
Novel Coronavir oV)
Nucleic Acid Diagno Kit
(PCR-Fluorescence Probing)
24 tests/kit
圣湘生物
Sansure Biotech
nCoV-PCR
20200016-1
20200301
20200831
-15℃
Keep away
Mix
96μl /tube
Control
500μl /tube
Control
500μl /tube

Inspection Report for 2019-nCoV Diagnostic Kits

543515-01 V02

Inspection Report No.: B-3-2019-nCoV-C-2020016-1

Product name	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Packing volume	24 tests/kit
Quantity of each batch	4948 boxes	Batch No.	**20200016-1**
Inspection request sheet No.	qywbz20200302-01	Date of expiration	08/31/2020 (month/date/year)
Sampling date	03/02/2020 (month/date/year)	Report date	03/02/2020 (month/date/year)
Inspection standard	**313060 Quality Standard for 2019-nCoV Diagnostic Kit**		
Inspection items	Quality standard	Test results	
Visual inspection	Outer packaging box should be intact with clear labels for product name, batch number and shelf life. Tubes inside the box should be intact with clear labels. Product manual inside the box should be clear and complete. When reagents are fully thawed, all solutions should be limpid with no precipitate or suspension.	√ Conformed ___Not conformed	
Quality control test	1 positive control should be tested positive.FAM/HEX/ROX channel with a Ct value ≤ 35. Negative control should be tested repeatedly 8 times.The Ct values for 8 times negative control of FAM/HEX/ROX should not be displayed, or Ct >40.	√ Conformed ___Not conformed	
Consistency rate of positive results	Positive references should be tested positive with a consistency rate of 100% (10/10).	√ Conformed ___Not conformed	
Consistency rate of negative results	Negative references should be tested negative with a consistency rate of 100% (15/15).	√ Conformed ___Not conformed	
Precision	Precision references R1 and R2 should be tested repeatedly 10 times, the CV of Ct should be <5%.	√ Conformed ___Not conformed	
Sensitivity	Sensitivity references S should be tested repeatedly 10 times,which are ≥ 2.0E+02 copies/mL should be tested positive.	√ Conformed ___Not conformed	
Conclusion:	√ qualified ___unqualified		
Tested by: SiHang Wang	Verified by: JiangLing Tang		
QC Manager: ZiHao He 03/02/2020(month/day/year)			
Remarks:			

This report is made in duplicate. One copy is distributed to inspection request dept. and the other one is kept by quality management dept.

People's Republic of China

Medical Device Registration Certificate (In-vitro Diagnostic Reagent)

Certificate Number: National Medical Device Registration No. 20203400064

Name of registrant	Sansure Biotech Inc.
Residence of registrant	No.680, Lusong Road, Hi-Tech Development Zone, Yuelu District, Changsha, Hunan Province, 410205, P.R. China
Production address	No.680, Lusong Road, Hi-Tech Development Zone, Yuelu District, Changsha, Hunan Province, 410205, P.R. China
Name of agent	/
Address of agent	/
Product name	2019-nCov nucleic acid-based diagnostic reagent kit (fluorescent PCR)
Packaging size	24 persons/kit
Main composition ingredient	2019-nCov-PCR-reaction solution, 2019-nCov-PCR-enzyme mixture, 2019-nCov-PCR-positive control, 2019-nCov-PCR-negative control. (see product instruction)
Intended use	This reagent kit is used for in-vitro qualitative test of suspected case of novel coronavirus-caused pneumonia, suspected patient of clustered case, other tests of nasopharyngeal swab or bronchoalveolar lavage containing 2019-nCov virus gene ORF1ab and gene N.
Attachment file	product technical requirements, product instructions
Storage requirements period of validity	Store in dark with temperature of -20±5℃. Provisional validity is 6 months.
Others	/
Notes	Please observe the following instructions after the product goes to market: 1. This product is only for additional diagnosis and emergency storage of 2019-nCov-caused pneumonia, with one-year certificate validity. 2. Registration renewal requires the following clinical trial reports: stats collected from over 3 clinical institutions (including centers for disease control). The clinical stats should be inclusive and the sample size should meet statistical requirement. Proper signature and seal needed. 3. For registration renewal, the registrant should submit all the application materials required by the Provisions for In-vitro Diagnostic Reagent Registration

Approving department: National Medical Products Administration

Approval date: January 28, 2020

Expiration date: January 27, 2021

Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

【 Reference Number 】

S3102E

【 Package Specification 】

24 tests/kit, 48 tests/kit

【 Intended Use 】

Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in pharyngeal swabs and alveolar lavage samples in suspected pneumonia cases with novel coronavirus infection, in patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection.

For in vitro diagnostic use only. For professional use only.

【 Summary 】

The definitions of "suspected cases" and "suspected clusters of patients" shall be defined by referring to the "Pneumonia Diagnosis and Treatment Program for Novel Coronavirus Infection" and "Pneumonia Case Monitoring Program for Novel Coronavirus infection" issued by China CDC (the current version).

Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is only used for the auxiliary diagnosis of related cases and the emergency reserve for in vitro diagnosis during the pneumonia outbreak of novel Coronavirus (2019-nCoV) infection since December 2019, this kit shouldn't be used as routine in vitro diagnostic in clinical practice. Please follow the relevant requirements of the "Pneumonia Diagnosis and Treatment Program for Novel Coronavirus Infection", "Pneumonia Prevention and Control Program for Novel Coronavirus infection" and other documents in use.

The novel Coronavirus nucleic acid tests should comply with "the technical guidelines for laboratory testing of novel Coronavirus of China CDC " and keep good biosafety.

【 Test Principle 】

By applying Real-time fluorescence quantitative RT-PCR technology on the fluorescence quantitative PCR instrument, this test utilizes the novel coronavirus (2019-nCoV) ORF 1ab and the specific conserved sequence of coding nucleocapsid protein N gene as the target regions which are designed for the conserved sequence of the double-target genes, to achieve detection of sample RNA through fluorescent signal changes.

The PCR detection system uses the positive internal control, which monitors the presence of PCR inhibitors in test specimens by detecting whether the internal control signal is normal, to avoid a false negative result.

【 Components of the Diagnostic Kit 】

This kit is an amplification reaction reagent and contains the following components:

No.	Reagent Name	Spec. & Qty.		Main Ingredients
		24 T	48 T	
1	2019-nCoV-PCR Mix	624 μL/ tube x 1	1248 μL/ tube x 1	Premiers(4.62%), Probes(1.15%), dNTPs(3.85%), $MgCl_2$(0.77%), Rnasin(0.48%), PCR buffer(89.13%)
2	2019-nCoV-PCR-Enzyme Mix	96 μL/ tube x 1	192 μL/ tube x 1	RT Enzyme(62.5%), Taq Enzyme (37.5%)
3	2019-nCoV-PCR-Positive Control	500 μL/tube x 1	500 μL/tube x 1	In vitro transcriptional RNA containing target genes (ORF1ab, N gene) and internal standard gene fragments (Rnase P)
4	2019-nCoV-PCR-Negative Control	500 μL tube x 1	500 μL tube x 1	Normal saline

Note:

1. Do not mix or exchange components from different kit lots.
2. All biological samples in the diagnostic kit have been inactivated.
3. Materials required but not provided: 1.5 mL DNase-free and RNase-free centrifuge tubes, 0.2 mL PCR reaction tubes, pipette tips (10 μL, 200 μL and 1000 μL tips with filters are preferred), desktop centrifuge, desktop vortex mixer various models of pipette guns.
4. Self-prepared reagent: Sample Release Reagent(Reference Number : S1014E) manufactured by Sansure Biotech Inc.

【 Storage and Stability 】

1. The diagnostic kit should be stored in a sealed pouch at -20±5°C and protected from light. The kit is provisionally valid for 6 months.
2. Please refer to the date of manufacture and expiry date on the outer package.
3. The reagents keep valid and stable within the expiry date if not used. As long as the container of the reagent is opened, the freeze/thaw cycles should not exceed three.

【 Compatible Instrument 】

The diagnostic kit is applicable to SLAN-96P, ABI7500, Life Technologies QuantStudio TM 5 , Roche Cobas Z480, MA-6000 PCR instrument.

【 Specimen Requirements 】

1. Applicable specimen type: Pharyngeal swab, alveolar lavage fluid.
2. Collection of specimen: Collect sample in accordance with the regular sample collection method, or in accordance with the relevant provisions of "Specimen Collection Method" in the "Pneumonia Laboratory Technical Guide for Novel Coronavirus Infection" in the document of "Pneumonia Prevention and Control Plan for Novel Coronavirus Infection".
3. Storage and delivery of specimens:

Specimens to be tested can be immediately processed, specimens to be tested within 24 hours can be stored at 4℃. Specimens that cannot be detected within 24 hours should be stored at -70℃ or below (in the absence of -70℃ storage conditions, specimens to be tested can be stored at -20℃ for 10 days, nucleic acid can be stored at -20±5℃ for 15 days). Multiple freeze/thaw cycles should be avoided. Specimens should be transported in a sealed frozen pitcher with ice or in a sealed foam box with ice.

【 Test Method 】

1. Preparation of reagent (performed at "reagent preparation region")

1.1 Take out each component from the diagnostic kit and place them at room temperature. Allow the reagents to equilibrate at room temperature, then vortex each of them respectively for later use.

1.2 According to the quantity of test specimens, 2019-nCoV-PCR-Positive Control and 2019-nCoV-PCR-Negative Control, pipette appropriate quantity of 2019-nCoV-PCR Mix and 2019-nCoV-PCR-Enzyme Mix (2019-nCoV-PCR Mix 26 μL/test + 2019-nCoV-PCR-Enzyme Mix 4 μL/test), mix them thoroughly to make a PCR-Mastermix, centrifuge it instantaneously for later use.

	1 sample	10 samples	24 samples	48 samples
2019-nCoV-PCR Mix (μL)	26	260	624	1248
2019-nCoV-PCR-Enzyme Mix (μL)	4	40	96	192
Note: The above configuration is just for your reference and to ensure enough volume of the PCR-Mastermix, more volume of the actual pipetting may be required.				

1.3 Transfer the above-prepared reagents to the "specimen processing region" for later use.

2. Processing and loading of specimens (performed at "specimen processing region")

2.1 Use Sample Release Reagent(Reference Number : S1014E) manufactured by Sansure Biotech Inc. to extract the nucleic acid as per the product manual.

2.2 Add 30 μL PCR-Mastermix into PCR reaction tube with 20 μL above processed sample. Fluorescence quantitative PCR was performed on a fluorescence PCR instrument.

3. PCR Amplification (Refer to user manual of each instrument to adjust the settings.)

3.1 Place PCR reaction tubes into the specimen wells of the amplification equipment. Set up the 2019-nCoV-PCR-Positive Control, 2019-nCoV-PCR-Negative Control and specimens to be tested in the corresponding sequence and input specimen name.

3.2 Select PCR test channel:

a) Select FAM (ORF-1ab region) and ROX (N gene) channels to test 2019-nCoV nucleic acid.

b) Select HEX channel to test internal control.

3.3 Set cycle parameters

	Steps	Temperature	Time	Cycle No.
1	Reverse transcription	50°C	30 min.	1
2	cDNA predenaturation	95°C	1 min.	1
3	Denaturation	95°C	15 sec.	45
	Annealing, extension and fluorescence collection	60°C	30 sec.*	
4	Device cooling	25°C	10 sec.	1

When the settings are completed, save the settings and carry out the reaction procedure.

4. Result Analysis (Refer to user manual of instrument to adjust the settings.)

Results will be saved automatically when reactions are completed. Analyze amplification curve of *target of detection* and internal control. Adjust Start, End and Threshold values of Baseline of the graph according to analysis result (Users can adjust the values according to the actual situation. Start value can be set between 3-15, and End value between 5-20. Adjust the amplification curve of negative control to be flat or below threshold). Click “Analyze” to implement the analysis, make sure each parameter satisfy the requirements given in “5. Quality Control”. Go to “Plate” window to record qualitative results.

5. Quality Control

	2019-nCoV-PCR-Negative Control	2019-nCoV-PCR-Positive Control
Ct value	No Ct or Ct > 40 at channel FAM, ROX and HEX (internal control)	≤ 35 at channel FAM, ROX and HEX (internal control)

The test result is treated as valid if all the conditions in the above-mentioned are met for the same test. Otherwise the test result is treated as invalid and needs to be re-tested.

【 Reference Range 】

Through the research on reference values, the Ct reference value of target gene is determined to be 40, the Ct reference value of internal control is determined to be 40.

【 Explanation of Detection Result 】

Conclusion	Amplification results
2019-nCoV Positive	There is typical S-shape amplification curve detected at FAM or ROX channel, and Ct≤40.
2019-nCoV Negative	There is no typical S-shape amplification curve detected at FAM and ROX channel, that is No Ct. Or there is amplification curve detected at HEX channel, Ct ≤ 40.

There is no typical S-shape amplification curve detected at FAM, ROX and HEX channel (No Ct), or Ct > 40. It is indicated that the specimen’ s concentration is too low, or there are interfering substances that inhibit the reaction. The test result is invalid. An investigation should be performed to find out and exclude the reasons, please collect specimen again and retest the specimens. (If repeated tests still produce invalid results, please contact Sansure Biotech.)

Note: For virus cultures, there is no requirements fpr internal control test results.

【 Limitations of Detection Method 】

1. Test results of the diagnostic kit can be used only for clinical reference. The symptoms and physical signs, disease history, other laboratory examinations and therapeutic reactions of the patients should be comprehensively considered during their clinical diagnosis and treatment.

2.The possibility analysis of false negative results:

2.1 The unreasonable of specimen collection, delivery, processing and specimen in low concentrations may lead to false negative results.

2.2 The mutation in the target sequence of 2019-nCoV novel coronavirus to be measured or the change in the sequence due to other causes may lead to false negative results.

2.3 The unreasonable of reagent storage may lead to false negative results.

2.4 Unverified interferences or PCR inhibitors may lead to false negative results.

2.5 Cross-contamination occurring in the specimen processing may lead to false positive results.

2.6 The clinical laboratory should be equipped with instruments and operators in strict accordance with relevant requirements outlined in local, state and national regulations. Operate in strict accordance with the product manual.

【 Product Performance Index 】

1. Accurancy

Test enterprise positive reference, the results are all positive.

2. Specificity

For Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing), there are also no cross-reaction with coronavirus (NL63, HKU1, 229E,OC43), SARS coronavirus, MERS coronavirus, influenza A virus, influenza B virus Type Yamagata and Type Victoria, influenza A (H1N1) virus, influenza A (H3N2) virus, influenza A (H5N1) virus, influenza A (H7N9) virus, respiratory syncytial virus type A and Type B, nasal virus Type A, Type B and Type C, adenovirus Type 1, 2, 3, 4, 5, 7 and 55, parainfluenza virus Type 1, 2 and 3, intestinal virus type A, type B, type C (EV-C95), type D(EV-D70), partial pulmonary virus, human lung virus, cryptococcus neoformans, pyogenic streptococcus, acinetobacter baumannii, pneumocystis carinii, klebsiella pneumoniae, streptococcus pneumoniae, haemophilus influenzae, pseudomonas aeruginosa, legionella pneumophilia, bordetella pertussis, staphylococcus aureus, mycoplasma pneumoniae pneumonia, streptococcus pneumoniae, klebsiella pneumoniae, chlamydia, EB virus, human cytomegalo virus, aspergillus fumigatus, candida albicans, candida glabrata, mycobacterium tuberculosis, non-tuberculous mycobacterium, norovirus, rotavirus, varicella zoster virus, measles virus, mumps virus, human genome DNA etc. positive samples. Test the enterprise negative reference, the result are all negative.

3. **Limit of detection:** The limit of detection of this kit is 200 copies/mL.

4. **Precision:** The coefficient of variation (CV%) of Ct value of the within-run precision is ≤ 5%.

5. **Possible interfering substances in specimens:** 100 ug/mL hydroxymezoline hydrochloride, 50 ug/mL dexamethasone, 50 ug/mL cefmenoxime hydrochloride, 100 ug/mL oseltamivir, 100 ug/mL zanamivir, 100 ug/mL ribavirin, 100 ug/mL azithromycin, 300U/mL α-interferon, 320 ug/mL budesonide, 125 ug/mL beniferin, 100 ug/mL tobramycin, 50 ug/mL beclometrasone, 100 ug/mL flunicasone, 100 ug/mL momethasone, 200 ug/mL fluticasone, 200 ug/mL histamine dihydrochloride, 100 ug/mL peramivir, 100 ug/mL lopenavir, 100 ug/mL mupiroxacin, 100 ug/mL triamcinolone, 100 ug/mL litonavir, 100 ug/mL abidor, 60 ug/mL sodium chloride, 100 ug/mL urea, 10 ug/mL heme, 20 ug/mL purified mucin, 20%(v/v) anhydrous ethanol, and 20%(v/v) human whole blood have no significant interference with the detection results of the kit.

6. **Clinical evaluation** is based on the recommend method of "Novel Coronavirus Infection Pneumonia Laboratory Testing Technology Guide”, “Novel Coronavirus Infection Pneumonia Cases Monitoring Programme (second edition)" to diagnosis/exclusion result as a comparision, in the Military Cademy of Military Medical Research Institute, Hunan Disease Control and Prevention Center, Hunan Province People's Hospital, Central South University Xiangya 2nd hospital, according to clinical data collected from the four institutions, such as statistical analysis, the preliminary evaluation, basic clinical confirmed the product performance can meet the emergency needs.The types of samples for clinical evaluation included pharyngeal swabs and alveolar lavage.Further clinical data will be collected after marketing to confirm the clinical performance of the product.

【 Precautions 】

1. The product can only be used for in vitro diagnosis. Please read the product manual carefully before operation.

2. Please learn and be familiar with the operation procedures and precautions for each instrument before test. Please make sure quality control for each test.

3. Laboratory management shall strictly follow management practices of PCR gene amplification laboratory, laboratory personnel must receive professional training, test processes must be performed in separated regions, all consumables should be for single use only after sterilization, special instruments and devices should be used for every process, all lab devices used in different processes and regions should not be cross-used.

4. All specimens for detection should be handled as if infectious. Wear laboratory coats, protective disposable gloves and change the gloves often to avoid cross-contamination between samples. Handling of specimens and waste must meet relevant requirements outlined in local, state and national regulations.

5. Note: Improper operation during the storage, transportation and use of the reagent may affect the test results. For example, improper storage and transportation, sample collection, sample processing and test process are not standardized, please strictly follow the instructions.

Due to the characteristics of swab and other sample collection process and viral infection process itself, false negative results may be caused by insufficient sample volume, which should be combined with other clinical diagnosis and treatment information for comprehensive judgment, retest when necessary.

【 Bibliography 】

1. Aslak Widerøe Kristoffersen, Svein Arne Nordbø, Rognlien A G W , et al. Coronavirus Causes Lower Respiratory Tract Infections Less Frequently Than RSV in Hospitalized Norwegian Children[J]. The Pediatric Infectious Disease Journal, 2010, 30(4):279-283.

2. E. Moës, Vijgen L , Keyaerts E , et al. A novel pancoronavirus RT-PCR assay: frequent detection of human coronavirus NL63 in children hospitalized with respiratory tract infections in Belgium[J]. BMC Infectious Diseases, 2005, 5.

【 Symbols 】

Symbols	Meanings	Symbols	Meanings
IVD	In Vitro Diagnostic Medical Device		Date of Manufacture
	Use By		Consult Instructions for Use
	Temperature Limitation		Manufacturer
LOT	Lot Number	REF	Reference Number
Σ	Number of Tests		Any warnings and/or precautions to take

Sansure Biotech Inc.

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For Professional Use Only

IVD

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1998

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: CMB 8764-2020

Order No.:CMB 8723-2020

BELGIUM

Date: 04/03/2020

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: SANSURE BIOTECH INC.

ADDRESS: SANSURE BIOTECH INC.
NO. 680, LUSONG ROAD, YUELU DISTRICT
410205 CHANGSHA 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 02/03/2020 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 (3 PAGES, 10 DEVICES)

As of the 03/03/2020, 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).

Obelis s.a. O.E.A.R.C

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 is not a CE mark and is only provided as a template for informational purposes.

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

6.	S3074E	*Coxsachievirus A6* Real Time RT-PCR Diagnostic Kit (PCR-Fluorescence Probing)	Enterovirus - NA Reagents	The *Coxsachievirus A6* Real Time RT-PCR Diagnostic Kit (PCR-Fluorescence Probing) is an in vitro nucleic acid amplification test for the qualitative detection of Coxsackievirus A6 nucleic acids in clinical throat swab by applying real-time fluorescence quantitative PCR technology. It is intended for use as an aid in the differential diagnosis of patients with suspected pathogens infection. For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: RNA Extraction Solution 1 RNA Extraction Solution 2 RNA Extraction Solution 3 RNA Extraction Solution 4 RNA Elution Buffer CA6 Internal Control CA6 PCR Mix CA6 Enzyme Mix CA6 Positive Control CA6 Negative Control	15.04.40.02	**Others**
7.	S3102E	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Coronavirus - NA Reagents	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood and feces from suspected pneumonia cases with novel coronavirus infection, patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection. For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: 2019-nCoV-PCR Mix 2019-nCoV-PCR-Enzyme Mix 2019-nCoV-PCR-Positive Control 2019-nCoV-PCR-Negative Control	15.04.40.19	**Others**
8.	S1014E	Sample Release Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	The Sample Release Reagent is intended for the pretreatment of the samples to be tested, the substances to be tested in the specimens can be released from the state of combining with other substances to facilitate the use of in vitro diagnostic reagents or instruments to test substances to be tested. Such as folate release agent, vitamin B12 release agent. Components of the Diagnostic Kit: Sample Release Reagent	15.90.40.01	**Others**
9.	S1015E	Sample Release Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	The Sample Release Reagent is intended for the pretreatment of the samples to be tested, the substances to be tested in the specimens can be released from the state of combining with other substances to facilitate the use of in vitro diagnostic reagents or instruments to test substances to be tested. Such as folate release agent, vitamin B12 release agent. Components of the Diagnostic Kit: Sample Release Reagent 1 Sample Release Reagent 2 Sample Release Reagent 3 Sample Release Reagent 4 Sample Release Reagent 5	15.90.40.01	**Others**
10.	X1002E	Sample Storage Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	The sample release reagent is intended for preservation and transportation of cells from human body. For in vitro analysis and testing use only, not for therapeutic use. Components of the Diagnostic Kit: Sample Storage Reagent	15.90.40.01	**Others**

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 074552 0010 Rev. 01

Holder of Certificate: **Sansure Biotech Inc.**
No.680, Lusong Road
Yuelu District
410205 Changsha, Hunan Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Sansure Biotech Inc.
No.680, Lusong Road, Yuelu District, 410205 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of PCR In-vitro Diagnostic Kit, Fully Automated Nucleic Acid Extraction System**

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.: GZ1916111

Valid from: 2019-11-23
Valid until: 2022-11-22

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Sansure Biotech Inc.

No.680, Lusong Road, Yuelu District
Changsha, Hunan Province, P.R. China
Post Code: 410205

Unified social credit code: 91430100673566826X

has established and applies
a Quality Management System for

Design and Development, Production and Distribution of PCR In-vitro Diagnostic Kit, Fully Automated Nucleic Acid Extraction System.

An audit was performed, Order No. **7484120397**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2019-11-23** until **2022-11-22**.

The certified organization shall undergo and pass
the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: **12 100 39661 TMS**.

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Product Compliance Management
Munich, 2019-10-29

IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00