

**BIOHIT**



# **SARS-CoV-2 Antigen Quantitative Assay Kit**

(Enzyme-linked immunoassay)



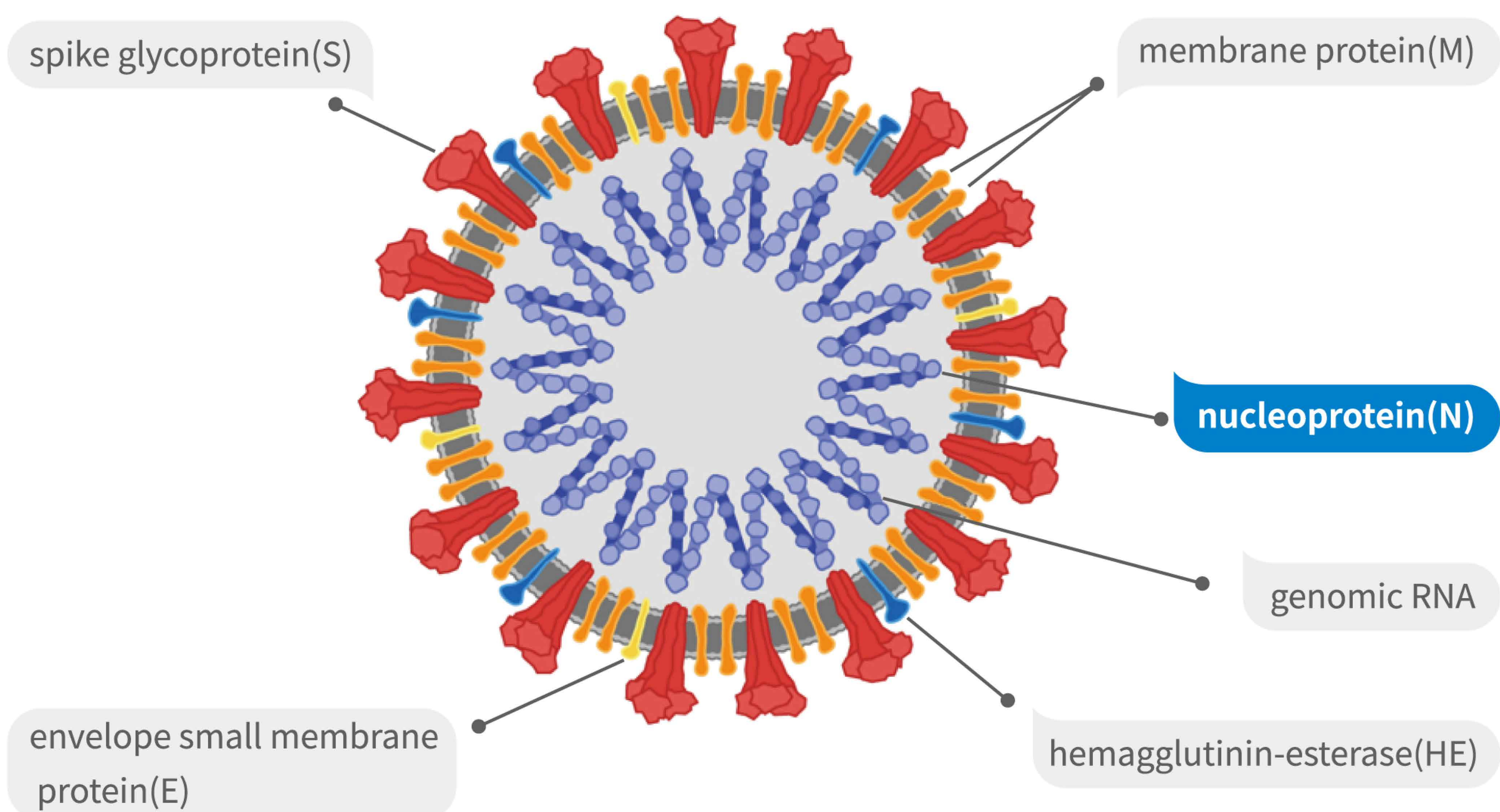
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[www.biohit.cn](http://www.biohit.cn)



# Principle introduction

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



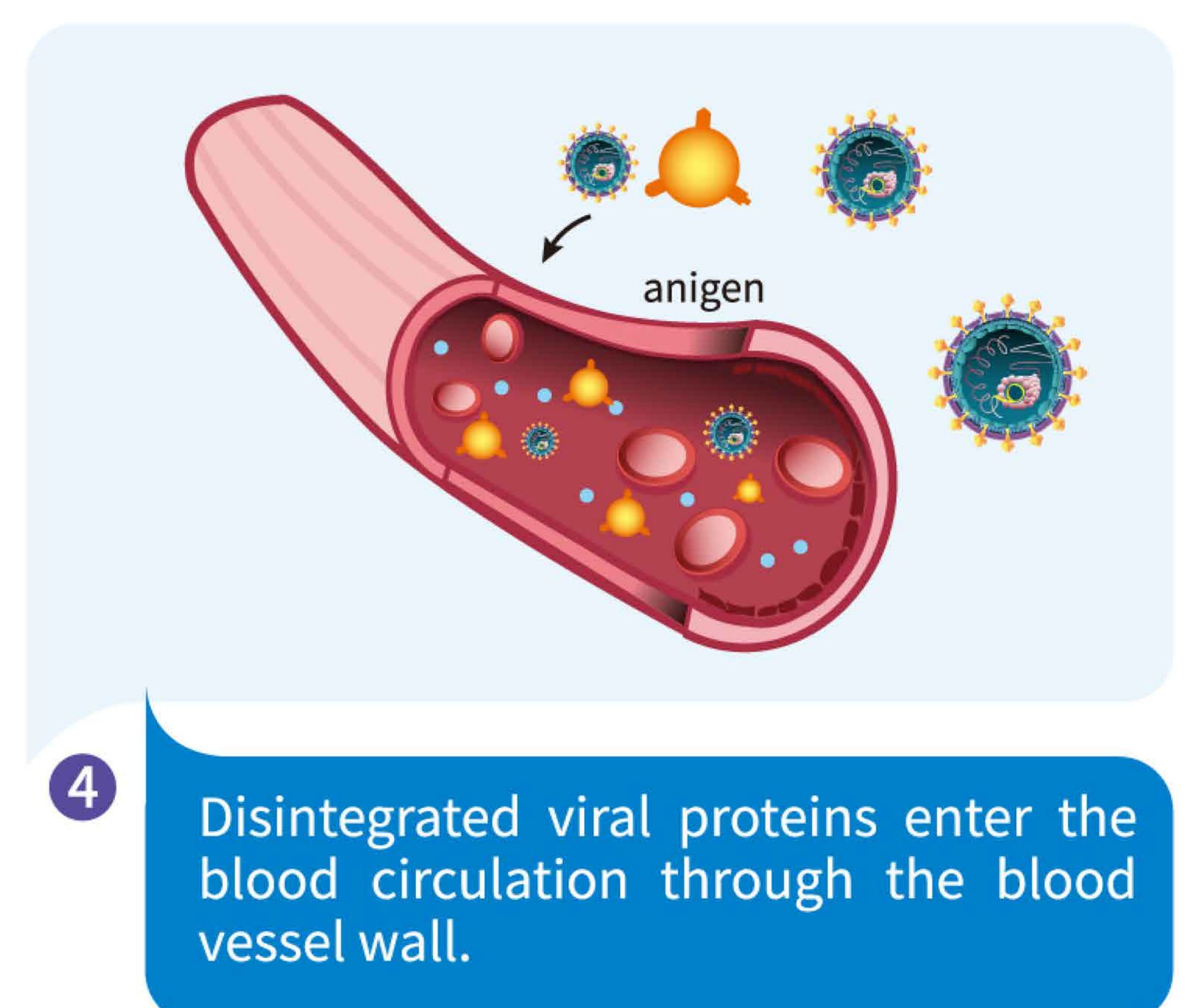
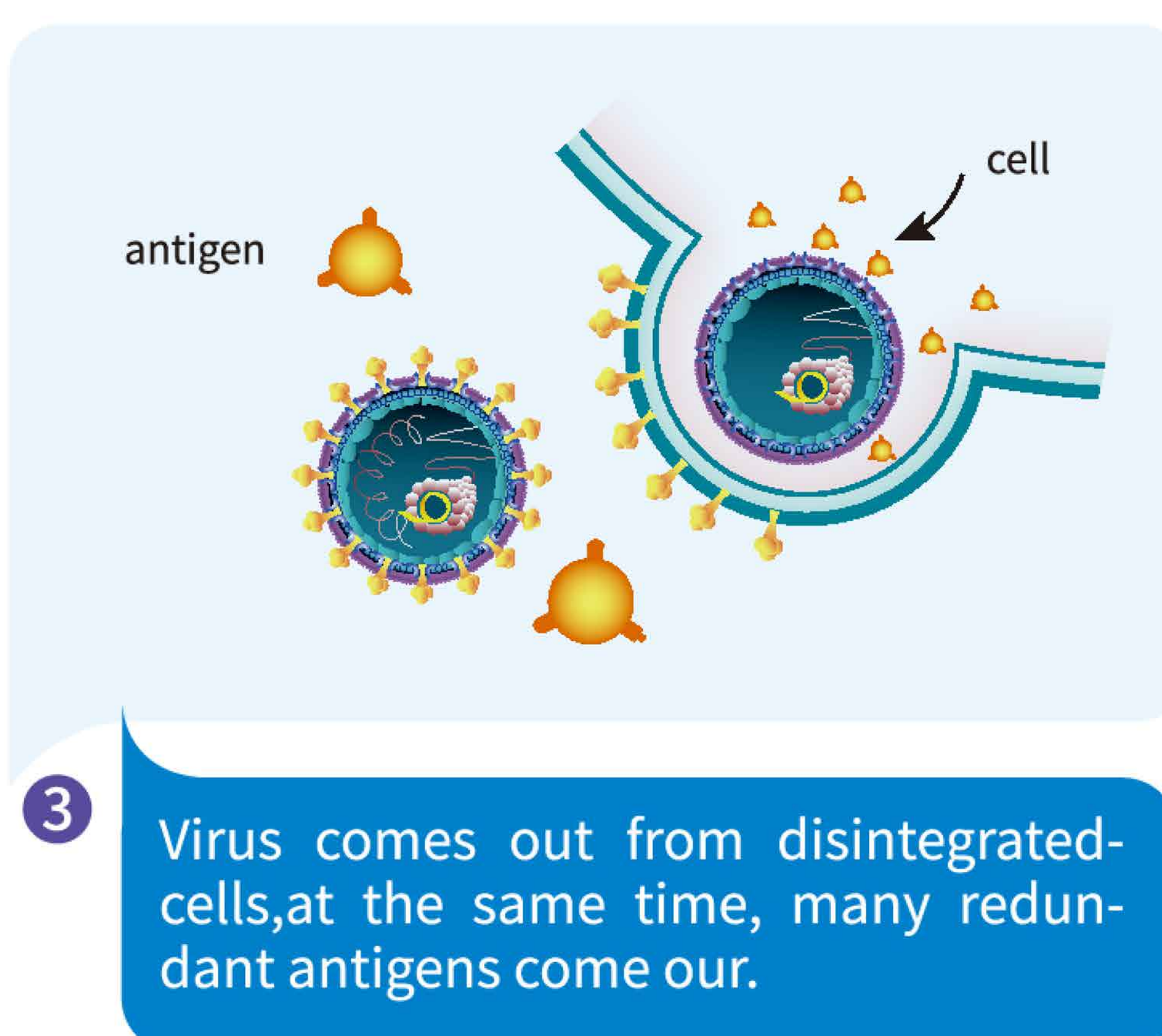
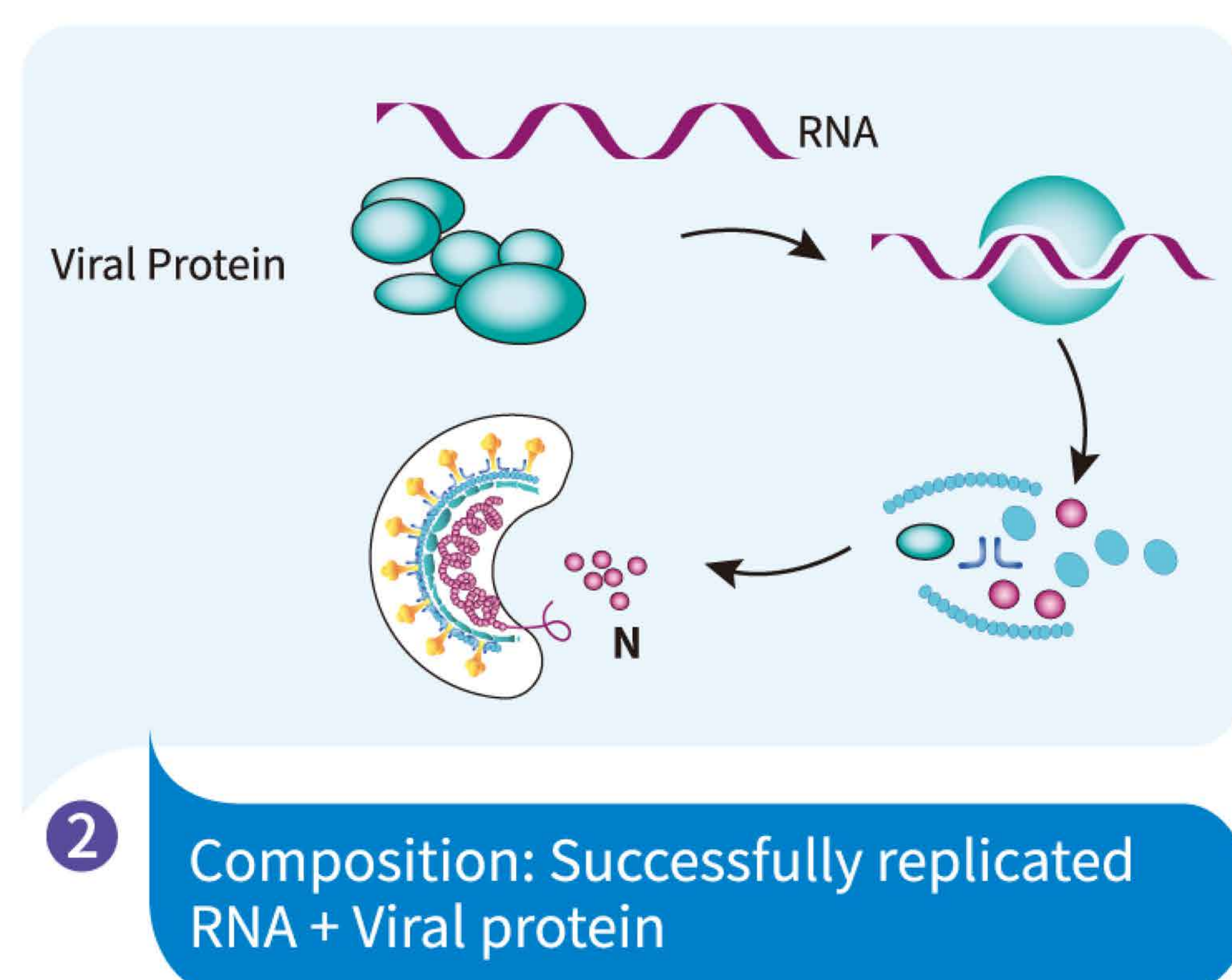
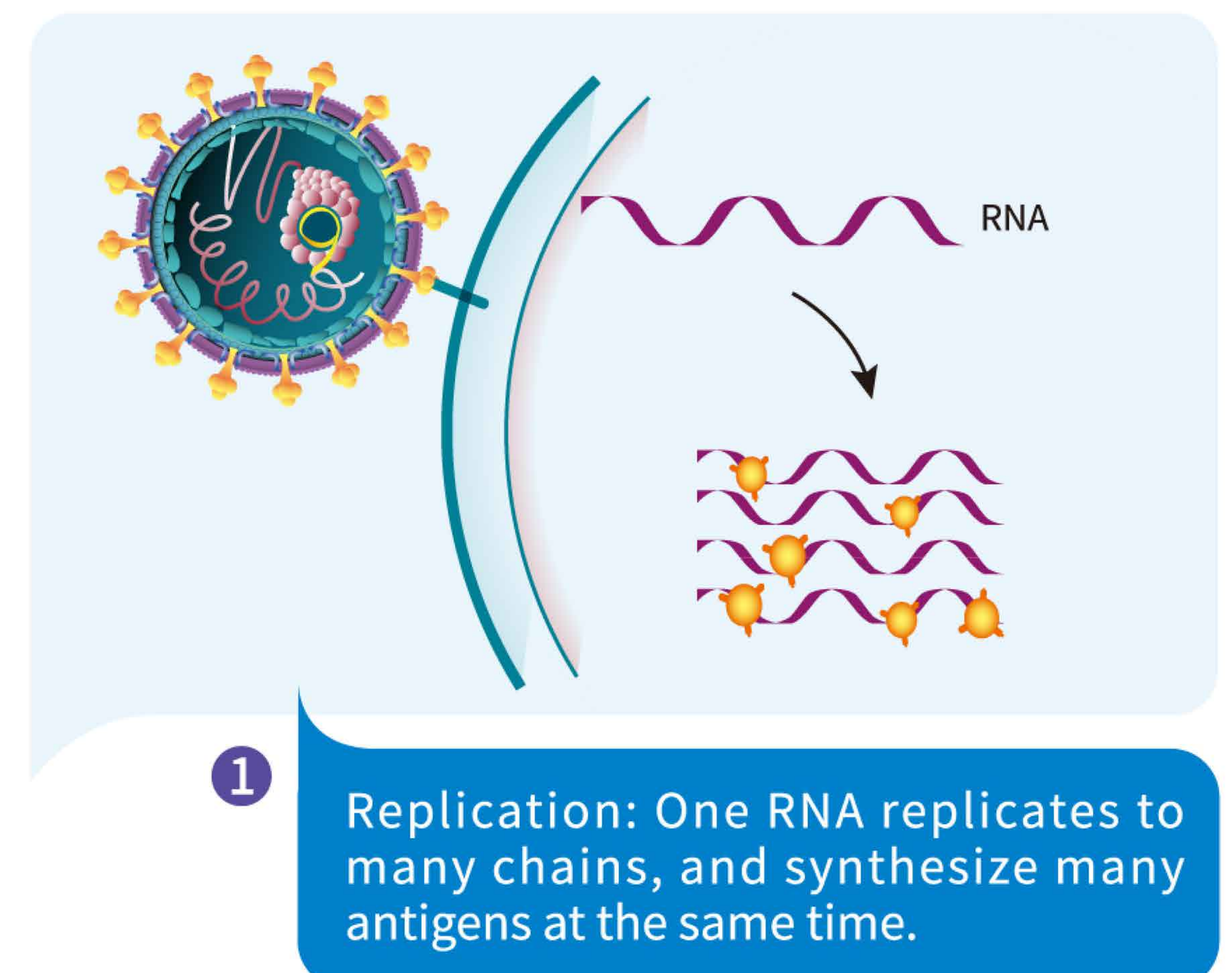
Novel coronavirus, a virus belonging to the family Coronaviridae, with approximately 120 nm in diameter. Club-shaped glycoprotein spikes in the envelope give the viruses a crownlike, or coronal, appearance. The nucleocapsid, made up of a protein shell known as a capsid and containing the viral nucleic 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.



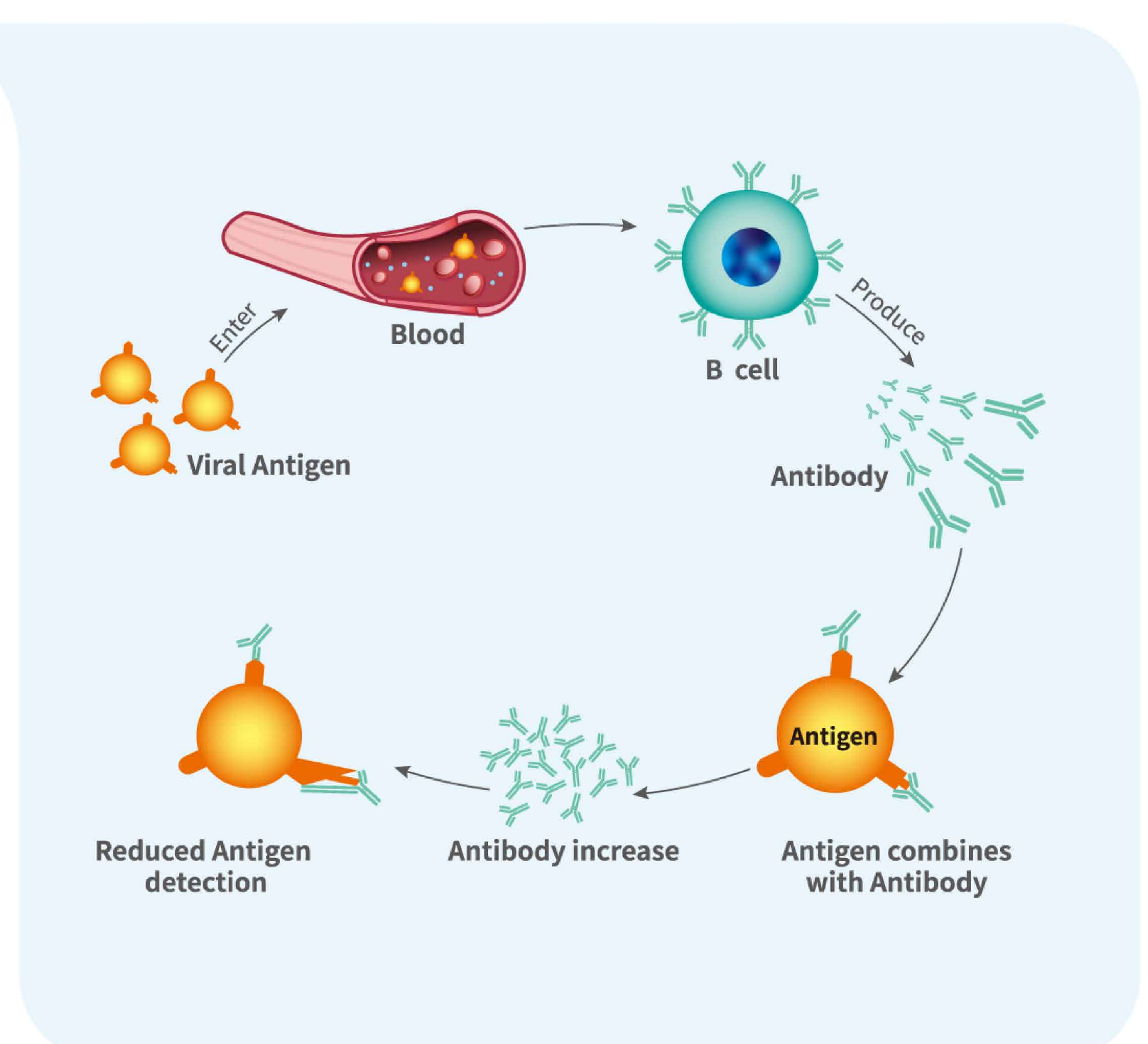
## » Main Mechanism of Antigen into Blood

- 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.



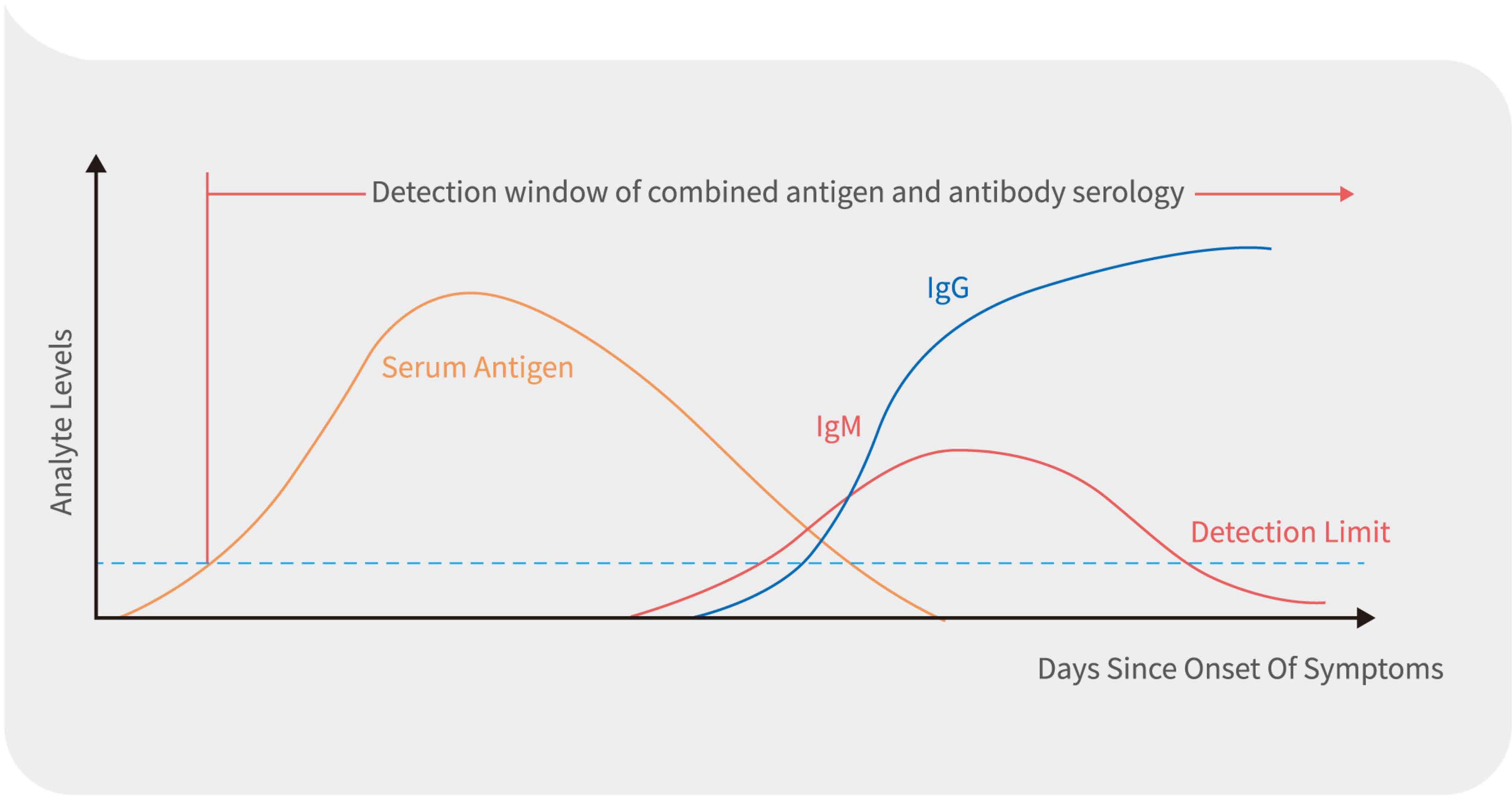
## » Mechanism of Reduction and Elimination of Antigen in Blood

- 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



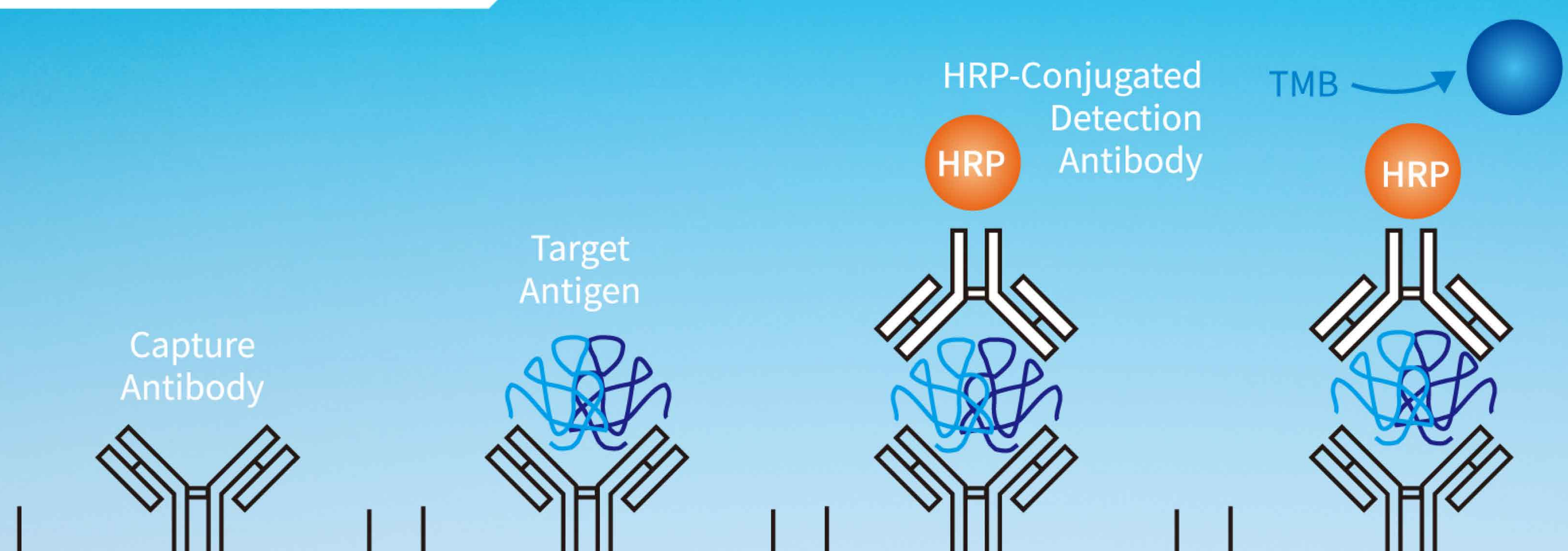
• Example of Combined Test Results of Antigen and Antibody in Blood

	Sample Number	Antigen Concentration (pg/mL)	Antigen Test Result (8.57pg/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



- **Sample Type:**  
Serum, Plasma

- **Performance index:**  
**Detection Sensitivity:** 1.0pg/mL  
**Linear Range:** 5.75~347.25pg/ml  
**Precision:** CV=1.5%-11.4%





# Clinical Evaluation

## » SARS-CoV-2 Antigen Test-Sensitivity

Cut-off value=8.57pg/mL

Group	Days from onset	Total number of samples	Number of antigen positive samples	Sensitivity
1	≤3 days	30	22	73.3%
2	4~7 days	26	25	96.2%
3	8~14 days	18	14	77.8%
SUM	/	74	61	82.4%

- **Sample source:** Samples from 74 patients with positive PCR results and negative for antibody test.

## » SARS-CoV-2 Antigen Test-Specificity

Cut-off value=8.57pg/mL

Group no.	Research samples	Total number of samples	Number of antigen positive samples	Specificity
1	Infection by other respiratory pathogens	369	0	100%
2	Pregnancy examination	100	0	100%
3	Elevated rheumatoid factor	119	0	100%
4	Health examiner Hemolysis sample	45	0	100%
SUM	/	633	0	100%

- **Sample source:** Samples from 633 people with negative PCR results.



## » SARS-CoV-2 Combined Detection of Antigen and Antibody – Average Positive Coincidence Rate

Stage	Time Period	Antigen Positive	Antibody Positive	Antigen + Antibody Testing Positive	Sample Number	Positive rate of combined test
1	≤3 days	38	5	38	53	71.7%
2	4~7 days	48	13	53	59	89.8%
3	8~14 days	49	55	81	89	91.0%
4	>14 days	11	138	138	139	99.3%

- Average positive coincidence rate of combined detection of antigen and antibody :  
 $(38+53+81+138) / (53+59+89+139) = 91.2\%$

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

Sensitivity 91.2%, specificity 100%

The detection of antigens in blood can effectively make up for the "window period" of antibody detection.

The combined detection of antigen and antibody in blood can verify each other at different disease stages, and provide complete serological evidence for the diagnosis of COVID-19.



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