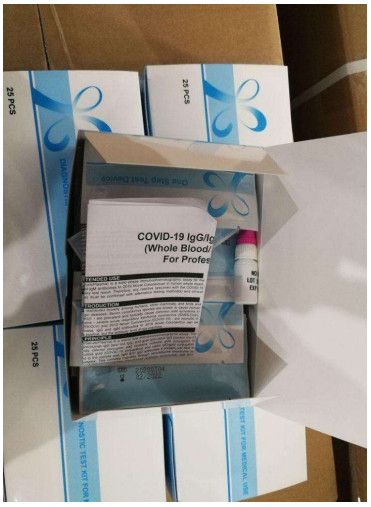
Beart & Gibson

COVID 19 TEST KIT

CORONA VIRUS RAPID TEST KIT

Widely used in Hospitals, Hygiene, Medical Lab, Household, Commercial Buildings, Personal Care



Rapid Test Kit, With all certificates, Instant Covid-19 Detection through blood analysis, used widely by professionals

SPECS:

IgG/ IgM Rapid Test through Whole Blood/ Serum/ Plasma

Fast results (2-10 mins)

All necessary reagents provided

No additional equipment needed

CERTIFICATION:

CE, FDA, ISO Certificate

QUANTITY:

Minimum 100,000 pcs

TERMS:

Video evidence will be provided

50% T/T Advance along with Purchase Order

50% T/T balance on invoice before shipment

PRICE:

$ TBC FOB per Set. 1 Million Plus

Quantities 500.000 1 Million + $1.

Quantities below 500.000 + $4

SHIPMENT:

FOB China CIF: Upon Request.

REMARKS:

- Shipment within 3 days of advance payment
- Air shipment 3-5 days
- **First come first serve basis**

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 058008 0029 Rev. 00

Regulatory Requirements:

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies):
GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663
Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:
Design and Development, Production, Service, Installation, and Distribution of In-Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Renal Injury Markers, Autoimmune Diseases, Infection and Inflammation Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System
DUNS No: 53-014-8055

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Date of Issue: 2019-02-18

(Arie Henkin)
Manager, Certification Body MHS
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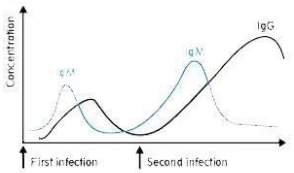
US-Letter / 07.17

SARS-CoV-2 Antibody Test
(Lateral flow method)

- As an auxiliary and supplementary method for the further diagnosis to the patients with negative result in PCR.
- Easy to use, instant result in 15 minutes

According to the Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (7th Edition) published by general office of national health committe, serology testing can be used as a diagnostic method of COVID-19 infection.



Antibodies can be detected as early as one week after infection, with slightly difference between individuals.

1. Negative result indicates no infection or infection at a very early stage (within first few days).
2. Positive result indicates an infection with coronavirus.

Order information

Product name	Packing size	Sample type	Storage condition	Shelf life
SARS-CoV-2Antibody Test (Lateral flow method)	20T	Whole blood, serum and plasma	2℃~30℃	6 months

Guangzhou Wondfo Biotech Co., Ltd.

CE EC Declaration of Conformity CE

in accordance with Directive 98/79/EC

Manufacturer:

Product/s	*Catalogue number*
2019-nCOV IgG/IgM Rapid Test Device	K460216D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 18113-3:2011; EN ISO 23640:2015;EN 62366:2008.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd,located at Suite B,29 Harley Street, London W1G 9QR,England,United Kingdom to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.3.5 — (Place and date of issue)

Dean — (Signature and position)

Signed for and on behalf of the manufacturer

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 058008 0029 Rev. 00

Certificate Holder:
GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:
Design and Development, Production, Service, Installation, and Distribution of In-Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Renal Injury Markers, Autoimmune Diseases, Infection and Inflammation Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System

Standard(s):
(ISO 13485:2016)

Regulatory Authority(ies):
Australia TGA, Brazil ANVISA, Health Canada, USA FDA. See attachment page for listing of specific regulatory requirements

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **53-014-8055**

Effective Date: **2019-02-04**

Expiry Date: **2022-02-03**

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(Arie Henkin)
Manager, Certification Body MHS
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US-Letter / 07.17

20 Tests/Kit

1 Test/Kit

Component:

Iodophor Disinfection Cotton Swab

Blood Sample Device

Dropper

Detection card of Novel Coronavirus (2019-nCoV) antibody IgG/IgM

Sample dilution of Novel Coronavirus (2019-nCoV)*

20Tests/Kit:1bottle × 4.5mL

1 Test/Kit: 1bottle × 1mL

Outer box size: 595*550*450mm

20Tests/Kit: Weight: 0.28kg

Quantity: 60Kits, 1200Tests, Total Weight:18.9kg

1 Test/Kit: Weight: 0.03kg

Quantity: 20Bags, 400Tests, Total Weight:15.2kg