

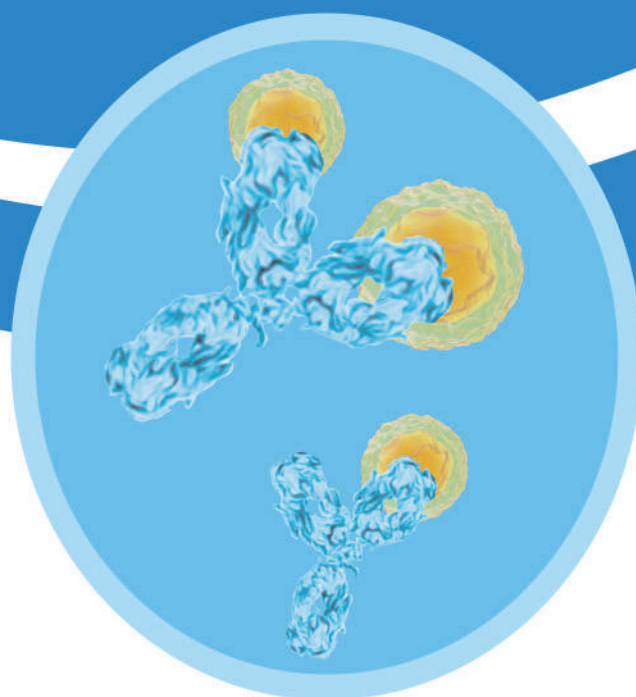
## About Us

CLONGENE is a high-tech enterprise specialized in biological raw materials and in vitro diagnostic products. Founded in 2004, Clongene is equipped with state-of-the-art ISO 13485:2016 accredited- China GMP compliant R&D and manufacturing facilities covering 19,000 square meters in Hangzhou, China. Our products have obtained CE certificates, FSC certificates and US FDA 510(k) Clearances.

CLONGENE keeps growing and pays much attention to the R & D of raw materials and vitro diagnostic products, in order to bringing more value to our clients. Our technology platforms including colloidal gold immunoassay (CGIA), enzyme-linked immunosorbent assay (ELISA), chemiluminescence immunoassay (CLIA), fluorescence immunoassay (FIA) and molecular diagnosis (RT-PCR).

CLONGENE provides high quality biological raw materials including antigen, antibody and enzyme products. Mainly in the fields of infectious diseases, drugs of abuse, fertility, inflammation, food safety, serum proteins, cardiac markers and tumor markers.

CLONGENE keeps bring more value to biopharmaceutical companies and scientific research units around the world, and bring more opportunities to distributors and partners with rich products and professional services.



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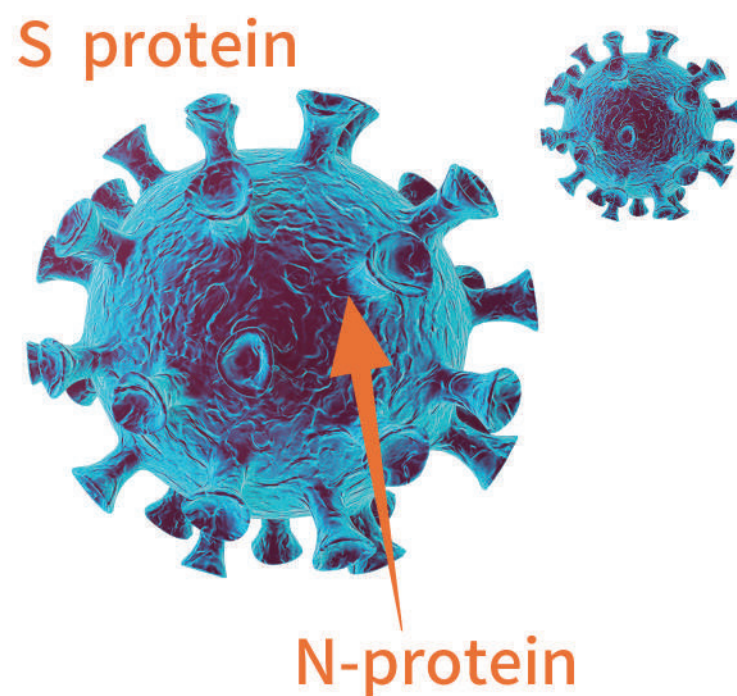
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## SARS-CoV-2 Proteins

Novel coronavirus includes four typical structural proteins: Spike Protein, Envelope Protein, Membrane Protein and Nucleocapsid Protein.

Spike (S) protein is the most important surface protein of SARS-CoV-2, which is related to the ability of virus infection. S protein contains two functional subunits, S1 and S2. The receptor-binding domain (RBD) of the S1 subunit is responsible for identifying and binding the angiotensin-converting enzyme 2 (ACE2) receptor. S2 subunit contains the basic components needed for the membrane fusion process, which is responsible for anchoring the S protein to the viral membrane and mediating the fusion between the viral membrane and the host cell membrane.



Nucleocapsid protein is an essential part of SARS-CoV-2. Due to its high immunogenicity, the nucleocapsid protein is always chosen to capture IgG/IgM in the COVID-19 serological kits.

**CLONGENE** has specifically designed the SARS-CoV-2 related products for serological test of COVID-19. The antigens include S, S1, RBD, N and ACE2 proteins with various tags. The antibodies include anti-S1 and N monoclonal antibody, anti-RBD-scFv and anti-S monoclonal with mouse / human chimeric antibody.

## Product list

Molecule	Cat. No.	Product Description
SARS-CoV-2 RBD-mFc	AI04501	Recombinant receptor binding domain (RBD) of SARS-CoV-2 Spike Protein with the Mouse Fc tag
SARS-CoV-2 RBD-His	AI04508	Recombinant receptor binding domain (RBD) of SARS-CoV-2 Spike Protein with the His tag
SARS-CoV-2 RBD-scFv	MI04503	Anti-RBD of SARS-CoV-2 Spike Protein single chain antibody fragment
SARS-CoV-2 S1-Fc	AI04502	Recombinant SARS-CoV-2 Spike Protein (S1 Subunit) with the human Fc tag
SARS-CoV-2 S1-His	AI04503	Recombinant SARS-CoV-2 Spike Protein (S1 Subunit) with the His tag
SARS-CoV-2 S1-mAb	MI04502	Rabbit anti-SARS-CoV-2 Spike Protein (S1 Subunit) monoclonal antibody
SARS-CoV-2 S1-mAb	MI04504	Mouse anti-SARS-CoV-2 Spike Protein (S1 Subunit) monoclonal antibody
SARS-CoV-2 S-His	AI04507	Recombinant SARS-CoV-2 Spike Protein (S1+S2 ECD) with the His tag
SARS-CoV-2 Spike antibody, Chimeric mAb	MI04505	SARS-CoV-2 Spike antibody, Chimeric mAb, Monoclonal mouse (variable region) /human (kappa/IgG1 constant) Chimeric antibody
SARS-CoV-2 NP-His	AI04504	Recombinant SARS-CoV-2 Nucleocapsid Protein with the His tag
SARS-CoV-2 NP-mAb	MI04501	Rabbit anti-SARS-CoV-2 Nucleocapsid Protein monoclonal antibody
ACE2-His	AI04505	Recombinant Human angiotensin-converting enzyme 2 with the His tag





# COVID-19 IgG/IgM Rapid Test

Serological immunoassay is an important auxiliary method for the diagnosis of COVID-19. The combination with molecular diagnostic is helpful to improve the accuracy of COVID-19 detection.



The colloidal gold immunoassay (CGIA) to detect COVID-19 utilizes the specific reaction between antigen and antibody to detect the anti-SARS-CoV-2 antibody in patients' sample. The advantages of CGIA is fast and convenient, stable sample collection, high throughput, and the result can be interpreted by naked eye.

## Product features

CE CE Marked

Instant result in 15 minutes

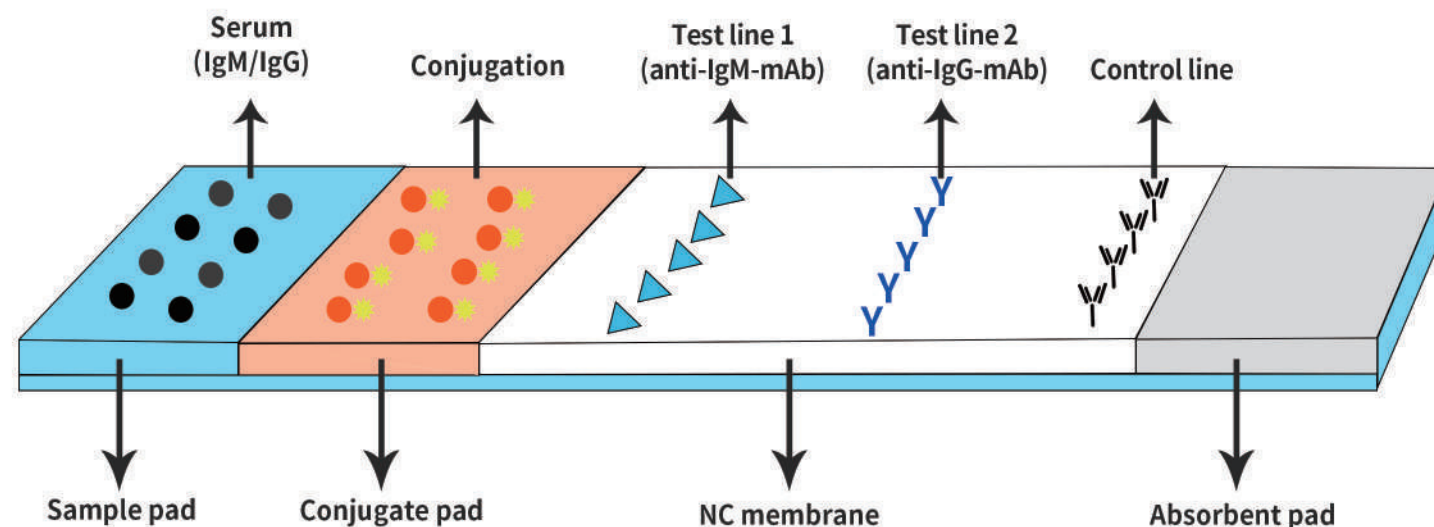
Detection for both IgG and IgM

Whole blood, serum and plasma can be detected

No equipment required

Easy storage, 4-30°C

## Principle



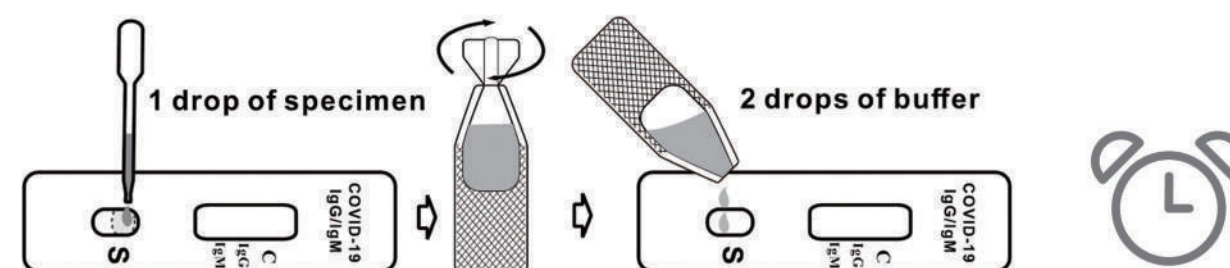
### IgM detection

If IgM antibody present in the specimen. IgM antibody bind to the SARS-CoV-2 antigens conjugate with colloidal gold. Then captured by the mouse anti-human IgM antibody pre-coated on the test line 1 (T1), and forming a burgundy colored line. Indicating anti-SARS-CoV-2 IgM positive test result.

### IgG detection

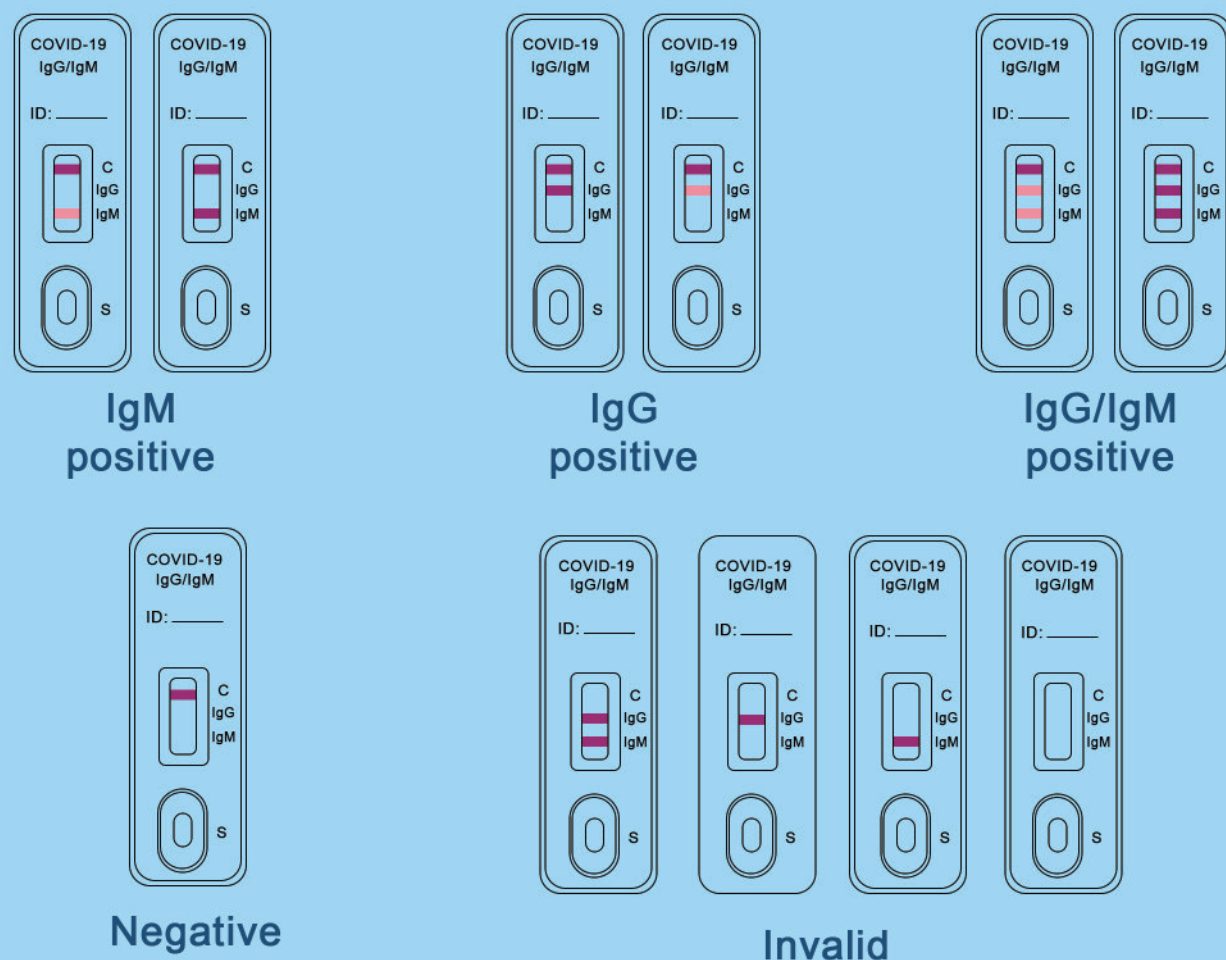
If IgG antibody present in the specimen. IgG antibody bind to the SARS-CoV-2 antigens labeled with colloidal gold. The immune-complex is then captured by the mouse anti-human IgG antibody coated on the test line 2 (T2). The burgundy colored T2 indicating IgG positive test result.

## Test procedure





## Interpretation of results



## Clinical performance

### COVID-19 IgM:

167 clinical specimens from individuals suspected of COVID-19 infection were detected by COVID-19 IgG/IgM rapid test cassette of CLONGENE.

The result was compared with that of RT-PCR.

COVID-19 IgM		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

A statistical comparison was made between the results yielding a sensitivity of 87.01%, a specificity of 98.89% and an accuracy of 93.41%.

### COVID-19 IgG:

Regarding the IgG test, we have counted the positive rate of the 77 patients during the convalescence period. The results yielding a sensitivity of 97.40%.

COVID-19 IgG		77 cases of novel coronavirus pneumonia
CLUNGENE®	Positive	75
	Negative	2
Total		77

### Cross-reactivity and interference

- No cross reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, TP, HTLV, CMV, FLUA, FLUB, RSV, MP, CP, HPIVs.
- Common serum components, such as albumin, bilirubin, hemoglobin, et. al., do not interfere with the COVID-19 IgG/IgM rapid test cassette of CLONGENE.
- No cross reactivity or interference was observed with common biological analytes.



# Certification

