Rapid & Reliable

COVID-19 Check

NEGATIVE POSITIVE

Product characteristics

Test sample	Serum、plasma or whole blood
Short detection time	Rapid detection of novel coronavirus within 15 minutes (SARS-CoV-2)
No Instru-mentation required	No need for instruments and equipment, suitable for rapid screening
Suitable for primary screening	Screening for suspected novel coronavirus patients

ACCURACY RATE

94.5 %

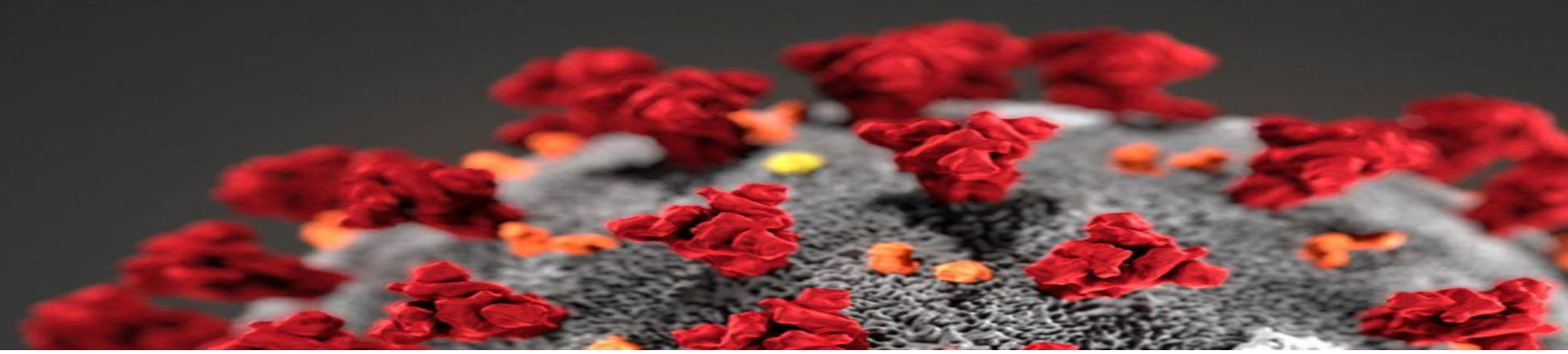
Screening for suspected novel coronavirus patients

CEATEC

ODC

Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

Company profile



CEATEC

Shanghai Xinchaowu is the only Chinese company producing detection reagents with the background of state-owned enterprises.

The founding team of Shanghai Xinchaowu is from a technical background and has advanced research and industrialization background.

Skilled and well educated R & D staff, built with famous scientists, Chengyuan Institute (16), hospital experts, etc.

A good cooperation relationship with state and international research centers. Chen Zhu, the leading scientist of Shanghai Xinchaowu, is the former Minister of Health of China.

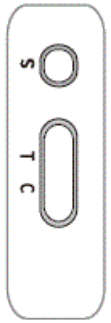
In their research team they have 16 academicians doing scientific research in identification and neutralization of COVID 19 coronavirus.

Schematic diagram of blood collection process

Step 1

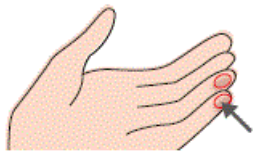
Before the test, the user manual must be read completely, and the reagent card and blood sample to be tested must be balanced to room temperature before use.

Before use, take out the reagent card from the original packaging aluminum foil bag and place it horizontally. The test reagent shall be used as soon as possible after the aluminum foil bag is opened.



Step 2

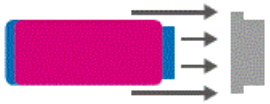
Before blood collection, try to make your hands warm, ruddy and full of blood. Gently rub and press the finger tips to collect blood for 1-2 minutes. See the reference drawing for blood collection parts. It is recommended to use the outside of ring finger or little thumb.



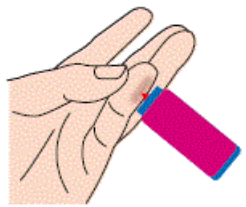
Sterilize the blood sampling finger with medical alcohol cotton ball, and wait for alcohol to volatilize completely about half a minute later, Use disposable blood collection device for blood collection

Step 3

Remove the blood collector protective cap.

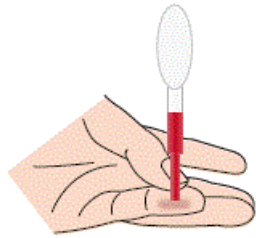


Press the finger to be taken blood with the thumb, and expose the blood taking part (for example, take blood from the outside of the thumb, that is, press the inside of the thumb with the thumb). Place the end face of the blood taking needle on the selected blood taking part, and then press it to the end. When you hear the "click" sound, it means that the needle has been finished.



Step 4

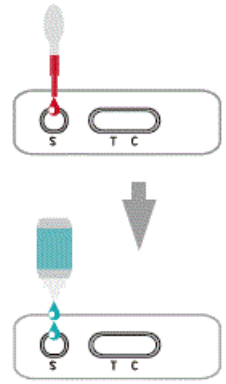
Gently squeeze the head of the disposable blood collection vessel, and then release it slowly. Under the negative pressure, fingertip blood will be collected into the blood collection vessel. Please avoid bubbles when sampling.



Step 5

Squeeze a drop of fingertip blood sample (about 10ul) collected from blood collection vessel into the sample hole of reagent card, and then immediately add two drops of diluent (about 70ul).

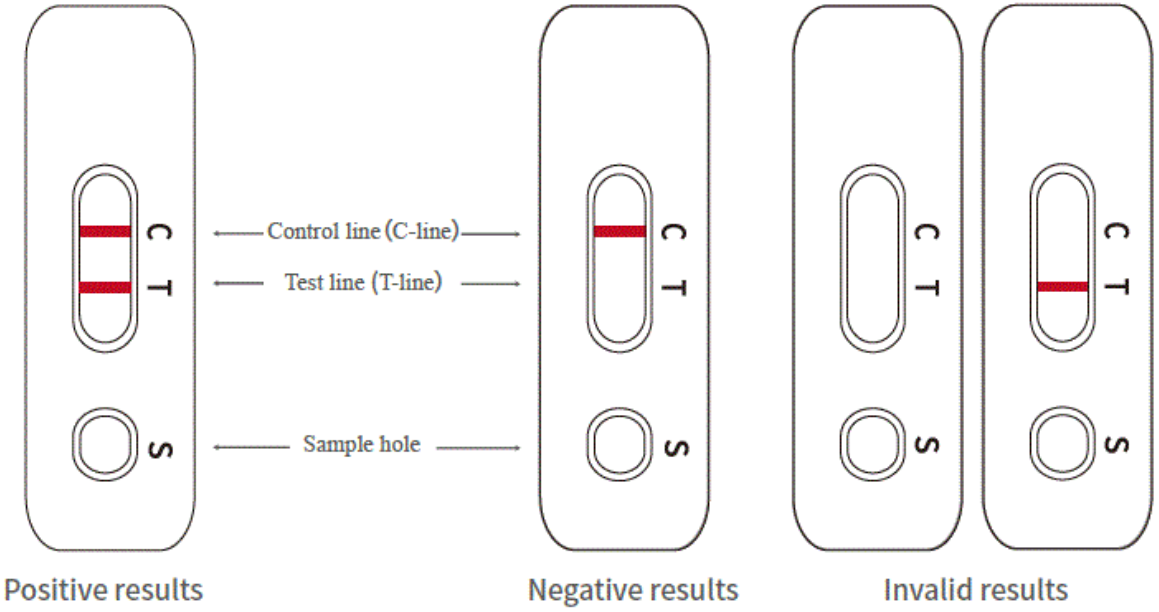
The results were observed within 15 minutes.



Other precautions

1. Please read the test results within 15 minutes after sample addition in strict accordance with the instructions.
2. Select the place with bright light when interpreting the results; if you are too old to interpret the results accurately, you can seek help from people around you.
3. In the process of this test, it is necessary to contact the blood sample, please use the applicable blood protection measures to deal with the relevant test materials; the blood sampling needle is a disposable item, do not share the blood sampling needle or equipment with others, and be sure to use a new sterile blood sampling needle.

Cutoff for Test



Interpretation of Results

【Positive results】
A red strip appears both on the control line (C-line) and the test line (T-line) of the cassette.

【Negative results】
A red strip appears only at the control line (C-line) of the cassette.

【Invalid results】
No red strip appeared on the test line or the control line of the cassette, or only a red line appeared on the test line, but no strip appeared on the control line.

【Description of test results】
1. When the test results show "negative", but relevant symptoms still occur, it is recommended to conduct further examinations in time to confirm the cause.
2. When the test results show "positive", it is recommended to conduct further review immediately.

INSTRUCTION USE

Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

Instruction for use

【Product Name】

Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test

【Packing Specifications】

1 test/bag, 1 test/box, 20 tests/box, 50 tests/box.

【Intended Use】

This kit uses immunocolloidal gold chromatography to detect novel coronavirus IgM/IgG antibodies in human serum, plasma or whole blood in vitro.

The 2019 novel coronavirus, abbreviated as 2019-nCov, is a new strain of coronavirus discovered in the human body and outbreaked in Wuhan in the end of 2019. The symptoms of the virus are fever, fatigue, dry cough, and progressive dyspnea. In severe cases, the symptoms are acute respiratory distress syndrome, septic shock, metabolic acidosis and coagulation dysfunction that can't be reversed. The virus has been confirmed the capacity of human-to-human transmission; the shortest incubation period of the virus is only 1 day, while the longest is 14 days. The patients in incubation period is contagious and there is no specific treatment for the disease. Once infected with a new virus, the body's immune system will start to defend and produce specific antibodies. Generally, IgM antibody will appear in 1-2 weeks and IgG antibody will appear in 4 weeks.

【Principle of the Procedure】

This product adopts the method of immunochromatography, the detection card contains colloidal gold labeled novel coronavirus recombinant antigen and gold labeled rabbit IgG antibody, and is coated with the mixture of anti-human IgM and anti-human IgG in the nitrocellulose-membrane detection line. The quality control line is coated with goat anti-rabbit IgG. When testing, if there is a novel coronavirus antibody in the sample, then the "(novel coronavirus antigen colloidal gold)-(coronavirus antibody)-(anti-human IgM/IgG)" complex is formed in the nitro cellulose membrane detection line to coagulate and display color, indicating a positive result. In the absence of antibodies to the novel coronavirus in the sample, the complex formed is insufficient to coagulate to produce color, indicating a negative result.

The product adopts the solid phase colloidal gold immunochromatographic technology. The detection cassette contains the gold-novel coronavirus recombinant antigen conjugate and the gold-rabbit IgG conjugate. The Test Line (anti-human IgM and anti-human IgG) and the Control Line (Goat anti rabbit IgG) are pre-coated on the surface of the NC membrane. When sample added, if there are enough antibodies to novel coronavirus, it migrates through the conjugate pad, reconstitutes and mixes with the colloidal gold-antigen conjugates. The mixture continues to migrate through the NC membrane to the anti-human IgM and anti-human IgG that present on the membrane. A red line will be visible in the strip, indicating a positive result. If antibodies to novel coronavirus are absent, or are present at very low level, then no color will appear in the Test Line, indicating a negative result.

【Materials provided】

1. Detection cassette: coated novel coronavirus recombinant antigen colloidal gold, rabbit IgG colloidal gold, anti-human IgM, anti-human IgG, Goat anti-rabbit IgG
2. Instruction for use (1 copy)
3. Sample diluent. The main component is phosphoric acid buffer
4. Materials required but not provided: sampler, timer and blood collector.

【Storage Requirements and Validity】

4 ~ 30℃ storage in dark and dry, the validity is tentatively 12 months.

Freezing or use after expiration is prohibited.

Production date and expiry date are shown on the packaging label.

【Sample Requirements】

(1) This kit can be used for the detection of serum, plasma or whole blood.

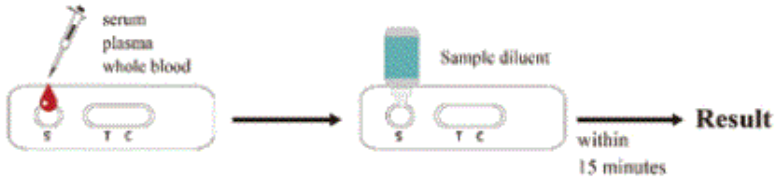
(2) Serum and plasma specimens can be stored at 2~8℃ for up to one week from time of draw, or at frozen (<-20℃) and avoid repeated freezing and thawing; whole blood samples must be fresh.

(3) Whole blood and plasma sample can be prepared with EDTA, heparin or sodium citrate as anticoagulant.

【Test Procedure】

Read the Instruction for use thoroughly before test and equilibrate all reagents kit and samples to room temperature before testing.

1. Take out a test cassette from a foil pouch before use, and place it on a flat surface. Test reagents should be used as soon as possible after the foil bag is opened.
2. Use the pipette to absorb 10uL sample, add it into the sample hole, and add two drops (about 70uL) diluent immediately.
3. Observe the results within 15 minutes after sample addition.

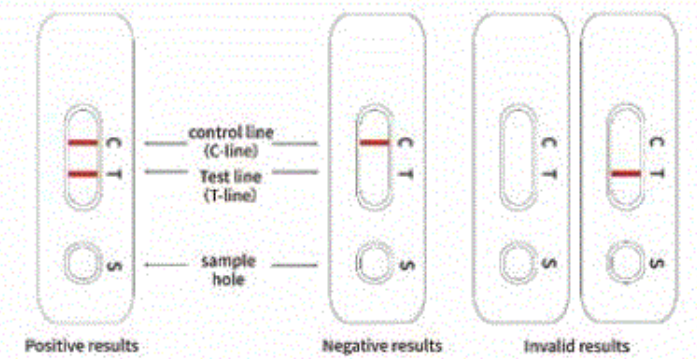


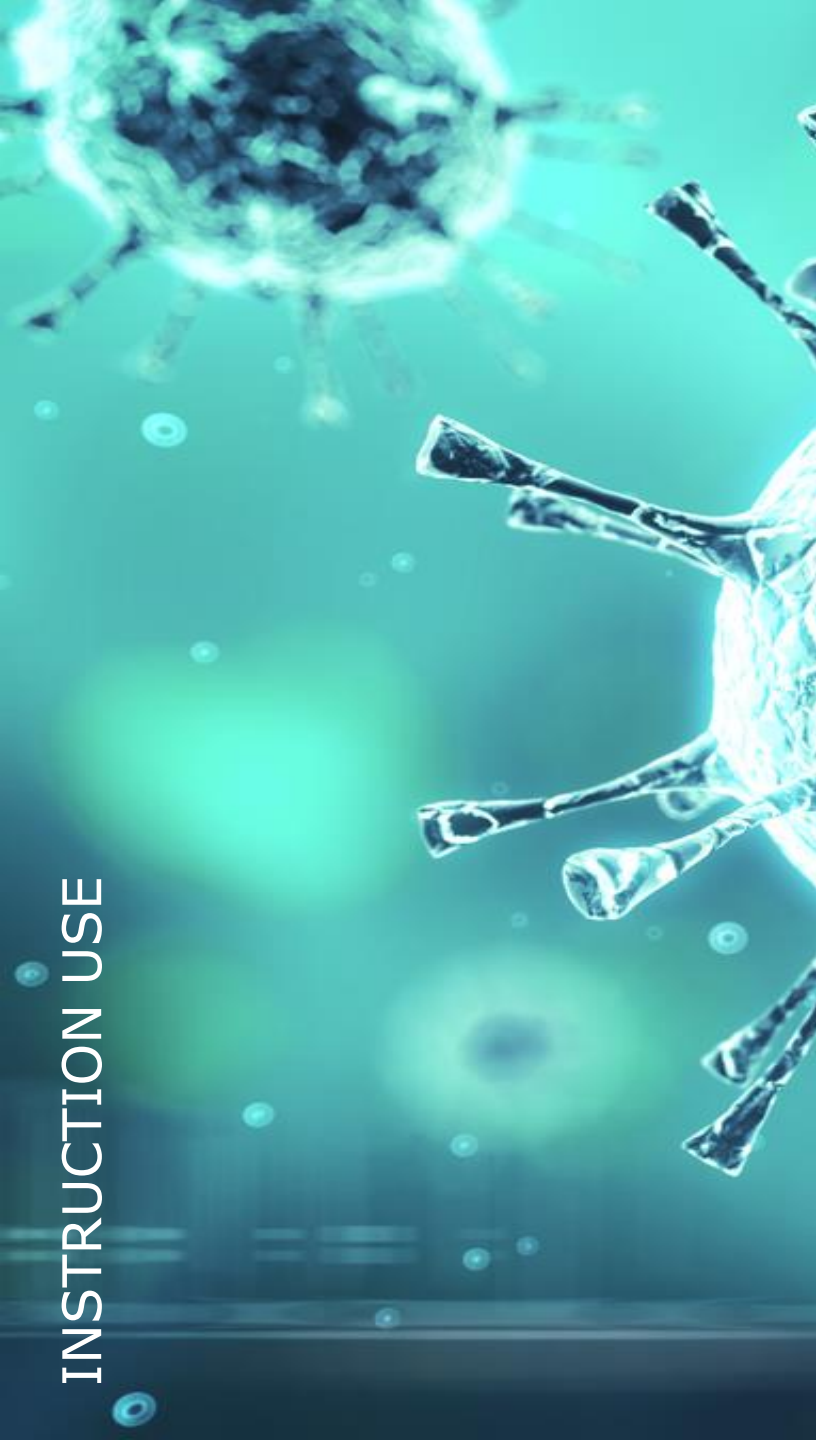
【Cutoff for Test】

Judging by visual observation results:

Positive result: A red strip (regardless of the depth of color rendering) can be observed with the naked eye at test line

Negative result: No red strip can be observed with the naked eye at test line.





INSTRUCTION USE

【Interpretation of Results】

Positive results: A red strip appears both on the control line (C-line) and the test line (T-line) of the cassette.

Negative results: A red strip appears only at the control line (C-line) of the cassette.

Invalid results: no red strip appeared on the test line or the control line of the cassette, or only a red line appeared on the test line, but no strip appeared on the control line.

Description of test results:

1. When the test results show "negative", but relevant symptoms still occur, it is recommended to conduct further examinations in time to confirm the cause.
2. When the test results show "positive", it is recommended to conduct further review immediately.

【Limitations of the Procedure】

1. This reagent is only used to detect IgM/IgG antibodies against novel coronavirus in human serum, plasma or whole blood/finger samples. Other body fluids and samples may not get correct results.
2. The reagent is a qualitative reagent.
3. Follow the instruction for use strictly for the test.
4. The test results obtained by other methods are not directly comparable with that of this product.
5. The test results of this kit are for reference only and shall not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment responses.
6. There may be suspicious results due to the operation and samples. At this time, repeated tests should be conducted to ensure the consistency of the results.

【Product Performance Indicators】

1. Negative reference: to test the negative reference of enterprises, the test results should be all negative, that is, the coincidence rate of negative is 100%
2. Positive reference: the enterprise positive reference should be tested, and the test results should be all positive, that is, the positive coincidence rate should be 100%.
3. Minimum detection limit: the minimum detection limit reference of the testing enterprise shall be positive.
4. Precision: the precision reference of the enterprise shall be tested for 10 times. The reaction results shall be consistent, and the chromaticity shall be uniform.

【Attentions】

1. This product is only used for in vitro diagnosis. Please read this manual carefully before use.
2. If the aluminum foil bag of test card is found broken, it should be discarded.
3. All samples and materials in the testing process shall be handled in strict accordance with the operating standards of the infectious disease laboratory.
4. Please ensure that sufficient samples are used for testing. Insufficiency may lead to invalid results.
5. This product is visual reading result. In order to ensure the accuracy of the reading result, please do not read the result in dim light.
6. Hemolytic samples should not be used for testing.
7. Samples containing a higher titer of heterophobic antibodies or rheumatoid factors may affect the expected results.
8. This kit is suitable for the initial screening of patients with suspected novel coronavirus, and the final results should be determined by the clinician in combination with clinical symptoms and other laboratory test indicators.

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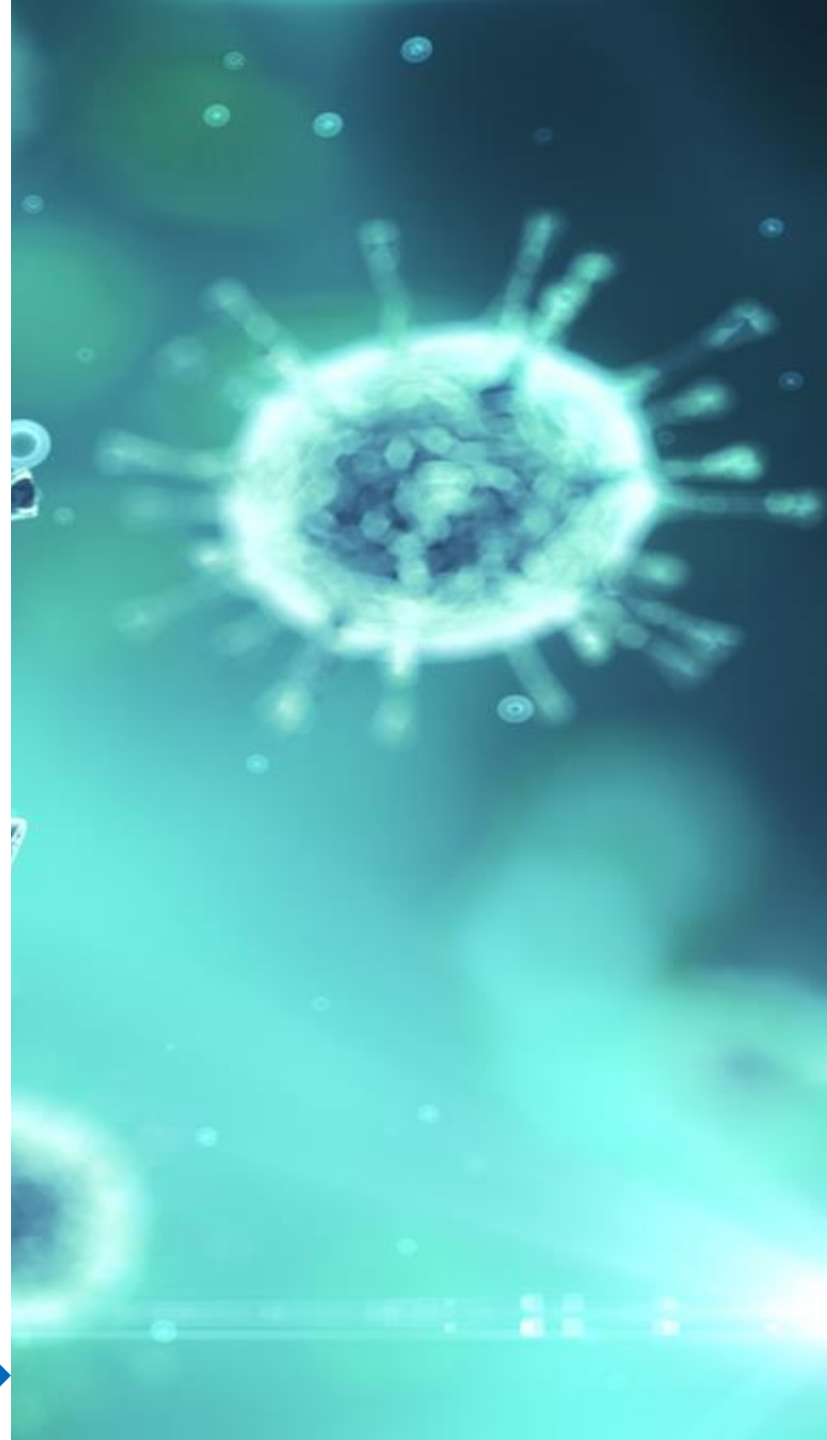


CERTIFICATES

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

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

TÜV SÜD Product Service

Certificate

No. Q5 086139 0003 Rev. 01

Holder of Certificate: **Shanghai Outdo Biotech Co., Ltd.**
3F Building 2, 3F Building 4
3F Building 5, No.151 Libing Rd.
Pilot Free Trade Zone
201203 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shanghai Outdo Biotech Co., Ltd.
3F Building 2, 3F Building 4, 3F Building 5, No.151 Libing Rd.,
Pilot Free Trade Zone, 201203 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of in Vitro Diagnostic Kit using PCR and Rapid Test Technologies**

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.: SH2080507

Valid from: 2020-03-19
Valid until: 2023-03-18

Date, 2020-03-04

Christoph Dicks
Head of Certification/Notified Body

CEATEC

TÜV®

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

MedPath

EC-Registration Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Article 10
No. R A001 39/A Rev. 01

Manufacturer: Shanghai Outdo Biotech Co., Ltd.
3F Building 2, 3F Building 4, 3F Building 5, No.151 Libing Rd., Pilot Free Trade Zone, 201203 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) and has allocated registration numbers shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

Date, 2020-03-19

MedPath GmbH
Mies-van-der-Rohe-Strasse 8-D-80807 München
Tel.089-189174474-Fax 089-54858884

MedPath GmbH • Mies-van-der-Rohe-Strasse 8 • 80807 Munich • Germany

CEATEC

CERTIFICATES

MedPath

Appendix A

Products	Class	EDMA Code	Form No.	Registration number
Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test	Others	[illegible]	00154146	[illegible]

MedPath GmbH
Mies-van-der-Rohe-Strasse 8-D-80807 Munchen
Tel.089-189174474 -Fax 089-54858884

CE

CEATEC

CE

DECLARATION OF CONFORMITY

Manufacturer:	Shanghai Outdo Biotech Co., Ltd.
Address:	3F Building 2, 3F building 4, 3F Building 5, No. 151 Libing Rd., Pilot Free Trade Zone, 201203, Shanghai, People's Republic of China

IVD Medical Devices:

Novel Coronavirus (SARS-CoV-2) Antibody (IgM/IgG) Test

We, (Shanghai Outdo Biotech Co., Ltd.) declare and ensure with sole responsibility that products listed above meet the applicable requirements of the European In Vitro Diagnostic Directive 98/79/EC. All supporting documentation is retained at the premise of the manufacturer.

Device Classification:	Others IVD
Conformity Assessment Route:	Annex III, except section 6.
EC Authorized Representative:	Medpath GmbH
Address:	Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
General applicable Directive:	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices.
Start of CE-mark:	March 12, 2020

Signature of Company Representative:

Date: March 12, 2020
Name: Xiaoyan Zhang
Title: vice general manager

CEATEC

Trial Laboratory Report

CEATEC

Trial product: Novel Coronavirus (SARS-CoV-2) Antibody (IgMIgG) Test

Trial time: February 19,2020

Sample type: serum, plasma or whole blood

Trial result:

Negative compliance rate: 315/319×100%=98.75%
Positive compliance rate: 252/281×100%=89.68%
The total coincidence rate: (315+252) /600×100%=94.50%

TEST REPORT

FULL REPORT AVAILABLE UPPON REQUEST

TEST REPORT

180000100599

中国认可
检测
TESTING
CNAS L0001

CEATEC

中国食品药品检定研究院

检验报告

报告编号：RZ20200[illegible]

检品名称：新型冠状病毒(2019-nCoV)IgM/IgG抗体检测试剂盒（胶体金免疫层析法）

生产单位/产地：上海芯超生物科技有限公司

检验目的：注册检验(国产体外诊断试剂/首次注册/质量标准复核)

检验依据：产品技术要求

FULL REPORT AVAILABLE UPPON REQUEST

CERTIFICATION FOR SAFE TRANSPORT OF CHEMICAL GOODS AND EXPORT OF MEDICAL DEVICE

空运 By Air

CEATEC

NO.2020151455

CNAS 中国认可 检验 INSPECTION CNAS IB0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新型冠状病毒(2019-nCoV)IgM/IgG抗体检测试剂盒（胶体金免疫层析法）

Sample Name: IgM/IgG antibody detection kit for novel coronavirus (2019-nCov) (colloidal gold immunochromatography)

委托单位： 上海芯超生物科技有限公司

生产单位： 上海芯超生物科技有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空运 By Air

空运 By Air

record form for export of medical device

001301520000853

CEATEC

上海市电子证照库 zwdtcert.sh.gov.cn

医疗器械出口备案表

备案编号： 沪浦 20200051

生产企业名称	上海芯超生物科技有限公司		
生产地址	上海市浦东新区张江镇李冰路 151 号 5 号楼 4 楼		
是否具有第三方认证	是	第三方认证机构	TUV
认证证书编号	SH[redacted]	认证证书有效期	2023-03-18
联系方式	[redacted]		
出口产品名称	新型冠状病毒(2019-nCoV)IgMIgG 抗体检测试剂盒（胶体金免疫层析法）		
出口企业名称	[redacted]		
出口企业地址	[redacted]		
销往国家（地区）	孟加拉国		
是否境外委托境内生产	否	是否获准境外上市	是
境外委托企业名称	否		
境外委托企业地址	否		
出口合同编号	[redacted]	出口合同期限	2020-04-15
产品规格	20 人份/盒	包装规格	50 盒/箱
出口数量	10000 人份		

申请出口备案产品未取得国内医疗器械注册证/备案凭证，属于接受境外企业委托生产在境外上市销售的医疗器械。

本企业承诺保证所生产出口的医疗器械符合进口国（地区）的要求，所提交的全部备案资料真实有效，并承担一切法律责任。

法定代表人（签字） （企业盖章）

年 月 日

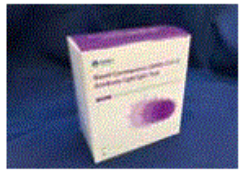
备案部门（公章）：

备案日期： 2020 年 03 月 25 日

1.生产企业应于产品出口前，填写本表向生产地址所在区（县）药品监督管理部门备案。

2.本表按实际内容填写，不涉及的可缺项。

PACKING

图片 Product Picture	规格 Unit	单位 Specification	尺寸 Size (length*width*height)	毛重 Gross weight
	1 Box	20 Tests	13.5*7.7*15cm	183 g
	1 Carton	50 Boxs/ 1000 Tests	75.5*34.8*40.5cm	11 kg

尺寸:13.5×7.7×15.0 cm

CEATEC