CE IVD

One Step Test for

Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)

User Manual REF CG2057

BACKGROUND

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.

When IgM antibodies are present, it may indicate that a patient has an active or recent infection with 2019-nCoV. And IgG antibodies develop later following infection. When IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. It is unknown how long IgM or IgG antibodies to 2019-nCoV will remain present in the body after infection and if they confer immunity to infection.

As it is a novel disease diagnosis of which are being explored, please refer to the latest guidelines for diagnosis and treatment of COVID-19.

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 or whole blood samples from patients suspected of COVID-19 infection by a healthcare provider. One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold) is an aid in the diagnosis of patients with suspected 2019-nCoV infection in conjunction with clinical presentation and the results of other laboratory tests. This test is only intended for professional and laboratory use, not for home testing. Results from the test should not be used as the sole basis for diagnosis and exclusion of 2019-nCoV infection.

Negative results do not exclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold) early after infection is unknown.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

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 IgG and IgM 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 IgG or IgM 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 IgG and IgM 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 IgG and IgM antibody in sample.

CONTENTS

1. A kit contains:

Package specifications: 25 tests/box

(1) Getein Novel Coronavirus (2019-nCoV) IgM/IgG antibody test card in a sealed pouch with desiccant

(2) Sample diluent: 2 bottles/box

(3) 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 IgG and IgM antibody respectively), the control line (coated with anti recombinant protein tag protein), absorbent paper and liner.

3. Sample diluent composition (2 mL/bottle):

Phosphate buffered saline (11 mM PBS)

STORAGE AND STABILITY

Store the test card at 4-30 ℃ with a valid period of 24 months.

Use the test card within 1 hour once the foil pouch is opened.

Store the sample diluent at 0-30 ℃ with a valid period of 24 months.

Store the sample diluent at 2-8 ℃ for better results.

PRECAUTIONS

1. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
2. 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.
3. 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 or 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. It is recommended to use serum or plasma for better results.
4. Heparin, sodium citrate and EDTA can be used as anticoagulant for plasma and whole blood sample.
5. Serum, plasma or whole blood sample should be tested within 4 hours after blood collection in room temperature. If testing is delayed, serum and plasma may be stored up to 5 days at 2-8 ℃ or stored for 6 months at -20 ℃ before testing (whole blood sample may be stored up to 3 days at 2-8 ℃). Do not heat the samples and discard hemolyzed samples.
6. Bring all samples to room temperature (15-30 ℃) 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 or plasma sample, ***20 μL*** of whole blood sample.

TEST PROCEDURE

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

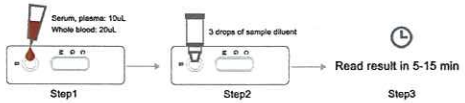
1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature (15-30 ℃) before test.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control

identification.

4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver sample (***10 μL*** of serum or plasma sample, ***20 μL*** of whole blood sample) into the sample port on the test card. Then add ***3*** drops of sample diluent immediately.
6. Read the result visually in ***5-10 min.*** The best reading time is about ***10-15 min.***

Note:

Don't read results after ***20 min***. To avoid confusion, discard the test card after interpreting the result.



TEST RESULTS

1. Valid Test

Positive (+):

(1) Three bands appear, one at the control area (C) and two at the test lines (M, G). The result indicates the presence of 2019-nCoV IgM and IgG antibody. The result is IgG and IgM positive or reactive, suggesting current or recent 2019-nCoV infection.

(2) Two bands appear, one at the control area (C) and one at the test line (M). The test indicates the presence of 2019-nCoV IgM antibody. The result is IgM positive or reactive, consistent with an acute or recent 2019-nCoV infection.

(3) Two bands appear, one at the control area (C) and one at the test line (G). The test indicates the presence of 2019-nCoV IgG antibody. The result is IgG positive or reactive, consistent with a recent or previous infection.

Negative (-):

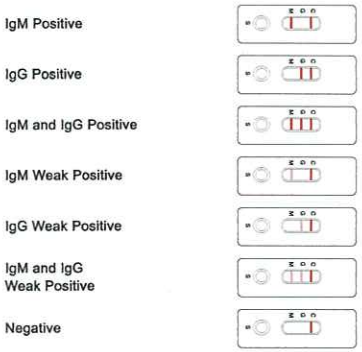
A single band appears at the control area (C) and no other band at test lines. The result indicates that the sample does not contain 2019-nCoV IgM or IgG antibody. Negative results do not exclude 2019-nCoV infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection.

Note:

Results from serological testing should not be used as the sole basis to diagnose or exclude 2019-nCoV infection.

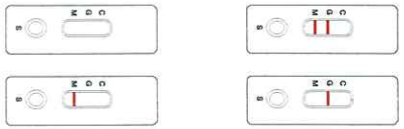
False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.



2. Invalid Test

If no band appears in the control area (C), the test result is invalid. The test should be repeated with a new test card and if the same situation reappears, please stop using this batch of products and contact your supplier.



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.

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	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	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.

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