Shanghai Outdo Biotech Co.,LTD.
Shanghai Engineering Center for Molecular Medicine
National Engineering Center for Biochip at Shanghai

Screening for suspected novel coronavirus patients

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

芯超生物
OUTDO BIOTECH

ODC

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

The 2019 novel coronavirus, abbreviated as SARS-CoV-2, is a new strain of coronavirus discovered in the human body. 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.

IgM/IgG antibody

IgM antibody is the first antibody in the first humoral immune response, and it is the "first force" to fight against infection. IgM antibody detected in serum indicates a new infection, which can be used for early diagnosis of infection. The detection of IgG antibody can be used for the overall diagnosis of infection.

Intended use

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

Product characteristics

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

Product information

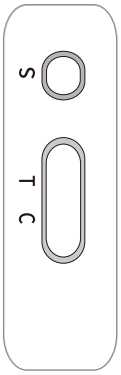
Product name	Specifications	Storage Conditions
Novel Coronavirus (SARS-CoV-2) Antibody (IgM / IgG) Test	20 tests/box, 50 tests/box	4 ~ 30°C storage in dark and dry

Schematic diagram of blood collection process

Step 1

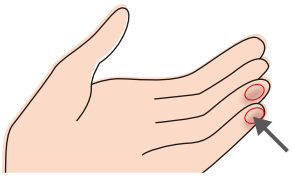
Before the test, the user manual must be read completely, and the reagent card and blood sample to be tested must be balanced to room temperature before use.

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.

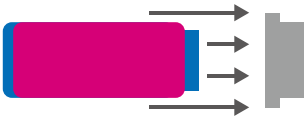


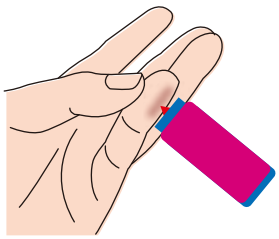
Sterilize the blood sampling finger with medical alcohol cotton ball, and wait for alcohol to volatilize completely about half a minute later, Use disposable blood collection device for blood collection

Step 3

Remove the blood collector protective cap.

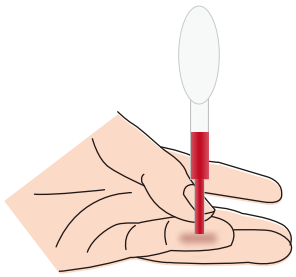
Press the finger to be taken blood with the thumb, and expose the blood taking part (for example, take blood from the outside of the thumb, that is, press the inside of the thumb with the thumb). Place the end face of the blood taking needle on the selected blood taking part, and then press it to the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





Step 4

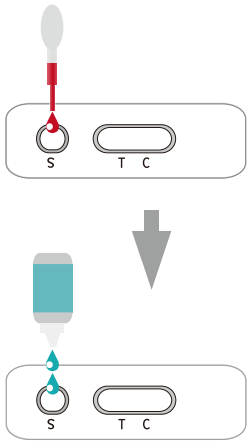
Gently squeeze the head of the disposable blood collection vessel, and then release it slowly. Under the negative pressure, fingertip blood will be collected into the blood collection vessel. Please avoid bubbles when sampling.



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).

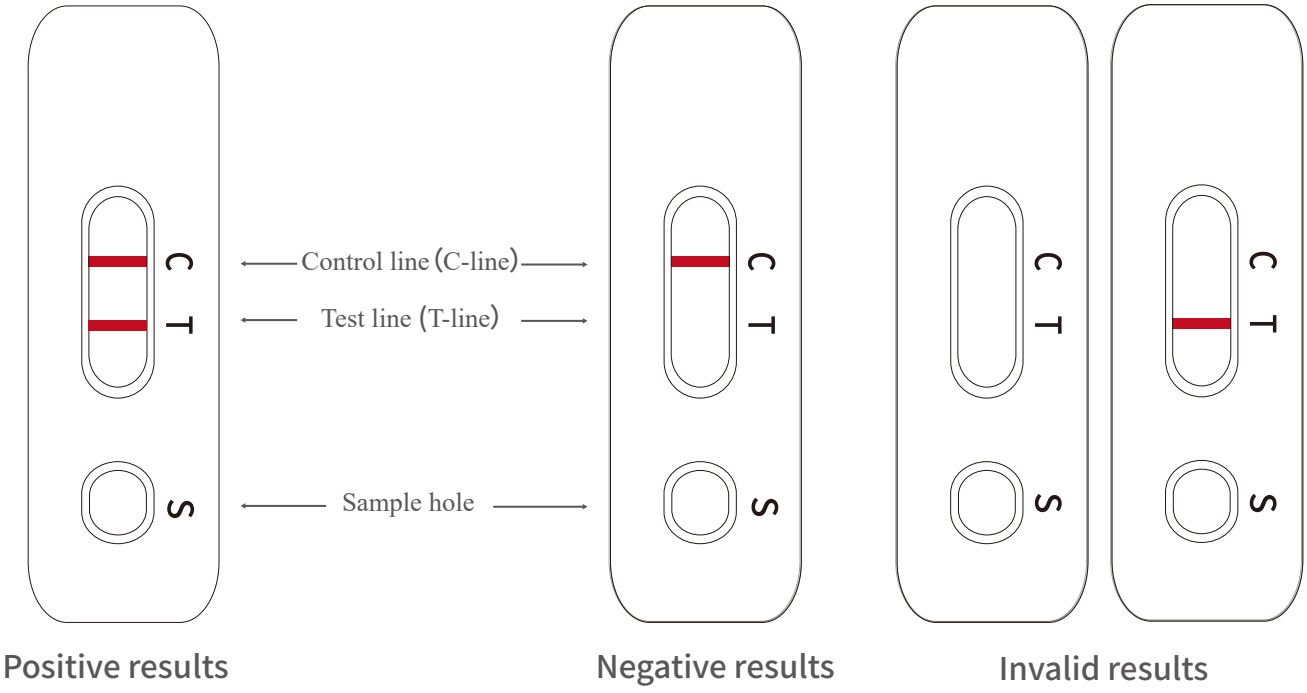
The results were observed within 15 minutes.



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 for 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.

Instruction for use

【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.

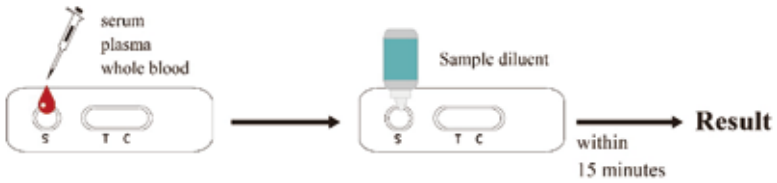
【Test Procedure】

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.

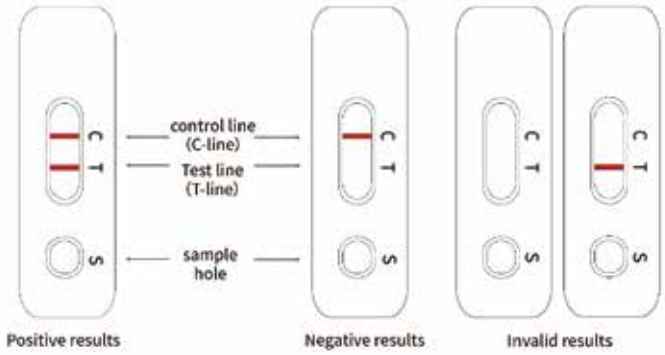


【Cutoff for Test】

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 for 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.

Instruction for use

【References】
1. "Pneumonia diagnosis and treatment program for novel coronavirus infection" of the National Health Commission of People's Republic of China (Trial Version 7)
2.World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance

【Manufacturer】

Manufacturer: Shanghai Outdo Biotech Co.,Ltd.
Production 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
Telephone: 86-21-51371392
Fax: 86-21-51320287
E-mail: ivdsales@shbiochip.com

【EC REP】

MedPath GmbH
Mies-van-der-Rohe-Strasse 8,80807 Munich,Germany
Tel: +49(0)89-189174474
Fax:+49(0)89-54858884

CE

ISO 13485

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

TÜV®

Page 1 of 1
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A4 / 07.17

EC-Registration Certificate

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.

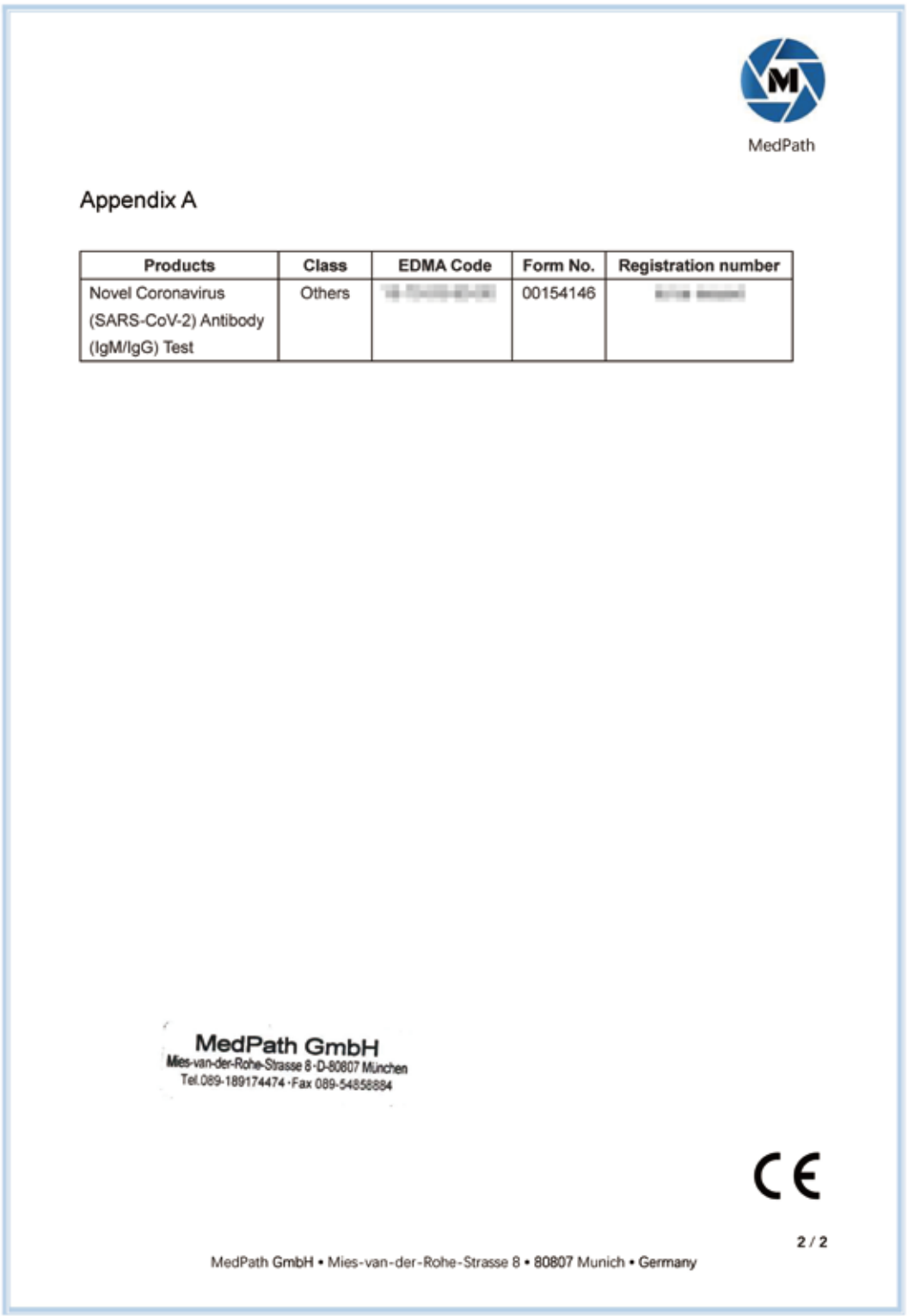
Date, 2020-03-19

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

1 / 2

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

EC-Registration Certificate



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 München
Tel.089-189174474 · Fax 089-54858884

CE

2 / 2

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

Declaration of Conformity

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

Trial Laboratory Report

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%

Trial Laboratory Report

CMA 180000100599 CNAS 中国认可 检测 TESTING CNAS L0001

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

Trial Laboratory Report

中国食品药品检定研究院检验报告

报告编号：RZ20200[illegible]　　共2页，第1页

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）	检品编号	RZ2804202002165
生产单位/产地	上海芯超生物科技有限公司	批　号	20200301
供样单位	上海市浦东新区市场监督管理局	规　格	20人份/盒
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)	剂型/型号	体外诊断试剂
检验项目	全检	包装规格	1人份/袋
收样日期	2020年3月12日	有效期至	2021年3月6日
检品数量	20盒	签封数量	/
检验依据	产品技术要求		

检验项目	标准规定	检验结果
2.1 物理性状		
2.1.1 外观	标签内容齐全，规范，文字清晰易认；检测卡表面应平整、无划伤、无开裂、无变形及污渍，各组分附着牢固、内容齐全	符合规定
2.1.2 膜条宽度	膜条宽度应不小于3.5mm	3.7mm
2.1.3 液体移行速度	液体移行速度应不低于10mm/min	70mm/min
2.2 性能检测	采用国家参考品或经标化的企业参考品进行检测	
2.2.1 IgM抗体检测试剂国家参考品		
2.2.1.1 阴性参考品符合率	用国家阴性参考品进行检测，结果应符合相应要求	符合规定
	阴性参考品符合率应不低于24/25	阴性参考品符合率为25/25
2.2.1.2 阳性参考品符合率	用国家阳性参考品进行检测，结果应符合相应要求	符合规定
	阳性参考品符合率应为10/10	阳性参考品符合率为10/10
2.2.1.3 最低检测限	用国家最低检测限参考品进行检测，结果应符合相应要求	符合规定
	L1、L2应均为阳性，L3～L10可为阳性或阴性	L1～L4阳性，其余阴性

接下页

Trial Laboratory Report

中国食品药品检定研究院检验报告

报告编号：RZ20200[illegible]　　共2页，第2页

接上页

检验项目	标准规定	检验结果
2.2.1.4 重复性	用国家精密度参考品平行检测10次，结果应均为阳性，且显色均一	10次平行检测结果均为阳性，且显色均一
2.2.2 IgG抗体检测试剂国家参考品		
2.2.2.1 阴性参考品符合率	用国家阴性参考品进行检测，结果应符合相应要求	符合规定
	阴性参考品符合率应不低于24/25	阴性参考品符合率为25/25
2.2.2.2 阳性参考品符合率	用国家阳性参考品进行检测，结果应符合相应要求	符合规定
	阳性参考品符合率应不低于9/10	阳性参考品符合率为10/10
2.2.2.3 最低检测限	用国家最低检测限参考品进行检测，结果应符合相应要求	符合规定
	L1应为阳性，L2～L10可为阳性或阴性	L1、L2阳性，其余阴性
2.2.2.4 重复性	用国家精密度参考品平行检测10次，结果应均为阳性，且显色均一	10次平行检测结果均为阳性，且显色均一

以下空白

备注：1. 检验用参考品为新型冠状病毒IgM抗体检测试剂国家参考品（应急用）和新型冠状病毒IgG抗体检测试剂国家参考品（应急用），批号分别为370096-202001和370097-202001。2. 根据产品说明书，检验中参考品的加样量为10μL，加样后15分钟时观察结果。3. 本产品检验结果不能区分IgM和IgG，建议修改产品名称。

检验结论	本品按产品技术要求检验，结果符合规定。		
授权签字人	[illegible]	签发日期	2020年3月13日

MSDS (Material Safety Data Sheet)

MATERIAL SAFETY DATA SHEET

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

Page: 1
Revision Date: 16/03/2020
MSDS Number: SDS202003162665
Version: 1.0

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY/UNDERTAKING

Product identifier
Product name : IgM/IgG antibody detection kit for novel coronavirus (2019-nCov) (colloidal gold immunochromatography)

Recommended use of the chemical and restrictions on use
Identified use : For *in vitro* diagnostic use only

Details of the supplier of the safety data sheet
Shanghai Outdo Biotech Co.Ltd.
Building 5, No.151 Libing Road,
Pudong District, Shanghai, 201203,
China.

Emergency telephone number
Tel: +86-13952516036, or contact your local emergency telephone number.
Product Information
Tel: +86-13952516036
E-mail: chenxi@shbiochip.com

2. HAZARDS IDENTIFICATION

Emergency Overview

This product is not considered as hazardous according to China GB standards(GB30000-2013).

GHS-Classification- China standards(GB30000-2013)

This product is not considered as hazardous according to China GB standards(GB30000-2013).

GHS-Labelling- China standards(GB30000-2013)

Hazard pictograms : Not applicable

Signal word : Not applicable

Hazard statements : Not applicable

Precautionary statements :

Prevention:
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.

Response:
Not applicable

Storage:
Not applicable

SHANGHAI RUIFU CO., LTD. MSDS

MSDS (Material Safety Data Sheet)

Disposal:
Not applicable

Physical and chemical hazards
Not classified based on available information.

Health hazards
Not classified based on available information.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Product type : Mixture

Hazardous components

This product does not contain any hazardous components required to reporting in this section according to relevant regulations.

4. FIRST AID MEASURES

General advice	:	Show this safety data sheet to the doctor in attendance.
If inhaled	:	Not required under normal conditions of use. Move to fresh air. If unconscious place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Not required under normal conditions of use. Wash off with soap and plenty of water. Consult a physician.
In case of eye contact	:	Not required under normal conditions of use. Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. If symptoms persist, call a physician.
If swallowed	:	Not required under normal conditions of use.

MSDS (Material Safety Data Sheet)

Rinse mouth with water.
If symptoms persist, call a physician.

Notes to physician

Symptoms	:	We have no description of any toxic symptoms.
Treatment	:	Treat symptomatically.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	:	For this product no limitations of extinguishing agents are given.
Specific hazards during firefighting	:	Combustible. Development of hazardous combustion gases or vapors possible in the event of fire.
Special protective equipment for firefighters	:	Stay in danger area only with self-contained breathing apparatus Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.
Further information	:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	:	Do not breathe vapors, aerosols. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.
Environmental precautions	:	Prevent product from entering soil, drains and waterways.
Methods for cleaning up	:	Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully with liquid-absorbent material. Clean up affected area. Keep in suitable, closed containers for disposal.
Additional advice	:	Comply with all applicable national and local regulations.

MSDS (Material Safety Data Sheet)

7. HANDLING AND STORAGE

Handling

Advice on safe handling	:	Work under hood or special environment. Do not inhale reagents. Avoid generation of vapors/aerosols. For personal protection see section 8. Dispose of rinse water in accordance with local and national regulations.
Advice on protection against fire and explosion	:	Normal fire protective measure.

Storage

Requirements for storage areas and containers	:	Tightly closed. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons. Store in according to instruction.
Materials to avoid	:	None known.
Other data	:	Hazardous decomposition products formed under fire conditions. - Carbon oxides.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Contains no ingredient with known occupational exposure limit.

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
				GBZ 2.1-2007

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Personal protective equipment

Respiratory protection	:	Respiratory protection is required when vapors/aerosols are generated.
Hand protection	:	Protective gloves.
Eye protection	:	Safety glasses.

MSDS (Material Safety Data Sheet)

Skin and body protection	:	Protective clothing.
Hygiene measures	:	Immediately change contaminated clothing. Wash hands before breaks and at the end of workday. When using do not eat or drink.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state/appearance	:	Diagnostic kit containing 1 bottles of liquid reagent.
Odour	:	Slight odour
Odour Threshold	:	No data available

Safety data

Flash point	:	No data available
Ignition temperature	:	No data available
Lower explosion limit	:	No data available
Upper explosion limit	:	No data available
Flammability (solid, gas)	:	No data available
Oxidizing properties	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Molecular weight	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Boiling point	:	No data available
Sublimation point	:	No data available
Vapour pressure	:	No data available
Density	:	No data available
Bulk density	:	No data available
Water solubility	:	Soluble in water
Partition coefficient: n-octanol/water	:	No data available
Solubility in other solvents	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Impact sensitivity	:	No data available
Relative vapour density	:	No data available
Surface tension	:	No data available
Evaporation rate	:	No data available

MSDS (Material Safety Data Sheet)

10. STABILITY AND REACTIVITY

Hazardous reactions	:	Non-reactive under normal use, storage and transport conditions.
Chemical stability	:	The product is chemically stable under standard ambient conditions (room temperature).
Conditions to avoid	:	Avoid direct sunlight exposure and low or high temperature.
Materials to avoid	:	None known.
Hazardous decomposition products	:	Hazardous decomposition products formed under fire conditions. - Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

MSDS (Material Safety Data Sheet)

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Ecotoxicology Assessment

Acute aquatic toxicity	:	Not classified based on available information.
Chronic aquatic toxicity	:	Not classified based on available information.

Persistence and degradability
No data available

Bioaccumulative potential

Partition coefficient: n-octanol/water	:	No data available

Mobility in soil
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

General advice	:	Dispose of in accordance with all applicable local, state and federal regulations.

14. TRANSPORT INFORMATION

International transport regulations

CHINA ROAD/US DOT(Land transport, JT/T 617-2018)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

MSDS (Material Safety Data Sheet)

INTERNATIONAL MARITIME DANGEROUS GOODS(IMDG, 39-18)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

INTERNATIONAL AIR TRANSPORT ASSOCIATION(IATA, 61th edition)
UN Number: not regulated/non-dangerous goods
Proper Shipping Name: N/A
Hazard classes: N/A
Packaging group: N/A

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15. REGULATORY INFORMATION

Regulations on the Control over Safety of Dangerous Chemicals (Decree No. 591 of the State Council of the People's Republic of China)
General rules for preparation of chemical safety data sheet (GB16483-2008)
Rules for classification and labelling of chemicals(GB30000-2013)
Classification and labels of dangerous chemical substances commonly used (GB13690-2009)
List of dangerous goods (GB12268-2012)
Classification and code of dangerous goods (GB6944-2012)

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16. OTHER INFORMATION

Further information
Revision Date: 16/03/2020

Disclaimer:
This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by us to be dependable and is accurate to the best of our knowledge.

This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate protective mechanisms to prevent employee exposures, property damage or release to the environment. We assumed no responsibility for injury to the recipient or third persons, or for any damage to any property resulting from misuse of the product.

****End of Material Safety Data Sheet*****

Certification for Safe Transport of Chemical Goods

空运 By Air

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

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货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020151455

Page 1 / 2

样品名称 Sample Name	中文 Chinese	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）
	英文 English	IgM/IgG antibody detection kit for novel coronavirus (2019-nCov) (colloidal gold immunochromatography)
委托单位 Consignor		上海芯超生物科技有限公司
生产单位 Manufacturer		上海芯超生物科技有限公司
检验方法、程序 Inspection Methods and Procedures		国际航空运输协会《危险品规则》61版 IATA Dangerous Goods Regulations (DGR) 61st Edition
样品外观与气味 Appearance & Odor		白色和蓝色纸盒(内含多种试剂)，稍有气味 White and blue Paper box(containing manifold reagents), Weak odor
IDENTIFICATION CONCLUSION 鉴定结论		1. 危险性识别(Hazards identification) 无。 None. 2. 空运按照IATA DGR办理的类项(Suggestion according to IATA DGR) 可按非限制性货物条件办理。 The substance is not subject to IATA DGR. 3. 包装要求(Packaging requirements) 无。 None. 检验日期: Inspection Date: 2020-03-19 签发日期: Issue Date: 2020-03-19 生效日期: Effective Date: 2020-03-19
备注 Comment		无。 None.

批准 Approver: 张小帆 审核 Checker: 董学胜 主检 Appraiser: 孙倩

Certification for Safe Transport of Chemical Goods

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020151455

Page 2 / 2

鉴定项目 Identification Items	鉴 定 结 果 Identification Conclusion Results
爆炸危险性鉴定 Identification of Explosive Hazard	该货物不属于爆炸品。 The product is not classified in Explosives.
易燃危险性鉴定 Identification of Flammable Hazards	该货物不属易燃危险品。 The product is not classified in flammable substance.
氧化危险性鉴定 Identification of Oxidative Hazards	该货物不属于氧化剂和有机过氧化物。 The product is not classified in oxidizing substances and organic peroxides.
毒害及传染危险性鉴定 Identification of Toxic & Infectious Hazards	该货物不属于有毒和感染性物质。 The product is not classified in toxic and infectious substances.
放射危险性鉴定 Identification of Radioactive Hazard	该货物无放射危险性。 The product is not classified in radioactive material.
腐蚀危险性鉴定 Identification of Corrosive Hazard	该货物不属于腐蚀品。 The product is not classified in corrosives.
其他危险性鉴定 Identification of other Hazards	该货物无其它危险性。 The product presents no other dangerous properties.

-验证码:190401-

报告结束

record form for export of medical device

001301520000853

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[illegible]	认证证书有效期	2023-03-18
联系方式	[illegible]		
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	[illegible]		
出口企业地址	[illegible]		
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	[illegible]	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

填表说明：

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。

第 1 页 共 2 页

Size

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