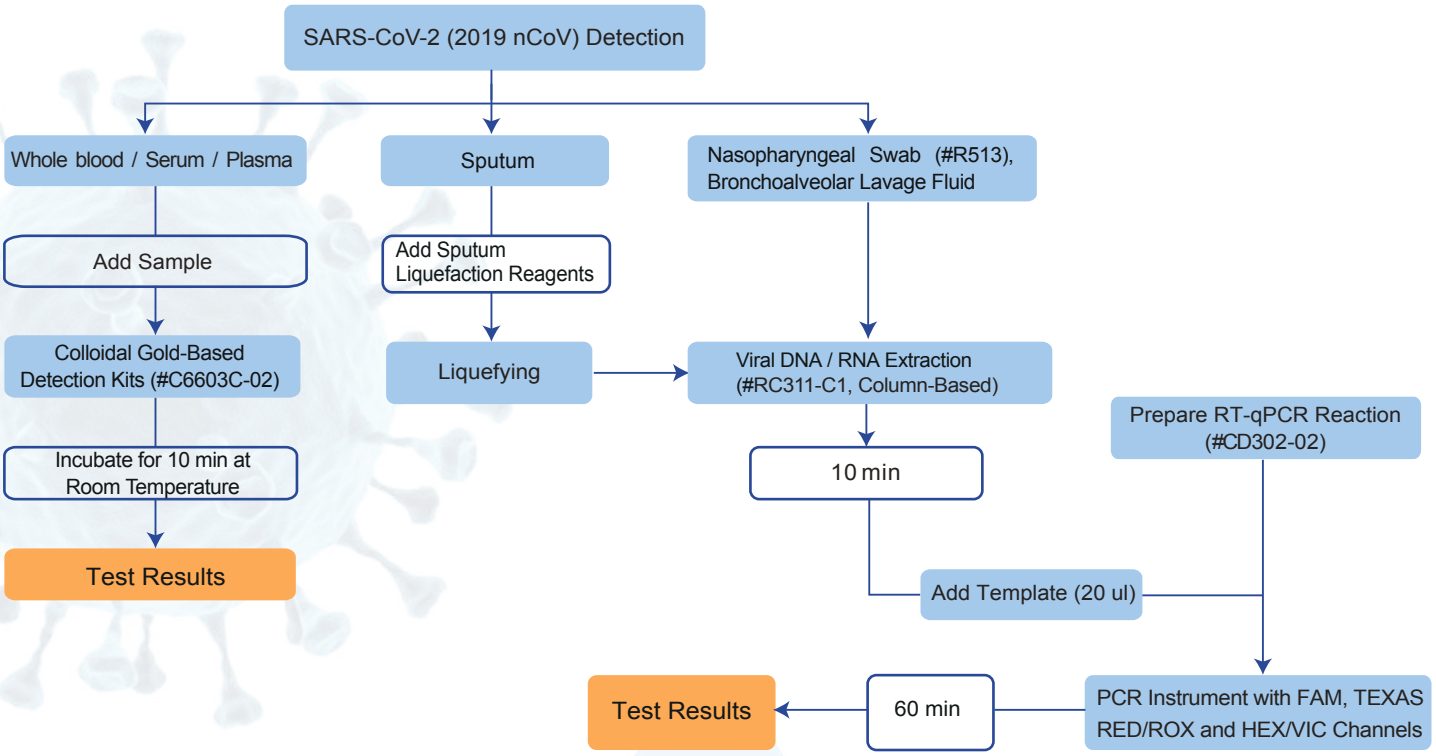
Vazyme Solutions for SARS-CoV-2 (2019-nCoV) Detection



Product	Cat.#	Size	Introduction
Virus Sample Stabilizer (with Nasopharyngeal Swab)	R513-01	50 tubes, 1.5 ml / tube	Applicable to specimen collection from human nasopharyngeal swab specimen and nucleic acid preservation.
	R513-02	50 tubes, 3 ml / tube	

Product	Cat.#	Size	Introduction
FastPure Viral DNA/RNA Mini Kit	RC311-C1	100 tests / kit	Applicable to specimen collection from plasma, serum, nasopharyngeal swabs, sputum, bronchoalveolar lavage fluid, ascites, supernatant of cultured cell and urine.

Product	Cat.#	Size	Introduction
2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	CD302-02	100 tests / kit	1) Adding 20 ul of extracted RNA to increase detection sensitivity and reduce false negatives; 2) Positive control (2019-nCoV-pseudoviruse) provides a nucleic acid extraction and a reverse transcription control to validate the entire procedure and reagent integrity. 3) Internal control (RNAse P gene) provides a nucleic acid extraction procedural control and a secondary negative control.

Product	Cat.#	Size	Introduction
2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based)	C6603C-02	50 tests / kit	Applicable to detection of 2019-nCoV IgG / IgM antibodies from human whole blood, serum or plasma within 10 min. No instruments needed.




Vazyme Medical Technology Co., LTD. Add: Bldg. C2, Red Maple Sci-Tech Park, Kechuang Rd., Nanjing, China. Tel: +86 18616767852 Email: global@vazyme.com Web: www.vazyme.com

Vazyme
Nanjing Vazyme Medical Technology Co., Ltd.
Address: Building C1-2, Red Maple Park of Technological Industry, Nanjing, China
Tel: +86 25 83772625
Website: www.vazyme.com

2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

1. Product Information

Product Name: 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)
Cat.#: C6603C-02
Size: 50 tests / kit
Certificate: FDA (Submission#: PEUA200226), CE - IVD, CFDA, ISO 13485, Singapore HSA, Philippines FDA

2. Features

- Rapid Test within 10 min. No additional instruments needed.
- Certificated by CFDA, CE, HSA, and FDA (Submitted)
- Clinical test for 2000+ samples.
- Wildly used in multiple hospitals and CDCs in Hubei (including Wuhan), Hunan, Jiangsu, Guangdong, Henan, Hebei, etc.
- Exported to Germany, Poland, Japan, Singapore, Indonesia, etc.

3. Pictures

4. Package

Per Kit (50 tests / kit): 270 * 132 * 110 mm, NW 0.56 kg, GW 0.6 kg
Per Shipping Box (12 kits / box): 560 * 280 * 370 mm, NW 7.2 kg, GW 8.0 kg
Number of tests per shipping boxes: 12 Kits / 600 Tests;

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5. HS Code:

3822009000

Vazyme

Vazyme Medical Technology Co., Ltd.

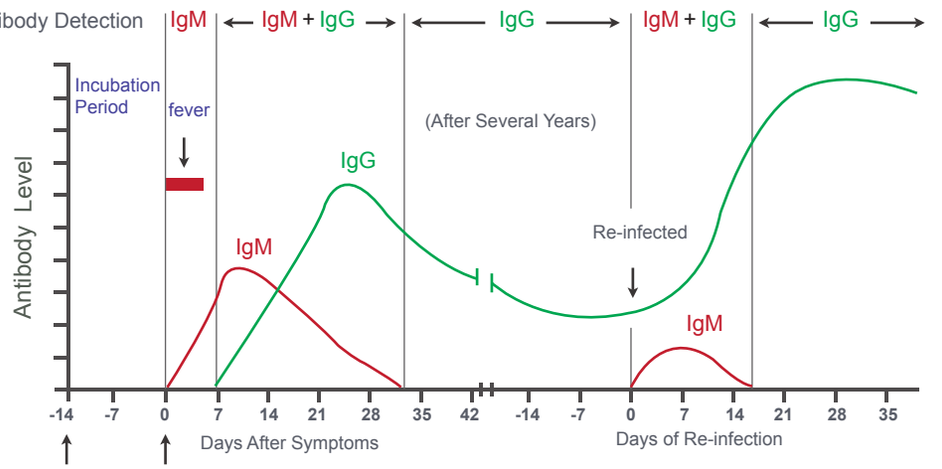
2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

Rapid detection within 10 min. No equipments required.

IgM and IgG Antibodies

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. Some patients with negative results in nucleic acid test show positive in IgM test, indicating that the IgG / IgM detection is one of the effective methods for the diagnosis of 2019-nCoV.

The level of IgM antibody begins to rise after 1 week after the initial infection, while the IgG appears later than IgM (usually in 14 days after infection) and can last for 6 months or even several years, which means that the IgG serves as an indicator of previous infection. Suspected patients that are infected by 2019-nCoV can be rapidly identified by simultaneous monitoring of IgM and IgG. During the outbreak period of 2003-SARS and the 2016-Zika, IgM / IgG antibody detection was used as one of the recommended diagnostic methods.



Advantages of IgG / IgM Detection

01 Indicating both recent infections and previous infections, reducing missed detection rates.

02 Low requirements of instruments; suitable for primary hospitals and conventional outpatient clinics.

03 Blood testing; low requirements for sampling; no special virus collection tube required.

04 Suitable for combined detection with nucleic-acid testing kit to improve the diagnosis rate of suspected patients.

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Tel: +86 18616767852 Email: global@vazyme.com Web: www.vazyme.com
Add: Bldg.C2, Red Maple Sci-Tech Park, Kechuang Rd., Nanjing, China.

2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

Product Advantages

01 Rapid-screening within 10 minutes.

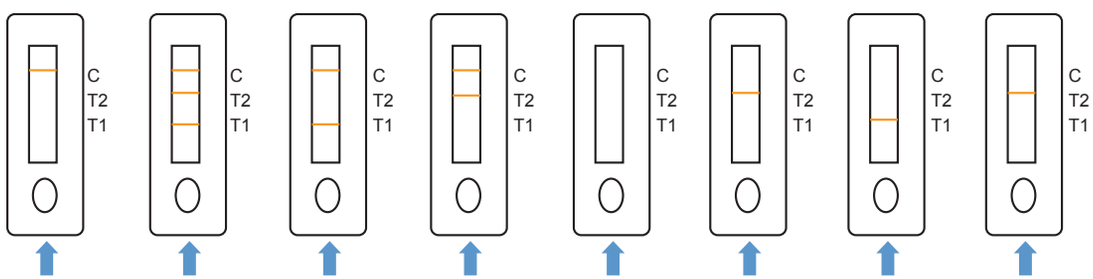
02 High detection efficiency: simultaneous monitoring of IgM and IgG.

03 Detection without any equipments.

04 Easy to operate, and is compatible with serum/ whole blood/ plasma.

05 Room-temperature storage.

Interpreting Test Results



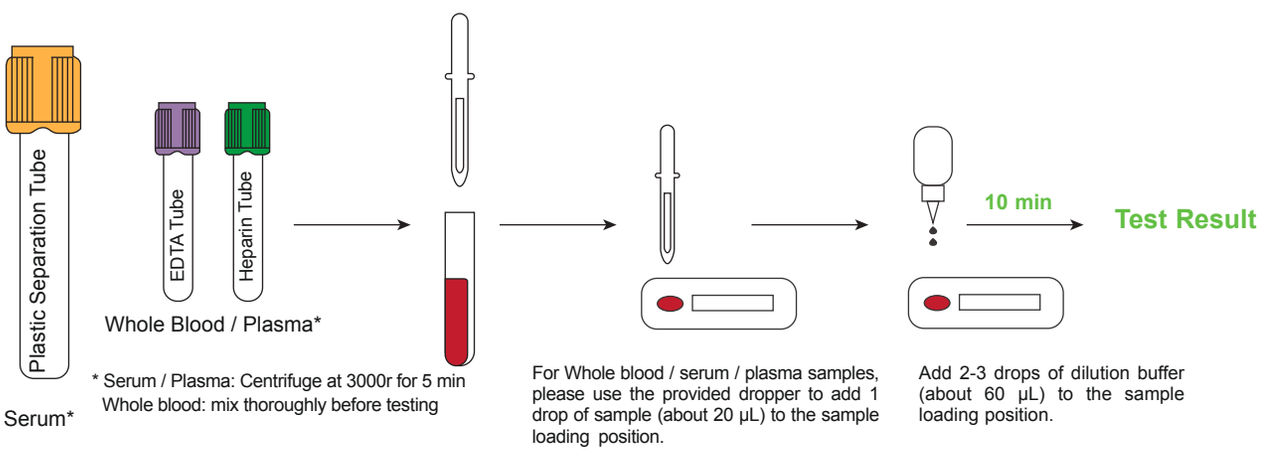
Results	Interpreting
IgM positive, IgG positive	Indicates that it may be a recent infection with 2019-nCoV.
IgM positive, IgG negative	Indicates that it may be a recent infection with 2019-nCoV.
IgM negative, IgG positive	Indicates that it may be a previous infection with 2019-nCoV.
IgM negative, IgG negative	Indicates that it may be no infection with 2019-nCoV, or there is not enough detectable antibodies in the early infection.

Nanjing Vazyme Medical Technology Co., Ltd.
Tel: +86 18616767852 Email: global@vazyme.com Web: www.vazyme.com
Add: Bldg.C2, Red Maple Sci-Tech Park, Kechuang Rd., Nanjing, China.

Product Information

Product Name	2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)
Size	50 Tests / Kit
Specimen	Serum / Plasma / Whole Blood
Required Volume of Specimen	20 ul
Storage	4℃ - 30℃. Sealed.

Workflow



* Serum / Plasma: Centrifuge at 3000r for 5 min
Whole blood: mix thoroughly before testing

For Whole blood / serum / plasma samples, please use the provided dropper to add 1 drop of sample (about 20 μL) to the sample loading position.

Add 2-3 drops of dilution buffer (about 60 μL) to the sample loading position.

Nanjing Vazyme Medical Technology Co., Ltd.

Tel: +86 18616767852 Email: global@vazyme.com Web: www.vazyme.com
Add: Bldg.C2, Red Maple Sci-Tech Park, Kechuang Rd., Nanjing, China.

2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)
Instruction for Use

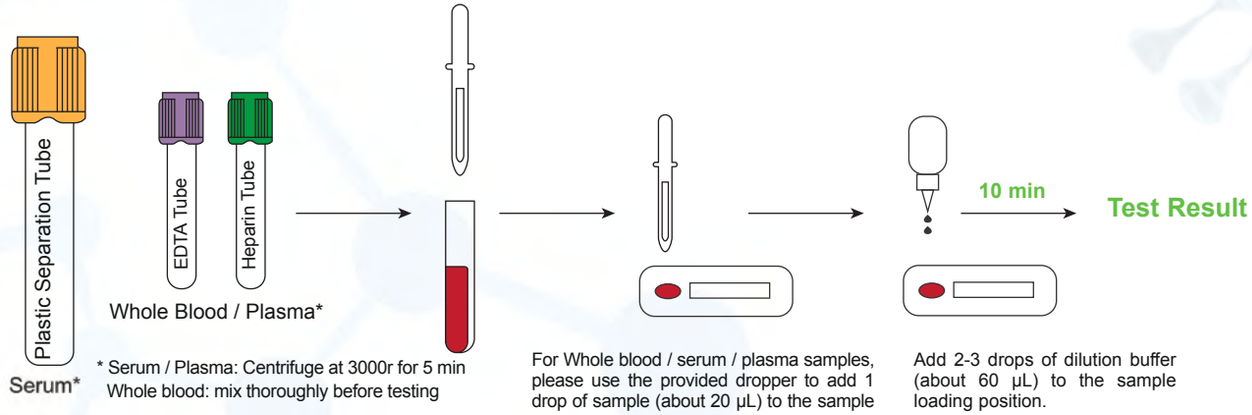
Intended Use

This product is intended to detect the IgG / IgM of 2019-Novel Coronavirus (2019-nCoV) from human serum, plasma and whole blood.

IgM / IgG Antibody

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. Normally, the level of IgM begins to rise after 1 week after the initial infection, while the IgG appears later than IgM (usually about 14 days after infection). Suspected patients that are infected by 2019-nCoV can be rapidly identified by simultaneous monitoring of IgM and IgG.

Workflow



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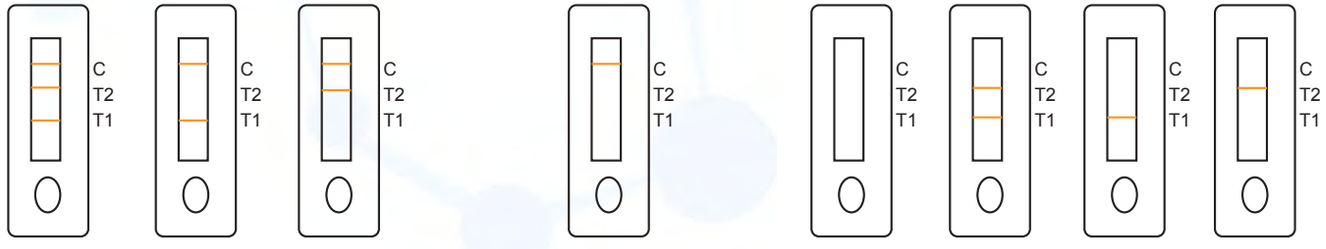

Positive: At least one red test line (T1, T2 line) and one red quality control line (C line) appear in the detection area.

Negative: Only one red quality control line (C line) appears in the detection area.

Invalid: No red quality control line (C line) appears in the detection area (e.g. without any red lines or only test lines (T1, T2 line).

Interpreting Test Results

Positive: (1) If asymptomatic, it is recommended to use the nucleic acid detection kit to test again immediately; (2) If symptomatic, it is recommended to go to the hospital immediately.

Negative: (1) If asymptomatic, indicates that there is no novel coronavirus infection; (2) If symptomatic, it is recommended to use the nucleic acid detection kit to test again immediately.

Invalid: It is recommended to test again in strict accordance with the operating instructions.

After the detection, all the test strips should be treated as medical wastes.

Nanjing Vazyme Medical Technology Co., Ltd. Add: Bldg.C2, Red Maple Sci-Tech Park, Kechuang Rd., Nanjing, China. Tel: +86 18616767852 Email: global@vazyme.com Web: www.vazyme.com

Acknowledgment Letter

3/26/2020

Jinjie Hu, President and Principal Consultant
Axteria BioMed Consulting, Inc.
8040 Cobble Creek Circle
Potomac, MD 20854
UNITED STATES

Dear Jinjie Hu:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: PEUA200226
Received: 3/26/2020
Applicant: Nanjing Vazyme Medical Technology Co., Ltd.
Device: NanJiang 2019-nCoV IgG / IgM Detection Kit

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Vazyme

EC Declaration of Conformity

Manufacturer:

Name: Nanjing Vazyme Medical Technology Co., LTD.

Address: Building C1-2, Red Maple Park of Technological Industry, Nanjing, China

European Representative:

Name: POLGEN Spółka z ograniczoną odpowiedzialnością - Spółka komandytowa

Address: 92-516 Łódź, ul. Puszkina 80, Poland

Product Name: 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

Model: Cassette / Dipstick

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into nationallaw,the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

Signature:

Name: Bo TANG

Position: CEO

Place: Nanjing

DateofIssue: 28th Feb, 2020

CE

Nanjing Vazyme Medical Technology Co., LTD.
Websit: www.vazyme.com Tel: +86 25 8438 8701 Email: global@vazyme.com
Add: Building C1-2, Red Maple Park of Technological Industry, Nanjing, China

Statement

Acting on behalf of Polgen Sp. z o.o., Sp. K., registered in the city of Łódź, Poland, Puszkina 80 st. (*the Company)*, I hereby declare that *the Company*, as an official, authorized representative of the Nanjing Vazyme Medical, Co, Ltd., Building C1-2, Red Maple Park of Technological Industry, 210033 Nanjing, China (*the Manufacturer*), has submitted the application for authorisation of offering the following product on the EU market as Medical Device for the in vitro diagnostic (**CE IVD)**, to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (*the Office)*.

The Company's application is registered by *the Office* under following entry:
[ID: 267483902149] „The application for authorisation offering on the market the following product as Medical Device for in vitro diagnostic (CE IVD):

2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based) – No 361104847982
(identification number of the form delivered to the Office)",

here and after: (*the Product*).

The Company states, that the forms were submitted to *the Office* on March 2nd 2020 and that *the Office* did not deliver any objections in the legal timeframe. Thus resulting in legal eligibility for the Manufacturer to offer *the Product* on the EU markets as medical devices for in vitro diagnostics.

On behalf of Polgen Sp. z o.o. - Sp. K.

POLGEN Sp. z o.o. - Sp.K.
92-516 Łódź, ul. Puszkina 80
NIP 725-14-47-400, KRS 0000315261
tel. (42) 677 04 60, fax (42) 677 04 61

Paweł Machejko

CEO

CE IVD

POLGEN

中华人民共和国

医疗器械注册证（体外诊断试剂）

注册证编号：国械注准 20203400239

注册人名称	南京诺唯赞医疗科技有限公司
注册人住所	南京经济技术开发区科创路红枫科技园C2栋东段1-3层
生产地址	南京经济技术开发区科创路红枫科技园C2栋东段1-3层
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）IgM / IgG抗体检测试剂盒（胶体金法）
包装规格	10人份/盒，20人份/盒，25人份/盒，30人份/盒，40人份/盒，50人份/盒。
主要组成成分	检测卡、样本稀释液、吸滴管。（具体内容详见产品说明书）
预期用途	本试剂盒用于体外定性检测人血清、血浆样本中新型冠状病毒（2019-nCoV）IgM/IgG抗体。仅用作对新型冠状病毒核酸检测阴性疑似病例的补充检测指标或疑似病例诊断中与核酸检测协同使用，不能作为新型冠状病毒感染的肺炎确诊和排除的依据，不适用于一般人群的筛查。 该产品仅限医疗机构使用。
附件	产品技术要求、说明书
产品储存条件及有效期	试剂盒于4～30℃，有效期暂定6个月。
其他内容	/
备注	上市后进一步完成以下工作： 1. 本产品仅为新型冠状病毒（2019-nCoV）感染的肺炎的辅助诊断及应急储备，注册证有效期为一年。 2. 延续注册时应按照如下要求提交临床应用数据的总结报告：应在三家以上临床医疗机构（包括各级疾病预防控制中心）收集该产品连续临床应用数据。临床应用数据应具有完善的信息，样本量符合统计学要求，签字盖章符合要求。 3. 企业应当延续注册时按照体外诊断试剂注册管理办法的要求完善所有注册申报资料。

审批部门：国家药品监督管理局

批准日期：二〇二〇年三月十三日

有效期至：二〇二五年三月十二日

Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

HSA 600:36/01

26 March 2020

[redacted]

[redacted]

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation for supply in Singapore and may be exported from Singapore.

No.	Device Proprietary Name	Intended Use
1	(a) Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit (C6603C) *(also marketed as)* (b) Biolidics 2019-nCoV IgG/IgM Detection Kit (CBB-F015016-B1)	2019-nCoV IgG/IgM Detection Kit is intended for the qualitative detection of 2019-nCoV IgG/IgM antibodies in human serum, plasma and whole blood. The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR). The kit is not intended for finger prick testing.

Product Owner(s):

(a) Nanjing Vazyme Medical Technology Co.,Ltd
Floor 1-3, Building C2
Red Maple Park of Technological Industry
State Economy & Technology Development Zone 210038 Nanjing PRC
China

(b) [redacted]

Manufacturing Site: Nanjing Vazyme Medical Technology Co.,Ltd.
Floor 1-3, Building C2
Red Maple Park of Technological Industry
State Economy & Technology Development Zone 210038 Nanjing PRC
China

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR CHRISTOPHER LAM
SENIOR REGULATORY SPECIALIST
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

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

Product Service

CERTIFICATE

No. Q5 18 02 03027 001

Holder of Certificate: **Nanjing Vazyme Medical Technology Co.,Ltd.**

F1-F3, Building C2
Red Maple Park of Technological Industry
State Economy & Technology Development Zone
210038 Nanjing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Nanjing Vazyme Medical Technology Co.,Ltd.
F1-F3, Building C2, Red Maple Park of Technological Industry, State Economy & Technology Development Zone, 210038 Nanjing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In-vitro Diagnostic Test Kits based on Latex Particle-enhanced Turbidimetric Immunoassay and Quantum Dot Immunofluorescence Assay, Dry-type Fluorescence Immunity Analyzer**

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.: SH17128101

Valid from: 2018-05-09

Valid until: 2021-05-08

Date, 2018-05-09

Stefan Preiß

040527685811129

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

Page 1 of 1

TÜV®

DAkkS CRT2 / A4 07.17 ZM

2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based)

Clinical Test Report

<table>
<tr><td>Product Name</td><td>2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based)</td></tr>
<tr><td>Manufacturer</td><td>Nanjing Vazyme Medical Technology Co., LTD.</td></tr>
<tr><td>Clinical Trial Organizations</td><td>The Central Hospital of Yongzhou, Foshan Nanhai District People's Hospital, Xishui People's Hospital, Huangzhou District People's Hospital, Gong An County People's Hospital.</td></tr>
<tr><td>Clinical Validation Method</td><td>The test results of 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based) were compared with the diagnosis results (based on nucleic acid detection method) obtained by the above clinical trial organization. Then, the positive rate, negative rate, total coincidence rates and KaPPa were analyzed.</td></tr>
<tr><td>Analysis of Clinical Data</td><td>
<table>
<tr><td colspan="2">Serum, Plasma and Whole Blood Samples (n = 570)</td><td colspan="2">Clinical Diagnosis</td></tr>
<tr><td></td><td></td><td>Positive</td><td>Negative</td></tr>
<tr><td rowspan="2">2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit</td><td>Positive</td><td>184</td><td>11</td></tr>
<tr><td>Negative</td><td>17</td><td>358</td></tr>
</table>
Total Sensitivity = 91.54% (95%CI 86.87 – 94.65)
Total Specificity = 97.02% (95%CI 94.74 – 98.33)
Total Conformity = 95.09% (95%CI 92.99 – 96.58)
</td></tr>
<tr><td>Conclusion</td><td>The test results show that the Vazyme 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit has a high specificity and is one of the effective methods for the diagnosis of 2019-nCoV.</td></tr>
<tr><td>Report Provided by</td><td>Nanjing Vazyme Medical Technology Co., LTD.</td></tr>
<tr><td>Date</td><td>March 5th, 2020</td></tr>
</table>

Safety Data Sheet

（SDS）

Creation Date: 23/03/2020
Revision Date: 23/03/2020
Version: 20200323
Prepared according to UN GHS (the 8th revised edition)

Product Name: 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

Model: C6603C-02：50 tests/kit

Company Name:Vazyme Medical Technology Co., Ltd.

Written by TJTest Technology（Shanghai）Co., Ltd.

1、Identification of the chemical and supplier

1.1 Product identifier

Product Name： 2019-nCoV IgG / IgM Detection Kit(Colloidal Gold-Based)

Product Model： C6603C-02：50 tests / kit

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses： It is suitable for qualitative detection of IgG /IgM antibodies in human serum, plasma, and whole blood.

Uses advised against： Please consult manufacturer.

1.3 Details of the supplier of the Safety Data Sheet

Name of the company： Vazyme Medical Technology Co., Ltd.

Address of the company： Building C1-2, Red Maple Park of Technological Industry, Nanjing, China.

Telephone number： 400-969-0586

Fax number： +86（0）25-84365701

Zip code： /

Email address： marketing@vazyme.com

1.4 Emergency phone number：+86（0）400-969-0586

2、Hazards identification

2.1 Hazard classification according to GHS:

The product is not dangerous and it has no hazardous classification.

2.2 Label elements

Hazard pictograms: None.

Signal word: None.

2.3 Hazard statements:

None.

2.4 Precautionary statements

2.4.1 Prevention

None.

2.4.2 Response

None.

2.4.3 Storage

None.

2.4.4 Disposal

None.

2.5 Hazard description

2.5.1 Physical and chemical hazards

This product is normally used without hazard.

2.5.2 Health hazards

None.

2.5.3 Environmental hazards

Please refer to 12th chapter of SDS.

3、Composition/information on ingredients

Substance☐ Prepation☑

Component	CAS No.	EC No.	Concentration
PVC	9002-86-2	618-338-8	/
PET	25038-59-9	607-507-1	/
Glass Fiber	65997-17-3	266-046-0	/
Nitrocellulose	9004-70-0	618-392-2	/
Casein	9014-01-1	232-752-2	0.5%
HEPES buffer	7365-45-9	230-907-9	0.2M

4、First aid measures

4.1 Description of first aid measures

General advice: Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.

Skin contact: Wash off with plenty of water, take off contaminated clothing and shoes immediately.

Eye contact: Wash with running water or saline,Seek medical attention if necessary.

Inhalation: Move to fresh air,Keep the airway open,Seek medical attention if you feel unwell.

Intake: Clean up the mouth, induce vomiting, seek medical attention.

Protecting of first-aiders: Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination.

4.2 Indication of any immediate medical attention and special treatment needed

1、Treat symptomatically.

2、Symptoms may be delayed.

5、Firefighting measures

5.1 Extinguishing media

1、Suitable extinguishing media: Misty water, alcohol-resistant foam, dry powder, carbon dioxide, sand.

2、Unsuitable extinguishing media: Do not use a solid water stream as it may scatter or spread fire.

5.2 Specific hazards arising from the substance or mixture

1、No data available.

5.3 Advice for firefighters

1、As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.

2、Fight fire from a safe distance, with adequate cover.

3、Prevent fire extinguishing water from contaminating surface water or the ground water system.

6、Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

1、Emergency personnel wear positive pressure self-contained breathing apparatus. Wear protective and anti-static clothing. Wear chemical impermeable gloves.

2、Ensure adequate ventilation. Remove all sources of ignition.

3、Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

4、Use personal protective equipment. Avoid breathing vapours, mist, gas or dust.

6.2 Environmental precautions

1、Prevent further leakage or spillage if safe to do so.

2、Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

1、Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

2、Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

7、Handling and storage

7.1 Precautions for handling

1、Closed operation, full ventilation.

2、Operators must be specially trained to strictly abide by the operating procedures.

3、It is recommended that operators wear self-priming filter dust masks and chemical safety glasses.

4、Keep away from fire, heat, and smoking in the workplace.

5、Use explosion-proof ventilation systems and equipment.

6、Avoid contact with oxidizing agents, reducing agents, and halogens.

7、Equipped with the corresponding variety and quantity of fire-fighting equipment.

7.2 Precautions for storage

1、Store in a cool, ventilated warehouse.

2、Keep away from fire and heat.

3、It should be stored separately from oxidants, reducing agents, halogens, etc., and should not be mixed.

4、Use explosion-proof lighting and ventilation facilities.

5、It is forbidden to use mechanical equipment and tools that are prone to sparks.

6、The storage area should be equipped with leakage emergency treatment equipment and suitable containment materials.

8、Exposure controls/personal protection

8.1 Control Parameters

8.1.1 Occupational exposure limits

Occupational Exposure limit values

Component	Country/Region	Limit value - Eight hours		Limit value - Short term	
		ppm	mg/m³	ppm	mg/m³
All components	USA - OSHA	Unspecified	Unspecified	Unspecified	Unspecified
	South Korea	Unspecified	Unspecified	Unspecified	Unspecified
	Ireland	Unspecified	Unspecified	Unspecified	Unspecified
	Germany(AGS)	Unspecified	Unspecified	Unspecified	Unspecified

	Denmark	Unspecified	Unspecified	Unspecified	Unspecified
	Australia	Unspecified	Unspecified	Unspecified	Unspecified

8.1.2 Biological limit values

Biological limit values:No information available

8.1.3 Monitoring methods

1、EN 14042 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

2、BZ/T 160.1~GBZ/T 160.81-2004 Determination of toxic substances in workplace air（Series standard）.

8.2 Engineering controls

1、Ensure adequate ventilation, especially in confined areas.

2、Ensure that eyewash stations and safety showers are close to the workstation location.

3、Use explosion-proof electrical/ventilating/lighting/equipment.

4、Set up emergency exit and necessary risk-elimination area.

8.3 Personal protection equipment

General requirement:

Eye protection: Tightly fitting safety goggles (approved by EN 166(EU) or NIOSH (US).

Hand protection: Wear protective gloves（such as butyl rubber）, passing the tests according toEN 374(EU),US F739 or AS/NZS 2161.1 standard.

Respiratory protection: If exposure limits are exceeded or if irritation or other symptoms are experienced, use a full- face respirator with multi-purpose combination (US) or type AXBEK (EN 14387) respirator cartridges.

Skin and body protection: Wear fire/flame resistant/retardant clothing and antistatic boots.

Other protection: Smoking, eating and drinking are forbidden on the job site. Maintain good hygiene habits.

9、Physical and chemical properties

Appearance： Reference sample photo.

Odor： Weak odor.

Odor threshold： No data available.

PH value： No data available.

Melting point/freezing point（°C）： No data available.

Initial boiling point and boiling range（°C）： No data available.

Flash point（closed cup, °C）： No data available.

Evaporation rate： No data available.

Flammability（solid or gas）： Non-flammable.

Explosion upper/lower limit [%(v/v)]： No data available.

Vapor pressure（kPa）： No data available.

Vapor density（air = 1）： No data available.

Relative density（water = 1）： No data available.
Solubility（mg/L）： No data available.
Octanol/water partition coefficient： No data available.
Auto-ignition temperature（°C）： No data available.
Decomposition temperature（°C）： No data available.
Viscosity： No data available.
Others:Resistance value： No data available.

10、Stability and Reactivity

Reactivity: Contact with incompatible materials can cause decomposition or other chemical reactions.
Chemical stability: Stable under the correct conditions of use and storage.
Possibility of hazardous reactions: No data available.
Conditions to avoid: Electrostatic discharge, heat, humidity, etc.
Incompatible materials: Strong oxides, strong acids, strong bases.
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11、Toxicological information

11.1 Acute toxicity

Component	LD_{50}(oral)	LD_{50}(Transcutaneous)	LC_{50}(inhalation, 4h)
All components	Not available	Not available	Not available

11.2 Carcinogenicity

Component	IARC	NTP
All components	Not Listed	Not Listed

11.3 Others

Component	Corrosive skin/ irritation	Serious eye damage/irritation	Skin sensitization	Respiratory sensitization	Reproductive toxicity	Specific target organ toxicity - single exposure	Specific target organ toxicity - repeated exposure	Aspiration hazard	Germ cell mutagenicity	Reproductive toxicity
All components	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available	Not available

12、Ecological information

12.1 Acute aquatic toxicity

Component	Fish	Crustaceans	Algae

All components	Not available	Not available	Not available

12.2 Chronic aquatic toxicity

Component	Fish	Crustaceans	Algae
All components	Not available	Not available	Not available

12.3 Others

Component	Persistence and degradability	Bioaccumulation or bioaccumulation	Soil mobility	Evaluation of PBT and vPvB results
All components	Not available	Not available	Not available	Not available

13、Disposal considerations

Disposal considerations: Recycle as much as possible.If it cannot be recycled, use incineration for disposal.Do not dispose of this product by means of discharge to the sewer.

Waste chemicals: Contaminated packaging: Residual hazards may still exist after the contents of the packaging are emptied. Keep away from heat and sources of ignition. If possible, recycle them to the supplier for recycling.

Disposal considerations: Refer to the "Disposal" section.

14、Transportation information

United Nations Dangerous Goods Number (UN No.): The product is not dangerous.
UN proper shipping name: None
UN Risk Classification: None
Packing Category: None
Packaging label: None
Marine Pollutants (Yes/No): No
Packing method: Pack according to the manufacturer's recommendations.
Transportation Note:

It is strictly prohibited to mix and transport with acids, alkalis, oxidants, foods and food additives. The exhaust pipe of the vehicle carrying this item must be equipped with a fire-retardant device, which prohibits the use of mechanical equipment and tools that generate sparks. Avoid exposure, rain, and high temperature during transportation. The tank (tank) used for transportation shall have a grounding chain, and a hole partition may be arranged in the tank to reduce the static electricity generated by the vibration.

It is strictly prohibited to mix and transport with oxidants, acids, foods and food additives. It is strictly forbidden to use wooden boats and cement ships for bulk transportation. Avoid exposure, rain, and high temperature during transportation. Transportation vehicles shall be equipped with fire fighting equipment and emergency response treatment equipment of corresponding types and quantities. Before shipping, check whether the packaging container is complete and sealed. On the transportation means, hazard signs and announcements should be posted in accordance with the relevant transportation requirements.

15、Regulatory information

International chemical inventory

Component	EINECS	TSCA	DSL	IECSC	NZIoC	PICCS	KECL	AICS
PVC	Not Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
PET	Not Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
Glass Fiber	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
Nitrocellulose	Not Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
Casein	Listed	Listed	Not Listed	Listed	Listed	Listed	Not Listed	Listed
HEPES buffer	Listed	Listed	Listed	Listed	Listed	Listed	Not Listed	Listed

【EINECS】 European Inventory of Existing Commercial Chemical Substances
【TSCA】 United States Toxic Substances Control Act Inventory
【DSL】 Canadian Domestic Substances List
【IECSC】 China Inventory of Existing Chemical Substances
【NZIoC】 New Zealand Inventory of Chemicals
【PICCS】 Philippines Inventory of Chemicals and Chemical Substances
【KECL】 Korea Existing Chemical List
【AICS】 Australia Inventory of Chemical Substances

16、Others

16.1 Reference:

【1】IPCS:The International Chemical Safety Cards (ICSC),website:http://www.ilo.org
【2】IARC,website:http://www.iarc.fr
【3】OECD:The Global Portal to Information on Chemical Substances,website:http://www.echemportal.org
【4】CAMEO Chemicals,website:http://cameochemicals.noaa.gov
【5】NLM:ChemIDplus,website:http://chem.sis.nlm.nih.gov
【6】EPA:Integrated Risk Information System,website:http://cfpub.epa.gov
【7】U.S. Department of Transportation:ERG,website:http://www.phmsa.dot.gov
【8】Germany GESTIS-database on hazard substance,website:http://gestis-en.itrust.de

16.2 Others:

1、Abbreviations and acronyms

CAS-Chemical Abstracts Service
PC-STEL- Short term exposure limit
DNEL-Derived No Effect Level
RPE-Respiratory Protective Equipment
LC50-Lethal Concentration 50%
NOEC-No Observed Effect Concentration
PBT-Persistent, Bioaccumulative,Toxic
BCF-Bioconcentration factor (BCF)

IMDG-International Maritime Dangerous Goods
UN-The United Nations
NFPA-National Fire Protection Association
CMR-Carcinogens, mutagens or substances toxic to reproduction
PC-TWA -Time Weighted Average
IARC-International Agency for Research on Cancer
PNEC-Predicted No Effect Concentration
LD50-Lethal Dose 50%
EC50-Effective Concentration 50%
POW-Partition coefficient Octanol:Water
vPvB-very Persistent,very Bioaccumulative
ICAO/IATA-InternationalCivil Aviation Organization/International Air Transportation Association
ACGIH-American Conference of Governmental Industrial Hygienists
OECD-Organization for Economic Co-operation and Development

2、Disclaimer

This Safety Data Sheet (SDS) was prepared according to UN GHS (the 8th revised edition). The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

Sample photo

**********END**********

SDS Creation Date: 23/03/2020（Valid in the year）

空 运
By Air

NO.2020028942

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： 样本稀释液

Sample Name: /

委托单位： 南京诺唯赞医疗科技有限公司

生产单位： 南京诺唯赞医疗科技有限公司

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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声　　明
Statement

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   The certification is invalid if it is not affixed the dedicated inspection and testing seal of Shanghai Research Institute of Chemical Industry Testing Co., Ltd. And QR Code on it.
2. 鉴定书复印件无效。
   Copies of the certification are invalid.
3. 鉴定书无主检、审核、批准签字无效。
   The certification is invalid without the signatures of appraiser, checker and approver.
4. 鉴定书涂改无效。
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   The certification is valid in the year subscribed on it except when transported by rail. Please refer to the comment of Certification on special occasion.
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9. 鉴定结果中的运输方式应与货物的运输方式相一致，不同的运输方式，鉴定结果可能会有差异。
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11. 送检申请可登入本公司网站 http://www.ghs.cn进行网上委托。
    The application of the certification can be done via our website: http://www.ghs.cn.

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网址：www.ghs.cn

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020028942

样品名称 Sample Name	中文 Chinese	样本稀释液
	英文 English	/
委托单位 Consignor		南京诺唯赞医疗科技有限公司
生产单位 Manufacturer		南京诺唯赞医疗科技有限公司
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		淡黄色透明液体，稍有气味 Pale yellow transparent Liquid, 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: 2020-02-27　签发日期: Issue Date: 2020-02-27　生效日期: Effective Date: 2020-02-27

备注 Comment	无。 None.

批准 Approver: 张小欣　审核 Checker: 董学雅　主检 Appraiser: 刘晓卿

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods NO. 2020028942

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	经闭杯闪点测试，在70度下没有发生闪燃，表明该货物不属于第3类易燃液体。 In the closed-cup flash point test, no flash was detected below 70℃, so the product is not classified in Class 3 (Flammable Liquids).
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:442830-

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