Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit

FOSUNPHARMA 复星医药
DIAGNOSTICS 医学诊断

Content

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1 Certificate

NMPA Certificate

English Translated Version

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20203400299

注册人名称	上海复星长征医学科学有限公司
注册人住所	上海市宝山区城银路830号
生产地址	上海市宝山区城银路830号
代理人名称	/
代理人住所	/
产品名称	新型冠状病毒（2019-nCoV）核酸检测试剂盒（荧光PCR法）
包装规格	32人份/盒、48人份/盒、96人份/盒。
主要组成成分	2019-nCoV反应液、RT-PCR酶、2019-nCoV阳性对照、阴性对照、内参A。（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新型冠状病毒感染的肺炎疑似病例、疑似聚集性病例患者、其他需要进行新型冠状病毒感染诊断或鉴别诊断者的咽拭子、痰液样本中，新型冠状病毒（2019-nCoV）ORF1ab和N基因、E基因。
附件	产品技术要求、说明书
产品储存条件及有效期	试剂盒应于-15℃~-25℃条件下避光、密封保存，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. 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：二〇二〇年三月二十四日
有效期至：二〇二一年三月二十三日

国家药品监督管理局 医疗器械注册专用章

PEOPLE'S REPUBLIC OF CHINA

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE (IVD REAGENT)

Registration Certificate No.: GUOXIEZHUZHUN20203400299

Registrant Name	Shanghai Fosun Long March Medical Science Co., Ltd
Registrant Domicile	830 Chengyin Road, Baoshan District, Shanghai
Registrant Address	830 Chengyin Road, Baoshan District, Shanghai
Agent Name	/
Agent Domicile	/
Name of Device	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit
Size	32 tests/kit, 48 tests/kit, 96 tests/kit
Components of Product	2019-nCOV reaction reagent, RT-PCR enzyme, Positive control of 2019-nCOV, Negative control, Internal reference A
Intended Use	The kit is intended for qualitative detection of novel coronavirus (2019-nCoV) ORF1ab, N gene and E gene in throat or sputum samples in suspected pneumonia cases, suspected clustering cases or others who need diagnosis.
Appendix	Product technical requirements, Instruction for Use
Storage & Shelf Life	All reagents should be stored at -15°C~-25°C with protection from light, and the reagents are stable for 6 months (to be determined) when stored at the recommended condition.
Other	/
Notes	The following work should be completed after being listed: 1. The product is the diagnosis and emergency reserve of novel coronavirus (2019-nCOV) pneumonia, and the registration certificate is valid for one year. 2. The enterprise shall complete all registration application materials in accordance with the requirements of in vitro diagnostic reagents registration method when continuing the registration.

Approval Department: National Medical Products Administration

Approval Date: 2020-03-24
Valid To: 2021-03-23

FDA EUA

U.S. FOOD & DRUG ADMINISTRATION

April 17, 2020

Weicheng Wu, Ph.D., RAC
Vice President, Regulatory Affairs
Fosun Pharma USA Inc.
104 Carnegie Center, Suite 204
Princeton, NJ 08540

Device:	Fosun COVID-19 RT-PCR Detection Kit
Company:	Fosun Pharma USA Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

CE Certificate

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: GZ 8821-2020
Order No.: GZ 8776-2020

BELGIUM

Date: 17/03/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: SHANGHAI FOSUN LONG MARCH MEDICAL SCIENCE CO., LTD

ADDRESS: 200444, 830 CHENGYIN ROAD, BAOSHAN DISTRICT, PEOPLE'S REPUBLIC OF CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 16/03/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (2 PAGES, 6 DEVICES)

As of the 17/03/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53 - 1030 Brussels | Registered Office Address: Bd Brand Whitlock 30, B – 1200 Brussels - Belgium
T. + 32 (0) 2 732 5954 | F. + 32 (0) 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net
V3 – ID: 00454716 – 22/02/2019

Order No.: GZ 8776-2020
Ref No.: GZ 8821-2020

Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN/ EDMS Code	Class
1.	PCSYHF	Fosun 2019-nCoV qPCR	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit	This product is intended for the rapid detection of 2019-nCoV by TaqMan multiplex real-time PCR in human throat swab or sputum samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
2	PCSYHG	Fosun FluA/FluB/2019-nCoV qPCR	FluA/FluB/2019-nCoV RT-PCR Detection Kit	This product is intended for the rapid detection of Influenza A virus (FluA), Influenza B virus (FluB), 2019-nCoV by TaqMan multiplex real-time PCR in human nasopharyngeal swabs, throat swab, sputum samples or bronchoalveolar lavage fluid samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
3	PCSYHE	Fosun 2019-nCoV rapid	Novel Coronavirus (2019-nCoV) Real-Time Isothermal Amplification Kit	This product is intended for the rapid detection of 2019-nCoV by real-time isothermal amplification in human nasopharyngeal swabs, throat swab, sputum samples.	15 04 40 90 (Other Virology - NA Reagents)	Others
4	PCSYHB	Fosun RSV rapid	Respiratory syncytial virus Real-time Isothermal Amplification Kit	This product is intended for the rapid detection of Respiratory syncytial virus by real-time isothermal amplification in human nasopharyngeal swabs, throat swab samples	15 04 40 05 (Respiratory Syncytial Virus (RSV) - NA Reagents)	Others
5	PCSYHA	Fosun CP/MP rapid	Chlamydia pneumoniae/ Mycoplasma pneumoniae Real-time Isothermal Amplification Kit	This product is intended for the rapid detection of Chlamydia pneumoniae and Mycoplasma pneumoniae by real-time isothermal amplification in human nasopharyngeal swabs, throat swab samples.	15 01 40 90 (Other Bacteriology - NA Reagents)	Others

6	PCSYHH	Fosun 2019-nCoV IgM/IgG rapid	Novel Coronavirus (2019-nCoV) IgM/IgG test Kit	The product is a solid phase immunochromatographic assay for the rapid, qualitative/ semi-quantitative and differential detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma.	15 04 80 90 (Other Viral Antigen/Antibody Detection)	Others

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.

Signature:

Stamp:

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

ISO 13485

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11323-01-00

Product Service

Certificate

No. Q5 068067 0004 Rev. 01

Holder of Certificate: **Shanghai Fosun Long March Medical Science Co., Ltd.**
No.830 Cheng Yin Road
Baoshan District
200444 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shanghai Fosun Long March Medical Science Co., Ltd.
No.830 Cheng Yin Road, Baoshan District, 200444 Shanghai,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kits, Immunological Diagnostic Kits for the Detection of Infections and Special Proteins, Chemiluminescence Immunoassay Kits, Microbial Detection Kits, Clinical Chemistry Analyzers, Automated Blood Culture Systems, MultiCycler Real-Time Systems, Fully-automatic Chemiluminescence Immunoassay Systems, Production and Distribution of Nucleic Acid Diagnostic Kits**

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.: SH1841711

Valid from: 2019-02-15
Valid until: 2020-12-31

Date, 2019-02-15

Stefan Preiß

TÜV®

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

A4 / 07.17

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。
获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。
その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Exportation of Medical Products

上海市电子证照库
zwdtcert.sh.gov.cn

003157220000884

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号： 沪食药监械出 20200096 号
Certificate NO.: 沪食药监械出 20200096 号

产品名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（荧光 PCR 法）
Product(s): Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit

规格型号：32 人份/盒、48 人份/盒、96 人份/盒
Model: 32 tests / kit, 48 tests / kit, 96 tests / kit

产品注册或备案凭证号：国械注准 20203400299
Registration certificate(s): 国械注准 20203400299

生产企业：上海复星长征医学科学有限公司
Manufacturer: SHANGHAI FOSUN LONG MARCH MEDICAL SCIENCE CO, LTD.

生产企业住所：上海市宝山区城银路 830 号
Address of manufacturer: 830 chengyin road, baoshan district, Shanghai, China

生产许可或备案凭证号：沪食药监械生产许 20020886 号
Manufacturing License(s): 沪食药监械生产许 20020886 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2021 年 03 月 23 日
This certification valid until: Mar, 23, 2021

备注： /
Remark: /

上海市药品监督管理局

2020 年 04 月 02 日
（发证单位盖章）

2 Product Information & Advantages

Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit

- **Packing size:** 32/48/96 tests/kit
- **Specimen type:** nasopharyngeal swabs, throat swabs, sputum or BALF, etc.
- **PCR Instruments :** ABI 7500, LightCycler480, SLAN96, LM2012, etc. with four-channel PCR instrument
- **Detection time:** about 1 hour and 20 minutes
- **Storage and Period of Validity:** -15 ℃ to -25 ℃, 12 months

Detection Principle and Performance Evaluation

- **Detection Principle:**
  - TaqMan real-time PCR technology, FAM channel detect ORF1ab gene, JOE channel detect N gene, ROX channel detect E gene, CY5 channel detect internal control
- **Performance Evaluation:**
  - **Limit of detection:** 300 copies/mL
  - **Precision:** CV of CT value within / between batches is less than 5%
  - **Specificity:** No cross reaction of other related pathogens with the same or similar infection site

Clinical Data

FOSUN	Clinical Diagnostic Results		Total
	Positive	Negative	
Positive	203	14	217
Negative	1	379	380
Total	204	393	597

临床试验总结报告

产品通用名称：新型冠状病毒（2019-nCoV）核酸检测试剂盒（荧光 PCR 法）

临床试验机构：浙江大学医学院附属第一医院

主要研究者：陈瑜

临床试验机构：浙江省疾病预防控制中心

主要研究者：张严峻

临床试验机构：温州市中心医院

主要研究者：唐少华

统计学负责人：金捷

统计学单位：[illegible]科学科技发展有限公司

申办方：[illegible]上海复星长征医学科学有限公司

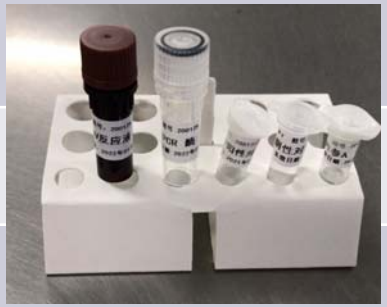
联系人及联系方式：夏熙 18616022301

报告日期：2020 年 3 月 9 日

- Clinical sensitivity = **99.51%**
- Clinical specificity = **96.44%**
- Overall coincidence rate = **97.49%**

Main Components

Component name	Components
2019-nCoV Reaction Buffer	Deoxyribonucleotide, magnesium chloride, 2019-nCoV ORF1ab、E、N gene primer, fluorescence probe
RT-PCR Enzyme Mix	Taq DNA polymerase, reverse transcriptase, UNG enzyme
2019-nCoV Positive Control	Nucleic acid templates
2019-nCoV Negative Control	Normal saline
Internal control A	Nucleic acid templates



Note: the components in different batches of kits can not be interchanged, and the freeze-thaw times shall not exceed 5 times.

Advantages of Novel Coronavirus(2019-nCoV) RT-PCR Detection Kit (Commercial Name: Fosun 2019-nCoV qPCR):

- 1. High sensitivity to minimize false negative rate;
- 2. Detect three target genes at the same time to ensure the accuracy of detection;
- 3. A unique anti-pollution system is adopted to avoid false negative and false positive results at the same time;
- 4. The clinical effect has been fully verified after strict multicenter trials.

Advantages of Novel Coronavirus(2019-nCoV) RT-PCR Detection Kit (Commercial Name: Fosun 2019-nCoV qPCR):

- **The sensitivity of the kit is determined by the LoD. The LoD of Fosun 2019-nCoV qPCR is 300 copies/mL. It means the 2019-nCOV can be detected as long as the concentration of 2019-nCOV in the sample is greater than 300 copies/mL. The LoD of previously marketed products is generally 500-1000 copies/mL.**

- **Under the guidance of "Registration Technology Review Points of 2019-nCOV nucleic acid detection reagent " issued by NMPA, We have completed the registration and submitted the clinical application summary report of Fosun 2019-nCoV qPCR, ensuring the reliability of the test results.**

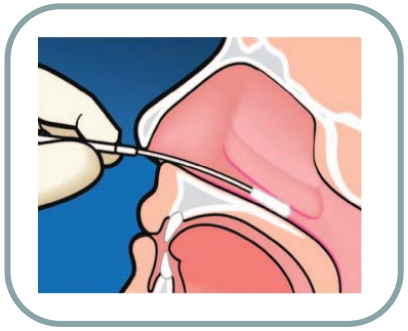
3 Competitive Product Analysis

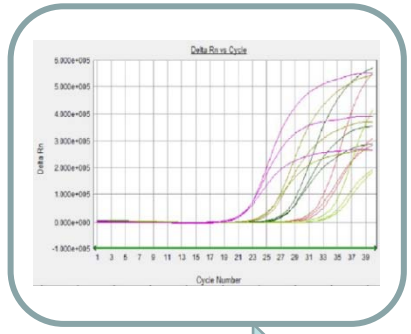
Comparison table

Company	Fosun	Jienuo	Zhijiang	Daan Gene	Sansure	Bojie	BSI
Specimen type	nasopharyngeal swabs, pharynx swabs, sputum, BALF	nasopharyngeal swabs, sputum	pharynx swabs, sputum, BALF	pharynx swabs, sputum	pharynx swabs, BALF	nasopharyngeal swabs, pharynx swabs, sputum	pharynx swabs, BALF
Detection of targets	ORF1ab, N, E genes	ORF1ab, N gene	ORF1ab, N, E genes	ORF1ab, N gene	ORF1ab, N gene	ORF1ab, N gene	ORF1ab gene
TAT	2h	1h	2h	2h	2h	1.5h	3h
Sensitivity	300 copies/mL	500 copies/mL	1000 copies/mL	1000 copies/mL	200 copies/mL	1000 copies/mL	?
Introl Control	Yes	No	Yes	Yes	Yes	Yes	No
UNG Enzyme and dUTP	Yes	No	No	No	No	No	No

4 Workflow

2019-nCoV RT-PCR Workflow





Sample Collection	Nucleic Acid Extraction	PCR Amplification	Results Analysis
10 min	30 min	80 min	

Reagents and Consumables for 2019-nCoV RT-PCR Detection

Sample Collection	Sample preservation	Nucleic acid extraction Kit	Amplification Kit	Real-Time PCR System
Nasopharyngeal Swab	Cell Preservation Solution (Fosun Buffer)	Nucleic Acid Extraction and Purification Kit (Magnetic-bead or Silica membrane based)	Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (Amplification Kit)	X960 Real-Time PCR System
CE Certificate	NMPA Certificate, Preparing to apply for CE certificate	NMPA Certificate, Preparing to apply for CE certificate	NMPA, CE Certificates, FDA EUA	NMPA, CE Certificates

Sample Collection Tool

Cell preservation solution

This product is intended for the collection, preservation and transportation of clinical specimens.

Flocked Swab

This product is intended for the collection of clinical specimens.

Sample Collection Method

- **Nasopharynx swab:** press the nasopharynx swab against the nasal septum and slowly penetrate into the back of nasopharynx, rotate it several times to obtain secretion; quickly immerse the swab into the sample collection tube, discard the tail, and tighten the tube cover to seal to prevent drying.
- **Throat Swab:** Use the plastic rod swab with polypropylene fiber head to wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall at the same time, immerse the swab head into the tube containing physiological saline, discard the tail, and tighten the tube cover.

Sample Collection Method

- **Sputum:** Cough up the sputum in the deep part of the respiratory tract and collect it in the container. Liquefying method: add equal volume of acetylcysteine (10 g/L) into the sputum sample, shake at room temperature for 30 minutes, and then carry out RNA extraction after sufficient liquefying.
- **Bronchoalveolar Lavage:** Collect bronchoalveolar lavage for test.

The sample can be stored for 24 hours at 2~8℃ and for a long time below -70℃. It can also be stored in refrigerator at -20℃ temporarily.

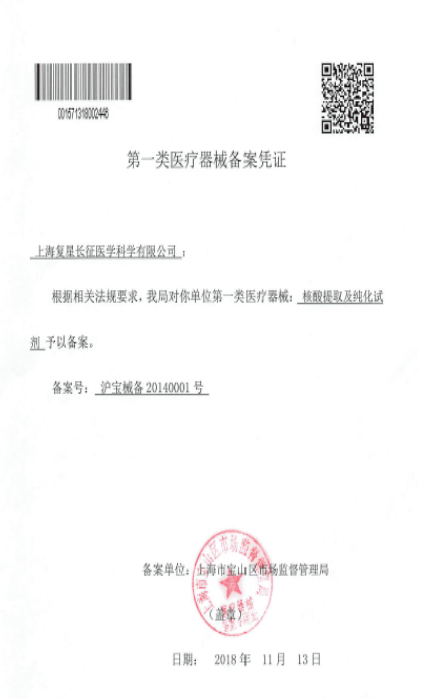
Nucleic Acid Extraction

- It is recommended to use the **nucleic acid extraction and purification reagent (universal)** produced by our company, **QIAamp Viral RNA Mini Kit of QIAGEN**, and **NX-48 Viral RNA Kit of Genolution** for extraction.
- The required sample volume is **200 µL**, and **5 µL** internal control is added to each sample to be extracted (including the controls).
- After extraction, the nucleic acid extract should be added to the reaction tube within 10 minutes or transferred to the centrifuge tube and stored at - 15 ℃ ~ - 25 ℃.

Nucleic Acid Extraction Reagent

External photo of kit

Inside photo of kit



第一类医疗器械备案凭证

上海复星长征医学科学有限公司：

根据相关法规要求，我局对你单位第一类医疗器械：核酸提取及纯化试剂予以备案。

备案号：沪宝械备20140001号

备案单位：上海市宝山区市场监督管理局

日期：2018年11月13日

NMPA Certificate

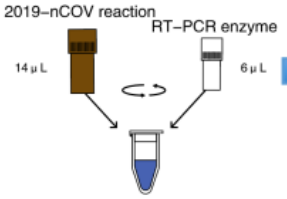
This product is intended for extraction, enrichment and purification of nucleic acids based on silica-membrane absorption method or magnetic-bead method.

Nucleic Acid Extractor

42cm(h)×43cm(d)×45cm(w)

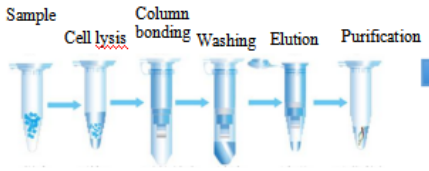
- **备案号：国械备20140202**
- Max sample volume: 1000ul
- Operation time: 35min/batch
- Max number of samples: 32 samples/batch
- Colored touch screen
- Small size, can be used in biosafety cabinet
- Program editing, U disk import and export function
- Adjustable heating function, UV light sterilization with timing switch

2019-nCoV RT-PCR Workflow



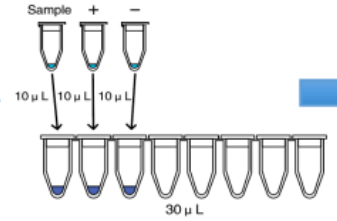
Step 1: Reagent preparation

Add n × 6 μL of RT-PCR enzyme and n × 14 μL of 2019-nCOV reaction reagent into the centrifuge tube, mix by shaking, and centrifugate at low speed for a few seconds, then make aliquots of 20 μL into different PCR reaction tubes.



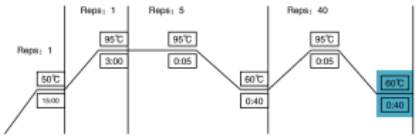
Step 2: Nucleic Acid Extraction

The volume of sample to be extracted is 200 μL, and 5 μl of internal reference A will be added to each sample (including the reference);



Step 3: Template Addition

Add 10 μL of extracted Negative Control, 10 μL of extracted Positive Control, and 10 μL of extracted RNA from sample to different PCR reaction tubes. Centrifuge them at low speed. Then, move them to the Real-time PCR instrument.



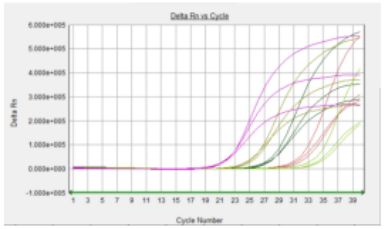
Step 4: PCR Amplification

Step1: 50℃ for 15 minutes, 1 cycle;

Step2: 95℃ for 3 minutes, 1 cycle;

Step3: 95℃ for 5 seconds to 60℃ for 40 seconds, 5 cycles;

Step4: 95℃ for 5 seconds to 60℃ for 40 seconds, 40 cycles. The signals of FAM, JOE, ROX and CY5 fluorescence



Step 5: Data Analysis

Test data file need to be saved after PCR reaction. Please set the parameters and analysis the results of FAM, JOE, ROX and CY5 channels respectively.

Note: The nucleic acid extraction reagent used in Step 2 is not provided in **Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit**, which needs to be purchased by customers separately.

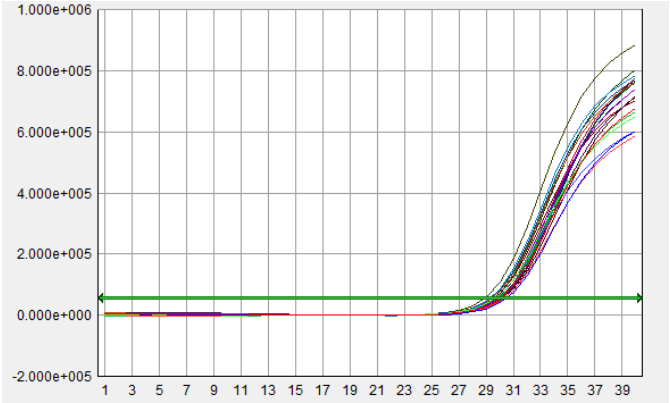
X960 Real time PCR System

- Four fluorescence channels
- 96-well high-throughput block
- Accurate and reliable results
- Long-life LED light source
- Fast heating and cooling ramp rate
- Built-in WIFI module for remote operation
- Exclusive dual-optical path design without interference
- Industrial-grade cooled CCD camera for synchronous signal acquisition

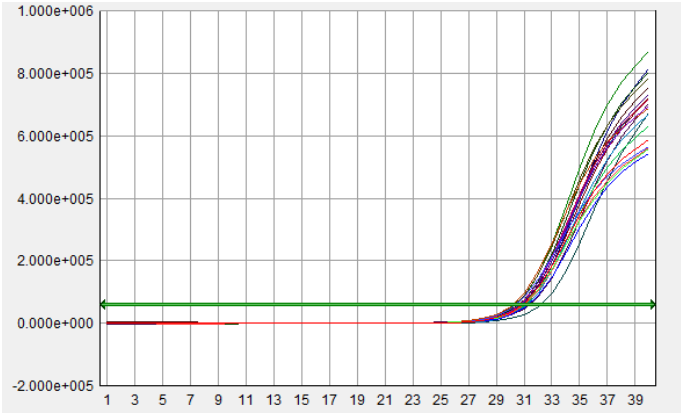
Additional Equipment Required

- Computer and printer required by Real-time PCR analyzer
- Metal Bath
- Mini centrifuge
- High speed frozen centrifuge
- Pipettes(0.5-10ul, 20-200ul, 100-1000ul)
- Vortex
- ……

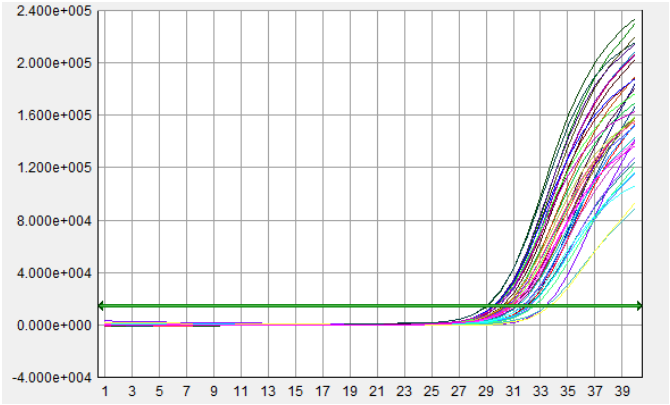

Example of amplification curve of 2019-nCoV nucleic acid detection reagent



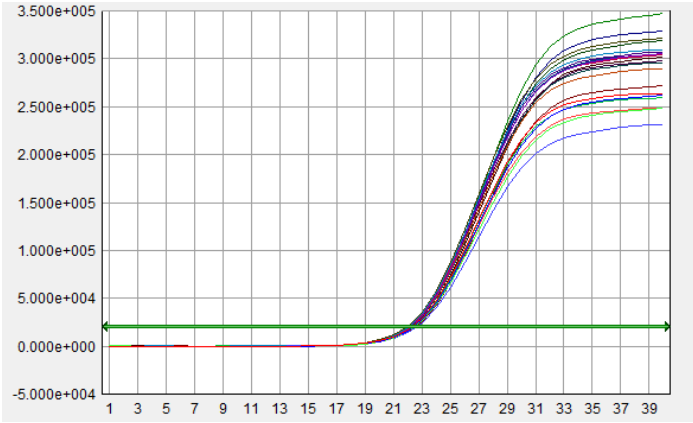
Amplification curve of FAM Channel-ORF1ab Gene



Amplification curve of JOE Channel-N Gene



Amplification Curve of ROX Channel - E Gene in Different Samples



Amplification curve of CY5 Channel-Internal Control

Quality Control

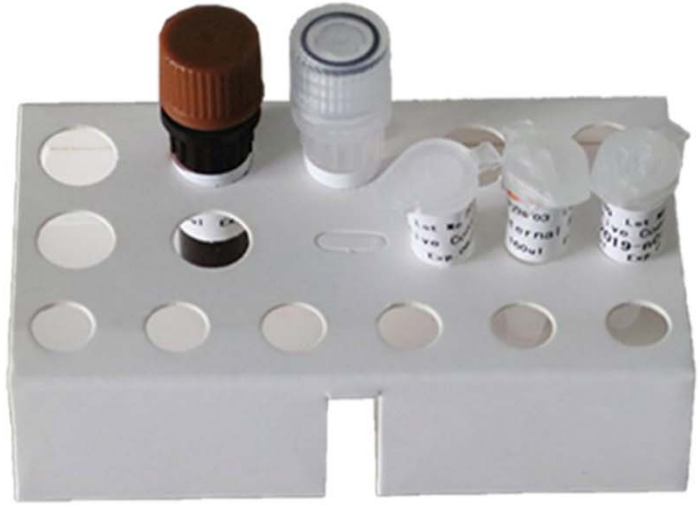
- Negative control and positive control shall be set for each test.
- The test results shall meet the requirements of the table below, otherwise the test is invalid, and the errors of instruments, reagents, amplification conditions, etc. shall be checked, and the experiment shall be repeated.

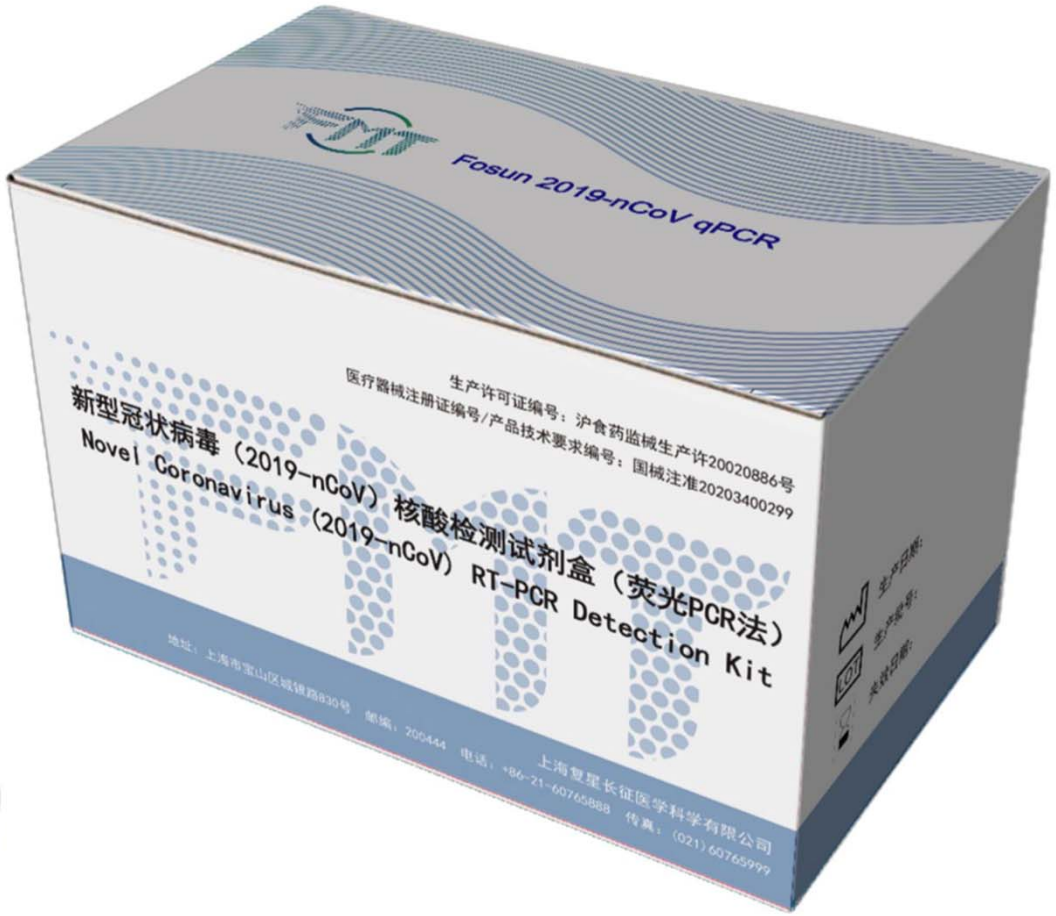
Quality controls	Quality Control Requirements			
	FAM Channel	JOE Channel	ROX Channel	CY5 Channel
Positive Control	Ct≤30	Ct≤30	Ct≤30	CT value is not required
Negative Control	Undet	Undet	Undet	Ct≤32

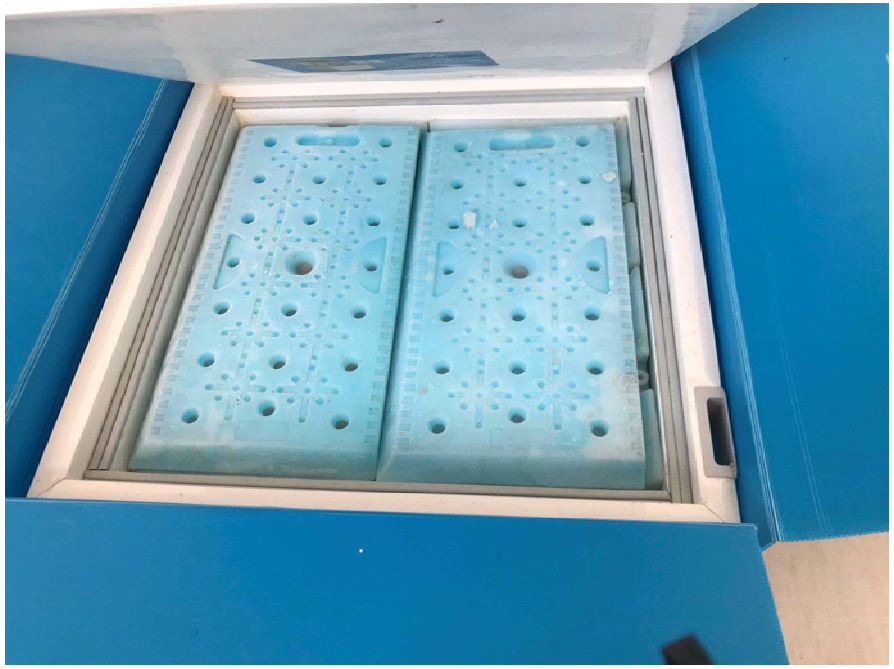
2019-nCoV Results Interpretation

Test Result	Results Interpretation
OrF1ab gene, N gene and E gene have two or more (+)	2019-nCoV (+)
Only ORF1ab gene (+)	If repeat amplification is still positive, 2019-nCoV (+)
Only N gene or E gene (+)	2019-nCoV (-)
ORF1ab gene, N gene and E gene are all (-)	2019-nCoV (-)

5 Packaging and Transportation




Fosun 2019-nCoV qPCR
生产许可证编号：沪食药监械生产许20020886号
医疗器械注册证编号/产品技术要求编号：国械注准20203400299
新型冠状病毒（2019-nCoV）核酸检测试剂盒（荧光PCR法）
Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit
生产日期：
失效日期：
上海复星长征医学科学有限公司
地址：上海市宝山区城银路830号 邮编：200444 电话：+86-21-60765888 传真：(021)60765999



Low temperature transport box					
Volume	28 L	56 L	70 L	97 L	130 L
Length * Width * Height /cm	45.7*45.7*46.7	53.3*53.3*54.3	65.7*53.2*54.2	62.7*62.7*63.7	79.7*61.7*62.7
Net weight /kg	25	40	43	53	52
Capacity	96 kits	203 kits	280 kits	418 kits	560 kits
Time	3 days	3 days	3 days	3 days	3 days
Price /USD	300	360	450	550	600

6 Requirement

Biosafety practices of RT-PCR detection of 2019-nCoV in the laboratory

- Staff are trained for appropriate specimen collection, storage, packaging, and transport.

- All specimens collected for laboratory investigations should be regarded as potentially infectious.

- Specimen handling for molecular testing would require BSL-2 or equivalent facilities.

7 Summary

Summary

- 3 target detection, reduce recheck and improve detection efficiency
- Complete the detection of 96 samples in 2 hours with the automatic extractor
- Internal control, UNG enzyme and dUTP were used to avoid false negative and false positive results
- Reagents have been clinically tested in 3 hospitals, and preliminary results show that reagents are highly sensitive and specific.

Innovation for Good Health!

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