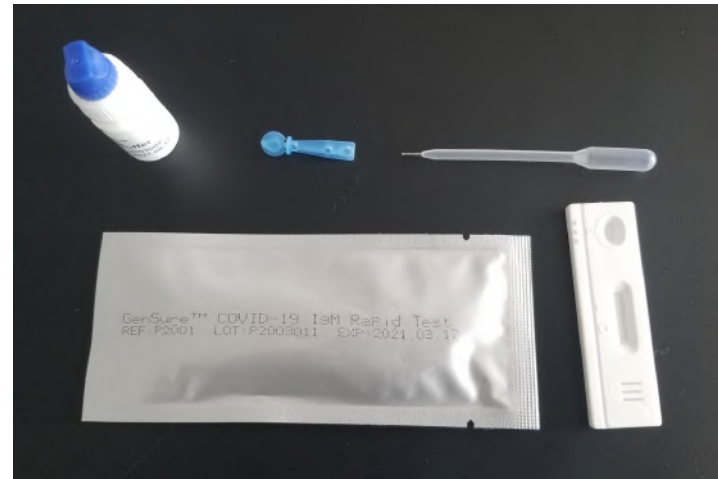


# Production List

- ❖ **GenSure™ COVID-19 IgM Rapid Test** REF : P2001
- ❖ **GenSure™ COVID-19 IgG/IgM Rapid Test** REF : P2002
- ❖ **GenSure™ COVID-19 IgG/IgM Rapid Test** REF : P2003
- ❖ **GenSure™ COVID-19 IgG Rapid Test** REF : P2004
- ❖ **GenSure™ COVID-19 Antigen Rapid Test** REF : P2005
- ❖ **GenSure™ COVID-19 IgM Rapid Test (Fluorescence  
Immunochromatographic Assay)** REF : P2006
- ❖ **GenSure™ COVID-19 IgG/IgM Rapid Test ( Fluorescence  
Immunochromatographic Assay)** REF : P2007
- ❖ **GenSure™ COVID-19 IgG Rapid Test (Fluorescence  
Immunochromatographic Assay)** REF : P2008
- ❖ **GenSure™ COVID-19 Antigen Rapid Test ( Fluorescence  
Immunochromatographic Assay)** REF: P2009



# Packaging and Certification



## EC Declaration of Conformity

<b>Name and address of the manufacturer:</b>	GenSure Biotech Inc., 3/F, Block 1, Boyun Building, No.9 Fengchan Rd, Economic-Tech Development Zone, Shijiazhuang, 050000, Hebei, P.R China
<b>Product Name</b>	COVID-19 IgM Rapid Test (NL-CA002-2020-49727) COVID-19 IgG/IgM Rapid Test (NL-CA002-2020-49726)
<b>Classification</b>	Other

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. This declaration is based on conformity to Annex III (excluding Annex III.6). All supporting documentation is retained under the premises of the manufacturer and can be available through EU representative.

<b>Name and address of the Authorised Representative</b>	QualRep Services B.V. Utrechtseweg 310 - Bldg B42, NL-6812 AR Arnhem, The Netherlands
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CE

Name Print: Terry Chan  
Position: Manufacture Representative  
Date: 2020-03-11

河北精硕生物科技有限公司  
GENSURE BIOTECH INC.

# COVID-19 IgM Rapid Test

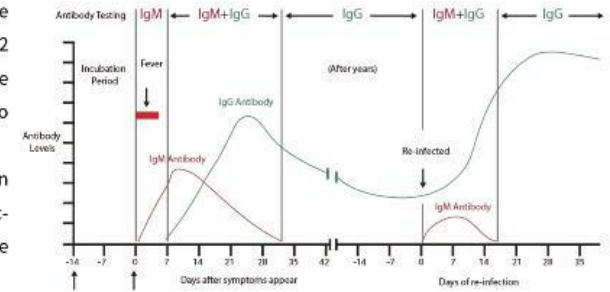
REF:P2001



## IgM is a sign of recent infection

During the infection process, IgM is the first antibody appearing in the human immune system. Detection of the new coronavirus SRAS-CoV-2 specific IgM antibody during the acute infection period has the advantages of high sensitivity, early diagnosis, and the ability to determine whether the suspect is infected.

IgM antibodies are produced several days after virus infection, and can be detected as soon as one week. Different individuals have differences. A negative result indicates that they are not infected or are in the very early stage of infection.



## EASY TO READ RESULTS



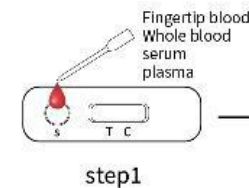
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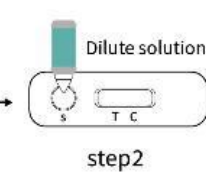
2



3



step1

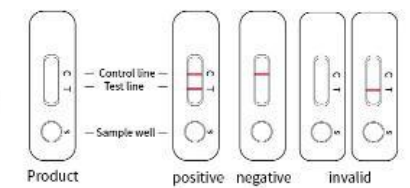


step2

5 minutes

To get results

step3



### ADVANTAGES

- Easy to use
- Can be used to test whole blood, serum and plasma
- 3 simple steps
- Results in 5 min
- Easy to read results
- No equipment needed
- No sample transport Required



# COVID-19 IgG/IgM Rapid Test

REF:P2002



Dual Cassette

## COMPARISON WITH PCR NUCLEIC ACID TESTS

	PCR Nucleic Acid Tests	IgM/IgG Combined Test
Turnaround time	>1 hour	15 min
Facility Requirement	PCR Laboratory	None
Operation	<ul style="list-style-type: none"> <li>- Requires technicians</li> <li>- Expensive equipment</li> <li>- Complicated operation</li> <li>- Prone to false negatives</li> </ul>	<ul style="list-style-type: none"> <li>- Whole blood, serum and plasma can be used</li> <li>- Easy operation</li> <li>- Test anywhere, any time</li> <li>- Easy-to-read results</li> </ul>
Transport/Storage	Freezing conditions	Room Temperature
Clinical Value	Commonly used standard	Highly specific, real-time monitoring

# Donation to Korea and Japan

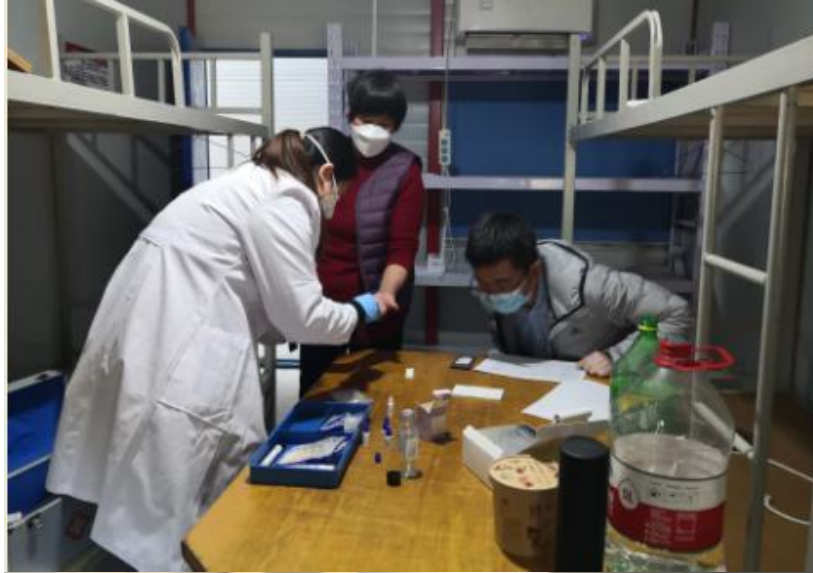


品名	规格	单位	数量	单价	金额
新型冠状病毒快速检测试剂盒	20人份/盒	人份	500	100元/人份	50000元RMB





# Volunteer Test Subway Construction Workers



# Contact Us:Japan and Africa



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Shinagawa-ku, Tokyo, 140-0004, Japan.

