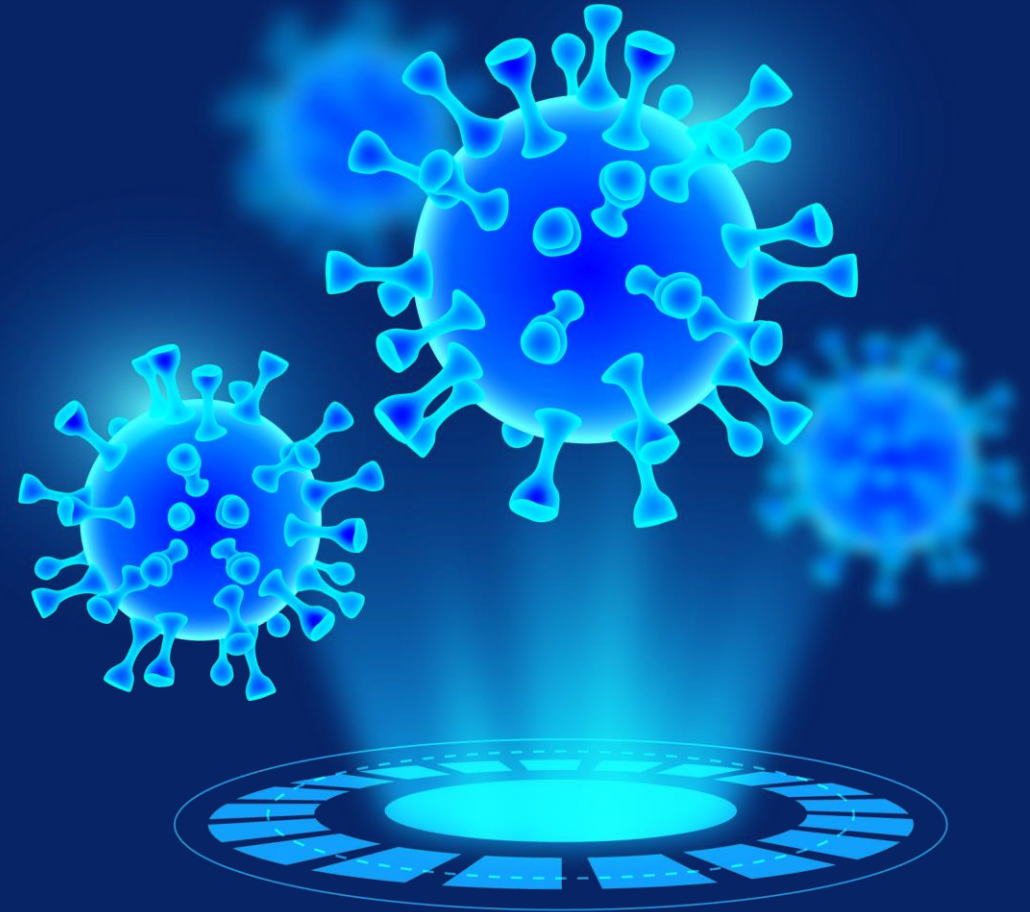


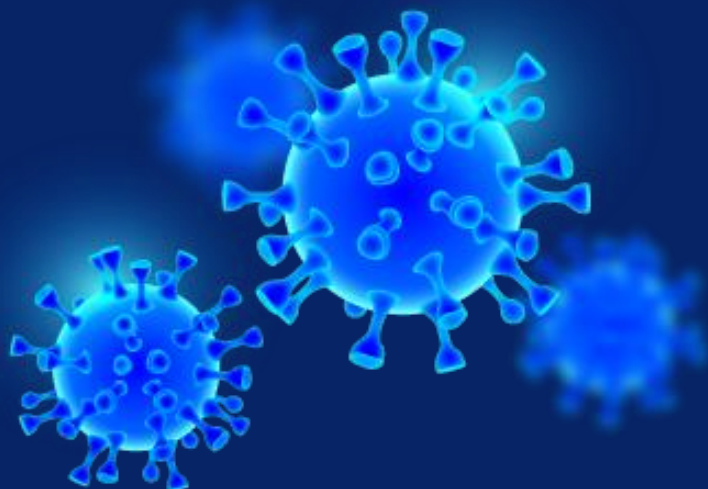
**SARS-CoV-2 Whole  
Course Blood  
Detection Technique**





# CONTENTS

- 01** SARS-CoV-2 Brief Introduction
- 02** Blood Antigen Detection and Relationship With Antibody
- 03** Product Introduction



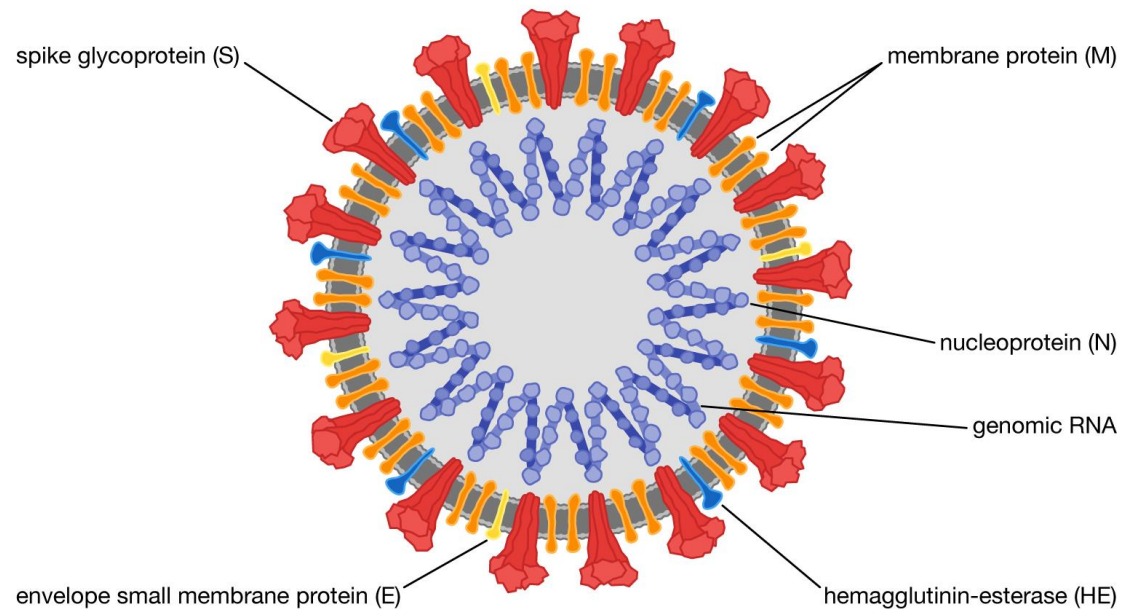
# 01

## SARS-CoV-2 Brief Introduction

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# SARS-CoV-2 Fundamental Structure

## Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)



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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.

# Replication of SARS-CoV-2 in the Cell

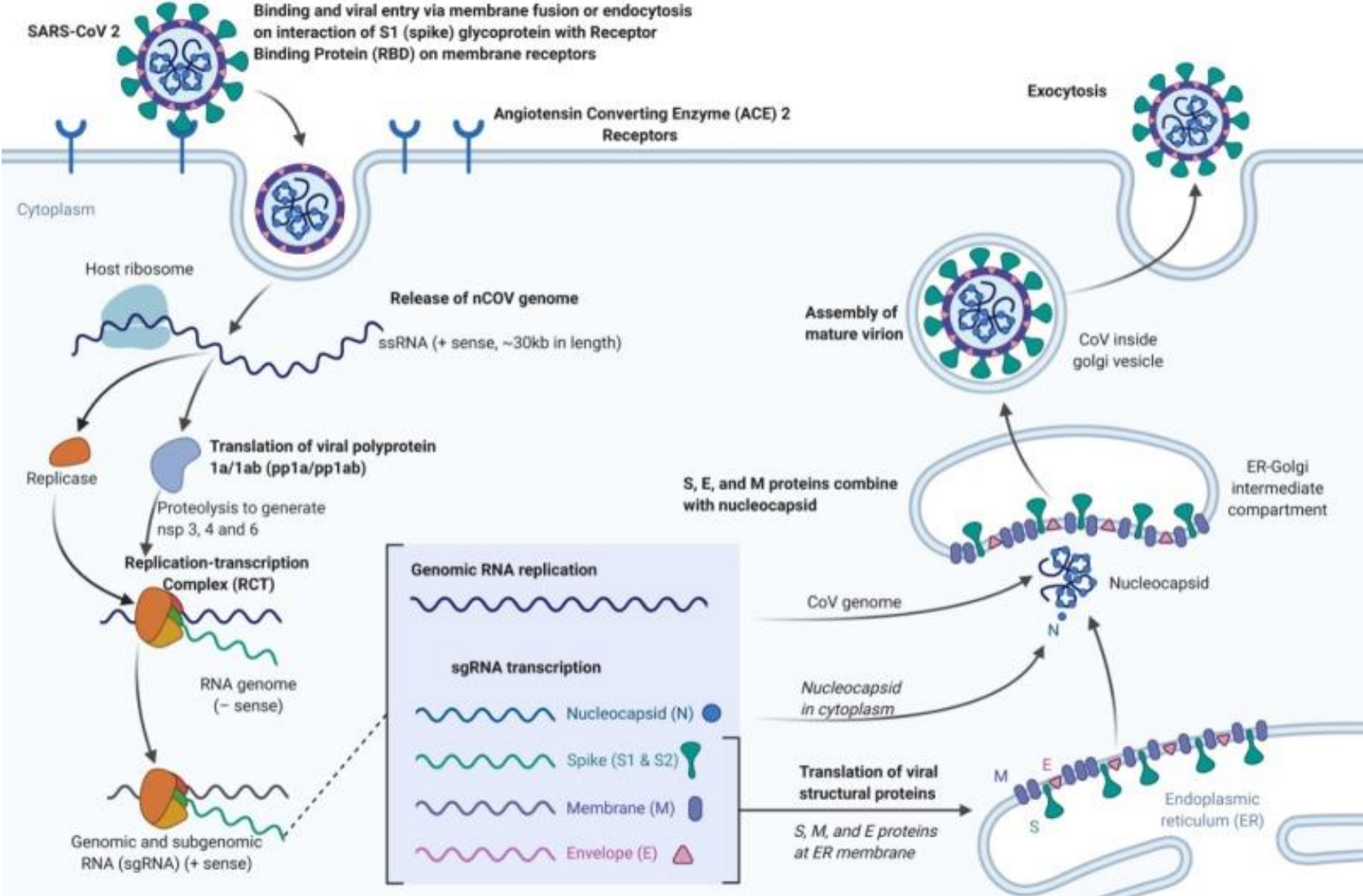
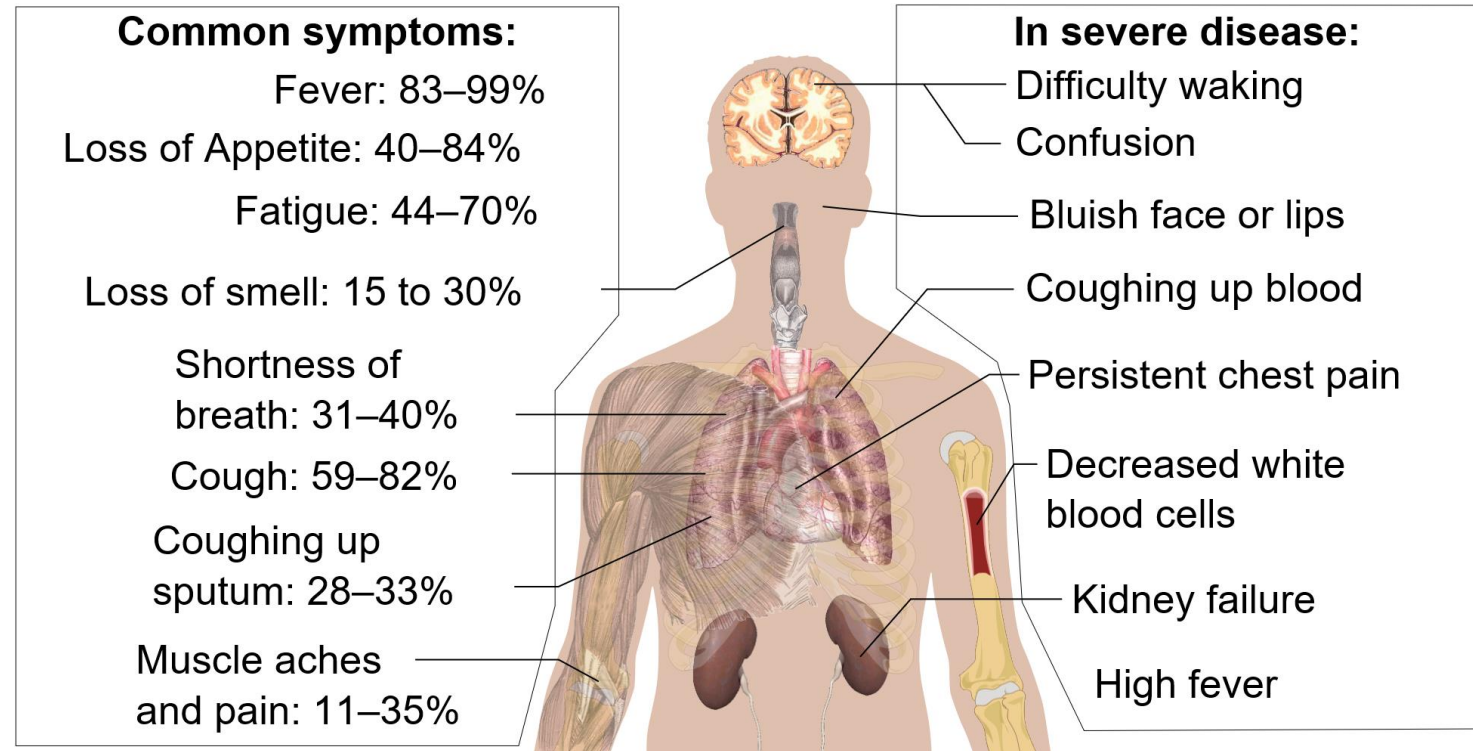
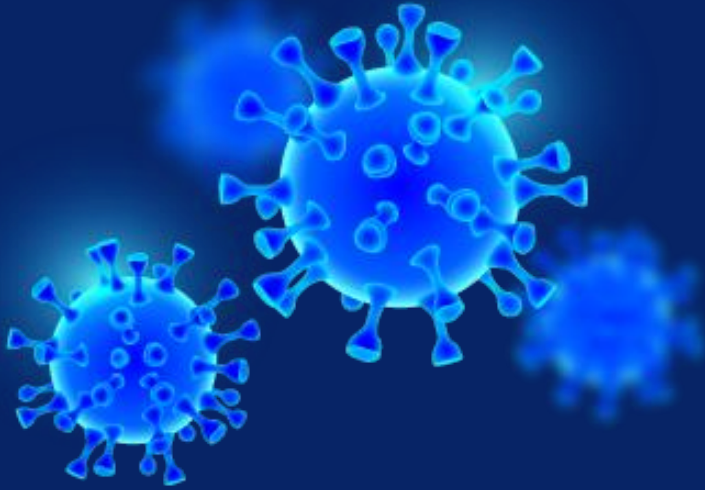


Figure: Replication of Coronavirus (SARS-CoV-2). Image Source: NCBI Book created with biorender.com

# Symptoms of COVID-19 Patients



The signs and symptoms of COVID-19 present at illness onset vary, but over the course of the disease, most persons with COVID-19 will experience the following: Fever, Cough, Fatigue, Anorexia, Shortness of breath, Sputum production and Myalgia. Atypical symptoms such as headache, confusion, rhinorrhea, sore throat, hemoptysis, vomiting, and diarrhea.

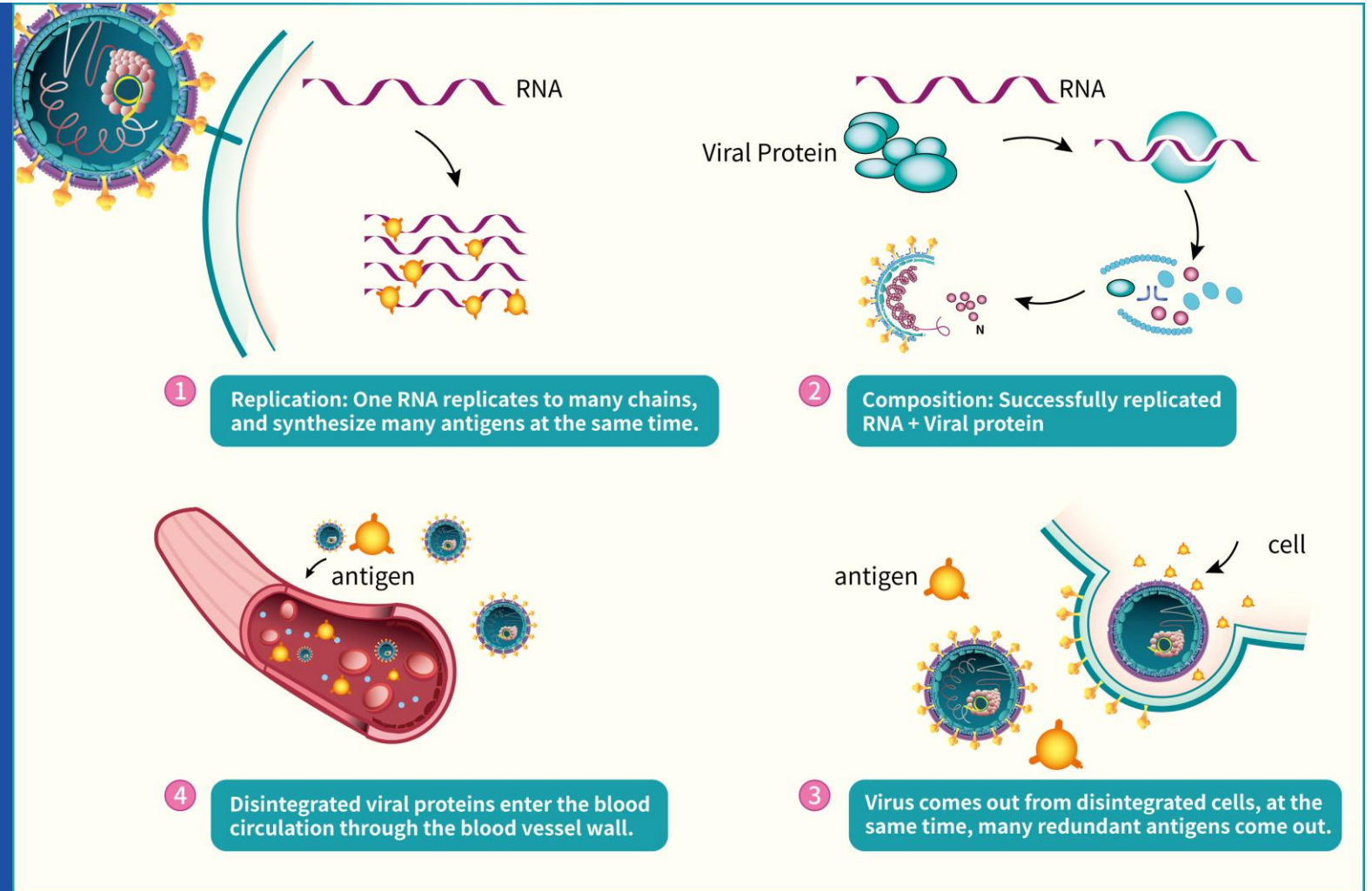


# 02 Blood Antigen Detection and Relationship With Antibody

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# Main Mechanism of Antigen into Blood

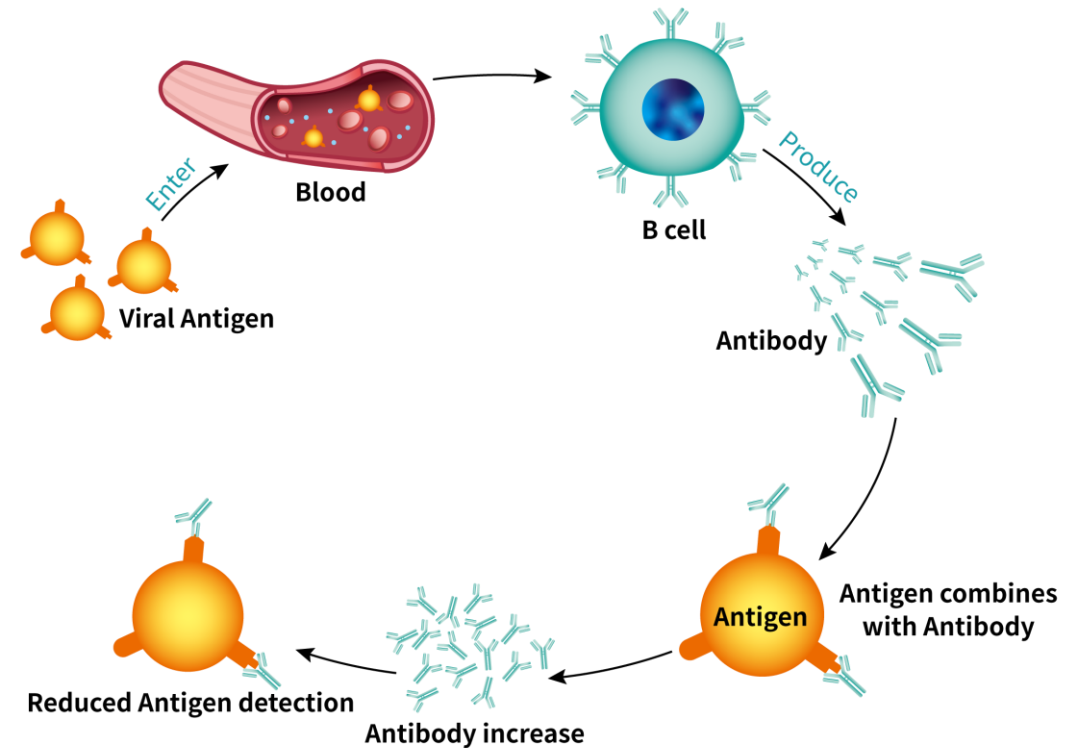
When SARS-CoV-2 invades the lung cells, it will express a large amount of self protein to reassemble the virus particles, causing cell damage and forming inflammation. The virus protein expressed in excess and the virus protein released from the disintegration of virus particles killed by the body in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



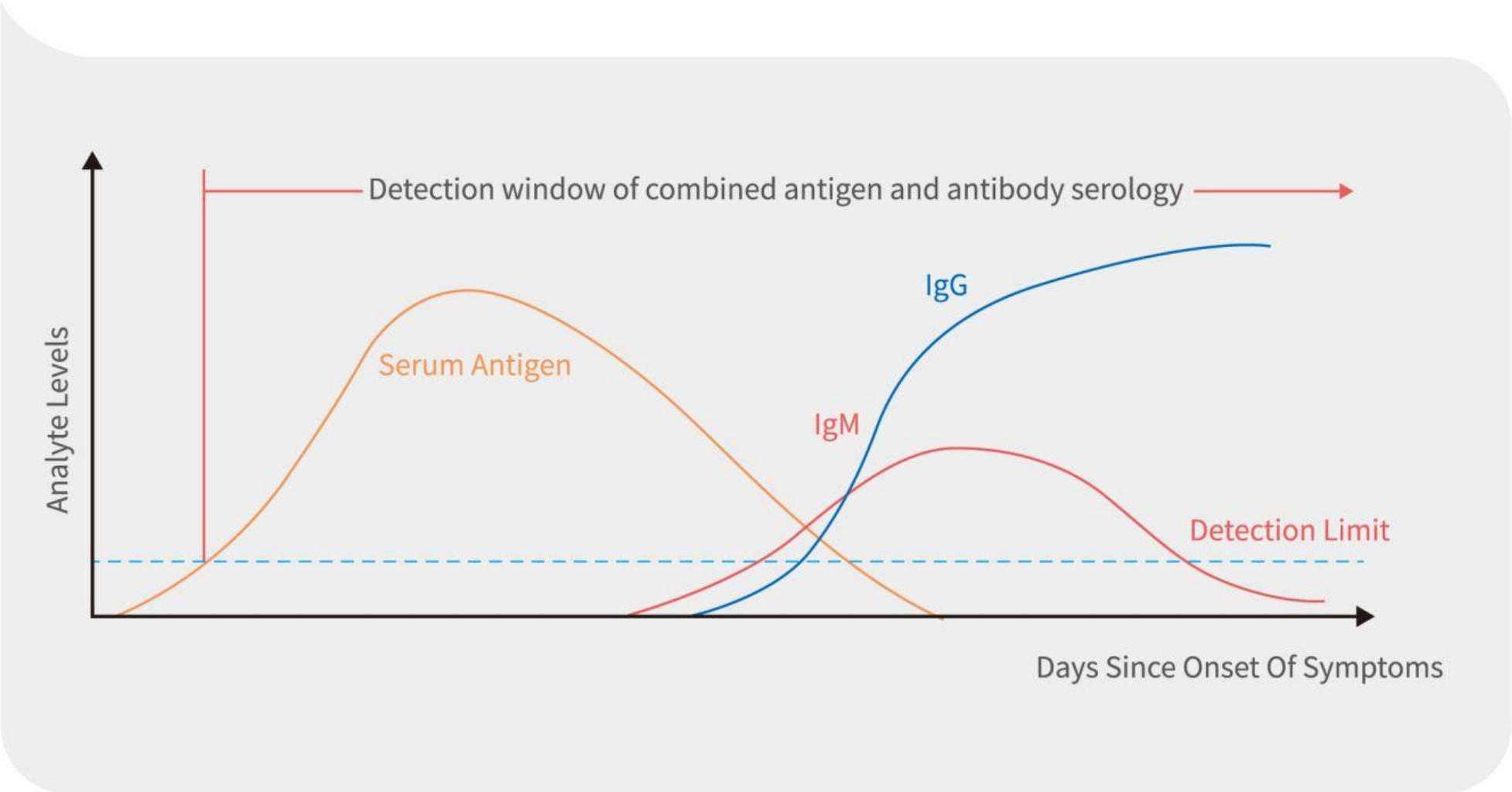


# Mechanism of Reduction and Elimination of Antigen in Blood

- 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



# Significance of Combined Detection of Antigen and Antibody in Blood

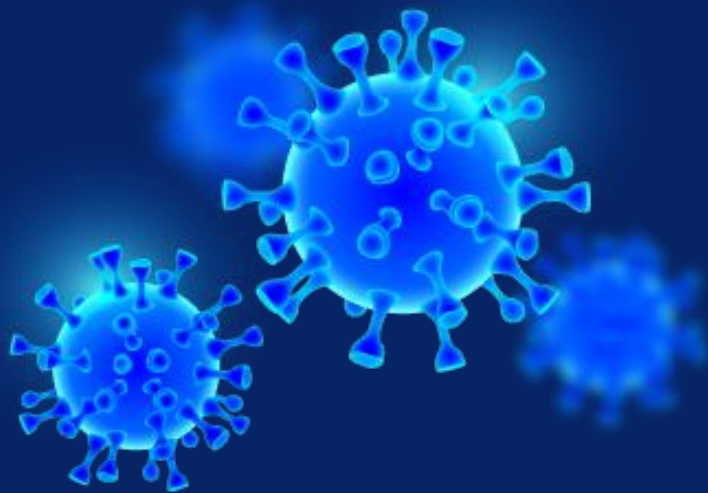
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- The detection of antigens in blood can effectively make up for the "window period" of antibody detection.
- The detection of antibody in blood can avoid the problem that antigen can not be detected in the middle and later stage of infection.
- The 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.

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

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



# 03. Product Introduction

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# SARS-CoV-2 Antigen Rapid Test Kit (Fluorescence Immunochromatography)



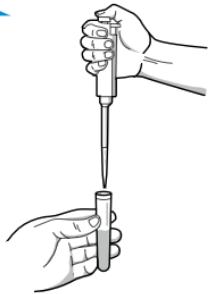
## CONTENTS:

Instruction for use	1 piece
Test cassette	25 cassettes

**Limit of Detection: 20 TCID<sub>50</sub>/ml**

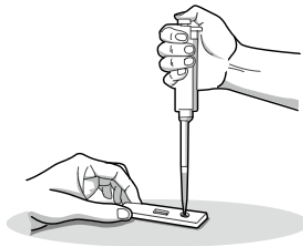
## TEST PROCEDURES

Step1



Pipette the serum: 80µl

Step2



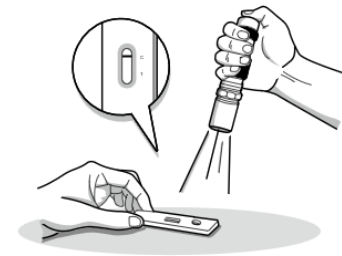
Add sample: 80µl

Step3



Incubate at room temperature: 15 Minutes

Step4



Observe the result immediately (within 10 seconds) under the UV flashlight

# SARS-CoV-2 Antigen Rapid Test -Sensitivity

Serial number	Days from onset	Number of antigen positive samples	Total number of samples	Sensitivity
1	0-3	27	29	93.10% ( 95CI:77.23%~99.15% )
2	4-7	33	33	100% ( 95CI:89.42% ~ 100.00% )
Total	≤7	60	62	96.77% ( 95CI:88.83%~99.61% )

➤ Sample source: The samples were collected from 62 patients covid-19 confirmed by PCR



# SARS-CoV-2 Antigen Rapid Test -Specificity

No	Number of antigen negative samples	Total number of samples	Specificity
1	186	188	98.9% ( 95CI : 96.21% ~ 99.87% )

➤ Sample source: The 188 samples were confirmed negative by PCR.



# Comparison of the detection rate of different samples

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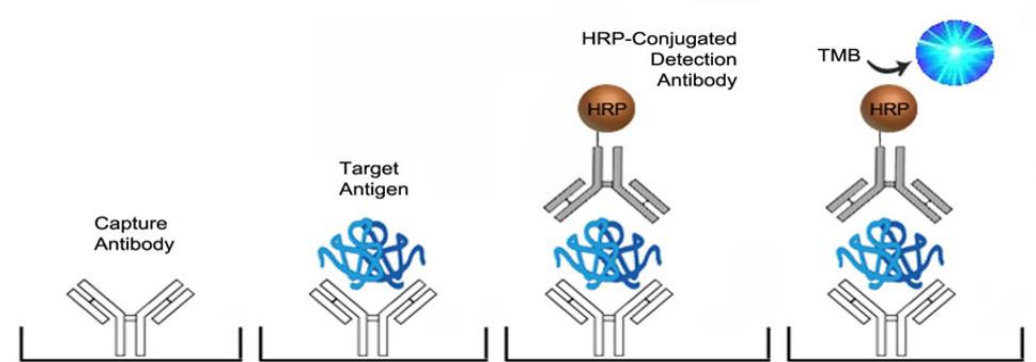
COVID-19 patients	Nucleic acid detection in nasopharyngeal swab	Antigen detection in serum	Nucleic acid detection in sputum
62	60.78%	96.77%	100%

# SARS-CoV-2 Antigen quantitative assay kit (ELISA)

**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%



**Limit of Detection : 2 TCID<sub>50</sub>/mL**

Contrast with FDA-EUA approved antigenic product

- BD Veritor System for Rapid Detection of SARS-CoV-2 : 113 TCID<sub>50</sub>/mL
- Sofia 2 SARS Antigen FIA :140 TCID<sub>50</sub>/mL

## SARS-CoV-2 Antigen Test (ELISA) -Sensitivity

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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%
<b>SUM</b>	/	101	96	95.0%

---

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

## SARS-CoV-2 Antigen Test (ELISA) -Specificity

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%
<b>SUM</b>	/	649	0	100%

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

# SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold)

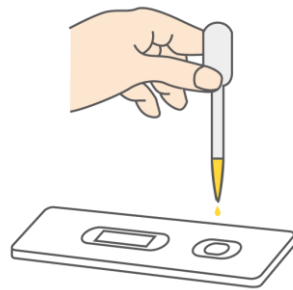


## SPECIFICATION

Sample : 10 $\mu$ l

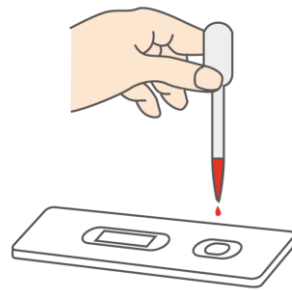
Reaction Time: 15mins

One test, two results

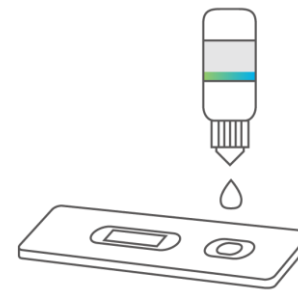


10 $\mu$ l serum or plasma

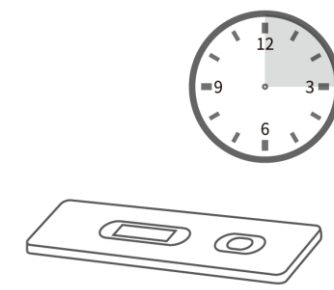
or



10 $\mu$ l whole blood



2 drops



15 minutes

## SARS-CoV-2 IgM/IgG Antibody Test Result Sample



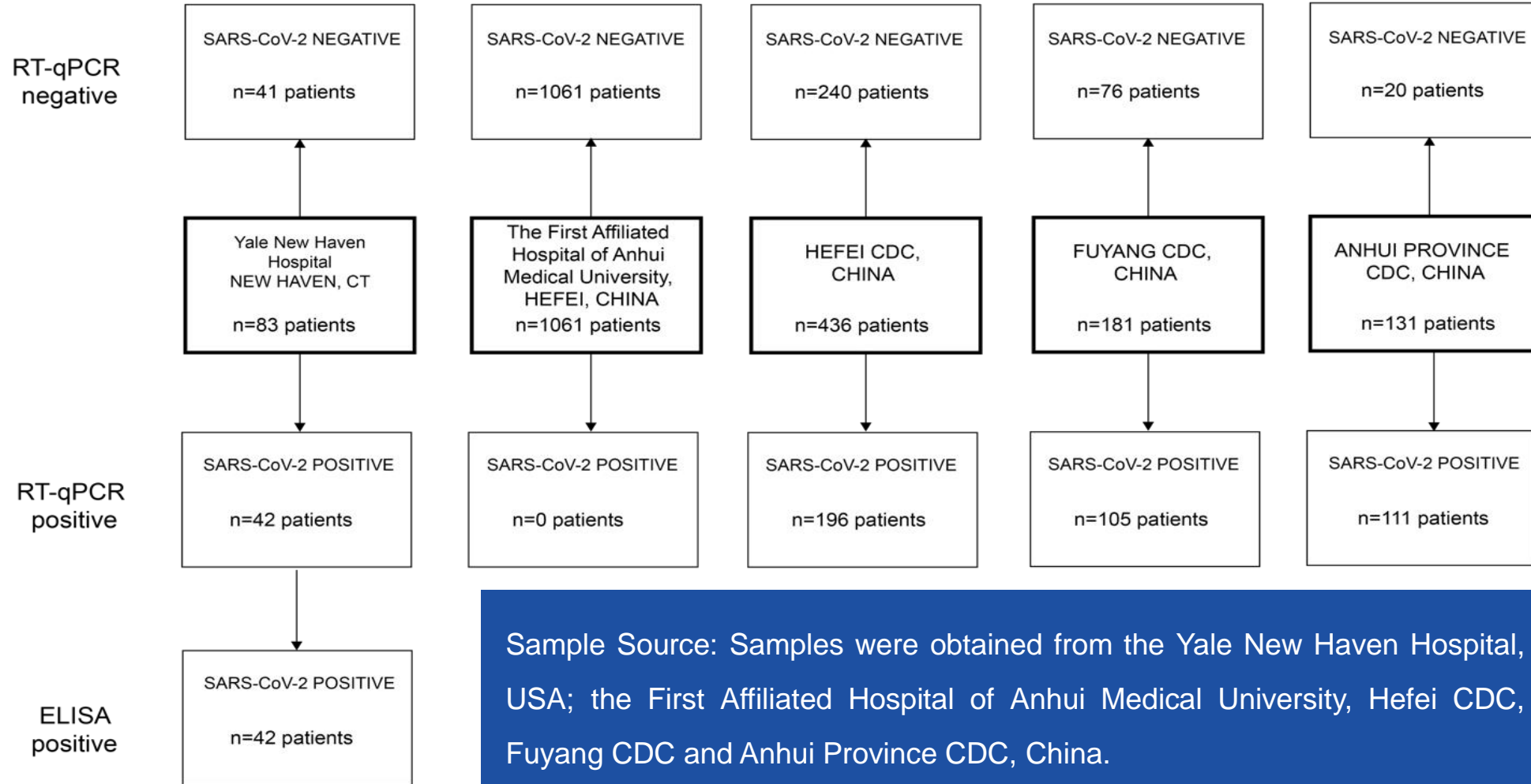
Representative photo of SARS-CoV-2 IgM/IgG results. Note :

Sample 42= Negative (0),  
Sample 43= Weak Positive (1),  
Sample 44=Positive (2),  
Sample 45= Strong Positive (3)

- **Semi-quantification can be realized, which is of great significance for follow-up.**

# SARS-CoV-2 IgM/IgG Antibody Test Clinical Data

Diagnostic method:



Sample Source: Samples were obtained from the Yale New Haven Hospital, USA; the First Affiliated Hospital of Anhui Medical University, Hefei CDC, Fuyang CDC and Anhui Province CDC, China.



# SARS-CoV-2 IgM/IgG Antibody Test - Sensitivity

	SARS-CoV-2 Positive Samples			
Clinical site(s)	Hefei CDC, Fuyang CDC, Anhui Province CDC, CHINA		Yale New Haven Hospital, New Haven, CT, USA	
Infection time	1-14 days	>14 days	1-14 days	>14 days
Sample quantity	294	118	31	9
IgM/IgG positive	134	111	24	9
IgM positive	133	111	24	9
IgG positive	103	109	24	9
None	160	7	7	0
Sensitivity - IgM/IgG [95% CI]	45.6% [39.8-51.46%]	94.1% [88.2-97.6%]	77.4% [58.9-90.4%]	100% [66.4-100%]
Sensitivity - IgM [95% CI]	45.2% [39.5-51.1%]	94.1% [88.2-97.6%]	77.4% [58.9-90.4%]	100% [66.4-100%]
Sensitivity - IgG [95% CI]	35.0% [29.6-40.8%]	92.4% [86.0-96.5%]	77.4% [58.9-90.4%]	100% [66.4-100%]

# SARS-CoV-2 IgM/IgG Antibody Test -Specificity

	SARS-CoV-2 Negative Samples					
Clinical site(s)	Hefei, CHINA				Hefei , Fuyang , Anhui Province , CHINA	New Haven, CT, USA
Sample type	Other respiratory samples	Pregnant women	Inpatient's in other departments	Physical examination	Healthy controls	Healthy controls
Sample quantity	281	416	252	112	336	41
IgM positive	6	2	0	0	3	1
IgG positive	0	0	0	0	1	0
None	275	414	252	112	333	40
Specificity - IgM [95% CI]	97.9% [95.4-99.2%]	99.5% [98.3-99.9%]	100% [98.6-100%]	100% [96.8-100%]	99.1% [97.4-99.8%]	97.6% [87.1-99.9%]
Specificity - IgG [95% CI]	100% [98.7-100%]	100% [99.1-100%]	100% [98.6-100%]	100% [96.8-100%]	99.7% [98.4-99.9%]	100% [91.4-100%]

## SARS-CoV-2 IgM/IgG Antibody Test – Different Stages

Days from onset of symptoms	PCR positive at any time	IgG			IgM		
		Samples with Positive results (Serum)	PPA*	95%CI	Samples with Positive results (Serum)	PPA *	95%CI
≤7	12	0	0		4	33.33%	13.81% - 60.93%
8-14	53	30	56.6%	43.26% - 69.05%	44	83.02%	70.78% - 90.80%
≥15	132	127	96.21%	91.43% - 98.37%	129	97.73%	93.53% - 99.22%
<b>Total</b>	197						

- Sample Source: Samples were collected from 197 serum samples of 40 patients with COVID-19 on 1-7 days, 8-14 days and at least 15 days after the onset of the disease to evaluate the coincidence rate of IgM / IgG over time.

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

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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

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

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- ❖ 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.

# THANKS

