For Rapid Detection of SARS-CoV-2

For In Vitro Diagnostic Use Only

reOpenTest

SARS-CoV-2 IgM/IgG Antibody Test

(Colloidal Gold)

INTENT OF USE

The SARS-CoV-2 IgM/IgG Antibody Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimen. The SARS-CoV-2 IgM/IgG Antibody Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Not suitable for general population screening.

SUMMARY AND EXPLAINATION

The novel coronaviruses belong to the β genus. SARS-CoV-2, also known as the COVID-19 virus, 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.

PRINCIPLE OF THE TEST

The SARS-CoV-2 IgM/IgG Antibody Test is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, serum or plasma specimen. The test consists of two components, an IgG and an IgM component. In the IgG component, anti-human IgG is coated in the IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen conjugate coated particles on the nitrocellulose membrane. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to SARS-CoV-2, the conjugate-specimen complex reacts with anti-human IgM and a colored line appears in IgM test line region.

In summary, if the specimen contains SARS-CoV-2 IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains SARS-CoV-2 IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain SARS-CoV-2 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS SUPPLIED

25-Test Kit:

- Individually Packaged Test cassettes (25)
- 10 µL Volume Droppers (25)
- Package Insert (1)
- NCP Buffer (Professional Package / 4.0mL*1, Home Package / 80µL*25)

MATERIALS NOT SUPPLIED IN KIT*

- Specimen Collection Containers
- Centrifuge (For Plasma Only)
- Timer
- Pipette
- Lancet

**Note: Home Package Includes Alcohol Pads (25), Lancets (25)*

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only. The test is intended for professional use only and is limited to medical institutions.
- The storage, transportation and operation of the kit should comply with the requirements in the manual, otherwise there will be potential for influencing the test results.
- Do not freeze reagents.
- Reagent to avoid contamination.
- There is animal-derived protein material in the kit, so the used product should be treated as bio-waste.
- Materials in the testing process may be infectious. These should be treated according to laboratory biosafety requirements based on biohazardous substances.
- Do not use the Test Device if the pouch is damaged or the seal broken.

KIT STORAGE AND STABILITY

Store the kit at room temperature 2℃ to 30℃(36°F~86°F), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) can be performed using whole blood, serum or plasma.

1. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2℃~8°C for up to 3 days, for long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2℃~8°C if the test is to be run within 2 days after collection. Do not freeze whole blood specimens.

2. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

If specimens are to be transported, they should be packed in compliance with local regulations covering the transportation of etiological agents.

EDTA, Heparin and Sodium Citrate can be used as the anticoagulant for collecting the specimens.

TEST PROCEDURE

Allow the test kit, specimen, buffer and/or controls to equilibrate to room temperature (15℃~30℃) prior to testing.

1. Remove the Test Cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the Test cassette on a clean and horizontal surface.

For Serum or Plasma specimen:

a) To use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 10µL), and transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 70µL*), and start the timer.

b) To use a pipette: To transfer 10µL of specimen to the specimen well(S), then add 2 drops of buffer (approximately 70µL*), and start the timer.

* Each individual packaged buffer in *Home Package* carries 80µL buffer shall be fully applied.

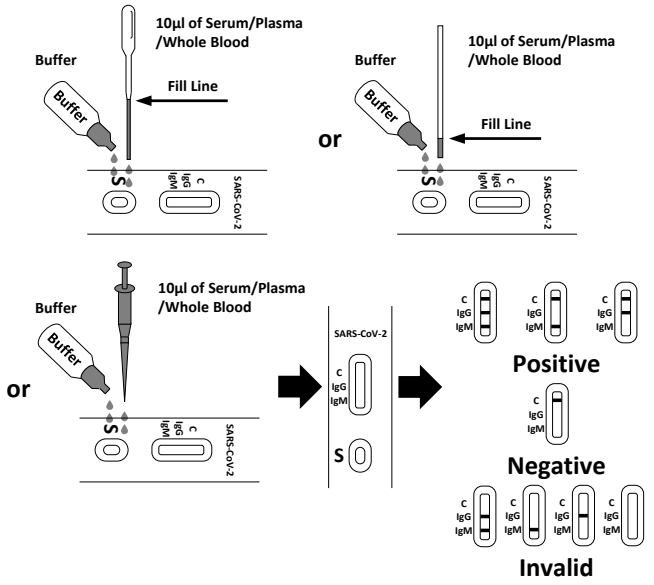
For Whole Blood specimen:

a) To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 10µL) of specimen to the sample well(S). Then add 2 drops of buffer (approximately 70µL) and start the timer.

b) To use a pipette: To transfer 10µL of whole blood to the specimen well(S), then add 2 drops of buffer (approximately 70µL), and start the timer.

3. Wait for the colored line(s) to appear. Read results between 10 ~ 15 minutes. Invalid results before 10 minutes or after 15 minutes.

Note: NOT recommended to use the buffer 6 months later after opening the vial.



INTERPRETATION OF RESULTS

IgG POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE: Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE: Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

Note: The intensity of the color in the test line regions may vary depending on the concentration of SARS-CoV-2 antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM region.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL PROCEDURES
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice test procedure and to verify proper test performance.

LIMITATIONS
1. The SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) is intended for in vitro diagnostic use only. For prescription use only. For emergency use authorization use only. This test should not be used for screening of donated blood. This test should be used for detection of IgG and IgM antibody to SARS-CoV-2 in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to SARS-CoV-2 can be determined by this qualitative test.
2. The SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of SARS-CoV-2 infection.
5. The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
6. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
7. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

PERFORMANCE CHARACTERISTICS
1. Sensitivity and Specificity
The SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) was compared with a leading commercial PCR; the results show that SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) has high sensitivity and specificity.

Method		PCR		Total Results
	Results	Positive	Negative	
SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold)	Positive	171	2	173
	Negative	10	270	280
Total Result		181	272	453

Relative Sensitivity: 94.48%（95%CI：90.07%～97.32%）
Relative Specificity: 99.26%（95%CI：97.37%～99.91%）
Accuracy: 97.35%（95%CI：95.42%～98.62%）

2. Cross-reactivity
The SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAb, anti-H.Pylori, and anti-HIV positive specimens. The results showed no cross-reactivity.
3. Interfering Substances
The following compounds have been tested using the SARS-CoV-2 IgM/IgG Antibody Test (Colloidal Gold) and no interference was observed.

Interfering Substances	Concentration	Interfering Substances	Concentration
Triglyceride	50 mg/dL	Ascorbic Acid	20mg/dL
Hemoglobin	1000mg/dL	Bilirubin	60mg/dL

REFERENCE
1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164. PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2.
2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502. PMID:27012512 DOI:10.1016 / j.tim.2016.03.003.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9.

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ISO 15223 Symbols

CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
	Read instructions for use
	Use by
	Do not re-use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
Σ	Contains sufficient for <n> tests
EC REP	Authorized Representative in the European Community / European Union
LOT	Batch code
REF	Catalog number
IVD	In vitro diagnostic medical
SN	Serial number
	Biological risks
	Manufacturer
	Date of manufacture
	Caution