COVID-19 IgM/IgGRapid Test

(Colloidal Gold)

What is COVID-19

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.

Intended Use

COVID-19 IgM/IgG Rapid Test is an *in vitro* diagnostic test for the qualitative determination of COVID-19 IgM and IgG antibodies in human whole blood (fingertip), serum or plasma.

The test kit consists of test devices and buffer. It is for *in vitro* diagnostic use only, and can be used in point-of-care testing settings and central laboratories.

Summary

The test kit is based on chromatographic immunoassay technology. The test device contains: 1) Conjugate pad: colloidal goldlabeled with recombinant SARS-CoV-2antigen and quality control antibody gold marker. 2) NC membrane: coated with two detection lines (IgG line and IgM line) and one quality control line (C line). The IgM linecoated with mouse anti-human IgM antibody detects the COVID-19 IgM antibody. The IgG line coated with mouse anti-human IgG antibody detects the COVID-19 IgG antibody. The C line coated with quality control antibody.

Principle

When appropriate amount of sample is added to the sample well of the test device, it will move forward along the test device under the action of the capillary. If the sample contains IgM antibody, the antibody will bind to the recombinant SARS-CoV-2 antigen labeled with colloidal gold, then forms a sandwich complex with the coated anti-human IgM antibody at IgM line, IgM line will appear purple-red, prompting the COVID-19 IgM antibody is positive.

If the sample contains IgG antibody, the antibody will bind to the recombinant SARS-CoV-2 antigen labeled with colloidal gold, then forms a sandwich complex with the coated anti-human IgG antibody at IgG line, IgG line will appear purple-red, prompting the COVID-19 IgG antibody is positive.

If the lines of IgG and IgM are not colored, the negative result will be displayed. The test device also contains a quality control line C. The quality control line C should display purple-red regardless whether there is a test line or not. Test result will be invalid if quality control line C does not show color, this sample needs to be retested with a new test device.

Composition

Each test kit contains the test device, buffer, pipette (optional), lancet (optional, for fingertip blood), alcohol pad (optional) and package insert.

Materials required but not provided: Specimen collection containers,Centrifuge (for plasma only), Micropipette and Timer.

Storage and Handling

The original packaging test kit should be storedat 2-30℃ (36-86℉). Keep away from light. The test device must remain in sealed pouch until use. Do not freeze or refrigerate.

Use the test kits at temperatures between 18-25℃.

Use the test kits between 10-90% humidity.

Do not use the test devices beyond the expiration date (printed on the foil pouch and box label).

Note: *The test kit is recommended to store between 2-8℃ if it not used in a short time.*

Specimen Collection and Preparation

1. The COVID-19 IgM/IgG Rapid Test is intended for use with human whole blood, serum, plasma specimen only.

2. Only clear, non-hemolyzed specimens are recommended for use with this test, Serum or plasma should be separated as soon as possible to avoid hemolysis.

3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8℃ for up to 3 days. For long term storage, serum or plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days after collection. Do not freeze whole blood specimens. Whole blood collected by fingertip should be tested immediately.

4. Container containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood collection.

5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of the specimens.

Test Procedure

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

1. Bring the test deviceto room temperature for before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Put a test device on a dust-free clean surface.
3. Apply 10μL whole blood (from vein or fingertip), serum or plasma onto the sample well of thetest device, and then apply 2 drops (about 60-80μL) of buffer onto the sample well of the test device.
4. Read the result after 10 minutes.Do not interpret the result after 15 minutes.

Note:

For in vitro diagnostic use.

Avoid contact with eyes and skin. Flush abundantly with water upon disposal if reagents are spilled.

If you apply fingertip blood with pipette, please wipe the rest of blood on the fingertip with alcohol pad.

Disposal

Waste must be disposed of in compliance with local legislation. Take the appropriate precautions for infected material if necessary.

Limitations

The test result can't be used for diagnosis of COVID-19. If the result does not match the clinical evaluation, please do more testing.

Please do not use highly hemolytic samples.

Please do not reuse the test device.

The test kit can only be used with whole blood (from vein or fingertip), serum or plasma. If use other samples, it may cause wrong results.

Please follow the package insert when testing.

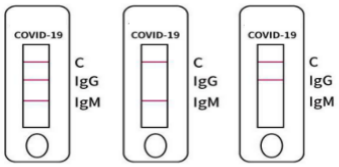
Interpretation of the test results

1. Positive result:

1) The COVID-19 IgM antibody is detected if thecontrolline (C) and the detection line (T) IgM are both colored, and the detection (T) IgG line is not colored, that means the COVID-19 IgM antibody is positive.

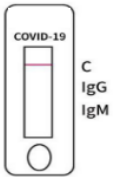
2) The COVID-19 IgG antibody is detected if the control line (C) and the detection (T) IgG line are both colored, and the detection line (T) IgM is not colored, that means the COVID-19 IgG antibody is positive.

3) The COVID-19 IgG and IgM antibodies are detected if the control line (C), the detection line (T) IgM and IgG are both colored, which means both the COVID-19 IgG and IgM antibodies are positive.



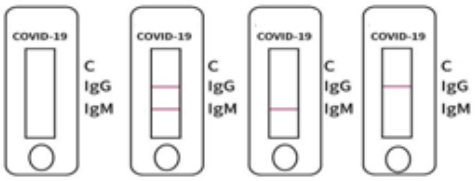
2. Negative result:

If there is only quality control line C is colored, IgG and IgM detection lines are not colored, the COVID-19 IgM/IgG antibody is not detected, that means the result is negative.



3. Invalid result:

If the quality control line C is not colored, no matter whether the detection line IgM/IgG is colored or not, the result is invalid and needs to be tested again.



Note:

1. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

2. 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.

3. Positive results may be due to past or present infection with nonSARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Performance Characteristics

The COVID-19 IgM/IgG Rapid Test Device was compared with PCR Reagent using clinical specimens from 80 healthy persons and 70 identified patients.The results are summarized as below.

The results show that the relative specificity is 100%; the relative sensitivity is 97.1%. The accuracy is 98.67%.

Clinical Performance of negative sample	
Negative Cases(By PCR)	80
Negative coincidence rate(COVID-19 IgM)	80 (100%)
Negative coincidence rate(COVID-19 IgG)	80 (100%)
Negative coincidence rate(Total)	80 (100%)
Clinical Performance of positive sample	
Positive Cases(By PCR)	70
Positive coincidence rate(COVID-19 IgM)	68 (97.1%)
Positive coincidence rate(COVID-19 IgG)	67 (95.7%)
Positive coincidence rate(Total)	68 (97.1%)

Reference

1. Long Q. et al., Antibody responses to SARS-CoV2 in patients with COVID-19. Nature Medicine, Brief communication, https://doi.org/10.1038/s41591-020-0897-1

Manufactured By:

Jiangsu Well Biotech Co., Ltd.

NO. 9 Changyang Rd., Changzhou, Jiangsu, China 213149

Tel: +86-519-80191660 Fax: +86-519-80191663

European Representative:

Lotus NL B.V.Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

Symbols

Caution, Consult accompanying documents

Temperature Limitation

Sufficient for Use

Keep away from sunlight

Keep away from moisture

Do not reuse

In-Vitro Diagnostic Medical Device

Batch Code

Use by

Manufacturer

Authorized Representative

Consult instruction for use

Meet the requirements of EC Directive 98/79/EC