Green Spring®

GF101A1 2020-01

COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit

(Colloidal gold)

Instructions for use

Intended Use

Green Spring® COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit for COVID-19 is used to qualitatively detect total IgG and IgM antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

Summary

Coronavirus (CoV) belongs to the Cronoaviridae family and is divided into three types: α, β and γ. Alpha and beta are only pathogenic to mammals and gamma mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route as well. So far there are seven types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and the novel coronavirus (2019).

Test Principle

Green Spring® COVID-19 (2019-nCoV) Coronavirus IgG/IgM Rapid Test Kit for COVID-19 is Colloidal gold immunochromatography based. The test card contains (1) colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody colloidal gold marker, (2) detection lines (T lines) and quality control line (C) fixed on a nitrocellulose membrane. T is fixed with recombinant novel coronavirus antigen for detecting the novel coronavirus total IgM and IgG antibody. The quality control antibody is fixed on the C line.

When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test card via capillary action. If the sample contains IgM and IgG antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen. The antibody/antigen complex will be captured by the recombinant novel coronavirus antigen immobilized on the membrane, forming a red T line and indicating a positive result for the total IgG/IgM antibody.

If neither antibody is present, a negative result is displayed. The card also contains a quality control line (C). Regardless of what antibodies are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear it indicates that the test result is invalid and a new, unopened test cassette is required to retest the sample.

Contents of the Kit

One test kit contains:
25 Test Cassettes | 25 Dropper | 1 Buffer Solution Bottle | 1 Package Insert

Materials not provided but required:
Capillary Sampler | Lancet | Alcohol wipes | Gloves | Timer

Warnings and Precautions

- Only for human in vitro clinical diagnostics only.
- The product should only be used by trained clinical professionals.
- After opening the sealed cassette pouch the test should be used within one hour.
- Do not immerse test cassette in water.
- Do not freeze test cassette or buffer solution.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Dispose of all used or damaged test cassettes, capillary samplers, or other kit component as biohazardous materials.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- Do not use samples containing lipids, hemolysis, or turbidity which can affect results.

Storage Instructions

The reagent should be stored in the dark at room temperature (2°C to 30°C) and has a shelf-life of 12 months. The container should be protected from light after being opened. Do not freeze.

Sample Requirements

- Suitable for human serum, plasma, or whole blood samples including samples prepared by commonly-used anticoagulants (EDTA, heparin, sodium citrate).
- Fresh samples should be collected and tested immediately.
- Serum and plasma samples can be stored at 2-8°C for 5 days. If long-term storage of serum or plasma samples is required, store at -20°C and avoid repeated freeze /thaw cycles.
- Anticoagulated whole blood samples can be stored at 2-8°C for 7 days.
- Before testing, samples stored in refrigerated or frozen storage should be slowly returned to room temperature (15-30°C) and stirred. When particulates are clearly visible in the sample the precipitate should be removed by centrifugation before testing.

Test Procedure

Do not open pouch until ready to use. Prep necessary materials: Test cassette | Buffer solution | Capillary Sampler Label Test cassette with patient ID.
1.Obtain a specimen using standard laboratory protocols.
Using capillary sampler, obtain 20μL of fingerstick or venous whole blood specimen or 10μL of serum or plasma.

- For intravenous sampling follow standard laboratory protocols.

2.Dispense the specimen into the Test Cassette sample well.

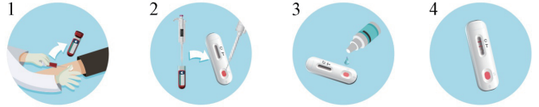
- Ensure that the entire sample is dispensed into the sample well.

3.Remove cap of the Buffer Solution bottle and dispense 2-3 drops into the Test Cassette sample well.

- Remove any air bubbles in the dropper.
- Test on a level surface at room temperature.

4.Allow test to run for 15 minutes. Read the results by viewing the detection window.

- Test results that have run over 20 minutes are invalid.



Collect blood sample | Add sample to the well | Place 2-3 drop buffer in the well | Read results after 15 minutes

Test Method Limitations

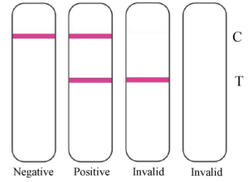
- This product can only be used to detect the IgG/IgM antibodies of the novel coronavirus in human blood, serum, or plasma. It cannot be used with other body fluids or secretions.
- This product is only for qualitative testing and the specific content of each indicator must be measured using other quantitative methodologies.
- Negative results may be caused by low concentrations of the novel coronavirus IgG/IgM antibody in the sample and therefore cannot completely rule out the possibility of infection.
- 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.

Display of Results/Expected Values

A total of two detection lines are possible, with the control (C) line appearing when sample has been flowed through the cassette.

1.Negative Result

If only the quality control line (C) appears and the detection T line is not visible, then no novel coronavirus antibody has been detected and the result is negative.



2.Positive Result, G and M

If the quality control line (C) and the detection T lines appear, then the novel coronavirus IgG/IgM antibodies have been detected and the result is positive for coronavirus antibodies.

Internal Quality Control Procedure

Each Test Cassette device has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or Green Spring® for technical support.

R&D Joint by **Third Affiliated Hospital of Sun Yat-sen University**
School of Biology and Medicine, Guangdong University of Technology
Shenzhen Lvshiyuan Biotechnology Co.,Ltd

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