About Us

Nanjing Vazyme Medical Co.,Ltd is a high-tech private enterprises, focusing on the in vitro diagnostic products, the research and development, production, sales and service of equipment, products cover heart head blood-vessel, eugenics, tumor, renal function, infection, children's respiratory tract and other fields, is one of the most comprehensive enterprise of domestic POCT product line.

Vazyme Medical Co.,Ltd was successfully selected into the list of **"potential enterprises of Forbes unlisted companies"** and the first group of **"unicorns" and "gazelle enterprises"** cultivated in Nanjing at 2018.

1 Company Profile

Vazyme

LIFE Science research reagent

Scientific experiments, industrial production

colleges and universities

Industrial production

IVD reagent

Medical diagnosis

Third party laboratory

Hospital

Emergency department

Clicnic

编 号 320192000201807060010

请于每年1月1日至6月30日上网申报上一年度工商年报，逾期未报将被标记为经营异常状态或列入经营异常名录并向社会公示，年报网址见营业执照左下方。

营业执照

(副 本)

统一社会信用代码 91320192MA1MFEWD9E （1/1）

名　　称	南京诺唯赞医疗科技有限公司
类　　型	有限责任公司（法人独资）
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、中段1-3层
法定代表人	曹林
注册资本	8000万元整
成立日期	2016年02月23日
营业期限	2016年02月23日至******
经营范围	医疗试剂、生物诊断仪器研发、生产、销售、技术咨询、技术服务、技术转让。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

登记机关

南京市工商行政管理局

2018年 07月 06日

医疗器械经营许可证

许可证编号：苏宁食药监械经营许20190221号

企业名称：南京诺唯赞医疗科技有限公司　　法定代表人：曹林

经营方式：批发　　企业负责人：曹林

住　　所：南京市经济技术开发区科创路红枫科技园C2栋东段1-3层，中段1-3层　　经营范围：批发：Ⅲ类：6828医用磁共振设备，6830医用X射线设备，6840临床检验分析仪器及诊断试剂（诊断试剂需低温冷藏运输贮存），6841医用化验和基础设备器具，6854手术室、急救室、诊疗室设备及器具***

经营场所：南京市经济技术开发区科创路红枫科技园C2栋B303,B304,C325室

库房地址：南京市经济技术开发区红枫科技产业园C2栋A201,A202,Y201室　　发证部门：南京市市场监督管理局

有效期限：至 2024 年 05 月 26 日　　发证日期：2019 年 05 月 27 日

国家药品监督管理局制

1900228

医疗器械生产许可证

许可证编号：苏食药监械生产许20170028号

企业名称：南京诺唯赞医疗科技有限公司

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

法定代表人：曹林

生产范围：见医疗器械生产产品登记表

企业负责人：曹林

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

发证部门：江苏省药品监督管理局

有效期限：至 2022 年 03 月 31 日

发证日期：2017 年 04 月 01 日

国家食品药品监督管理总局制

医疗器械生产产品登记表

企业名称	南京诺唯赞医疗科技有限公司
许可证编号	苏食药监械生产许20170028号
许可证有效期限	2017-04-01 至 2022-03-31
生产范围	Ⅱ类:6840-1-用于蛋白质检测的试剂，6840-3-免疫分析系统，22-04-免疫分析设备 Ⅲ类:6840-1-与致病性病原体抗原、抗体以及核酸等检测相关的试剂

生产产品列表

序号	产品名称	注册号	登载日期	备注
1	肌红蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20172400408	2017-04-01	
2	中性粒细胞明胶酶相关脂质运载蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20172400409	2017-04-01	
3	心型脂肪酸结合蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20172400407	2017-04-01	
4	肌红蛋白校准品	苏械注准20172401591	2017-09-15	
5	中性粒细胞明胶酶相关脂质运载蛋白质控品	苏械注准20172401588	2017-09-15	
6	中性粒细胞明胶酶相关脂质运载蛋白校准品	苏械注准20172401592	2017-09-15	
7	心型脂肪酸结合蛋白校准品	苏械注准20172401590	2017-09-15	
8	心型脂肪酸结合蛋白/肌红蛋白质控品	苏械注准20172401589	2017-09-15	
9	N末端脑钠肽前体检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401963	2017-10-30	
10	脂蛋白相关磷脂酶A2检测试剂盒（胶乳增强免疫比浊法）	苏械注准20172401964	2017-10-30	
11	脂蛋白磷脂酶A2检测试剂盒（量子点荧光免疫法）	苏械注准20172401967	2017-10-30	
12	中性粒细胞明胶酶相关脂质运载蛋白检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401968	2017-10-30	
13	血清淀粉样蛋白A检测试剂盒（量子点荧光免疫法）	苏械注准20172401966	2017-10-30	
14	心型脂肪酸结合蛋白检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401962	2017-10-30	
15	心肌肌钙蛋白I检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401970	2017-10-30	

序号	产品名称	注册号	登载日期	备注
16	全量程C反应蛋白检测试剂盒（量子点荧光免疫法）	苏械注准20172401969	2017-10-30	
17	肌酸激酶同工酶检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401971	2017-10-30	
18	肌红蛋白检测试剂盒（量子点荧光免疫层析法）	苏械注准20172401965	2017-10-30	
19	干式荧光免疫分析仪	苏械注准20182400636	2018-04-09	
20	降钙素原检测试剂盒（量子点荧光免疫法）	苏械注准20182400705	2018-04-09	
21	抗缪勒氏管激素检测试剂盒（量子点荧光免疫法）	苏械注准20182400783	2018-04-26	
22	脂蛋白相关磷脂酶A2质控品	苏械注准20182400741	2018-04-26	
23	脂蛋白相关磷脂酶A2校准品	苏械注准20182400740	2018-04-26	
24	全量程C反应蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20182400882	2018-05-17	
25	血清淀粉样蛋白A检测试剂盒（胶乳增强免疫比浊法）	苏械注准20182400883	2018-05-17	
26	D-二聚体检测试剂盒（量子点荧光免疫法）	苏械注准20182401264	2018-08-22	
27	血清淀粉样蛋白A质控品	苏械注准20182401143	2018-08-22	
28	D-二聚体质控品	苏械注准20182401145	2018-08-22	
29	D-二聚体校准品	苏械注准20182401144	2018-08-22	
30	高敏心肌肌钙蛋白I检测试剂盒（量子点荧光免疫法）	苏械注准20182401297	2018-09-12	
31	糖化血红蛋白检测试剂盒（量子点荧光免疫法）	苏械注准20182401296	2018-09-12	
32	胃蛋白酶原Ⅰ检测试剂盒（胶乳增强免疫比浊法）	苏械注准20182401361	2018-09-19	
33	胃蛋白酶原Ⅱ检测试剂盒（胶乳增强免疫比浊法）	苏械注准20182401362	2018-09-19	
34	B型脑钠肽检测试剂盒（量子点荧光免疫法）	苏械注准20182401628	2018-12-11	
35	髓过氧化物酶检测试剂盒（量子点荧光免疫法）	苏械注准20182401629	2018-12-11	
36	高敏心肌肌钙蛋白T检测试剂盒（量子点荧光免疫法）	苏械注准20182401627	2018-12-11	
37	抗磷脂酶A2受体抗体IgG检测试剂盒（量子点荧光免疫法）	苏械注准20192400239	2019-03-20	

序号	产品名称	注册号	登载日期	备注
38	白介素6检测试剂盒（量子点荧光免疫法）	苏械注准20192400279	2019-04-04	
39	降钙素原检测试剂盒（胶乳增强免疫比浊法）	苏械注准20192400255	2019-04-04	
40	25-羟基维生素D检测试剂盒（量子点荧光免疫法）	苏械注准20192400377	2019-06-03	
41	全自动特定蛋白分析仪	苏械注准20192220721	2019-07-08	
42	人S100蛋白检测试剂盒(量子点荧光免疫法)	苏械注准20192400610	2019-07-08	
43	超敏C反应蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20192400901	2019-10-10	
44	血清淀粉样蛋白A、C反应蛋白联合检测试剂盒(量子点荧光免疫法)	苏械注准20192401024	2019-10-10	
45	糖化血红蛋白检测试剂盒（胶乳增强免疫比浊法）	苏械注准20192400861	2019-10-10	
46	肌酸激酶同工酶、心肌肌钙蛋白I、肌红蛋白联合检测试剂盒(量子点荧光免疫法)	苏械注准20192401025	2019-10-10	
47	C-反应蛋白质控品	苏械注准20192401161	2019-11-19	
48	脂蛋白磷脂酶A2质控品	苏械注准20192401152	2019-11-19	
49	血清淀粉样蛋白A质控品	苏械注准20192401154	2019-11-19	
50	中性粒细胞明胶酶相关脂质运载蛋白质控品	苏械注准20192401155	2019-11-19	
51	心型脂肪酸结合蛋白质控品	苏械注准20192401157	2019-11-19	
52	心肌肌钙蛋白I质控品	苏械注准20192401153	2019-11-19	
53	胃蛋白酶原I、胃蛋白酶原II联合检测试剂盒（量子点荧光免疫法）	苏械注准20192401224	2019-11-19	
54	全自动量子点荧光免疫分析仪	苏械注准20192221272	2019-11-19	
55	D-二聚体、心肌肌钙蛋白I联合检测试剂盒（量子点荧光免疫法）	苏械注准20192401156	2019-11-19	
56	N末端脑钠肽前体质控品	苏械注准20192401151	2019-11-19	
57	肌红蛋白质控品	苏械注准20192401162	2019-11-19	
58	肌酸激酶同工酶质控品	苏械注准20192401158	2019-11-19	
59	降钙素原质控品	苏械注准20192401159	2019-11-19	
60	抗缪勒氏管激素质控品	苏械注准20192401160	2019-11-19	
61	量子点荧光免疫分析仪	苏械注准20192221429	2019-12-24	

序号	产品名称	注册号	登载日期	备注
62	胃泌素17检测试剂盒（量子点荧光免疫法）	苏械注准20192401428	2019-12-24	
63	新型冠状病毒（2019-nCoV）IgM/IgG抗体检测试剂盒（胶体金法）	国械注准20203400239	2020-03-16	

发证部门(公章)：江苏省药品监督管理局

2020年03月16日

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

开户许可证

核准号：J3010054770401　　编　号：3010- 05303073

经审核，南京诺唯赞医疗科技有限公司　　符合开户条件，准予开立基本存款账户。

法定代表人（单位负责人）曹林　　开户银行南京银行股份有限公司城东支行

账　号 01500120210022322

发证机关（盖章）
2016 年 03 月 09 日

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-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
Instruction for Use (Version 2.0)

PRODUCT NAME

2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit

CATALOG NUMBER & SIZE

CD302-02: 100 tests / kit

INTENDED USE

This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV).

The detection result of this product is only for clinical reference, and it should not be used as the only evidence for clinical diagnosis and treatment.

PRINCIPLE OF DETECTION

This product is a multiplex fluorescent probe-based Taqman® RT-qPCR assay system. The Taqman fluorescent probe is a specific oligonucleotide based on a reporter-quencher mechanism. For each probe, the 5'-end is labeled with a fluorophore, while the 3'-end was labeled with a quencher. When the probe is intact, the fluorescence emitted by the fluorophore is absorbed by the quencher, and no fluorescent signal is detected. However, during amplification of the template, the probe will be degraded due to the 5'-3' exonuclease activity of Taq DNA polymerase, and the fluorescent reporter and the quencher are cleaved and separated, then a fluorescent signal can be detected. The generation of each molecular amplicon is accompanied by the generation of a fluorescent signal. Real-time monitoring of the entire PCR process can be assessed by monitoring the accumulation of fluorescent signals.

This product provides triplex-detections in a single tube, including two independent genes of 2019-nCoV and an internal control which targets the human RNAse P (RNP) gene to assess specimen quality. Specific primers and probes were designed for the detection of conserved region of 2019-nCoV's ORF1ab gene (RdRP region) and N gene, respectively, avoiding non-specific interference of SARS2003 and BatSARS-like virus strains. Internal control (RNAse P gene) provides a nucleic acid extraction procedural control and a secondary negative control. Positive control (2019-nCoV-pseudoviruse) provides a nucleic acid extraction and a reverse transcription control to validate the entire procedure and reagent integrity.

PRODUCT CONTENTS

Components	Amount	Ingredient	Cap Color
Detection Buffer	900 µL × 3 tubes	Buffer, dNTPs, Primers, Probes.	
Enzyme Mix	400 µL × 1 tube	RNase Inhibitor, UDG, Reverse Transcriptase, Taq DNA polymerase.	
Positive Control	250 µL × 1 tube	RNA pseudovirus containing target gene.	
Negative Control	250 µL × 1 tube	DEPC-Treated Water.	

Note:
1. Do not mix the components from different batches for detection.
2. Additional Materials Required: Nucleic acid extraction reagents.
3. Nucleic acid extraction must be performed simultaneously with the Positive control (2019-nCoV-pseudoviruse) and Negative Control (DEPC-Treated Water) for monitoring the entire procedure to reduce false negative or false positive rates.

STORAGE & SHELF LIFE

All reagents should be stored at -30°C~-15°C with protection from light.

The reagents are stable for 6 months when stored at the recommended condition.

The expiration date will not change if the kit is opened and stored at the recommended condition.

The expiration date will not change if the kit is transported with ice-packs for 4 days and/or treated with 10 freeze-thaw cycles.

INSTRUMENTS

Real-time PCR instrument with FAM, TEXAS RED/ROX and HEX/VIC channels, such as ABI7500, ABI Q3, ABI Q6, Roche LightCycler480, Bio-Rad CFX96.

SAMPLING & HANDLING

1. Suitable specimen type: upper respiratory specimen (including nasal swabs, nasopharyngeal swabs / aspirates / washes, and sputum) and lower respiratory specimen (including respiratory aspirates, bronchial washes, bronchoalveolar lavage fluids, and lung biopsy specimens).
2. For detailed methods of specimen collection, please refer to the protocol in the "Microbiology Specimen Collection Manual".
3. The collected specimen should be used for detection within the same day. Otherwise, please store the specimen as follows:

Store at 2°C - 8°C for no more than 24 hours;

Store at < -20°C for no more than 10 days;

Store at < -70°C for long-term, avoiding repeated freeze-thaw cycles.

4. The specimen should be transported using sealed foam box with dry ice.

PROTOCOL

1. Specimen Preparation (Specimen Preparation Area)

The samples should be extracted according to the corresponding requirements and procedures of viral RNA extraction kits. Each nucleic acid extraction procedure must be performed simultaneously with one Positive control (add 5 µL, dilute with sterile saline solutions to desired volume) and one Negative Control (add 5 µL, dilute with sterile saline solutions to desired volume).The extracted RNA can be directly used for detection. If the extracted RNA is not used for detection immediately, please store the RNA at below -70°C, avoiding repeated freeze-thaw.

2. Reagent Preparation (PCR Reagent Preparation Area)

Thaw the required reagents, mix by shaking, and centrifuge briefly before use.

Prepare the mixture in a RNase-free centrifuge tube as follows[1]:

Components	Volume (µL Per Reaction)
Detection Buffer	26
Enzyme Mix	4
Total Volume	**30**

[1] Calculate the number of reaction tubes (sample number + positive control + negative control). It is recommended to set both negative and positive controls for each test.

Mix the above mixture thoroughly, and make aliquots of 30 µL into different PCR reaction tubes. Then, move to the Specimen Preparation Area.

3. Template Addition (Specimen Preparation Area)

Add 20 µL of extracted Negative Control products, 20 µL of extracted Positive Control products, and 20 µL of extracted RNA from specimen to different PCR reaction tubes which contained 30 µL of PCR mix. The total volume is 50 µL. Cap the reaction tubes tightly, centrifuge them at low speed. Then, move to the Detection Area.

4. RT-PCR Amplification (Detection Area)

Put the reaction tubes on a PCR instrument, setup and run the following cycling protocol:

Step 1	Reverse Transcription	Cycles: 1	50℃	15 min
Step 2	Pre-denaturation	Cycles: 1	95℃	30 sec
Step 3	PCR Cycles	Cycles: 45	95℃	10 sec
			58℃ (Read)	30 sec

Settings of detection fluorescence: ORF1ab gene (FAM), N gene (TEXAS RED / ROX), Internal Control (HEX/VIC). Please set the internal reference parameter of fluorescence of the instrument to "None". For example: for ABI series instruments, please set "Passive Reference" to "None".

5. Data Analysis (refer to Instrument User Manual)

Take ABI7500 as an example: after the qPCR reaction, the results were saved automatically. According to the analyzed image, please adjust the Start value, End value, and Threshold value of the Baseline (Start value: 3 ~ 15; End value: 5 ~ 20; Threshold value could be set in the Log window, and the threshold line should be in the exponential phase of the amplification curve; the amplification curve of the negative control should be straight or below the threshold line).

Click "Analysis" to obtain the analysis result automatically, and read the detection result in the "Report" window.

QUALITY CONTROL

	Channel	Normal Ct
Negative Control	FAM	No Ct or Ct > 38
	TEXAS RED/ROX	No Ct or Ct > 38
	HEX/VIC	No Ct or Ct > 38
Positive Control	FAM	Ct ≤ 33
	TEXAS RED/ROX	Ct ≤ 33
	HEX/VIC	Ct ≤ 33

The result is *valid* if ALL the above criteria is met. Otherwise, the result is *invalid*.

INTERPRETING TEST RESULTS

If the criteria of QUALITY CONTROL is met, analysis the data of sample as follows:

*1. If the Ct value of HEX/VIC (Internal Control) channel is >33, it may indicate that the detected specimen contains lower concentration of cells, extracted nucleic acid was degraded or certain inhibitors were present in the reaction.

*2. If the Ct value of HEX/VIC channel is ≤ 33, analyzing the results according to the following table:

Interpreting Test Results		FAM (ORF1ab gene)	
		Ct ≤ 38	No Ct or Ct > 38
TEXAS RED/ROX (N gene)	Ct ≤ 38	2019-nCoV ***Positive***	Test Again, and if repeated: 2019-nCoV ***Negative***; If not: ***suspicious****
	No Ct or Ct> 38	Test Again, and if repeated: 2019-nCoV ***Positive***; If not: ***suspicious****	2019-nCoV ***Negative***

*No requirement for HEX/VIC channel test results, if the sample is extracted from virus culture.

*For suspicious samples, it is recommended to re-collect specimen or change the collection location, then test the specimen again.

ASSAY LIMITATIONS

1. The detection result of this product is only for clinical reference, and it should not be used as the only evidence for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses. The detection results should not be directly used as the evidence for clinical diagnosis, and are only for the reference of clinicians.

2. The detection result can be affected by operations, including specimen collection, storage and transportation. False negative result may occur if there is any mistakes in the operation. Cross contamination during specimen treatment may lead to false positive result.

3. The detected target sequences of this products are the conservative region of 2019-nCoV's ORF1ab gene and N gene. However, target sequence variations may lead to false negative result.

PERFORMANCE SPECIFICATIONS

1. Detection limitation: 200 copies /mL.

2. Precision: using precision reference CV1 and CV2 for within-batch and between-batch detection, the coefficient of variation (CV) of their Ct values is ≤5.0%.

3. Conformity rate of Negative Control: 100%

4. Conformity rate of Positive Control: 100%

5. Specificity: No non-specific interference of Influenza A Virus (H1N1, H3N2, H7N9, H5N1), Influenza B Virus (Yamagata, Victoria), Respiratory Syncytial Virus (type B), Respiratory Adenovirus (type 3, type 7), Haemophilus influenzae, Staphylococcus aureus, Streptococcus Pneumoniae, etc.

ATTENTIONS

1. Please read this manual carefully before beginning the experiment, and strictly follow the instructions.

2. This product should be only used by trained labor personnel in safety-protected laboratories and wear appropriate protective equipments.

3. This product should be protected from light. Please use sterile, DNase-free, and RNase-free tubes and tips during the detection.

4. The tested specimen of this product is regarded as infectious material.

The operation and treatment should meet the requirements of the local regulations and laws.

CONTACT

Manufacturer: Nanjing Vazyme Medical Technology Co., LTD.

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

Tel: +86 25 8436 5701

Customer Service Provider: Nanjing Vazyme Medical Technology Co., LTD.

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

Tel: +86 25 8436 5701

REFERENCE

Hui DS, I Azhar E, et. al. (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China. *International Journal of Infectious Diseases*, 91, 264-266.

DATE OF APPROVAL AND MODIFICATION OF INSTRUCTION

February 28th , 2020

DATE OF MANUFACTURE AND EXPIRATION

See packaging.

Symbols

EC REP	Authorized Representative
IVD	For in vitro diagnostic use only
-15°C / -30°C	Store between -30 °C~ -15 °C

Σ	Tests per kit
REF	Catalog #
LOT	Lot Number

Vazyme
Nanjing Vazyme Medical Technology Co., LTD.
Building C1-2, Red Maple Park of Technological Industry, Nanjing, China
www.vazymemedical.com

CE
EC REP
Polgen Sp. z o.o. Sp. K.
92-516 Łódź, ul. Puszkina 80, Poland

CD302-02 包装盒与包装箱尺寸与重量

一、英文版包装盒（袋装）

	规格/容量	尺寸（㎜）	净重	毛重
试剂盒	100 人份/袋	170*120*10	13G	29G
打包箱	90 袋/箱	600*500*460	2.6KG	20KG

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-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit

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 8436 5701 Email: global@vazyme.com
Add: Building C1-2, Red Maple Park of Technological Industry, Nanjing, China

Safety Data Sheet (SDS) for 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
According to ISO & SANS 11014:2010 & SANS 10234

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product identifier:

Identification as on the label/Trade name: **2019-Novel Coronavirus (2019-nCoV)Triplex RT-qPCR Detection Kit**

Additional information: Product codes CD302.

Relevant identification uses of the substance and uses advised against: Identified uses:

This product is intended for the detection of 2019-Novel Coronavirus(2019-nCoV).

Uses advised against: Not known.

Details of the supplier of the Safety Data Sheet:

Vazyme medical co., ltd.

Nanjing State Economy & Technology
Development Zone, Red Maple Technology
Industrial Park, building C 1-2, China

Emergency telephone numbers:

400-600-9335 (08:30-17:30 GMT+8)

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substances or mixture:

The mixture is classified according to: SANS 10234:2008, Regulation EC 1272/2008 [EU-GHS/CLP]

Hazard classes/Hazard categories:
Not classified.

Hazard statement:
Not required.

For full text of H-Statements see section 16.

The most important adverse effects:

The most important adverse physiochemical effects:
None. **The most important adverse human health effects:**
None.

Label elements:

Hazard pictograms: Not required.
Signal Words: Not required.
Hazard Statements: Not required.
Precautionary Statements: P264 Wash thoroughly after handling. P270 Do not eat, drink or smoke when using this product.
Special labelling of certain mixtures: None known. **Other hazards:** None known.

Safety Data Sheet (SDS) for 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
According to ISO & SANS 11014:2010 & SANS 10234

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance/Mixture: Mixture
Ingredients: Not hazardous.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available listed in Section 8. For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: FIRST-AID MEASURES

Description of first aid measures:

Most important symptoms and effects, both acute and delayed:

In case of inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. In case of discomfort seek medical attention.
In case of skin contact: Wash off with soap and plenty of water for at least 15 minutes. In case of discomfort seek medical attention.
In case of eye contact: Flush eyes thoroughly with water for 15 minutes. Remove contact lenses after the initial 1-2 minutes and continue flushing. In case of discomfort seek medical attention.
In case of ingestion: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. In case of discomfort seek medical attention.
Inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. In case of discomfort seek medical attention.
Ingestion: Not known.
Skin Contact: Not known.
Eye Contact: Not known.

Indication of any immediate medical attention and special treatment needed:
None known.

SECTION 5: FIRE-FIGHTING

MEASURES Extinguisher media:

Suitable extinguisher media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Prevent contamination of drains or waterways.
Unsuitable extinguishing media: None known.

Special hazards arising from the mixture:
Sealed containers may rupture when heated.

Advice for fire-fighters:
Evacuate area and contact emergency services. Wear full protective equipment including Self Contained Breathing Apparatus (SCBA) when combating fire.

Safety Data Sheet (SDS) for 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
According to ISO & SANS 11014:2010 & SANS 10234

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel: Isolate area. Keep unnecessary and unprotected personnel from entering the area. Refer to Section 7, Handling, for additional precautionary measures. Use appropriate safety equipment. For additional information, refer to Section 8, Exposure Controls and Personal Protection. **For emergency responders:** Isolate area. Keep unnecessary and unprotected personnel from entering the area. Refer to Section 7, Handling, for additional precautionary measures. Use appropriate safety equipment. For additional information, refer to Section 8, Exposure Controls and Personal Protection.

Environmental precautions:
Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Methods for containment and cleaning up:
For small spills: Contain spilled material if possible. Clay, soil or commercially available absorbents may be used, collect in suitable and properly labelled containers.
For large spills: Contain area to prevent spill from spreading. Minimize adverse effects on the environment. Clay, soil or commercially available absorbents.

Reference to other sections:
See section 7 for information on safe handling.
See section 8 for information on personal protection equipment.
See section 13 for information on disposal.

Additional information:
None known.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Protective measures: Observe directions on label and instructions for use. Avoid contact with skin and eyes.
Advice on general occupational hygiene: Do not smoke. Do not eat, drink or smoke when handling this product.

Conditions for safe storage, including incompatibilities:
Store in a cool place. Keep container tightly closed in a dry and well ventilated place.

Specific end uses:
Analytical reagent use only as directed.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL

PROTECTION Control parameters:

Occupational exposure limits: No data available.
Biological exposure indices (BEI): No data available.
Additional exposure limits under the conditions of use: No data available.

Safety Data Sheet (SDS) for 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
According to ISO & SANS 11014:2010 & SANS 10234

Exposure control:

Appropriate engineering controls: Avoid inhalation. Use in well ventilated areas. Where an inhalation risk exists, mechanical extraction ventilation is recommended.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Use safety glasses. If there is a potential for exposure to particles which could cause eye discomfort, wear chemical goggles.
Hand protection: Use chemical resistant gloves. Examples of preferred glove barrier materials include: Butyl rubber, Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, polyvinyl alcohol, Polyvinyl chloride.
Body protection: Not necessary under normal use.
Respiratory protection: If discomfort is experienced, use an approved air-purifying respirator. Respiratory protection should be worn when there is a potential to exceed the exposure limit requirements or guidelines.
Environmental exposure controls: None required.

SECTION 9: PHYSICAL AND CHEMICAL

PROPERTIES Information on basic physical and

chemical properties Appearance (form): Liquid.
Colour: colourless / Light to dark brown suspension.
Odour: Odourless.
Odour threshold: Not known.
pH (concentration): Not known.
Melting point/range (° C): Not known.
Boiling point/range (° C): Not known.
Flash point (° C): Not known.
Evaporation rate: Not known.
Flammability (solid, gas): Not known.
Ignition temperature (° C): Not known.
Upper/lower flammability/explosive limits: Not known.
Vapour pressure (20 °C): Not known.
Vapour density: Not known.
Relative density (25 °C): Not known.
Water solubility (g/l) at 20 °C: Not known.
n-Octanol/Water partition coefficient: Not known.
Auto-ignition temperature: Not known.
Decomposition temperature: Not known.
Viscosity, dynamic (mPa s): Not known.

Physical hazards:

None.

Other information:

Fat solubility (solvent-oil to be specified): Not known
Bulk density: Not known.
Dissociation constant in water (p Ka): Not known.

Oxidation-reduction potential: Not known.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability: Stable under recommended conditions of storage. Product will not undergo hazardous polymerization.
Possibility of hazardous reactions: Hazardous polymerization is not expected to occur.
Conditions to avoid: Do not store next to heat source, in direct sunlight, or elevated storage temperature.
Incompatible materials: Not known.
Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicokinetics, metabolism and distribution:

Non-human toxicological data: No data available
Method: No data available.
Dosage: No data available.
Routes of administration: No data available
Results: No data available.
Absorption: No data available.
Distribution: No data available.
Metabolism: No data available.
Excretion: No data available.

Information on toxicological effects:

Acute toxicity: No data available.
Skin corrosion/irritation: No data available
Skin corrosion/irritation: No data available.
Serious eye damage/irritation: No data available.
Respiratory or skin sensitization: No data available.
Germ cell mutagenicity: No data available.
Carcinogenicity: Not data available.
Reproductive toxicity: No data available.
STOT-single exposure: No data available.
STOT-repeated exposure: No data available.
Aspiration hazard: No data available.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity: No data available.
Persistence and degradability: No data available
Bioaccumulative potential: No data available.
Mobility in soil: No data available.
Results of PBT & vPvB assessment: No data available.

Other adverse effects: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods: Dispose of in accordance with municipal, provincial and national regulations.
Product/packaging disposal: Recycle where possible.

SECTION 14: TRANSPORT INFORMATION

	Land transport (ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not required	Not required	Not required
UN Proper shipping name:	Not required	Not required	Not required
Transport hazard class:	Not required	Not required	Not required
Packaging group:	Not required	Not required	Not required
Marine pollutant:	Not required	Not required	Not required
Special precautions for user:	Not required	Not required	Not required
Transport in bulk according to MARPOL 73/78 Annex II and the IBC code	Not required	Not required	Not required

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation for the mixture:

Relevant information regarding authorization: Occupational Health and Safety Act 1993 Regulation for Hazardous Chemical Substances.

Relevant information regarding restrictions: None known
EU regulations: Regulation EC 1272/2008 [EU-GHS/CLP]
Other National regulations: None.
Chemical Safety Assessment carried out? No.

SECTION 16: OTHER INFORMATION

Indication of changes: GHS aligned.
Relevant classification and H statements (number and full text): None.
Training instructions: Use as instructed.
Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.
Notice to readers: Employers should use this information only as a supplement to other information gathered by them, and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees.

This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

中国认可
检验
INSPECTION
CNAS IB0078

航 空 运 输 条 件 鉴 别 报 告 书

Identification and Classification Report for Air Transport of Goods

非限制性货物
NOT RESTRICTED

报告编号：
Issued No.: PEKSH2020022606 99SN140001

签发日期：
Issued Date: 2020.02.28

委托单位：
Applicant: 南京诺唯赞生物科技有限公司

物品名称：
Name of Goods: CD302 新型冠状病毒（2019-nCoV） 核酸检测试剂盒（三重荧光 RT-PCR 法）
CD302 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit

北京迪捷姆空运技术开发有限公司

Beijing DGM Air Transport Technology Development Co.,Ltd.

报 告 书 使 用 约 定

Terms of the Using of the Report

1. 本公司依据本年度国际航协《危险品规则》以及委托人（托运人或其代理人）提供的物品及其运输信息，确定货物的航空运输条件并出具此报告书。
   The report is issued by DGM China according to IATA ***Dangerous Goods Regulations*** published in the current year and the information of the goods and the information of its shipping provided by the applicant (shipper or his agent).

2. 依据鉴别的需要，本公司要求委托人提供真实、完整的货物样品及资料。
   According to the demand of identification and classification, DGM China requires the applicant to provide true and exact sample and data of the cargo.

3. 委托人保证申报的物品和/或提供的样品与交运的货物是同一种物质。
   The applicant guarantees that the declared goods and/or the sample who provides should be identical with the contents of cargo that is to be transported.

4. 本公司仅对样品的鉴别结果负责。
   DGM China is only responsible for the identification and classification of the sample provided by the applicant.

5. 本报告书经主检员、审核人和批准人签字并加盖本公司印章后生效。
   This report will be effective only after it is signed by the inspector, checker and approver, and stamped by DGM China.

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   This report is only valid within the year in which the IATA ***Dangerous Goods Regulations*** is effective.

地址：北京首都国际机场货运北路天竺综合保税区BGS货运楼249室　　邮编：101300

电话：010-69479673　　传真：010-69479621

网址：www.dgmchina.com.cn　　E-mail: test@dgmchina.com.cn

项目编号 Item No.		PEKSH202002260699		
鉴别目的 Identification Purpose		是否属于航空运输危险物品 Dangerous Goods or not restricted	鉴别日期 Identification Date	2020. 02. 27
鉴别依据 Identification Criteria		IATA DGR 61st, 2020		
物品名称 Name of Goods	中文 Chinese	CD302 新型冠状病毒（2019-nCoV） 核酸检测试剂盒（三重荧光 RT-PCR 法）		
	英文 English	CD302 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit		
生产厂家 Manufacturer		南京诺唯赞生物科技有限公司		
件数 Pieces			注：本栏内容为托运人或其代理人在使用本报告书时候填写的运输信息，不属于鉴定内容。运输信息与报告书的关联性以及实际运输货物与报告书的一致性由托运人或其代理人保证，如发生任何不一致由托运人或其代理人承担全部责任。 （请认真填写本栏内容，并盖章） 负责人： 联系方式：	
运单号 Air waybill No.				
目的港 Destination				
物品信息 Nature of the goods		该样品为试剂盒，盒内含4种(6管)液体试剂，略有气味。 闪点：>80℃。 The sample is a kit containing 4 kinds (6 tubes) of transparent liquid reagents with slight odor. Flash point: >80℃.		

项目编号 Item No.		PEKSH202002260699
物品名称 Name of Goods	中文 Chinese	CD302 新型冠状病毒（2019-nCoV） 核酸检测试剂盒（三重荧光 RT-PCR 法）
	英文 English	CD302 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit
鉴别结论 Conclusions		根据IATA的"Dangerous Goods Regulation"中的标准进行闪点试验，该样品闪点大于80℃，不属易燃液体。 该样品与多种还原剂不发生反应，不属5.1项氧化剂。 该样品与锌、铝等金属不反应，对皮肤无伤害，不属腐蚀品。 根据有关资料和使用经验分析,该物质不会引起人员急性中毒，不属毒害品。 该样品无刺激性、麻醉性，不属第9类危险物品。该样品无其他危险性。 根据DGR特殊规定A3，本品不受限制，即“NOT RESTRICTED,AS PER SPECIAL PROVISION A3”。 The flash point test is operated according to the criteria of IATA Dangerous Goods Regulations, the flash point of this substance is above 80℃. So it does not belong to the flammable liquids. The sample does not react with many deoxidizing materials, so it does not belong to oxidizer of division 5.1. The sample does not react with metals such as Zn or Al and has no harm to skin, so it does not belong to corrosives. According to the experience and the relevant materials, the substance does not cause acute poisoning to human. It does not belong to toxic substance. The sample does not have narcotic, noxious, irritating and other characters to cause extreme annoyance or discomfort to crewmembers and passengers, so it does not belong to miscellaneous dangerous goods. According to IATA DGR, this product can be classified as "NOT RESTRICTED, AS PER SPECIAL PROVISION A3".

建议运输条件 Suggestion for Transport Condition	UN/ID 编号 UN/ID No.	运输专用名称 Proper Shipping Name	类或项 Class or Div. (次要危险性) (Subsidiary Risk)	包装等级 Packing Group
	/	/	/	/

包装说明 Packing Inst.	客货机 Passenger and Cargo Aircraft	/
	仅限货机 Cargo Aircraft only	/
注意事项 Remarks	建议包装符合质检部门或航空公司关于空运包装要求 Packaging is suggested to meet the requirements of Department of Quality Supervision, Inspection and Quarantine or Airline's criteria	

主检员 Prepared by: 审核人 Checked by: 批准人 Approved by:

报告单位（盖章） Stamp

制单： 唐娜斐

CD302

产品	组分	成分含量
新型冠状病毒（2019-nCoV）核酸检测试剂盒（三重荧光 RT-PCR 法） 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit	检测缓冲液 3 支 900ul	RNase free ddH2O 无核酸酶的蒸馏水 dNTPs 脱氧核苷酸 0.01-1% 引物探针0.01-10%
	酶混合液 1 支 400 μl	甘油（CAS:56-81-5）50-60% Taq酶 0.5-1.5mM 逆转录酶10%~20%，UDG酶5%~10% **（生产原料：大肠杆菌（从 takara 宝生物工程大连有限公司购买）** **制备工艺：层析柱纯化蛋白** **除菌操作： 0.22μm 过滤）**
	阳性对照品 1 支 250 μl	甘油（CAS:56-81-5）40-70%， 三羟甲基氨基甲烷（CAS:77-86-1）10-15%， 氯化镁(六水合物， CAS: 7791-18-6）50mM ED-TA乙二氨四乙酸 0.5-1% 含目的基因的RNA假病毒
	阴性对照品 1支 250 μl	DEPC水

该产品的化学成分均为化学合成。其用途为：销售给科研院校实验室及科研单位，是专门快速检测新型冠状病毒核酸的试剂。

以上情况均属实，如有不符，我公司承担相应的法律责任。

南京诺唯赞医疗科技有限公司