CE IVD

COVID-19 IgG/IgM Test

Novel Coronavirus（2019-nCoV）IgG/IgM Antibody Rapid Test Kit (Colloidal Gold Immunochromatography) Instruction for use

Product Name

Novel Coronavirus（2019-nCoV）IgG/IgM Antibody Rapid Test Kit (Colloidal Gold Immunochromatography)

Packaging Specification

20 Tests / Kit

Intended Use

The kit is intended for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2（2019-nCoV）in human whole blood, serum or plasma as an aid in the diagnosis of primary and secondary SARS-CoV-2 infections.

Summary

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 kit provides an accurate, simple and rapid method for the detection of SARS-CoV-2 IgG/IgM, which can detect both IgM and IgG antibodies in human serum, plasma or whole blood to identify potential infected persons. The detection of IgM antibody usually indicates the acute infection of SARS-CoV-2, while the detection of IgG antibody usually indicates the later stage of infection. Therefore, simultaneous detection of SARS-CoV-2 IgM and IgG antibodies is an effective strategy for the rapid and precise diagnosis of SARS-CoV-2, and this combined test could also provide information on the stage of infection.

Test Principle

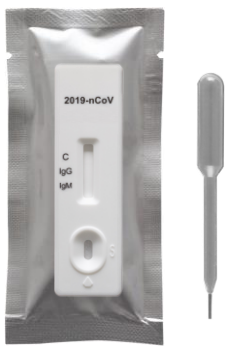
The test is based on the colloidal gold immunochromatography technology. This test consists of two test lines, an IgG line and an IgM line.

During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG/IgM in IgG/IgM test line region.

If the specimen contains IgG/IgM antibodies to SARS-CoV-2, a colored line will appear in IgG/IgM test line region, respectively. If the specimen does not contain antibodies to SARS-CoV-2, 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.

Composition

1. Test Cassette: 20T/Kit. The test cassette contains antigen conjugated gold colloid particles and anti-human IgG/IgM coated on the membrane. It is packaged in a sealed foil pack together with a micropipette for sample collection.
2. Specimen Diluent: 20 Vials/Kit and 0.3mL/Vial
3. Lancets and Alcohol Prep Pads (optional configuration): 20 pouches/Kit. Each pouch contains one lancet and two alcohol prep pad.
4. Instructions for use:1 copy/kit.



Test Cassette and Micropipette in Sealed Foil Pack

Specimen Diluent

Lancet and Alcohol Prep Pad in Sealed Pouch

Storage Conditions and Validity

Keep kits in a cool and dry place at 2-30°C. The individual kits and/or box correctly stored kits are valid for 12 months (see the kit box for expiration information). **DO NOT FREEZE.**

Specimen Collection and Preparation

1. The kit is suitable for human serum, plasma, or whole blood samples.
2. Specimens Collection

(1) Fingerstick Whole Blood (Capillary Blood) Collection

① Massage:

Massage pulp of the left ring finger.

② Disinfect:

Wipe the needle puncture site with alcohol prep pad.

③ Puncture

Hold the disposable sterile blood collection needle to puncture a depth of 2-3mm on the ventral ulnar side of fingertip by right hand, and then pull out the needle immediately.

④ Wipe off

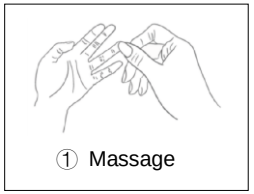
After the blood flows naturally, wipe off the first drop with alcohol prep pad.

⑤ Specimen collection

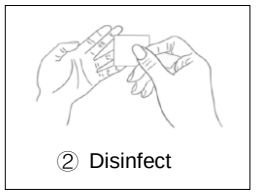
Suck blood to the tick mark of the disposable micropipette, and then press wound with the alcohol prep pad to stop bleeding; If the blood flows is not enough, press the left ring finger (from the palm towards the fingertip) slightly to make blood flow out.

⑥ Specimen for detection

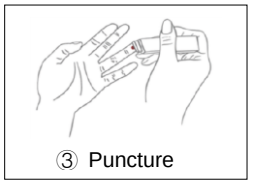
Use fingerstick whole blood (Capillary Blood) for detection directly.



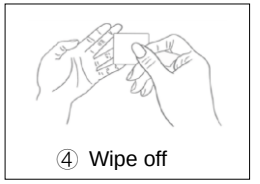
① Massage



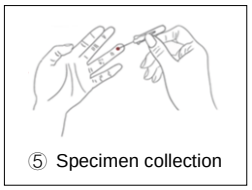
② Disinfect



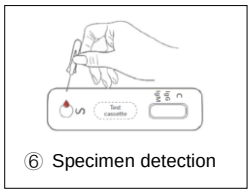
③ Puncture



④ Wipe off



⑤ Specimen collection

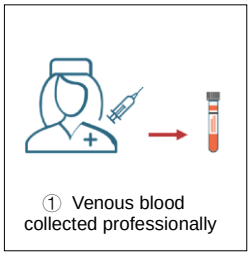


⑥ Specimen detection

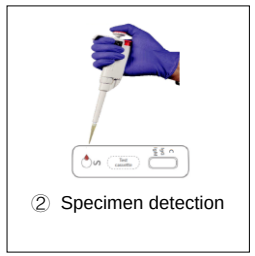
(2) Venous Whole Blood or Serum/Plasma Collection

① Venous blood collection should be carried out in a professional laboratory by standard protocol.

② Whole venous blood or separated serum/plasma was used for detection.



① Venous blood collected professionally



② Specimen detection

3. Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. When an immediate testing is not available, Serum and plasma specimens can be stored at 2-8°C for 3 days, or at -20°C for 12 months, or below -70°C for 48 months. Do not freeze whole blood specimens. Whole blood collected by fingertip should be tested immediately.

Test Procedure

1. Keep the test cassette, specimen, Diluent, and/or controls to room temperature (15-30℃) prior to testing.

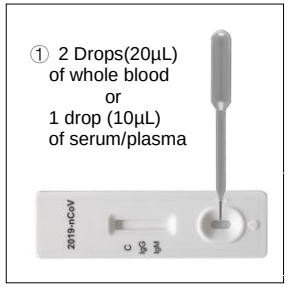
2. Remove the test device from the sealed foil pack and use it as soon as possible.

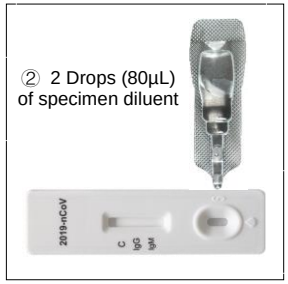
3. Place the test device on a clean and level surface.

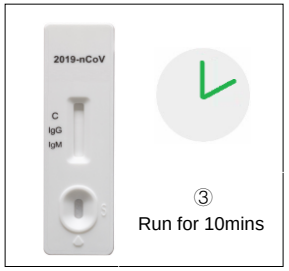
4. Add 2 drops (20μL) of fingerstick/venous whole blood by micropipette， or 1 drop (10μL) of serum/plasma specimen by micropipette into each specimen well.

5. Add 2 drops (80μL) of specimen diluent into each specimen well.

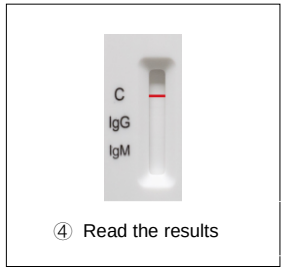
6. Allow test to run for 10 minutes. Read the results by viewing the detection window. Test results that have run over 20 minutes are invalid.







③
Run for 10mins



④ Read the results

Interpretation of Results

1. NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

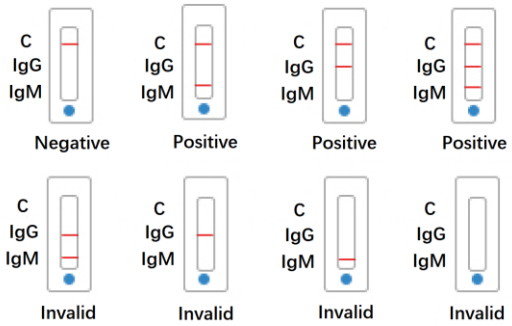
2. IgM POSITIVE: Two lines appear.
One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-CoV-2 specific-IgM antibodies and is indicative of primary SARS-CoV-2 infection.

3. IgG POSITIVE: Two lines appear.
One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for SARS-CoV-2 specific-IgG and is probably indicative of secondary SARS-CoV-2 infection.

4. IgG and IgM POSITIVE: Three lines appear.
One colored line should be in the control line region(C), and two-colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG & IgM antibodies and is indicative of secondary SARS-CoV-2 infection.

5. INVALID: Control line fails to appear.

Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Quality Control

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Detection Method

1. The kit is for qualitative detection and auxiliary diagnosis use only.

2. In the early phase of infection, no IgM or IgG antibody will be produced, or the titer will be very low, thus, negative result will occur. Re-testing will be conducted in 7-14 days, and the sample that is collected last time will be detected in parallel during re-testing to confirm whether the serology turns positive or the titer increases significantly.

3. The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods. Test results can be affected by temperature and humidity.

4. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

5. Results from immunosuppressed patients should be interpreted with caution.

Product Performance

1. Use the enterprise reference controls for testing, and the results meet the detection requirements of enterprise reference controls.

a. Positive reference of product compliance rate: The positive reference of product compliance rate should be 5/5.

b. Negative reference of product compliance rate: The negative reference of product compliance rate should be 10/10.

c. Minimum detection limit: The minimum detection limit of reference product S1 should be negative, S2 and S3 should be positive.

d. Repeatability: Three reference products are tested for repeatability. Each test is repeated 10 times and should be positive.

2. In order to test the sensitivity and specificity of this method, 401 blood samples were tested. Using this kit, 45 cases out of 47 PCR test confirmed specimens are positive, with the sensitivity of 95.7%; 347 out of 354 PCR test excluded specimens are negative, the specificity was 98.0%. The overall consistency is 97.8%.

Method		PCR Test		Total Results
	Results	Positive	Negative	
COVID-19 IgG/IgM Test	Positive	45	7	52
	Negative	2	347	349
Total Results		47	354	401

Expected Values

Primary SARS-CoV-2 infection is characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection.

Secondary SARS-CoV-2 infection is characterized by the elevation of SARS-CoV-2-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.

Precaution

1. For in vitro diagnostic use only.
2. Do not use this kit beyond the expiration date printed on the outside carton.
3. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
4. Do not reuse any kit components.
5. Use fresh specimens whenever possible.
6. Results after 20 minutes are considered invalid.
7. The product should be used as soon as possible once the foil pouch is open, in case of long-term exposure to environment.
8. Follow standard biosafety guidelines for handling and disposal of potential infective material.

References

1. Templeton, K.E., Scheltinga, S.A., et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4 [J]. Journal of clinical microbiology 42(4): 1564-1569.

2. Smith, A.B., Mock, V., et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR [J]. Journal of Clinical Virology 28(1): 51-58.

Instruction Approval and Revision Date

Approval Date: 6/APR/2020
Revision Date: 25/AUG/2020
Date of Issue: 26/AUG/2020

Index of Symbols

IVD	The product is used in vitro, please don't swallow it.		Please don't reuse it
	Validity		Please read the instruction book carefully before using
	Manufacturer		Temperature scope within which the product is reserved
LOT	Batch number		Warning, please refer to the instruction in the annex
	Date of manufacture		Biological risks
	Upward		Avoid overexposure to the sun
EC REP	European union authorization representative		Keep dry
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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EC REP

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