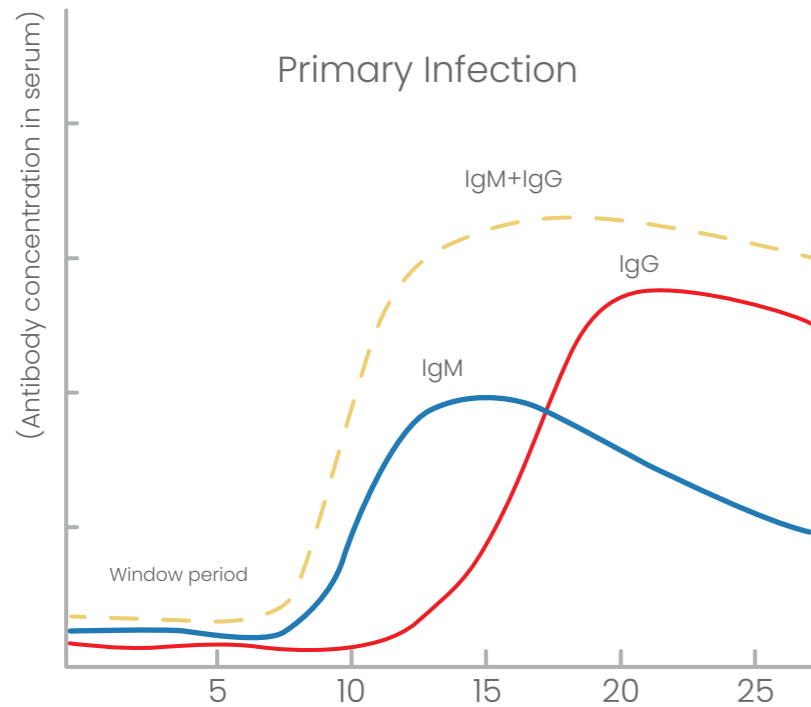


SARS-CoV-2 ANTIBODY TEST STRIP Colloidal Gold Method

IGM/IGM ANTIBODY TEST SIGNIFICANCE:

Sinocare SARS-CoV-2 Antibody Test Strip is a rapid, accurate and simple point-of-care IgG-IgM combined antibody test kit, using colloidal gold immunochromatography assay, which can qualitatively detect IgM and IgG antibodies simultaneously against SARS-CoV-2 virus in human blood within 15-20 minutes.

Recent study shows incubation period of COVID-19 would be about 0-10 days, IgM can be detected about 7 days after onset, IgG would appear about 10 days after onset.



RAPID DETECTION & SIMPLE OPERATION

The novel virus, now known as SARS-CoV-2 (also known as 2019-nCoV), a RNA virus of the beta coronavirus family. IgG-IgM combined antibody test is suitable for rapid detection and screening of the large amount of suspected patients and asymptomatic carriers to prevent secondary transmission and assure timely treatment of infections.

PRODUCT SPECIFICATIONS:

Product: SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method)

Specimen: Whole blood / Serum / Plasma

Sample Volume: 10µL of whole blood / serum / plasma

Test time: 15-20 minutes

Package: 25strips/box; 5 strips/box; 1 strip/box

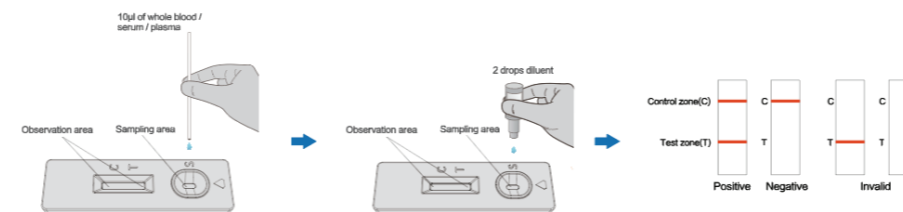
Storage condition: Store at 4°C - 30°C in the foil punch, keep away from direct sunlight, moisture and heat. Do not freeze.

Method	RT-PCR	IgG-IgM antibody test
Specimen	Swab	Whole blood / Serum / Plasma
Test time	Over 2-3 hours	Within 15-20 minutes
Operation	Professional	Simple
Detection condition	Specific equipment required	Point-of-care
Precision	About 50% false negative	IgM-IgG test 90%

ASSAY PROCEDURES:

- Step 1:** Massaging the finger to promote blood.
- Step 2:** Wiping the finger with 75% alcohol pad for disinfection.
- Step 3:** After alcohol volatilization, using disposable blood lancet to collect blood sample.
- Step 4:** Using dropper to pipette 10µL blood sample.
- Step 5:** Adding the blood sample into sampling area.
- Step 6:** Adding 2 drops of diluent vertically into sampling area.
- Step 7:** Waiting for 15~20 minutes, then observe the result.

CONVENIENT PROCEDURE & VISUAL RESULT



ACCURATE RESULTS

Clinical Evaluation

Total test on 320 subjects, include 240 excluded patients, 80 confirmed patients.

Sampe Type	Sensitivity	Specificity
Serum / Plasma	96.3%	99.6%
Whole Blood	95.0%	99.2%

CERTIFICATION

CE certificate status Sinocare has passed ISO13485 system certification with CE qualification. TÜV Rheinland
EN ISO 13485:2016 certified by TÜV Rheinland LGA Products GmbH
Certificate Registration No.: SX 60139875 0001
Standards Applied

EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposed (ISO 13485:2016)
DIN EN ISO 13485:2016

GENERAL APPLICABLE DIRECTIVE

Directive 98/79/EC of European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic Medical Devices.
CONFORMITY ASSESSMENT PROCEDURE
Annex III, according to Article 9 of Directive 98/79/EC

MANUFACTURER:

Sinocare

Changsha Sinocare Inc.
No. 265 Guyuan Road, Hi-tech Zone, Changsha, Hunan Province, 410205, People's Republic of China.

EUROPEAN AUTHORIZED REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

OFFICIAL DISTRIBUTOR:

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