BIOHIT

SARS-CoV-2 Antigen Quantitative Assay Kit

(Enzyme-linked immunoassay)

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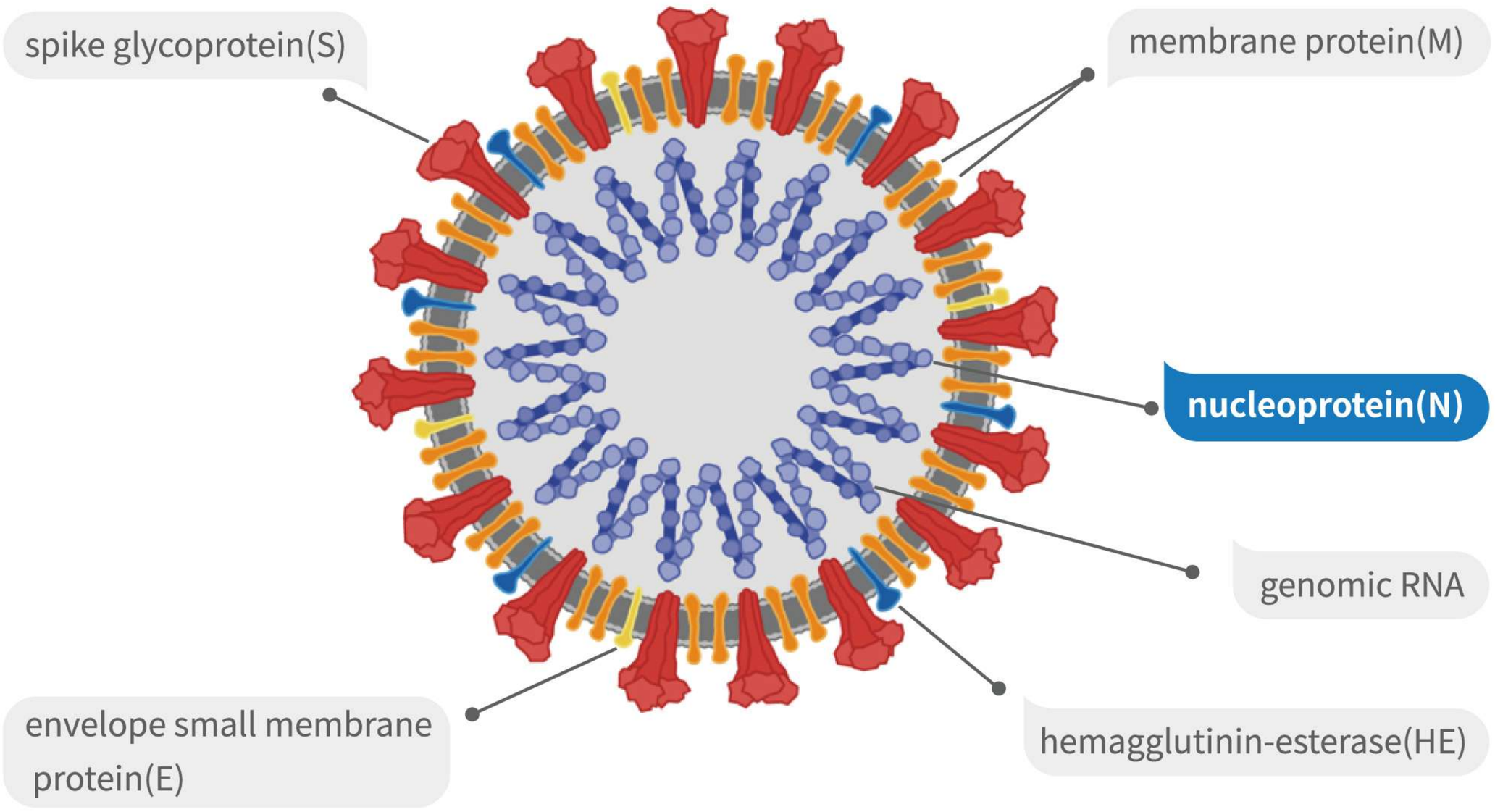
Principle introduction

» Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2)

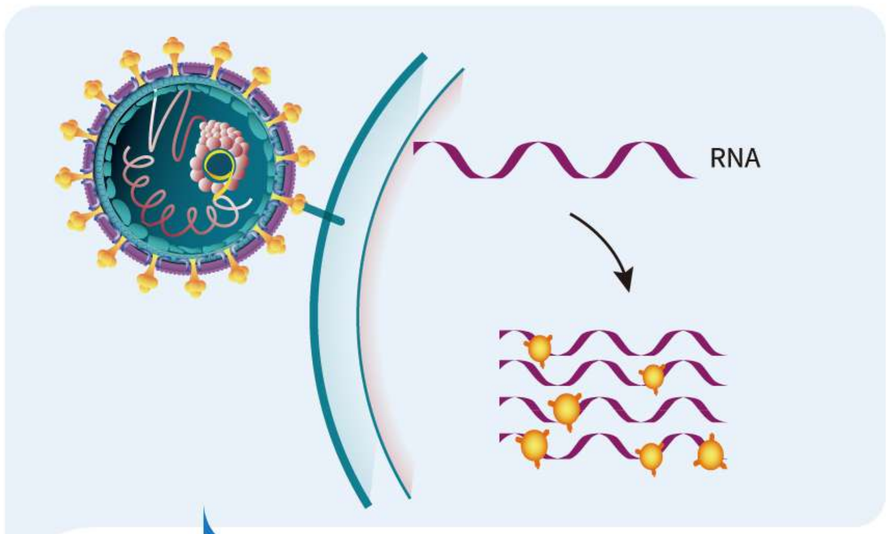


Novel coronavirus, a virus belonging to the family Coronaviridae, with approximately 120 nm in diameter. Club-shaped glycoprotein spikes in the envelope give the viruses a crownlike, or coronal, appearance. The nucleocapsid, made up of a protein shell known as a capsid and containing the viral nucleic acids, is helical or tubular. The coronavirus genome consists of a single strand of positive-sense RNA (ribonucleic acid).

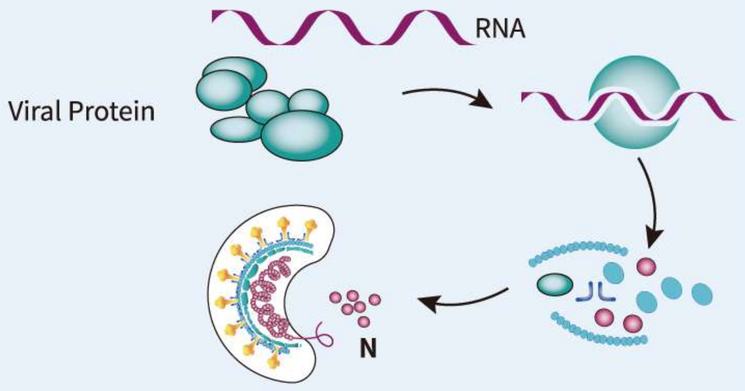
N antigen (N protein) is a component protein of nucleocapsid of SARS-CoV-2, with molecular weight of about 46kDa. It is highly conserved and rich in the virus. Currently, N protein is an ideal detection marker of SARS-CoV-2.

Main Mechanism of Antigen into Blood

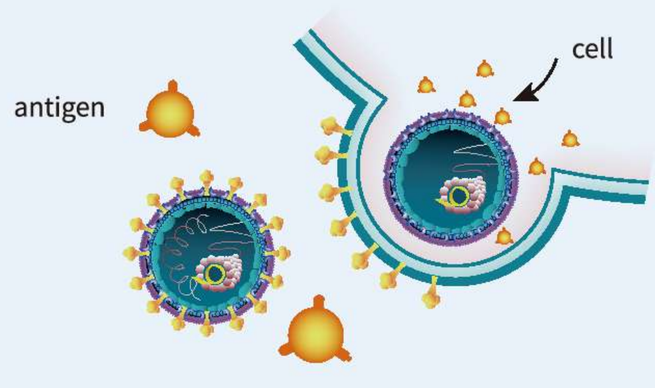
- When SARS-CoV-2 invades the lung cells, it will express a large amount of self protein to reassemble the virus particles, causing cell damage and forming inflammation. The virus protein expressed in excess and the virus protein released from the disintegration of virus particles killed by the body in the lesions will enter the blood circulation through the vessel wall with increased permeability due to inflammation in the lesions.



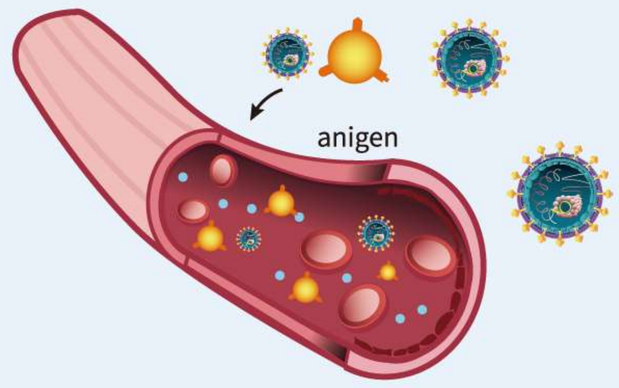
1 Replication: One RNA replicates to many chains, and synthesize many antigens at the same time.



2 Composition: Successfully replicated RNA + Viral protein



3 Virus comes out from disintegrated-cells,at the same time, many redundant antigens come our.

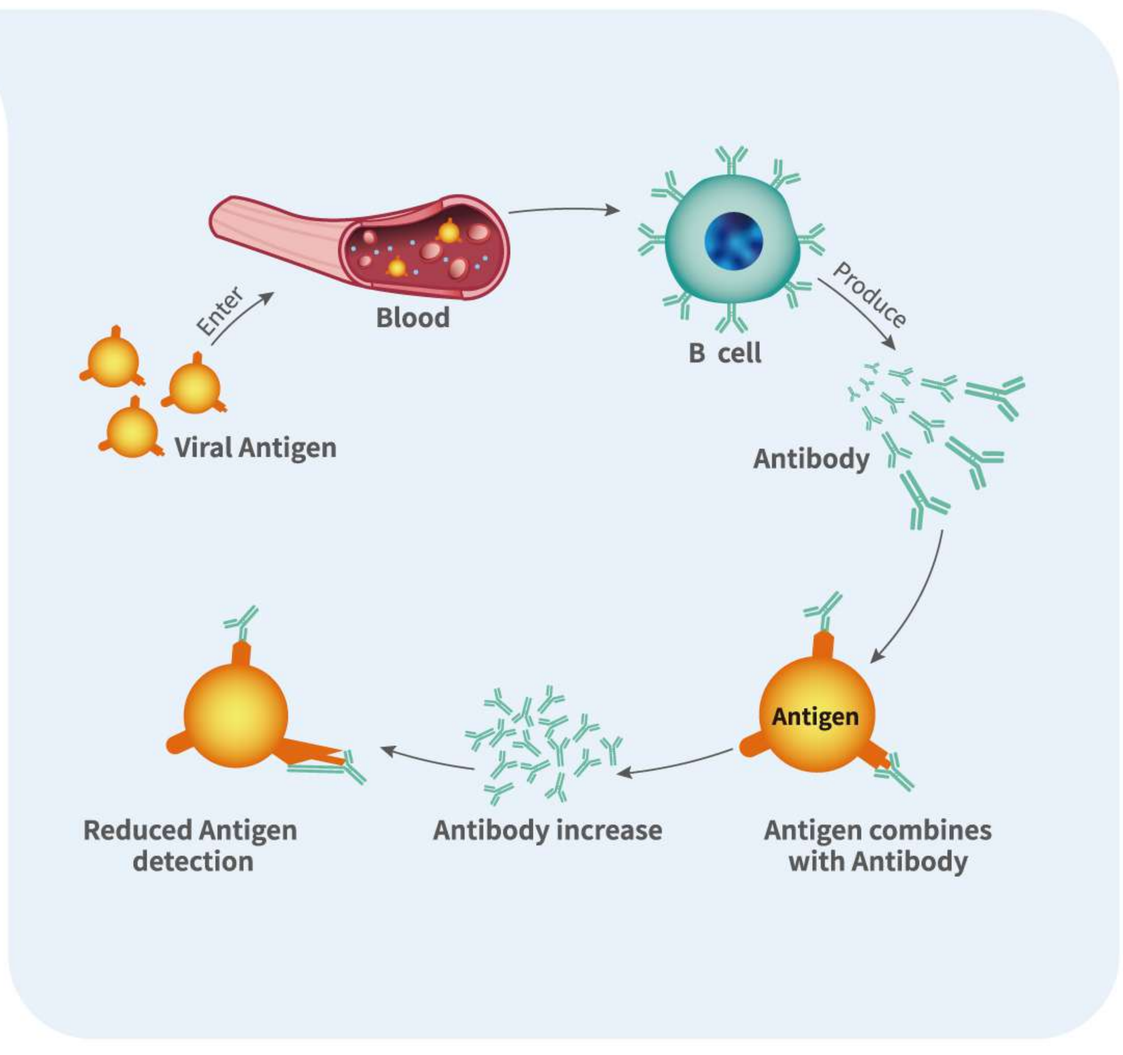


4 Disintegrated viral proteins enter the blood circulation through the blood vessel wall.

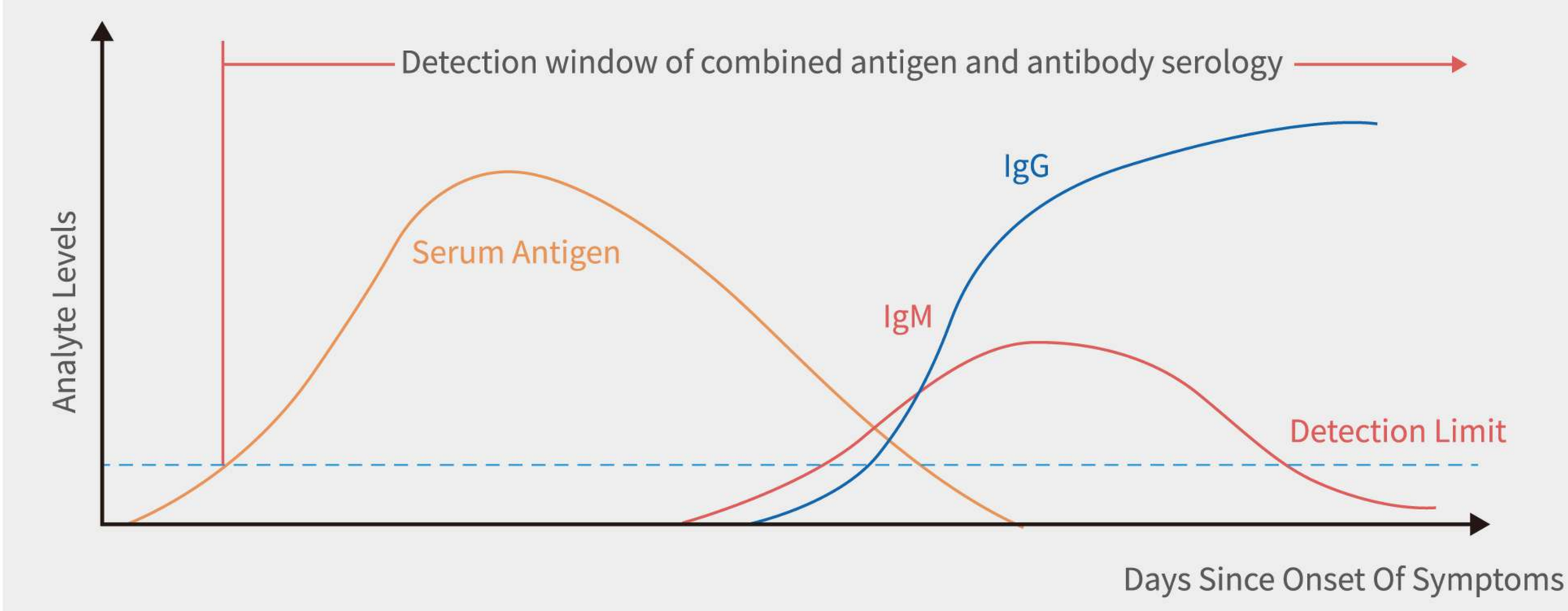
Mechanism of Reduction and Elimination of Antigen in Blood

- The virus antigen will stimulate the patient's body to produce the corresponding antibody, and the antibody produced by the body will produce the specific combination with the corresponding antigen, forming the antigen antibody immune complex to be cleared by the body's immune system. As the amount of antibody produced by the patient increases gradually, the amount of antigen cleared will also increase synchronously.

- With the activation of the immune system, the ability of killing virus is enhanced, the viral load in the body will gradually decrease, and the production of virus and blood antigen will gradually decrease.



» Schematic Diagram of Antigen and Antibody Changes in Blood



• Example of Combined Test Results of Antigen and Antibody in Blood

	Sample Number	Antigen Concentration (pg/mL)	Antigen Test Result (2.89pg/ml)	Antibody Test Result		Days from Onset
				IgM	IgG	
Sample	23-1	431.07	+	-	-	4
	23-2	33.90	+	+	-	7
	23-3	1.80	-	+	+	10
	23-4	0.85	-	+	+	13
	23-5	0.76	-	+	+	16
	23-6	0.59	-	+	+	20

In the early stage of the disease, the high content of antigen was detected immediately, and with the appearance of antibody, the content of antigen continued to decline.

SARS-CoV-2 Antigen quantitative assay kit (ELISA) Product Introduction

Virus Detection Limit:2 $TCID_{50}$/mL

- **Sample Type:**
  Serum

- **Performance index:**
  Detection limit: LOB-1.08pg/ml
  LOD-1.66 pg/ml
  LOQ-2.89 pg/mL
  Linear Range: 2.89~180.01pg/mL
  Precision: CV=4.80%~9.23%

Clinical Evaluation

SARS-CoV-2 Antigen Test-Sensitivity

Cut-off value=2.89pg/mL

Group	Days from onset	Total number of samples	Number of antigen positive samples	Sensitivity
1	⩽3 days	32	30	93.4%
2	4～7 days	38	38	100%
3	8～14 days	31	28	90.3%
SUM	/	101	96	95.0%

- **Sample source:** PCR confirmed COVID-19 patients serum samples

SARS-CoV-2 Antigen Test-Specificity

Cut-off value=2.89pg/mL

Group	Research samples	Total number of samples	Number of antigen positive samples	Specificity
1	Infection by other respiratory pathogens	246	0	100%
2	Pregnancy examination	85	0	100%
3	Elevated rheumatoid factor	77	0	100%
4	Physical examination serum samples	155	0	100%
5	Plasma samples of inpatients in other	86	0	100%
SUM	/	649	0	100%

- **Sample source:** 649 population samples with negative PCR test results.

» Positive Coincidence Rate Of SARS-CoV-2 Antigen and Antibody Detection (> 14 days)

Days from onset	Test categories	Number of positive samples	Total number of samples	Positive coincidence rate
＞14 days	Antigen	25	139	18.0%
＞14 days	Antibody	138	139	99.3%

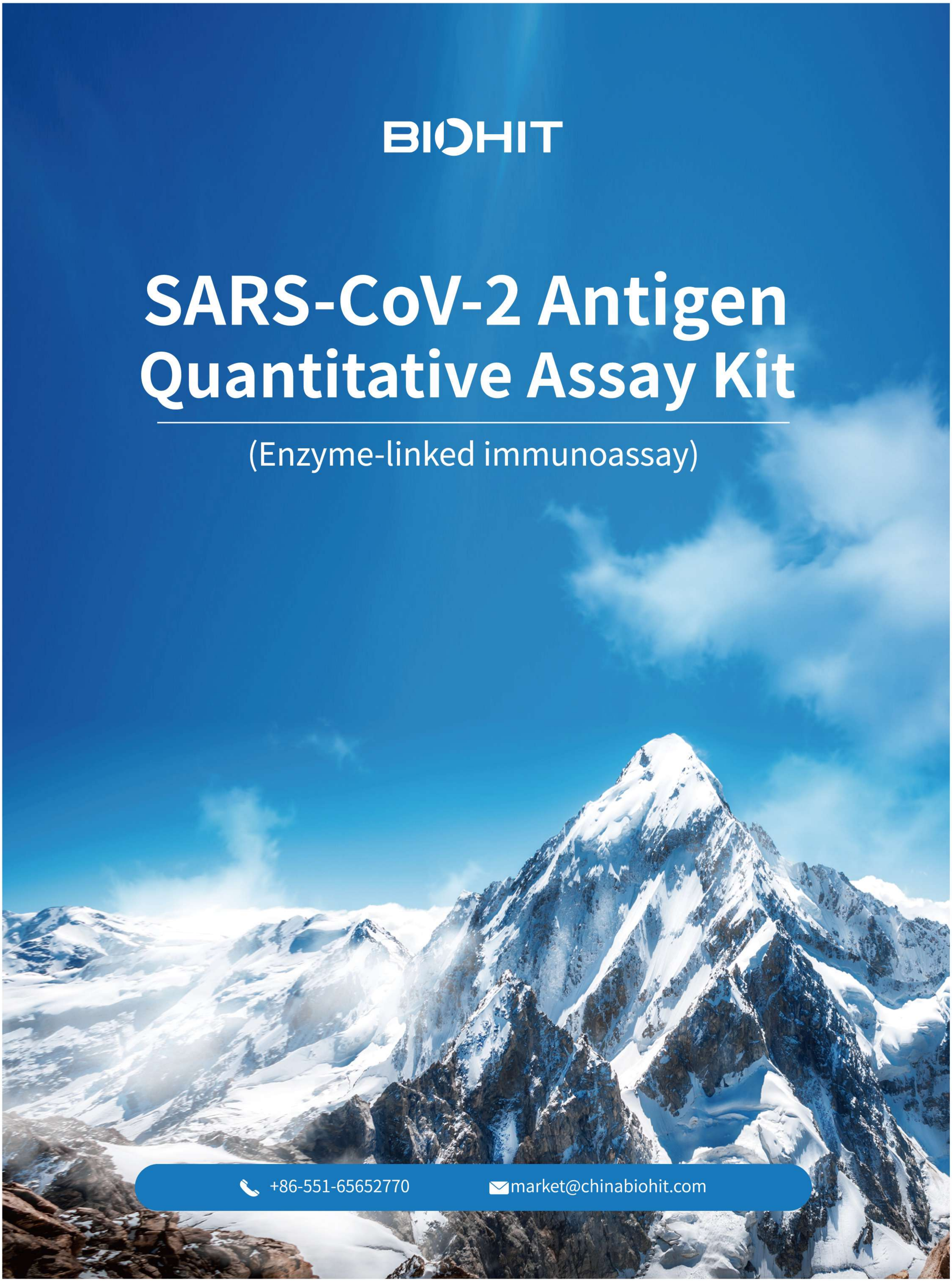
- **Sample source:** PCR confirmed COVID-19 patients serum samples

SARS-CoV-2 Combined Detection of Antigen and Antibody – Application Prospect

The whole course blood detection of SARS-CoV-2 has excellent sensitivity and specificity, which can meet the demand of clinical detection.

The test results have guiding significance for the selection of clinical treatment plan.

It is easy to operate, and is expected to be used in population screening and follow-up, and blocking the propagation path.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