CORPORATE OFFER

SARS-CoV-2 (COVID-19)

ANTIBODY TEST VIA LATERAL FLOW METHOD

FOR HOSPITALS AND PROFESSIONAL USE ONLY

HIGH ACCURACY - TESTED AND FDA REGULATED - IMMEDIATE RESULTS

Beart & Gibson

www.beartandgibson.com
Fletcher Way - Hemel Hemstead - United Kingdom - HP2 5SE
info@beartandgibson.com

Beart & Gibson

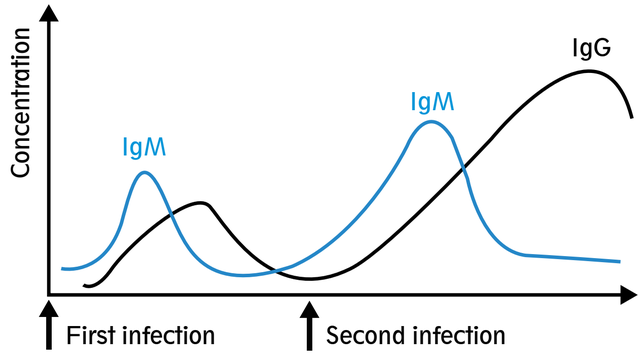
Wondfo®

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

Wondfo®
Guangzhou Wondfo Biotech Co., Ltd.
Add: No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Websites: en.wondfo.com.cn

MINIMUM ORDER 100,000 UNITS

MORE THAN 90% ACCURACY

Beart & Gibson

SARS-CoV-2
Nucleic Acid Detection Kit (Fluorescent PCR Method)

Wondfo®

LIMITED AVAILABILITY

Features

Easy to Transport
Lyophilized reagent, stable and easy to store and transport.

Whole Process Validation
Whole process control validate the entire process from extraction to PCR.

Powerful Performance
The precise test region is designed in accordance with the diagnosis and treatment guideline issued by the National Health Commission.

Specification

Target gene: ORF1ab, N gene	**Specimen:** Throat swab or deep sputum
Time to result: 60 mins after extraction	**Coincidence rate:** more than 90%
Storage condition: 2-8℃	**Detection Limit:** 10^3 cfu/mL

Order Information

Catalog No.	Product Name	Packing Size
W275	SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescent PCR Method)	24T

Guangzhou Wondfo Biotech Co., Ltd.
Add: No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Websites: www.wondfo.com.cn

MORE THAN 90% ACCURACY

MINIMUM ORDER 100,000 UNITS

SARS-CoV-2 Antibody Test (Lateral Flow Method)

Catalog No.: W195

INTENDED USE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only. For professional use only.

SUMMARY

On December 31, 2019, several cases of pneumonia in Wuhan City, Hubei Province of China were reported to the World Health Organization (WHO). The novel virus, now known as SARS-CoV-2 (previously known as 2019-nCoV), a RNA virus of the beta coronavirus family, has since spread across China and to other countries and territories. The WHO has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated "COVID-19").

PRINCIPLE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 antibodies level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only.
2. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents. And follow biosafety level 2 or higher guidelines.
3. Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handing the contents of this kit.
4. Proper specimen collection storage and transport are critical to the performance of this test.
5. Discard after first use. The test cannot be used more than once.
6. Do not touch the reaction area of test strip.
7. Do not use test kit beyond the expiration date.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIAL

Material Provided

1. 20 Individual sealed pouches, each pouch contains:
   - 1 x Test cassette
   - 1 x Desiccant pouch
2. 20 disposable droppers
3. Detection buffer (1*6 mL)
4. Instructions for use

Material Required but Not Provided

1. Specimen Collection Containers
2. Centrifuge (for serum/plasma sample)
3. Timer
4. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
5. Appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30ºC in the sealed pouch up to the expiration date printed on the package. Do not freeze.
2. The test cassette should be used within 1 hour after taking out from the foil envelope. Buffer solution should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with whole blood, serum and plasma.

For whole blood:

1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect result.
2. It is recommended that whole blood specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they may be stored at 2ºC～8ºC for up to 7 days. Prior to testing, mix the blood by gentle inversion several times, do not freeze or heat whole blood specimens.

For Serum and Plasma:

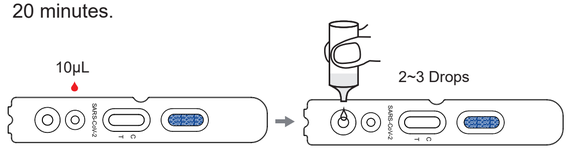
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give incorrect result.
2. Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.
3. Test should be performed within 8 houres after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2ºC～8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC for up to 9 days.

Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat-inactivated specimens are not recommended.

TEST PROCEDURE

Please read the instruction for use carefully before performing the test.

1. Allow the device, buffer and specimen to equilibrate to room temperature (10ºC ～30ºC) prior to testing.
2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Transfer 10 μL of whole blood or serum or plasma specimen to the sample well (small well) and then add 2-3 drops (80 μL) of buffer solution to the buffer well (large well).
4. As the test begins to work, you will see purple color move across the result window in the center of the test device.
5. Wait for 15 minutes and read the results. Do not read results after 20 minutes.



Note: the rightmost window on the cassette shows the product abbreviation "nCoV" to identify this product.

RESULT INTERPRETATION

Positive Result

Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.

Negative Result

Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antibodies is zero or below the

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**

Date of Issue: 2019-02-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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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

Date of Issue: 2019-02-18

(Arie Henkin)
Manager, Certification Body MHS

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TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 058008 0025 Rev. 00

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

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

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Production and Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System, Control Materials for Tumor Markers, ECG Event Recorder**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1814116

Valid from: 2019-03-11
Valid until: 2021-01-31

Date, 2019-03-11

Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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qarad
European Regulatory Services

DECLARATION OF NOTIFICATION

Date: March 5, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

Guangzhou Wondfo Biotech Co. Ltd.
No. 8 Lizhishan Road, Science City Luogang District,
Guangzhou 510663
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue numbers
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	W195
Finecare™ SARS-CoV-2 IgM Test	W277
Finecare™ SARS-CoV-2 Antibody Test	W276

The notification to the Belgian Competent Authorities has been carried out on March 5, 2020 by Qarad BVBA, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Sara Van Wouwe
Device Compliance Assistant
Qarad BVBA
Authorized Representative

Qarad BVBA | Office Address: Pas 257, B-2440 Geel, Belgium | Social Siege: Cipalstraat 3, B-2440 Geel, Belgium
Tel. +32 (0)14 49 04 22 | ECREP@qarad.com | www.qarad.com

Guangzhou Wondfo Biotech Co., Ltd.
QMR—009—09 **Valid From: November 13, 2019**

Report of Finished Product Inspection

Report Code：C-202002112

Name of Product	SARS-CoV-2 Antibody Test (Lateral Flow Method)		
Lot Number	W19500205	**Batch**	/
Specification	20 tests/kit	**Number**	100000T
Manufacture Date	2020-02-23	**Expiration Date**	2020-08-23
Sampling Date	2020-02-24	**Report Date**	2020-02-24
Inspection Reference	TS-PM-738	**Sampling Amount**	208T

Inspection Items	Quality Standards	Inspection Result	Determination of Result
Physical Examination	Appearance: The appearance should be flat, the logo should be clear. The components should be firmly attached, and the content should be complete.	Coincidence rate: (208/208)	☑Compatible ☐Incompatible
	Migration Speed: Liquid migration speed should be not lower than 10mm/min.	Liquid migration speed is (26) mm/min	☑Compatible ☐Incompatible
	Width of Membrane: The width of membrane should be wider than 2.5mm.	Width of membrane is (4.0) mm.	☑Compatible ☐Incompatible
Positive Reference Coincidence Rate	Positive Reference Coincidence Rate should be 5/5.	Coincidence Rate is (5/5).	☑Compatible ☐Incompatible
Negative Reference Coincidence Rate	Negative Reference Coincidence Rate should be 10/10.	Coincidence Rate is (10/10).	☑Compatible ☐Incompatible
Lowest Limit of Detection	Enterprise Reference of Lowest Limit of Detection S1 should be negative, S2 and S3 should be positive.	Coincidence Rate is (3/3).	☑Compatible ☐Incompatible
Repeatability	Test 2 Enterprise Repeatability References (J1~J2), and each repeat for 10 times respectively, the results should be positive.	Coincidence Rate is (10/10, 10/10).	☑Compatible ☐Incompatible
Conclusion	☑Pass ☐Failure	**Use Determination**	☑Agree to release ☐Disagree to release
Remark			
Quality Inspector/Date	Yufeng Lin, 2020-02-24	**Reviewer/Date:**	Xiongjian Zhou, 2020-02-24
Quality Authorizer/Date of Issue	Huadong Xu, 2020-02-24		

GUANGZHOU WONDFO BIOTECH CO.,LTD. 广州万孚生物技术股份有限公司 业务专用章 FOR BUSINESS ONLY

Clinical Report of Guangdong No.2 People's Hospital

Purpose: Evaluate the clinical performance of One Step SARS-CoV-2 Antibody Test (Lateral Flow Method)

Date: 1 Feb, 2020

Technician: Chunrong Huang (Wondfo), Ruimao Lin (Guangdong No.2 People's Hospital)

Test Procedure: Collect 10 μL plasma or serum sample, add into the sample well of test cassette and add 3 drops of buffer solution into the buffer well. Read result after 15 minutes.

Test Result

No.	Date of collection	Wondfo	PCR
1	1.29	C6	Positive
2	1.24	C9	Positive
3	1.24	C5	Positive
4	1.25	C7	Positive
5	1.25	C8	Positive
6	1.25	C8	Positive
7	1.26	C3+	Positive
8	1.24	C4	Positive
9	1.25	C8	Positive
10	1.27	C5	Positive
11	1.27	C6	Positive
12	1.30	C5	Positive
13	1.31	C7	Positive
14	1.30	C8	Positive
15	1.29	C7	Positive
16	1.31	C7	Positive
17	1.31	C6	Positive
18	1.29	C6	Positive

19	1.31	C8	Positive
20	1.31	C4	Positive
21	1.31	C5	Positive
22	1.30	C6	Positive
23	1.29	C6	Positive
24	1.28	C6	Positive
25	1.31	C5	Positive
26	1.24	C7	Positive
27	1.31	C8	Positive
28	1.31	C7	Positive
29	1.31	C5	Positive
30	1.27	C6	Positive
31	1.24	C7	Positive
32	1.27	C8	Positive
33	1.27	C7	Positive
34	1.24	C7	Positive
35	1.29	C8	Positive
36	1.24	C5	Positive
37	1.28	C7	Positive
38	1.28	C8	Positive

No.	Date of collection	Wondfo	PCR
1	1.30	B	Negative
2	2.01	B	Negative
3	1.30	B	Negative
4	1.30	C9	Negative
5	2.01	B	Negative
6	2.01	B	Negative
7	2.01	B	Negative

8	1.30	B	Negative
9	1.30	B	Negative
10	2.01	B	Negative

Wondfo result interpretation:

B indicates negative result

C8~C9 indicates slightly positive result

C6~C7 indicates moderate positive result

>C6 indications strong positive result

Result analysis

Conclusion		PCR		Total
		Positive	Negative	
Wondfo	Positive	38	1	39
	Negative	0	9	9
Total		38	10	48

Positive coincident rate: 39/38×100%=100%

Negative coincident rate: 9/10×100%=90%

Total coincident rate=（38+9）/（38+10）=97.92%

Kappa value is 0.9344,（95% CI 0.8075~1.0613）

广州万孚生物技术股份有限公司
GUANGZHOU WONDFO BIOTECH CO.,LTD.

2019 New Coronavirus Pneumonia

（C0VID-19）Total Solution

Project Proposal

GUANGZHOU WONDFO BIOTECH CO..LTD

2020-03-02

Contents

I. Brief Introduction of Wondfo

Wondfo belongs to *in vitro diagnostic* (IVD) industry under the medical equipment industry. Specializing in the R&D, manufacturing, sales and service of rapid diagnostic reagents and related equipment, Wondfo is one of the leading enterprises in Chinese domestic POCT.

With more than 20 years of development, Wondfo has established the most complete technology platforms and most abundant product lines comparing with other Chinese domestic POCT companies

Currently, Wondfo have immune-colloid gold technology platform, immune-fluorescence technology platform, electrochemical technology platform, dry biochemical technology platform, chemiluminescence technology platform, molecular diagnostic technology platform, instrument technology platform and biological raw material platform. Relying on the above eight technology platforms, Wondfo formed the rich product lines in the fields of cardiovascular and cerebrovascular diseases, inflammation, tumors, infectious diseases, drug tests (drug abuse), pregnancy, etc. Those products are sold to more than 140 countries and regions around the world, and are widely used in primary care, critical care, clinical testing, epidemic surveillance, blood stations, disaster relief, on-site law enforcement, and family personal health management. **Untill 30th Jun, 2019, the company has accumulatively obtained 406 CFDA, FDA, CE, Canadian MDALL and other product registration certificates**, ranking as one of the top level of the industry.

The company has been exploring overseas markets since 2004. Developed countries and regions such as the United States and Europe are the mature consumer areas of POCT in the world. Their market supervision is also the most stringent. Entering these markets requires not only high product quality requirements, but also a long market access qualification application cycle. In 2014, Wondfo passed the on-site assessment of the US FDA. In 2017, Wondfo obtained the *"ISO9001: 2015 Quality System Certificate"* issued by China Certification Authority. In 2018, Wondfo obtained the *ISO13485: 2016 Quality System Certificate* issued by TUV: SUD, Germany. After 15 years of unremitting efforts, the company has built prominent advantages in overseas market access and overseas channel construction[1].

II. Wondfo's R&D history in response to major outbreaks/ infectious diseases

- The SARS outbreak in 2003 arose the attention from all over the world. Wondfo

developed the SARS antigen colloidal gold detection reagent in response to this outbreak and obtained a patent authorization.

- In 2009, the United States, Mexico and other countries had outbreaks of H1N1 influenza, which killed at least 10,000 people worldwide. Same year, 14th Jul, the State Council organized the competition between the diagnostic products regarding antigen for the H1N1 joint prevention and control Wondfo ranking as the first.
- In 2013, Shanghai and Anhui province first discovered a new subtype of H7N9 avian influenza virus, and in the same year Wondfo took the lead to develop the detection of human infection with H7 subtype avian influenza antigens and obtained the CFDA registration certificate.
- On 29th Nov, 2018, Wondfo received the pre-qualification (PQ) confirmation letter from the World Health Organization (WHO), informing that the company's HIV testing products have passed the WHO's PQ certification and were listed by WHO as a recommended list of in vitro diagnostic products.
- In 2020, facing the outbreak of pneumonitis infected by a new coronavirus in Wuhan since Dec 2019, the company announced on 20th Jan, 2020 that it had successfully developed a new coronavirus multiple pathogen nucleic acid detection card;
- On 19th Feb, 2020, Wondfo has two new coronavirus products: "A new rapid detection reagent for coronavirus antigen suitable for the epidemic situation", "a new rapid detection reagent for coronavirus based on fluorescent microsphere / colloid gold immune-chromatography " that were recommended by the State Council's Office for Joint Prevention and Control of New Coronavirus Pneumonia Epidemic (Research and Scientific Research Team), and entered the emergency approval channel of the National Medical Products Administration (NMPA), with priority support.
- **On 22nd Feb 2020, Wondfo developed SARS-nCov-2 Antibody Test (Lateral Flow Method) that has successfully received NMPA certificate, approved by National Medical Products Administration.**

III. COVID-19 &SARS-CoV-2

During Dec 2019, Wuhan City, Hubei Province has discovered multiple cases of patients with new-type coronavirus pneumonia Due to the contagious propriety of this disease other cases in China and abroad have also been found one after another. As an acute respiratory infectious disease, the disease has been classified into Class B infectious diseases stipulated by the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and should be managed as a Class A infectious disease[2].

On 11th Feb, Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, announced that the new coronavirus-infected pneumonia was named

"COVID-19"[3].

On 30th Dec 2019, three bronchoalveolar lavage samples were collected from a patient with pneumonia of unknown etiology in Wuhan Jinyintan Hospital. Real-time PCR (RT-PCR) assays on these samples were positive for pan-Betacoronavirus. Using Illumina and nanopore sequencing, the whole genome sequences of the virus were acquired. Bioinformatic analyses indicated that the virus had features typical of the coronavirus family and belonged to the Beta-coronavirus 2B lineage[4].

On 11th Feb, the Coronavirus Research Group (CSG) of the International Virus Classification Commission officially named the new coronavirus SARS-CoV-2[5].

With the spread of the epidemic in China, a team of relevant experts organized by the National Health Commission of the People' s Republic of China have successively formulated the first version, the second version, the third version, the fourth version, and the Fifth version, totally five editions of *"Pneumonitis diagnosis and treatment plan for new coronavirus infection".* On 19th Feb, 2020, the General Office of the National Health Commission issued the *"Pneumonitis Diagnosis and Treatment Plan for New Coronavirus Infection (Trial Version 6)"*. The content of the sixth edition includes the coronavirus etiological characteristics, epidemiological characteristics, clinical characteristics, case definitions, differential diagnosis, case discovery and reporting, treatment, release and discharge standards, transfer principles and nosocomial infection control.

Clinical Characteristics. Based on the current epidemiological investigation, the incubation period is within 1-14 days, and most commonly is within3-7 days. The primary symptoms are fever, dry cough, and fatigue. A minority of patients have symptoms such as nasal congestion, nasal discharge, sore throat, muscle pain, and diarrhea. Severe patients often suffer from dyspnea and/or hypoxemia one week after onset, and severe patients can rapidly progress to acute respiratory distress syndrome, septic shock, metabolic acidosis, coagulation dysfunction and multiple organ failure. Notably, the severe and critical patients may have moderate to low fever or even no obvious fever during the course of the disease. Patients with the mild form of the disease present only as low fever, slight fatigue, and so forth, with no lung inflammation. Judging from the current cases, most patients have a good prognosis while a minority are in critical condition. The prognosis of the elderly and those with chronic underlying diseases is poorer. The symptoms for children are relatively mild.

Laboratory Examination. In the early stage of the disease, the total number of peripheral blood leukocytes is normal or decreased, and the lymphocyte count was decreased, and some patients may have increased liver enzyme, lactate dehydrogenase (LDH), myocardial enzymes and myoglobin, and some critically ill patients may have elevated troponin. C-reactive protein (CRP) and erythrocyte sedimentation rate increased in most patients, and procalcitonin (PCT) was normal. In severe cases, D-dimer increased and peripheral blood lymphocytes progressively decreased. Inflammatory cytokines often

increase in severe and critical patients. Novel coronavirus nucleic acid can be detected in nasopharyngeal swabs, sputum and other lower respiratory tract secretions, blood, feces and other samples. In order to improve the positive rate of nucleic acid detection, it is suggested that sputum be collected as much as possible, collecting secretions from the lower respiratory tract of patients undergoing tracheal intubation, and sending samples for examination as soon as possible after collection.

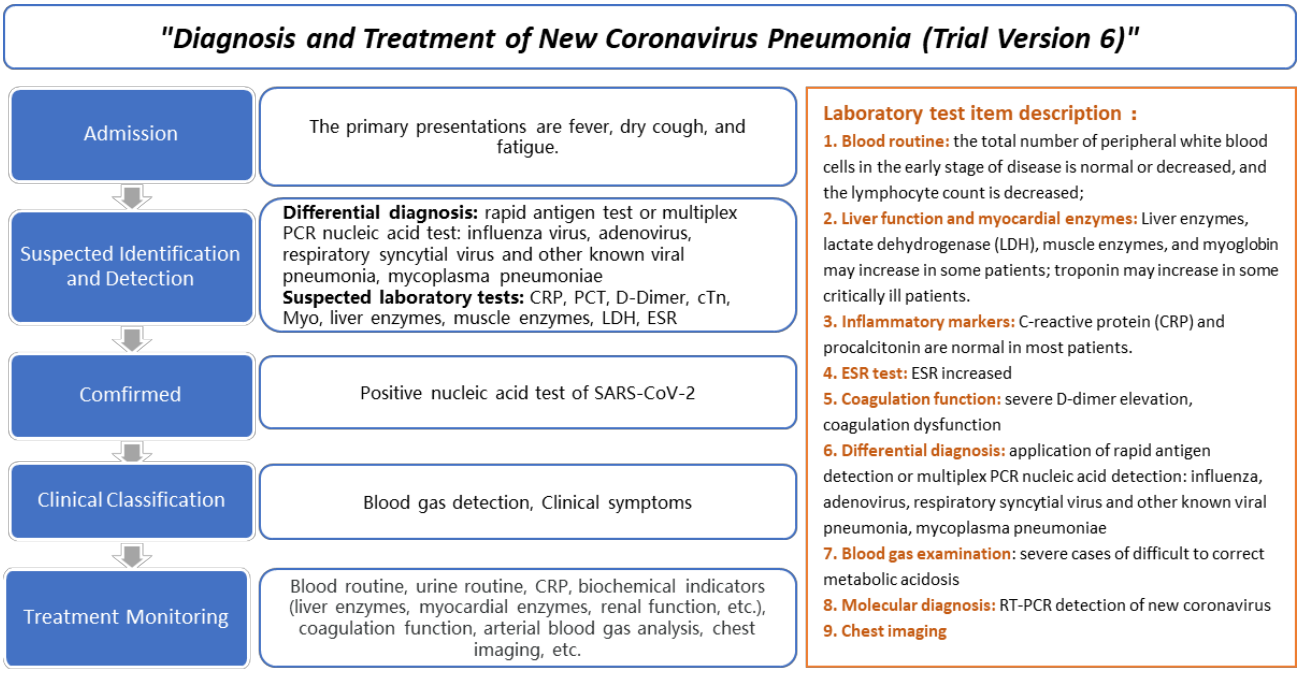
Confirmed cases. Suspected cases have one of the following pathological evidence:

1) Tests positive (respiratory tractor blood specimens) for real-time fluorescence RT-PCR detection of novel coronavirus nucleic acid; 2) The viral gene sequencing is highly homologous with the known novel coronavirus.

Differential Diagnosis. 1. The mild manifestations of new coronavirus infections need to be distinguished from upper respiratory tract infections caused by other viruses. 2. The new type of coronavirus pneumonia is mainly distinguished from influenza virus, adenovirus, respiratory syncytial virus and other known viral pneumonia and pneumoplasma infections. Especially for suspected cases, including rapid antigen detection and multiple PCR detection and other methods to detect common respiratory pathogens are needed. 3. It should also be distinguished from non-infectious diseases such as vasculitis, dermatomyositis, and organizing pneumonia.

Treatment Monitoring. Isolation: Suspected and confirmed cases should be isolated and treated at designated hospitals with effective isolation and protection conditions. Suspected cases should be treated with isolation and questioning alone. Multiple confirmed cases can be admitted to the same ward; according to the condition monitoring: blood routine and urine routine, CRP, biochemical indicators (liver enzyme, myocardial enzyme, renal function, etc.), coagulation function, arterial blood gas analysis, chest imaging, etc. If possible, cytokine detection is feasible.

IV. Recommended Diagnosis and Treatment Procedure and Detection Items



V. The Advantages of POCT in COVID-19 Diagnosis

Point-of-care testing (POCT) is the diagnosis performed near patients, and usually doesn't require professional operation. POCT has 3 key points: 1) Rapid result;2) On-site test, carrying reagents and handheld medical devices near the patients, conducting on-site testing, which can shorten the sample processing time in lab; 3) It is possible that the operator can be non-professional technicians or the patients themselves[6].

The Advantage of POCT test is to provide rapid analysis and immediate therapeutic intervention. Therapeutic turnaround time (TTAT) refers to the interval between sample test and therapy receive for patients. POCT can significantly reduce TTAT, which means patients can get earlier treatment, especially for the critically ill patient. Meanwhile, it is beneficial to improve the patient's condition, reduce complications and shorten the treatment time for the patient, which saves valuable medical and financial resources. Therefore, the fundamental purpose of POCT is to achieve medical effectiveness and economy through rapid detection and shortened TATT[6].

The new coronavirus has many ways to transmit and is highly contagious. The most effective way to prevent and control is ***"early detection, early diagnosis, early isolation, and early treatment."*** In terms of "early detection and early diagnosis", compared with other detection methods, POCT has the following three major

advantages: 1) Rapid results; 2) No restriction of test site; 3) No require professional operation skill. During SARS, H1N1, influenza B, H7N9 avian influenza and other epidemic periods, POCT has shown its potential for application scenario, helping to quickly respond to large-scale outbreaks. In response to the COVID-19 epidemic, the Ministry of Science and Technology released the *"Guidelines for the Application of New Coronavirus (2019-nCoV) Rapid Detection Products for R & D and Emergency Projects"* on 8th Feb, which is a comprehensive field-based rapid detection of new coronavirus products, with the hope to break through the limitations of existing detection technologies on people/places, shorten the detection time, improve convenience, promote the diagnosis to move down and achieve rapid diagnosis of suspected patients and on-site screening of close contacts. It can be seen that POCT is of great value in the treatment of sudden infectious diseases.

In the epidemic of infectious diseases represented by COVID-19, the application of POCT is mainly reflected in three types of products: 1) Rapid immunological detection reagents mainly based on colloidal gold products (including antigen detection and antibody detection), it is used for large-scale screening of early mild and asymptomatic patients, which can improve the detection rate of diseases; 2) Nucleic acid based on molecular diagnostic products, which are mainly used for the identification of viral pathogens, and provide on-site rapid detection for patients to confirm the diagnosis; 3) Miniaturized and portable diagnostic products such as Dry Chemistry Analyzer, Fluorescence Immunoassay Analyzer, Blood Gas Analyzer and Chemiluminescence Analyzer, all of them are mainly used for monitoring of biomarkers such as enzymes, proteins, electrolytes, and antibody detection, and provide solutions for the treatment and monitoring of confirmed cases in hospital[7].

During the epidemic prevention period, the closed *'1m^2 POC lab'* plays an important role, which can cover early asymptomatic screening, batch automatic screening, nucleic acid diagnosis, treatment monitoring, and reduce the risk of iatrogenic infection. For example, a hospital's laboratory urgently set up a POCT isolation laboratory within a week, integrating coagulation analyzers, blood gas analyzers, dry chemistry analyzers and other POCT equipment, conducting cTnI and CK-MB, Myo, D-dimer, PCT, CRP, coagulation, blood gas analysis, liver function, renal function, myocardial enzyme spectrum, serum glucose, mycoplasma pneumoniae IgM, chlamydia pneumoniae IgM and other items. After simple training, all staff in the lab are capable of operating. By providing protection and isolation and preventing cross-contamination, maximum biological safety is provided for the detection of specimens from fever patients[7].

VI. Biosafety Protection in COVID-19 Diagnosis

According to a large amount of clinical studies and national diagnosis and treatment programs, special attention needs to be paid to the safety protection during laboratory sample processing and testing and COVID-19 treatment.

According to the *New Coronavirus Pneumonia Prevention and Control (5th Edition)* issued by the General Office of the National Health and Health Commission, the main transmission routes are listed as follows:

1. Spread through respiratory droplets and contact;
2. There is a possibility of aerosol transmission in a relatively closed environment when exposed to high concentrations of aerosol for a long time;
3. Other transmission channels are yet to be clarified.

The guidelines for laboratory operations are described as follows: Experimental operations on animals infected with live virus, sampling of infected animals, processing and testing of infectious samples, special inspection of infected animals, and treatment of excreta of infected animals should be conducted in the biosafety laboratory and operate in a biological safety cabinet.

On 28th Feb, 2020, a report issued by the WHO described the route of transmission: novel coronavirus pneumonia spreads between person that already has infection and person that is being infected through droplets and close contact without protection. There are no reports of airborne COVID-19, and based on available evidence, airborne transmission is not considered to be the major transmission way. However, there may be the possibility of airborne transmission in medical institutions due to aerosols generated by medical procedures[4].

VII. Wondfo COVID-19 Solution

'early notice, early report, early isolation, early diagnosis, early treatment, early control' is the most effective way to tackle the COVID-19[8].

Based on the biosafety guideline for COVID-19 diagnosis and treatment, Wondfo unites product lines including immune-colloid gold, fluorescent immunoassay, chemiluminescent, blood gas, coagulation, dry chemistry and molecular diagnosis to provides the total solution for COVID-19 'screening-diagnosis-treatment monitoring'. The independent and close 1 m^2 POCT lab is tailored for COVID-19, achieving ***'1 m^2 independent POC lab'***. This tailored lab allows the best protection and isolation of samples, avoiding the samples cross contamination and aerosol contamination. Flexible combination of products and platforms in 1 m^2 lab simplifies the operation, and any combination can be made to form a specific solution according to the requirements from CDC, healthcare facilities, communities or primary healthcare.

1 m² Independent POC Lab
Better Isolation, Better Protection

Tailored for COVID-19 management by Wondfo

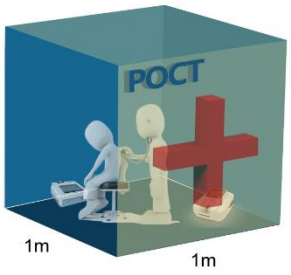
INDEPENDENT LAB

One isolated room for diagnosis of COVID-19, designed for one doctor and one patient.

1 m² LAB

1 m² enclosed POC lab was tailored by Wondfo based on its product lines including colloidal gold, fluorescence immunoassay, chemiluminescence, blood gas, coagulation, dry chemistry, molecular diagnosis.

- Joint detection using multiple platforms
- Easy to operate; instant result
- Prevent and control cross-infection
- Well enclosed and independent



Diagnosis for suspected cases	 Wondfo RDT Series	FluA/FluB（nasopharyngeal swab） Human IgM Antibody of Chlamydia Pneumoniae Human IgM Antibody of Mycoplasma Pneumoniae SARS-CoV-2 Antibody Test (Lateral flow method);
	 Finecare™ FIA Meters	Finecare™ SARS-CoV-2 Antibody Test Infection markers: *hsCRP+CRP*、*PCT*、*SAA*、*IL-6* Cardiac Markers *cTnI*、*cTnT*、*Myo*、*CK-MB*、*D-Dimer*
	 Dry Chemistry Analyzer（DC-101）	Myocardial Enzyme: *CK-MB*、*LDH*、*α-HBDH* Liver Function: *ALT*、*AST*、*ALB*、*CHE* Kidney Function: *BUN*、*CREA*、*EA*、*GLU*
Confirmed cases screening	 Wondfo molecular detection platform	SARS-CoV-2 Nucleic Acid Test (Fluorescent PCR)
Clinical classification	 BGA-101 Blood Gas Analyzer	Blood Gas Analysis: Basic blood-gas: *pH*, pCO_2, pO_2 Haematology: *Hct* Electrolyte: K^+, Na^+, Ca^{++}, Cl^- Biochemistry: *Glu*, *Lac*
Treatment monitoring	 Finecare™ FIA Meters  DC-101 Dry Chemistry Analyzer  BGA-101 Blood Gas Analyzer  OCG-102 Optical Coagulation Analyzer	Infection markers: *CRP*、*PCT* Thrombus Markers: D-Dimer : *Myocardial Enzyme:* *CK-MB*、*LDH*、*α-HBDH* Liver Function: *ALT*、*AST*、*ALB*、*CHE* Kidney Function: *BUN*、*CREA*、*EA*、*GLU* *blood routine examination* Blood Gas Analysis: Basic blood-gas Hematokrit Electrolyte Coagulation: *PT/INR*、*APTT*、*FIB*、*TT*、*ACT*

VIII. Case Sharing of Wondfo COVID-19 Solution in China

Mobile Cabin hospital: during the fight against COVID-19, China has been implementing a serial of actions. Among them, the mobile cabin hospital is a considerable and successful expedient. It can be considered as a cabin in our 'Noah's Ark', saving people's life under emergency. As one of the important modules of 'Field Mobile Medical System', 'Cabin hospital' can be easily assembled and quickly mobilized. The 'cabin hospital' is established based on the connection of vehicles, which we considered as 'cabin'. Each cabin has its own function, such as for medical, technical or logistical support, and together, a complete medical system is formed. The 'cabin hospital' in Wuhan is designed for the collection and treatment of COVID-19 patients with mild symptoms, for the purpose of triaging the patients with different severity of infection. For the patients in the 'cabin hospital', the anti-viral and immune-boosting medicine can satisfy the needs. Moreover, this collection of patients is convenient for the doctors to do the daily investigation, analysis and treatment, improving the efficacy dramatically[9].

Since the beginning of Lunar New Year, Wondfo employees Wenjie Mei and his 14 colleagues volunteered to visit the COVID-19-designated hospitals and 'cabin hospitals' in Wuhan. "We all hope to contribute to Wuhan", said by Wenjie and his colleagues.

On 26th Feb, at 2 pm, Wondfo employees Wenjie Mei and his colleagues installed the Wondfo Fincare analyzer, blood gas analyzer, coagulation analyzer, chemiluminescence analyzer and dry chemistry analyzer into the workspace of medical examiner Hanxin Yao located in the Haoyang sport school 'cabin hospital'.

According to Hanxin, the arrival of these analyzers is equal to the addition of a few assistants. These analyzers are simple in operation and fast in detection, which is very suitable for the 'cabin hospital' designed for emergent situation[10].

Case 1: Hanyang sport school 'cabin hospital'

Hanyang sport school 'module hospital' medical vehicle

A corner of 'module hospital': Wondfo blood gas analyzer + dry chemistry + Finecare analyzer + POC chemiluminescence

A corner of 'module hospital': Wondfo blood gas analyzer + Finecare analyzer

A corner of 'module hospital': Wondfo dry chemistry analyzer

POCT labs in hospitals during epidemic	
Case 2: Chaozhou people's hospital, Guangdong (Finecare analyzer+ blood gas analyzer + coagulation analyzer + dry chemistry) 	Case 3: Shantou central hospital, Guangdong (Finecare analyzer+ blood gas analyzer + coagulation analyzer + dry chemistry) 
Case 4: The eighth people's hospital of Guangzhou, Guangdong (Finecare analyzer+ blood gas analyzer + coagulation analyzer + dry chemistry) 	Case 5: Shengjing hospital affiliated to China medical university (Finecare analyzer+ blood gas analyzer + coagulation analyzer + dry chemistry) 

IX. Global Cooperation is Urgent

By midnight on 27th Feb, A total of 39 countries (excluding China) had confirmed COVID-19 cases, outbreaks in South Korea, Italy and Iran are particular worrisome [11]。

The WHO speaks highly of China's response to the coronavirus outbreak。

Achieving China's exceptional coverage with and adherence to these containment measures has only been possible due to the deep commitment of the Chinese people to collective action in the face of this common threat. At a community level this is reflected in the remarkable solidarity of provinces and cities in support of the most vulnerable

populations and communities. Despite ongoing outbreaks in their own areas, Governors and Mayors have continued to send thousands of health care workers and tons of vital PPE supplies into Hubei province and Wuhan city

China's bold approach to contain the rapid spread of this new respiratory pathogen has changed the course of a rapidly escalating and deadly epidemic. A particularly compelling statistic is that on the first day of the advance team's work there were 2478 newly confirmed cases of COVID-19 reported in China. Two weeks later, on the final day of this Mission, China reported 409 newly confirmed cases. This decline in COVID-19 cases across China is real.

The WHO's Recommendations for the international community: Recognize that true solidarity and collaboration is essential between nations to tackle the common threat that COVID-19 represents and operationalize this principle;

The WHO emphasized that as the country with the greatest knowledge on COVID-19, China' sharing of epidemiologic data, clinical results and experience is of great significance on informing the global response

The WHO's recommendations for countries with imported cases and/or outbreaks of COVID-19: Immediately activate the highest level of national response management protocols to ensure the all-of-government and all-of-society approach needed to contain COVID-19 with non-pharmaceutical public health measures. Prioritize active, exhaustive case finding and immediate testing and isolation, painstaking contact tracing and rigorous quarantine of close contacts. **Immediately expand surveillance to detect COVID-19 transmission chains, by testing all patients with atypical pneumonias.**

The WHO's recommendations for uninfected countries: Prepare to immediately activate the highest level of emergency response mechanisms to trigger the all-of-government and all-of society approach that is essential for early containment of a COVID-19 outbreak. Rapidly test national preparedness plans in light of new knowledge on the effectiveness of non-pharmaceutical measures against COVID-19; **incorporate rapid detection, largescale case isolation and respiratory support capacities, and rigorous contact tracing and management in national COVID-19 readiness and response plans and capacities**[4]**;**

Faced with the public health crisis, all countries should unite and cooperate to tide over the difficulties together. China Foreign Ministry spokesperson Zhao Lijian made the remarks that China will not relent its efforts and will well coordinate its next-stage epidemic prevention and control work, China will strengthen international and regional cooperation, keep good communication and coordination with WHO, share experiences with relevant countries, and do as much as China can to help those countries and regions affected by the virus as we are a community with a shared future for mankind[11].

X. Service and Guarantee

Thank you for choosing the products from Guangzhou Wondfo Biotech Co., Ltd. We will continue to provide service and guarantee the quality during this crisis. The full scale of after-sales service and academic support will be provided through our local partners. Online service from headquarter will also be offered continuingly. Thank you for your support!

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