



SARS-CoV-2 Antigen RAPID TEST KIT

(Fluorescence Immunochromatography)

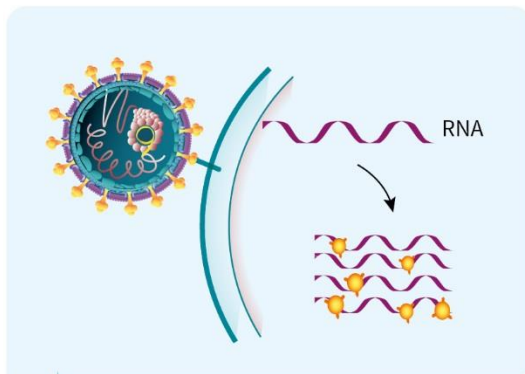


BIOHIT Healthcare (Hefei) Co., Ltd.

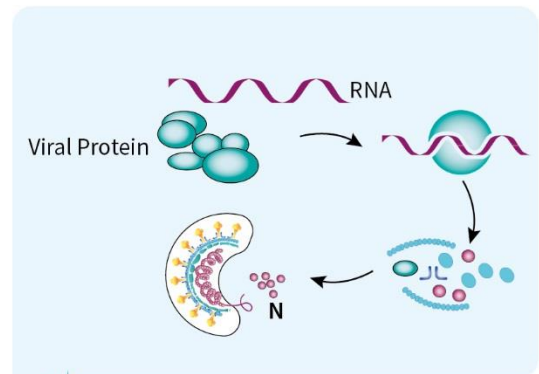
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» Main Mechanism of Antigen into Blood

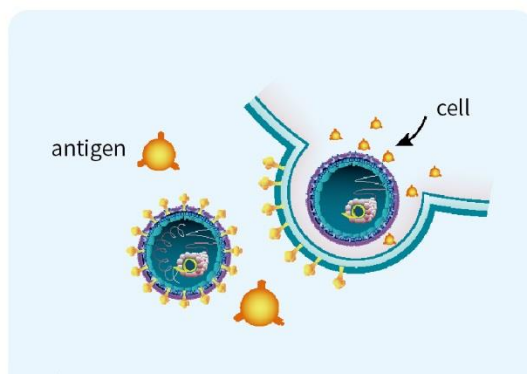
- When SARS-CoV-2 invades the lung cells, it will express a large amount of self protein to reassemble the virus particles, causing cell damage and forming inflammation. The virus protein expressed in excess and the virus protein released from the disintegration of virus particles killed by the body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



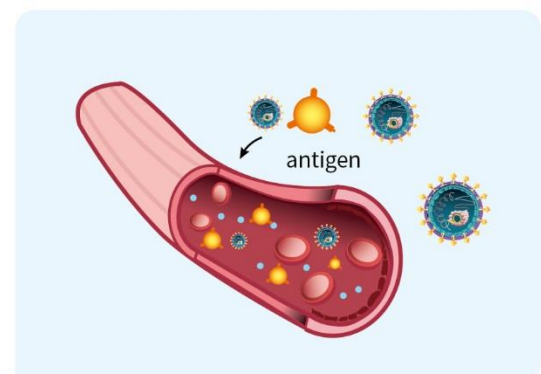
1 Replication: One RNA replicates to many chains, and synthesize many antigens at the same time.



2 Composition: Successfully replicated RNA + Viral protein



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

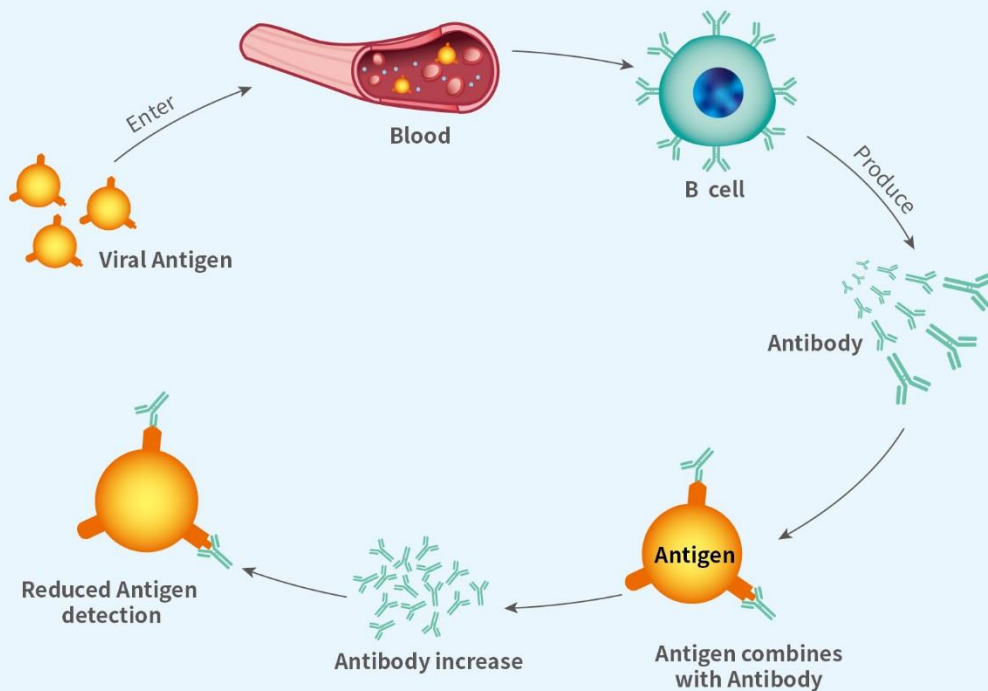


4 Disintegrated viral proteins enter the blood circulation through the blood vessel wall.

» Mechanism of Reduction and Elimination of Antigen in Blood

CORONAVIRUS NOVEL

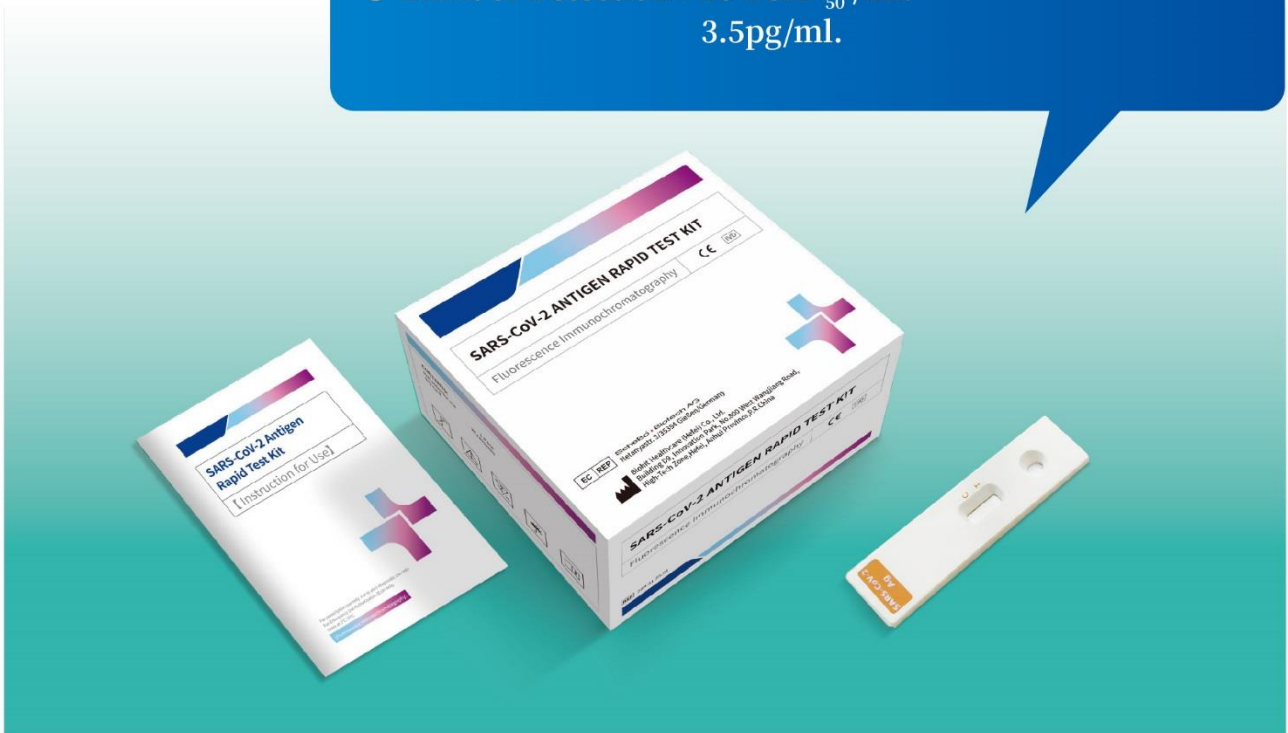
- The virus antigen will stimulate the patient's body to produce the corresponding antibody, and the antibody produced by the body will produce the specific combination with the corresponding antigen, forming the antigen antibody immune complex to be cleared by the body's immune system. As the amount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



Product Overview

CE

- ① The operation is simple, the results can be read in 15 minutes.
- ② The sample source of blood is stable, which can avoid the deviation of test results caused by sampling problems.
- ③ Limit of Detection : 20 TCID₅₀ /ml.
3.5pg/ml.

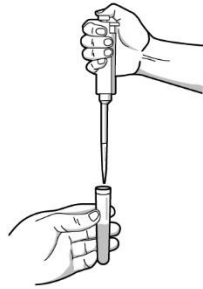


Product Specifications

Product Name	Sample type	Storage temperature	Packing Specification
SARS-CoV-2 ANTIGEN PAPID TEST KIT (Fluorescence Immunochromatography)	Serum	2°C-30°C	25 tests/kit

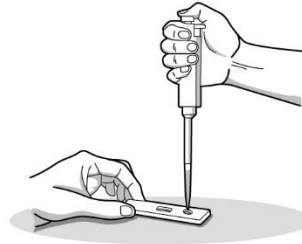
Operation Steps

Step1



- Pipette The Serum: 80µl

Step2



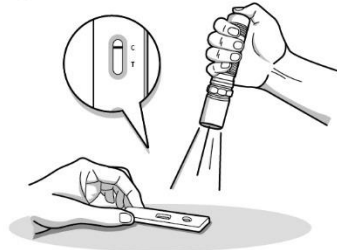
- Add Sample: 80µl

Step3



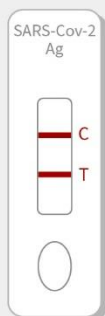
- Incubate At Room Temperature: 15 Minutes

Step4

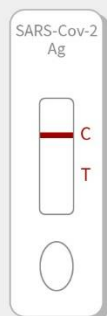


- Observe The Test Result Under The Illumination Of A Fluorescent Flashlight.

Result Interpretation



Positive result



Negative result



Invalid result



Invalid result

Product performance

» 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

» Specificity

No	Number of antigen negative samples	Total number of samples	Sensitivity
Total	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

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

BIOHIT

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