge blood to obtain a plasma sample. Carefully withdraw the plasma into a new pre-labeled tube.

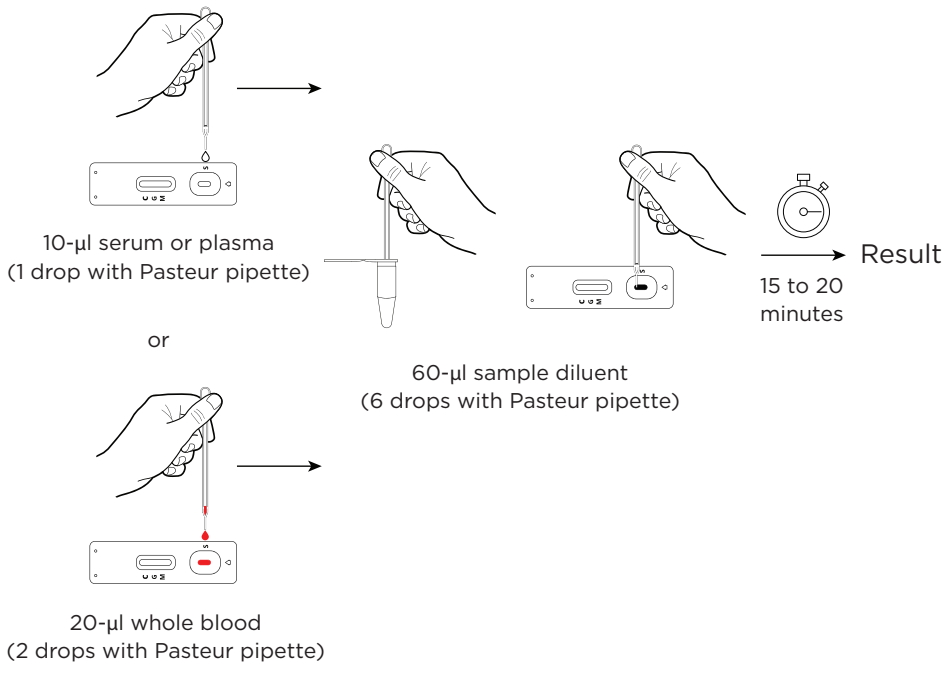
b. Serum
Collect the blood into the collection tube (NOT containing anticoagulants, such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation, and then centrifuge blood to obtain a serum sample of supernatant. Carefully withdraw the serum into a new pre-labeled tube.

c. Whole blood
Collect the blood into the collection tube (containing an EDTA anticoagulant) by venipuncture, and carefully withdraw the whole blood into a new pre-labeled tube.

- Apply to serum, heparin- anticoagulated or sodium citrate-anticoagulated plasma, or EDTA-anticoagulated whole-blood samples.
- The samples should be gently shaken up and down 5 to 10 times immediately after collection.
- Serum, plasma, and whole-blood samples can be stored at 2 to 8 °C for 7 days; serum and plasma samples can be stored frozen at -20 °C for 25 days. It should be recovered to room temperature before the test, and the test should be conducted as soon as possible within 8 hours after the sample is collected. If the samples cannot be analyzed timely, they should be stored at 2 to 8 °C, and avoid repeated freeze-thaw.
- Samples that are grossly-hemolyzed or lipemic, and with microbial contamination shall not be used for the test of this product; turbid samples affect the determination results of this product. The use of heat-inactivated samples is not recommended.

* https://www.who.int/health-topics/coronavirus#tab=tab_1
* https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it

TEST PROCEDURE (DIRECTIONS)



Step 1: The test card, sample diluent, and specimen sample should be recovered to room temperature (15 °C to 30 °C) before testing.

Step 2: Open the aluminum-foil bag of the test card, take out the test card and place it horizontally on the work surface. Best results will be obtained if the assay is performed within 30 minutes.

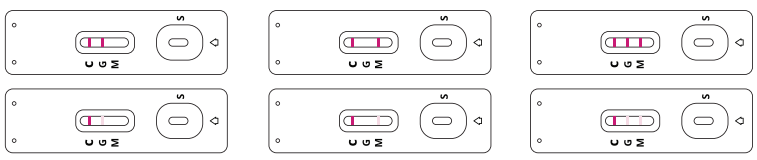
Step 3: Fill the Pasteur pipette and dispense 10 µl (1 drop with Pasteur pipette) of serum/plasma, or 20 µl (2 drops with Pasteur pipette) of whole blood into the sample hole of the test card marked (S).

Step 4: Fill the Pasteur pipette (the same pipette) and dispense 60 µl (6 drops with Pasteur pipette) of buffer into the sample hole of the test card marked (S).

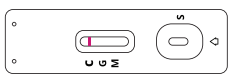
Step 5: Start timer.

Step 6: Wait for the line(s) to appear. Read results at 15-20 minutes. Do not interpret the results after 20 minutes.

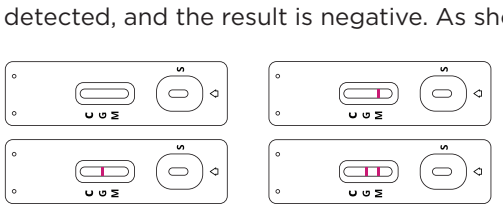
INTERPRETATION OF THE ASSAY



1. Positive results: Both the test line (G) and the control line (C) show color bands, indicating that IgG antibody of SARS-CoV-2 is positive; both the test line (M) and the control line (C) show color bands, indicating that the SARS-CoV-2 IgM antibody is positive. The test line (M), (G) and control line (C) all show color bands, indicating that the SARS-CoV-2 IgM and IgG antibodies are positive. As shown in the figure.



2. Negative result: If only the control line (C) produces color, and neither of the detection lines (G) (M) does, no SARS-CoV-2 IgM/IgG antibodies are detected, and the result is negative. As shown in the figure.



3. Invalid result: No band appears on the control line (C), and it is judged as an invalid result, whether the detection line (G) (M) shows a band or not. As shown in the figure.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line area (C) is considered an internal procedure control. This confirms adequate control performance. If the C line does not develop, review the whole procedure and repeat the test with a new device.

Control standards are not supplied with this test cassette; however, it is recommended that positive and negative controls be tested as a good laboratory practice to ensure the proper performance of the assay, particularly under the following circumstances:

A. To investigate the cause of repeated invalid results.

B. A new lot of test kits is used.

C. A new shipment of kits is used.

D. The temperature used during storage of the kit falls outside of 2 to 30°C.

E. The temperature of the test area falls outside of 15 to 30°C.

ASSAY CLINICAL STUDY RESULT

Type	# of Cases	Infection Time	IgM			IgG		
			IgM # Positive	PPA	95% CI	IgG # Positive	PPA	95% CI
Positive	16	0-7 Days	11	68.75%	44.40%-85.84%	12	75.00%	50.50%-89.82%
Positive	16	8-14 Days	14	87.50%	63.98%-96.50%	15	93.75%	71.67%-98.89%
Positive	18	≥15 Days	15	83.33%	60.78%-94.16%	18	100%	82.41%-100.00%
Negative	100	N/A	NPA: 97%		91.55%-98.97%	NPA: 97%		91.55%-98.97%
Overall IgM and IgG: The overall positive percent agreement (PPA) was 90.00%, and the 95% confidence interval was (78.64%, 95.65%). Overall negative percent agreement (NPA) was 97.00%, and the 95% confidence interval was (91.55%, 98.97%); the overall percent agreement was 94.67%, and the 95% confidence interval was (89.83%, 97.27%).								
Total IgM: IgM positive percent agreement (PPA) was 80.00%, and the 95% confidence interval was (66.96%, 88.76%). IgM negative percent agreement (NPA) was 97.00%, and the 95% confidence interval was (91.55%, 98.97%).								
Total IgG: IgG positive percent agreement (PPA) was 90.00%, and the 95% confidence interval was (78.64%, 95.65%). IgG negative percent agreement (NPA) was 97.00%, and the 95% confidence interval was (91.55%, 98.97%).								

LIMITATIONS OF THE TEST

1. The kit is only for the detection of human serum, plasma, and whole-blood samples.
2. The test results may be inaccurate due to technical reasons, operational errors, and other sample factors.
3. In the early stage of infection, if the virus-specific IgM antibody is not produced or the titer is very low, it will lead to negative results. If a virus infection is suspected, the patient should be prompted to get tested again within 7 to 14 days.
4. The test results of this product are only for clinical reference, and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, treatment response, epidemiology, and other information.
5. Patients with impaired immune function or receiving immunosuppressive therapy, such as those infected with human immunodeficiency virus (HIV) or receiving immunosuppressive therapy after organ transplantation, have limited reference value for serological IgM antibody detection, which may lead to wrong medical interpretation.
6. Positive test results in patients who have had blood transfusions or other blood products administered in recent months should have their results interpreted with caution.
7. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
8. This test has not been reviewed by the FDA.
9. Results from antibody testing should not be used as a sole basis to diagnose or exclude SARS-CoV-2 infection, or to inform infection status.
10. Not for screening of donated blood.
11. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
12. 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.

INDEX OF SYMBOLS

Rx	Rx		Manufacturer		Keep dry
LOT	Batch code		Caution		Do not reuse
REF	Catalog number	Σ	Contains sufficient for <n> tests		Consult Instructions for use
	Use-by date	30°C (86°F) 2°C (35.6°F)	Temperature limit	IVD	In-vitro diagnostic medical device
	Date of manufacture		Keep away from sunlight	ISO	ISO 13485

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English version