CE ISO ISO13485 CFS

Export Approval from the Ministry of Commerce

Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Precise Rapid Sensitive

ANVISA

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

EL GOBIERNO DE TODOS

Ministerstwo Zdrowia

Hangzhou Singclean Medical Products Co.,Ltd.

Singclean®

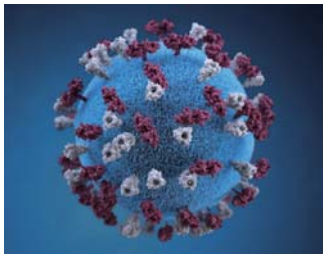
COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Intended Use

Singclean® COVID-19 IgG/IgM Test kit（Colloidal Gold Method）is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to Novel Coronavirus in human whole blood, serum or plasma to help reduce the spread of COVID-19. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Test kit（Colloidal Gold Method）must be confirmed with alternative testing method(s) and clinical findings.

Main Symptoms of COVID-19

- ☑ Fever
- ☑ Fatigue
- ☑ Cough
- ☑ Shortness of Breath

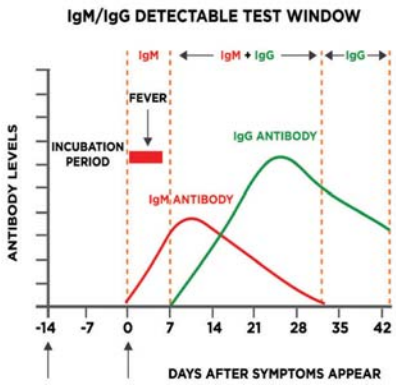


Antibody Generation

IgM and IgG are immunoglobulins produced by the immune system to provide protection against COVID-19 and can be detected in the serum, plasma or whole blood.

IgM: forms early in the immune response, normally appears 7 days of symptom onset.

IgG: appears later than IgM, IgG antibodies generally can be detected from 10 days of symptom onset and can last for months or even longer, remaining detectable in blood after the disease resolution.



FIGHT COVID-19

Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Product Information

Product Name	Singclean® COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)
Method of Detection	Colloidal Gold Method
Design Principle	Sandwich-based
Qualitative/ Quantitative	Qualitative
Specimen	Serum/Plasma/Whole Blood
Required Volume of Specimen	1 Drop

Packing

Specification	Pictures	Package Contents	Carton
20 tests/kit		1 Instruction 5 Buffers 20 Test Kits 20 Lancets 20 Disposable Micropipettes 20 Alcohol Tablets	600 pcs, L650*W270*H370mm, 6.88kg
1 test/kit		1 Instruction 1 Buffer 1 Test Kit 1 Lancet with Instruction 1 Disposable Micropipette 1 Alcohol Tablet	500 pcs, L680*W530*H400mm, 15.2kg

Storage and Stability

The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

FIGHT COVID-19

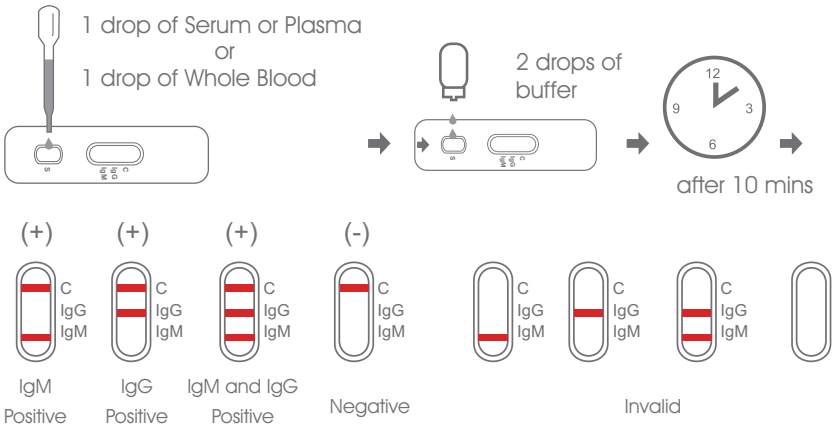
Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Product Advantages

Singclean®	PCR Nucleic Acid Test	IgG/IgM Antibody Test
Result Time	3-4 hours	10 minutes
Facility Requirement	PCR Laboratory	No special facilities needed but should only be operated by healthcare workers
Sample requirement	Saliva, nasal, oral or anal swabs	Whole blood, serum & plasma
Clinical Value	Commonly used, gold standard	Can be used in large scale, and can detect symptomatic or asymptomatic patients, patients who in the late or recurrent stage of infection
Limitation	1. High exposure risk to health workers when collecting samples 2. High false negative rate; low sensitivity	1. False negative and false positive could happen 2. Antibodies may not be detectable in the early stages of an infection
Storage	Cold Chain	Room Temperature

Test Procedures and Result Interpretation



FIGHT COVID-19

Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Clinical Data

The COVID-19 IgG/IgM detection kit (whole blood/serum/plasma) was evaluated with 1020 specimens. The results were compared with clinical diagnosis (based on RT-PCR).

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 IgG/IgM Test kit	Positive	192	14	206
	Negative	8	806	814
Total		200	820	1020
Relative sensitivity		96%（192/200）		
Relative specificity		98.29%（806/820）		
Accuracy		97.84% (998/1020）		

Global Network

Singclean® COVID-19 IgG/IgM Test Kit has been sold to more than 50 countries in the world, like Brazil, Chile, Poland, Spain, Bolivia, Greece, Lithuania, Ecuador, Ukraine and Turkey.

FIGHT COVID-19

Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

Test Method Limitations

•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, like CT images and other testing methods. Studies have shown that the combination of nucleic acid testing and antibody testing could effectively improve the detection rate.

•A false negative may occur if the amount of COVID-19 IgM or IgG antibody is below the detection level of the kit.

•It is not recommended to use the Product within 7 days after the clinical COVID-19 symptoms appear. COVID-19 positive patients may be tested negative by this Product at that period, as human body has not produced or produced very few antibodies at that period, which can't be detected by the Product.

Warnings and Precautions

•This COVID-19 Antibody Test Ki is not intended for at home use, it should only be operated by healthcare workers. Use by non-healthcare professionals can lead to deviation in test results and it is not safe for individuals to deal with the blood samples and used devices in the tests.

•Read the Package Insert prior to use. Directions should be read and followed carefully.

•Do not interpret the results after 20 minutes.

•Do not use kit or components beyond the expiration date.

•If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.

•Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity

COVID-19 Testing FAQs:

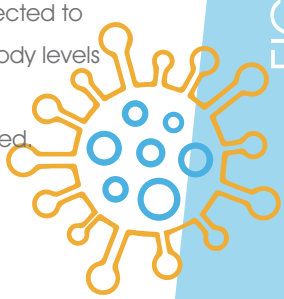
1.Who should get tested?

Anyone with symptoms of COVID-19, like fever, chills, cough, shortness of breath, or difficulty breathing or who has been exposed to COVID-19 should get tested. If you think you need to get tested, we recommend contacting your healthcare provider or a Respiratory Clinic and get scheduled for a test.

2.What does it mean if the specimen tests negative for COVID-19 IgM/IgG Antibodies?

A negative test result does not rule out COVID-19 virus infection and should not be used as the sole basis for treatment or patient management decisions. A negative result could happen if the patient specimen was collected prior to 7 days post-onset of symptoms (before IgM/IgG antibody levels are expected to become detectable by the assay) or more than 10 weeks after the infection (as IgM/IgG antibody levels are expected to drop).

When diagnostic testing is negative, the possibility of a false negative result should be considered.



FIGHT COVID-19

Singclean®

COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)

COVID-19 Testing FAQs

3. What can cause a false negative result?

a. Individual differences in test kits themselves;

b. Concentration of antibodies in the blood is low and doesn't reach the detection limit, it will also cause false negative;

c. The amount of blood added during the test may be insufficient;

d. Patients are at the early stage of infection and antibodies have not been produced.

e. False negative results can occur in elderly and immunocompromised patients.

4. What does it mean if the specimen tests positive for COVID-19 IgM/IgG Antibodies?

A positive test result indicates that anti-COVID-19 IgM/IgG antibodies were detected in the patient's specimen, which is not definitive for diagnosis of COVID-19 infection. Result must be combined with clinical observations, patient history and epidemiological information to make a final diagnosis.

Singclean® COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold Method) has been designed to minimize the likelihood of false positive test results while false positive result for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

5. When is it recommended to use antibody testing?

a. For IgM antibody testing, it is recommended to use samples from patients with an initial infection of 2-3 weeks (nucleic acid test is positive).During the test, only need to observe the color change of the IgM test line and control line, the IgG test line shouldn't be considered.

b. For IgG antibody testing, it is recommended to use samples from patients with an acute infection of more than 3 weeks or during recovery period (nucleic acid test is positive). During the test, only need to observe the color change of the IgG test line and control line, the IgM test line shouldn't be considered.

c. One patient's sample can only be used as one data, and multiple tests cannot indicate accuracy.

6. What is the validity period of buffer?

The validity period of buffer is the same as that of the test kits. The buffer is generally stable. In principle, opening the bottle does not affect the validity period .

FIGHT COVID-19

Dedicated to Healthcare Improvement

Hangzhou Singclean Medical Products Co.,Ltd.
Add:No.125(E),10th Street, Hangzhou Qiantang New Area, Zhejiang. China
P.C.:310018
Tel:+86-571-63431868 Fax:+86-571-63431886
E-mail: marketing@hzxhe.com
Web:www.Singclean.net