

**One Step Test for
Novel Coronavirus (2019-nCoV) IgM/IgG Antibody
(Colloidal Gold)**

User Manual
REF: CG2057

INTENDED USE

One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody (Colloidal Gold) is intended for the qualitative detection of 2019-Novel Coronavirus IgM and IgG antibody in serum, plasma, fingertip blood or whole blood samples of pneumonitis patients or suspected cases.

SUMMARY

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by 2019-nCoV, a new strain of coronavirus that has not been previously identified in humans. The disease is primarily spread between people via respiratory droplets from infected individuals when they cough or sneeze. Time from exposure to onset of symptoms is generally between 2 and 14 days. The disease may initially present with few or no symptoms, or may develop into fever, coughing, shortness of breath, pain in the muscles and tiredness. Further development may include pneumonia and acute respiratory distress syndrome.

Detection of 2019-nCoV IgM and IgG antibodies in human blood can be used as an auxiliary means for early screening of COVID-19. 2019-nCoV IgM antibody could be detected in patient blood in 3-5 days after onset and IgG could be detected in 7 days after onset. However, the trend of IgM and IgG changes in different cases is not exactly the same. As it is a novel disease diagnosis and treatment of which are being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

PRINCIPLE

The test uses mixed recombinant 2019-nCoV nucleocapsid protein (N protein) and spike protein (S protein) both conjugated with colloidal gold and anti-human IgM and IgG antibody coated on different test lines respectively. After the samples has been applied to the test strip, the gold-labelled recombinant 2019-nCoV N protein and S protein will bind with 2019-nCoV IgM or IgG antibody in sample and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by anti-human IgM and IgG antibody resulting in purplish red streaks on the test lines. The color intensity of each test line increases in proportion to the amount of 2019-nCoV IgM and IgG antibody in sample.

CONTENTS

1. A kit contains:

Package specifications: 100 tests/box, 50 tests/box, 25 tests/box, 5 tests/box, 3 tests/box, 1 test/box.

- 1) Getein Novel Coronavirus (2019-nCoV) IgM/IgG Antibody test card in a sealed pouch with desiccant
- 2) Disposable pipet
- 3) Sample diluent
- 4) User manual: 1 piece/box

Note: Do not mix or interchange different batches of kits.

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, a colloidal gold pad (coated with recombinant 2019-nCoV N protein and S protein), nitrocellulose membrane with two test lines (these two lines are coated with anti-human IgM and IgG antibody respectively), the control line (coated with anti recombinant protein tag protein), absorbent paper and liner.

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

STORAGE AND STABILITY

Store the test card at 4-30°C with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

1. Do not reuse the pipet to avoid cross contamination.
2. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
3. The test cards can be stored in room temperature with sealed pouches. And the test cards stored in low temperature should reach room temperature before testing.
4. Sodium azide is used as preservative which may react with copper drainage pipe or lead drainage pipe and cause explosive substance. Please cope with the preservative properly according to relevant local regulations.
5. There should be appropriate bio-safety assurance procedure for infectious sources or potential infectious sources. Some relevant precautions are showed below:
 - (1) Wear disposable gloves to deal with samples, or sterilize reagents.
 - (2) Sterilize spilled samples or reagents with sanitizer.
 - (3) Sterilize and cope with all of samples, reagents and potential contaminant with relevant local regulations.

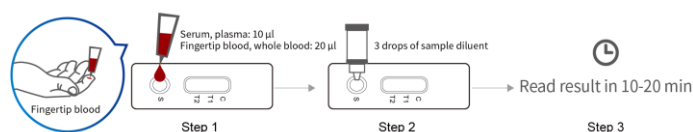
SPECIMEN COLLECTION AND PREPARATION

1. Sample should be **human serum, plasma, fingertip blood and whole blood**, other body fluid and samples may cause incorrect or inaccurate results.
2. Venous blood should be collected under sterile condition at any time of a day.
3. Suggest using serum or plasma for better results.
4. Heparin, sodium citrate and EDTA can be used as anticoagulant for plasma, fingertip blood and whole blood sample.
5. Serum, plasma, fingertip blood or whole blood sample should be tested within 4 hours after blood collection in room temperature. If testing will be delayed, serum and plasma may be stored up to 5 days at 2-8 °C or stored for 6 months at -20 °C before testing (fingertip blood and whole blood sample may be stored up to 3 days at 2-8 °C). Do not heat the samples and discard hemolyzed samples.
6. Bring all samples to room temperature (15-30 °C) before use. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
7. **SAMPLE VOLUME: 10 µl** of serum and plasma sample, **20 µl** of fingertip blood and whole blood sample.

TEST PROCEDURE

Read the manual carefully before using and operate according to the manual to avoid incorrect results.

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature (15-30 °C) before test.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver sample (**10 µl** of serum and plasma sample, **20 µl** of fingertip blood and whole blood sample) into the sample port on the test card. Then add three drops of sample diluent immediately.
6. Read the results visually in **10-20 min**.



TEST RESULTS

Positive (+):



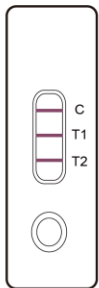
- (1) 3 purplish red bands appear, one at the control area (C) and two at the test lines (T1, T2). The result indicates that the sample contains both 2019-nCoV IgM and IgG antibody.
- (2) 2 purplish red bands appear, one at the control area (C) and one at the test line (T1). The result indicates that the sample contains 2019-nCoV IgM antibody.
- (3) 2 purplish red bands appear, one at the control area (C) and one at the test line (T2). The result indicates that the sample contains 2019-nCoV IgG antibody.

Negative (-):

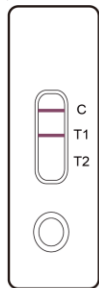
A single purplish red band appears at the control area (C) without any other band at test lines. The result indicates that the sample does not contain 2019-nCoV IgM or IgG antibody.

Invalid:

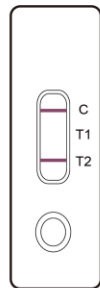
If no colored band appears in the control area (C) in 10-20 min, the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.



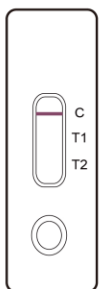
Positive 1



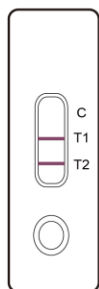
Positive 2



Positive 3



Negative



Invalid 1



Invalid 2



Invalid 3

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment response.

REFERENCES

- [1] David S. Hui, et al. The Continuing 2019-nCoV Epidemic Threat of Novel Coronaviruses to Global Health – The Latest 2019 Novel Coronavirus Outbreak in Wuhan, China. *Int J Infect Dis.* 2020 Jan 14;91:264–266.
- [2] Wang D, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China[J]. *JAMA.* 2020.
- [3] Peng Zhou, et al. A Pneumonia Outbreak Associated with a New Coronavirus of Probable Bat Origin[J]. *Nature.* 2020.
- [4] Xiaolong Tian, et al. Potent Binding of 2019 Novel Coronavirus Spike Protein by a SARS Coronavirus-Specific Human Monoclonal Antibody[J].

BioRxiv. 2020.

[5] Peng Zhou, et al. Discovery of a Novel Coronavirus Associated with the Recent Pneumonia Outbreak in Humans and Its Potential Bat Origin[J]. *BioRxiv.* 2020.

[6] Li Z, Yi Y, Luo X, et al. Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis [published online ahead of print, 2020 Feb 27]. *J Med Virol.* 2020;10.1002/jmv.25727.

[7] Jin Zhang, Jianhua Liu, et al. Serological detection of 2019-nCoV respond to the epidemic: A useful complement to nucleic acid testing. *medRxiv.* 2020.03.04.20030916.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody (Colloidal Gold) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		In vitro diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		Do not use if package is damaged
	Catalogue number		

Thank you for purchasing One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG Antibody (Colloidal Gold). Please read this user manual carefully before operating to ensure proper use.