

WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs PUBLIC REPORT

Product: Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)

EUL Number: EUL-0513-200-00

Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) code GZ-D2RM25, CE-mark regulatory version, manufactured by Shanghai GeneoDx Biotechnology Co., Ltd, 1st Floor, Building 3, Juke Bio-Park, 466 Yindu Road Xuhui District, Shanghai, China was listed as eligible for WHO procurement on 11 June 2020.

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the EUL product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	Fulfilment of robustness study post listing commitment for EUL and correction of regulatory version from RoW to CE-mark.	4-Dec-2020

Intended use:

According to the claim of intended use from Shanghai GeneoDx Biotechnology Co., Ltd, “the Novel 2019-nCoV detection kit is used for in vitro qualitative detection of the ORF1ab and N genes of SARS-CoV-2 RNA in nasopharyngeal swabs and sputum specimens of suspected pneumonia cases, suspected cluster cases infected by novel coronavirus, and other patients requiring diagnosis or differential diagnosis of the novel coronavirus infection. The 2019-nCoV detection kit is automated and intended for use with GenAct NE-48 or QIAamp Viral RNA Mini Kit for Extraction/Purification and ABI 7500 Instrument for amplification and detection. The kit is intended for professional use in a laboratory.”

Specimen type that was validated:

Nasopharyngeal swab and sputum specimens

Test kit contents:

Component	50 tests (product code GZ-D2RM25)
COV-Detection buffer D	770µL × 1 vial
COV-Master Mix	350µL × 1 vial
COV-Negative Control	1mL × 1 vial
COV-Positive Control	100µL × 1 vial
COV-Internal Control	100L x 1 vial

Items required but not provided:*Extraction/Purification kits and platforms (systems)*

- Manual nucleic acid extraction kit : QIAamp Viral RNA Mini Kit (50) extraction kit (QIAGEN, article number: 52904).
- Fully automatic nucleic acid extractant GenAct NE-48 (Shanghai GeneoDx Biotechnology Company ; Registration No. 20190001) and its matching reagent VR112 (48 persons) or VR102 (96 persons) (Genolution Article no. : RV1111, Registration No :20162019 ; RV1101, Registration No : 20180041).

General laboratory equipment and consumables:

- Swab specimens with a synthetic tip, such as nylon or Dacron, and an aluminum or plastic shaft. Recommended to use FLOQ Swabs® (COPAN, article number: A305CS01).

- Sample storage reagent is recommended to use Universal Transport Medium (UTM-RT) System (COPAN, article number: 305C).
- B2/A2 Biosafety Cabinet
- Vortex mixer.
- Microcentrifuge.
- Adjustable calibrated micropipettes (2 or 10 µL, 200 µL and 1000 µL).
- Racks for 1.5 mL microcentrifuge tubes.
- Disposable powder-free gloves and surgical gowns.
- Aerosol barrier pipette tips.
- 1.5 mL microcentrifuge tubes (DNase/RNase free).
- 96-well 0.2 mL PCR reaction plates (Applied Biosystems).

Amplification and detection instrument:

- ABI 7500 Instrument with software versions: v1.5.0 or above version.

Storage:

Store all reagents $-20^{\circ}\text{C}\pm 5^{\circ}\text{C}$.

Shelf-life upon manufacture:

6 months, real-time stability study is ongoing.

Warnings/limitations:

Refer to the instructions for use (IFU)

Product dossier assessment

Shanghai GeneoDx Biotechnology Co., Ltd submitted a product dossier for the Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as per the “*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347 version 4)*”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Post listing commitments for EUL:

As commitments to listing, the manufacturer is required to;

1. Determine the limit of detection with the WHO international standard when available.
2. Provide a robustness study report by 31 August 2020. This commitment was fulfilled.

3. Provide both interim and final stability reports by 31 May 2021.

Risk benefit assessment conclusion: acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Shanghai GeneoDx Biotechnology Co., Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that sufficient information was provided by Shanghai GeneoDx Biotechnology Co., Ltd to fulfil the requirements described in the *“Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_ 347 version 4)”*.

Quality management documentation assessment conclusion: acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:

1. Notification to WHO of any planned changes to a EUL product, in accordance with *“WHO procedure for changes to a WHO prequalified in vitro diagnostic”* (document number PQDx_121); and
2. Post-market surveillance activities, in accordance with *“WHO guidance on post-market surveillance of in vitro diagnostics”* (ISBN 978 92 4 150921 3).

Shanghai GeneoDx Biotechnology Co., Ltd is also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensure that post-emergency use listing safety, quality and performance monitoring activities are in place which are in accordance with WHO guidance *“WHO guidance on post-market surveillance of in vitro diagnostics”*.¹

¹ Available on the web page https://www.who.int/diagnostics_laboratory/postmarket/en/

Scope and duration of procurement eligibility

Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) code GZ-D2RM25 manufactured by Shanghai GeneoDx Biotechnology Co., Ltd is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may be used for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the on-going requirements for listing as eligible for WHO procurement, Shanghai GeneoDx Biotechnology Co., Ltd must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. Shanghai GeneoDx Biotechnology Co., Ltd is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days.

WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.

Labelling

1.0 Labels

2.0 Instructions for Use (IFU)

1.0 Outer box label and vial labels

 上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co., Ltd

**Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit
(Real Time PCR)**

REF GZ-D2RM25 (50T) **LOT** nCOV2020xxx **IVD**

COV-Detection buffer D: 770 uL COV-Negative Control: 1 mL
COV-Master Mix: 350 uL COV-Positive Control: 100 uL
COV-Internal Control: 100 uL

2020.xx.xx 2020.xx.xx -25°C -15°C

Shanghai GeneDx Biotechnology Co., Ltd.
1st Floor, Building 3, No. 466 Yindu Road, Xuhui District, Shanghai, China.
021-64960972

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany
DIMDI Code: DE/0000047791

For Emergency Use Only 其他内容详见说明书

CE

JN-W2-2018

上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co.,Ltd
COV阴性质控
COV-Negative Control
Vol: 1mL
Lot#: xxxxxxxxx
Exp: xx. xx. xx -25°C

上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co.,Ltd
COV检测缓冲液 D
COV-Detection buffer D
Vol: 770 μL
Lot#: xxxxxxxxx
Exp: xx. xx. xx -25°C

上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co.,Ltd
COV反应液
COV-Master Mix
Vol: 350 μL
Lot#: xxxxxxxxx
Exp: xx. xx. xx -25°C

上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co.,Ltd
COV阳性质控
COV-Positive Control
Vol: 100 μL
Lot#: xxxxxxxxx
Exp: xx. xx. xx -25°C

上海捷诺生物科技有限公司
Shanghai GeneDx Biotech Co.,Ltd
COV内部质控
COV-Internal Control
Vol: 100 μL
Lot#: xxxxxxxxx
Exp: xx. xx. xx -25°C

2.0 Instructions for use²

² English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)

Instructions for Use

[Product Name]

Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)

[Cat. no.] GZ-D2RM25

[Package] 50T

[Intended Use]

2019-nCoV detection kit is used for *in vitro* qualitative detection of the ORF1ab and N genes of SARS-CoV-2 RNA in nasopharyngeal swabs and sputum specimens of suspected pneumonia cases, suspected cluster cases infected by novel coronavirus, and other patients requiring diagnosis or differential diagnosis of the novel coronavirus infection. The 2019-nCoV detection kit is automated and intended for use with GenAct NE-48 or QIAamp Viral RNA Mini Kit for Extraction/Purification and ABI7500 Instrument for amplification and detection. The kit is intended for professional use in a laboratory.

For the definitions of ‘suspected cases’ and ‘suspected clustered cases’, refer to the documents (current version) such as ‘*Diagnosis and Treatment Plan for Pneumonia Infected by Novel Coronavirus*’ and ‘*Monitoring Plan for Pneumonia Cases Infected by Novel Coronavirus*’ issued by China CDC.

This product is only used in the pneumonia epidemic of SARS-CoV-2 infection since December 2019. The auxiliary diagnosis of related cases and the *in vitro* diagnostic epidemic reserve of this epidemic cannot be used as a conventional *in vitro* diagnostic reagent for clinical application. In use, the relevant requirements of the ‘*Pneumonitis Diagnosis and Treatment Scheme for Novel Coronavirus Infection*’ and ‘*Pneumonitis Prevention and Control Scheme for Novel Coronavirus Infection*’ should be complied. To carry out nucleic acid detection of novel coronavirus, experimenters should conduct biosafety procedures and conform to the requirements of ‘*Technical Guidelines for Laboratory Monitoring of novel coronavirus infected pneumonia*’ by China CDC.

[Principle of the Test]

The assay is based on the real-time polymerase chain reaction (PCR) technology and is composed of a ready to use optimized mixture with target specific primers and Taqman probes for the detection of SARS-CoV-2.

TaqMan probes consist of a fluorophore covalently attached to the 5’-end of the oligonucleotide probe and a quencher at the 3’-end. The quencher molecule quenches the fluorescence emitted by the fluorophore when excited by the cycler’s light source via FRET. As long as the fluorophore and the quencher are in proximity, quenching

inhibits any fluorescence signals.

Degradation of the probe releases the fluorophore from it and breaks the proximity to the quencher, thus relieving the quenching effect and allowing fluorescence of the fluorophore. Hence, fluorescence detected in the quantitative PCR thermal cycler is directly proportional to the fluorophore released and the amount of DNA template present in the PCR.

[Kit Contents]

Component	Inclusions	Color of screw cap	Volume
COV-Detection buffer D	Primers and probes	Blue	770 μ L \times 1
COV-Master Mix	dNTP, enzyme	Yellow	350 μ L \times 1
COV-Negative Control	-	Transparent	1mL \times 1
COV-Positive Control	Plasmid	Purple	100 μ L \times 1
COV-Internal Control	Plasmid	White	100 μ L \times 1

Note: Do not mix the components of kits of different brands and batches.

Reagents and equipment are required but not provided:

- Swab specimens with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Recommended to use FLOQSwabs® (COPAN, article number: A305CS01).
- Sample storage reagent is recommended to use Universal Transport Medium (UTM-RT) System (COPAN, article number: 305C).
- Fully automatic nucleic acid extractant GenAct NE-48 (Shanghai GeneoDx Biotechnology Company; Registration NO. 20190001) and its matching reagent VR112 (48 persons) or VR102 (96 persons) (Genolution Article no. : RV1111, Registration No:20162019; RV1101, Registration No:20180041).
- Manual nucleic acid extraction kit: QIAamp Viral RNA Mini Kit (50) extraction kit (QIAGEN, article number: 52904).
- B2/A2 Biosafety Cabinet
- Vortex mixer.
- Microcentrifuge.
- Adjustable calibrated micropipettes (2 or 10 μ L, 200 μ L and 1000 μ L).
- Racks for 1.5 mL microcentrifuge tubes.
- Disposable powder-free gloves and surgical gowns.
- Aerosol barrier pipette tips.
- 1.5 mL microcentrifuge tubes (DNase/RNase free).

- 96-well 0.2 mL PCR reaction plates (Applied Biosystems).

[Warning and Precautions]

1. This product is intended for *in vitro* diagnostic use only.
2. Read this user manual carefully before using the kit.
3. Detection of viruses and nucleic acids depends on proper sample handling, transportation, preparation, etc. Incorrect collection etc. may cause false negative.
4. The PCR tests should be operated by technical specialist or person with relevant qualifications.
5. The presence of unknown interfering substances or pathogenic microorganisms may lead to incorrect results.
6. Operators should operate in a biosafety laboratory and need to wear protective equipment.
7. This product may contain chemicals that are harmful to the human body or cause discomfort. Avoid direct skin contact during use. If the reagent or sample accidentally comes in contact with the skin, splashes into the eyes, or is inhaled, it should be quickly washed with plenty of water.
8. The experimental instrument shall be used within the validity period of calibration.
9. If the test run is interrupted for some reason, it may affect the results and should be repeated.
10. Before first use please check the product and its components for integrity, completeness, correct labelling and that the kit components are frozen upon arrival.
11. Avoid exposure of the test kit to certain environment (e.g. excessive temperature or humidity) and make sure that it is stored on a flat surface.
12. The internal control only controls for addition of specimen, and not for whether sufficient volume of specimen has been added.
13. All reagent should be fully thawed in room temperature before use, vortexed thoroughly and centrifuged instantaneously at a low speed.
14. Specimens should always be treated as infections and/or biohazardous in accordance with safe laboratory procedures.
15. Components from different lots of reagent kits should not be mixed or pooled (e.g. buffer bottles from different lots should not be exchanged across lots).
16. Repeated thawing and freezing (>3 x) should be avoided. We strongly recommend to discard the rest reagents after three times freeze-thaw.
17. Use separated and segregated working areas for (i) sample preparation, (ii) reaction setup and (iii) amplification/detection activities. The workflow in the laboratory should proceed in unidirectional manner. Always wear disposable gloves in each area and change them before entering a different area.
18. Dedicate supplies and equipment to the separate working areas and do not move

them from one area to another.

19. Avoid microbial and nuclease (DNase/RNase) contamination of the specimens and the components of the kit.
20. Wear protective disposable powder-free gloves, a laboratory coat and eye protection when handling specimens and kit components.
21. Always use DNase/RNase-free disposable pipette tips with aerosol barriers.
22. Do not open the reaction tubes/plates post amplification, to avoid contamination with amplicons.
23. After the test run, properly dispose of the experimental waste. The assay waste should be soaked in 10% sodium hypochlorite solution before discarded. Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.
24. Do not use components of the kit that have passed the expiration date.

[Storage and handling]

The kit should be stored at $-20^{\circ}\text{C}\pm 5^{\circ}\text{C}$, temperature range transportation is $2\sim 8^{\circ}\text{C}$. The validity period is tentatively 6 months.

[Equipment]

ABI7500 Instrument.

ABI software versions: v1.5.0 or above version.

[Specimens]

Nasopharyngeal swab and sputum specimen. Preservation conditions: Specimens should be transported to the laboratory as soon as possible. If specimens cannot be process within 24 hours, they should be stored at $2\sim 8^{\circ}\text{C}$.

It is recommended to store below -70°C for more than 24 hours. Repeated freezing and thawing for more than 5 cycles should be avoided.

[Instructions on Test Procedure]

Step 1. Nucleic Acid Extraction and Preparation (RNA):

- 1.1 Following extraction/purification protocol of the validated platform, 200 μL specimen is needed for nucleic acid extraction.
- 1.2 Automatic nucleic acid extractor is recommended to use (Shanghai GeneoDx NE-48, Registration NO:20190001) and support reagents VR112 (48 Tests) or VR102 (96 Test) (Genolution Article No: RV1111, Registration No:20162019; RV1101, Registration No:20180041).
- 1.3 Manual extraction is recommended to use the QIAamp Viral RNA Mini Kit (50 extraction Kit (Cat. No. 52904, QIAGEN).

Step 2. Preparation of Internal Control (IC):

- 2.1 Thaw COV-Internal Control and COV-Negative Control at room temperature (20°C —25°C).
- 2.2 Mix the COV-Internal Control and COV-Negative Control.
- 2.3 Vortex for 3 ± 1 sec at maximum speed and centrifuge at 2,000 rpm for 10 sec.

Table 1. Volume for IC Preparation for 1 Reaction

Volume of IC preparation for 1 Reaction	
Component (screw cap)	Volume
COV-Internal Control (white)	1.5 μ L
COV-Negative Control (transparent)	3.5 μ L
Total volume	5 μ L

Step 3. rRT-PCR Preparation:

3.1 Preparation of rRT-PCR mix:

Thaw COV-Detection Buffer D and COV-Master Mix at room temperature (20°C —25°C), vortex for 3 ± 1 sec at maximum speed and centrifuge at 2,000 rpm for 10 sec.

Prepare the amplification mix according to table 2 and recommend to keep it on ice.

- 3.2 All reagents need to be inverted for several times to ensure complete thawing and homogenization of the rRT-PCR mix.

Table 2. Volume for 1 Reaction

Component (screw cap)	Volume per Reaction
COV-Detection Buffer D (blue)	13.75 μ L
COV-Master Mix (yellow)	6.25 μ L
Total volume	20 μ L

- 3.3 Pipette 13.75 μ L COV-Detection Buffer D and 6.25 μ L COV-Master Mix into a test tube for one reaction. Place the test tube onto a vortex for 3 ± 1 sec at maximum speed and centrifuge at 2,000 rpm for 10 seconds to make the rRT-PCR mix. Dispense 20 μ l into 0.2ml PCR tubes using barrier filter tips.

Step 4. Adding Specimen

- 4.1 Pipette 5 μ L of each specimen, or internal control, or positive control, and adding into each individual rRT-PCR mix tube using barrier filter tips.
- 4.2 Seal the tubes, place the tubes back on ice after spin and centrifugation.

Step 5. rRT-PCR cycling program:

- 5.1 Place the reaction tubes or plate on PCR instrument, and perform PCR amplification according to the following procedures:
- 5.2 Detection fluorescence selection channel: ORF1ab (TEXAS RED 610), N gene (FAM), IC(CY5).
- 5.3 Sample setting: Fill in the name and type of each sample in the corresponding sample setting window of the software.
- 5.4 Perform PCR amplification according to the following procedures:

Time	Temperature		Comment
5min	50°C		Reverse transcription
20s	95°C		Initial denaturation
10s	95°C	45 cycles	PCR
60s	57°C*		

* Collect fluorescent signals

select the dye to use as the passive reference as 'NONE'

Quencher Option "NONE"

Step 6. Quality Control

The baseline setting takes 6-15 cycles of fluorescence signals. The threshold setting principle is that the threshold line just exceeds the highest point of the negative control amplification curve, and it can also be adjusted according to the instrument noise.

Before interpreting sample results, it is necessary to verify the success of the run. If the following criteria are not satisfied, then testing needs to be repeated:

Control	Target	Detection Channel	Ct Value	
Positive	ORF1ab	TEXAS RED 610	Ct <32	Ct ≥32
		Interpretation	Valid	Invalid
Control	N gene	FAM	Ct <32	Ct ≥32
		Interpretation	Valid	Invalid
Internal Control	GAPDH	Cy5	Ct <35	Ct ≥35
		Interpretation	Valid	Invalid

6.1.1 COV-Positive Control: Pathogen-specific amplification curves should appear for positive quality control. If not, repeat the test run.

6.1.2 COV-Internal Control: The result of IC cannot appear pathogen-specific amplification. Internal control amplification curve should appear and valid, if not, repeat the test run. Internal Control is a plasmid containing human genomic

fragments for quality control if there is the presence of PCR inhibitors during the PCR reaction. The internal control could monitor the efficacy of sampling.

Step 7. Result interpretation

Negative samples shall show internal control amplification curve, otherwise it may indicate that PCR may have inhibitors, and the test run needs to be repeated.

Positive samples may or may not show internal control amplification curve.

Target	Detection Channel	Ct Value		
ORF1ab	TEXAS RED 610	Ct <37	$37 \leq Ct < 40$	Undetermined or Ct =40
	Interpretation	Positive	Indeterminate*	Negative
N gene	FAM	Ct <37	$37 \leq Ct < 40$	Undetermined or Ct =40
	Interpretation	Positive	Indeterminate*	Negative
Internal Control	Cy5	Ct <35	--	Ct \geq 35
	Interpretation	Valid	--	Invalid

* It is recommended to repeat the test run. If the Ct value is less than 37, the assay of the sample is positive, otherwise it is negative.

SARS-CoV-2 nucleic acid test positive interpretation criteria:

Both 2019-nCoV-ORF1ab and N genes were positive in the same specimen;

If one of the two genes are positive and the other is negative, it is recommended to repeat the test. If it is still positive, the sample is considered positive.

[Performance Characteristics]

1. Precision

The precision reference material CV1, CV2 was tested. The result of CV1 should be positive, and the coefficient of variation of Ct value (CV,%) <10.0%. The negative precision reference material CV2 was tested, and results were all negative.

2. Limit of detection (LOD):

The minimum detection limit reference product S was tested, and the test result should be positive for 2019-nCoV.

Limited of Detection: 500 copies/mL

3. Interference substances and cross reactions

3.1 Interfering substance

The following interfering substances have no effect on the detection results of this kit. Endogenous interfering substances: human blood (1% v/v), human mucosal protein (1% v/v), human genome DNA(300ng), nasal spray or nasal drops:

benfolin, hydroxymezolin, sodium chloride (with preservatives)(1% v/v), preservation solution; And exogenous interfering substances: beclomethasone, dexamethasone, fluniconazole, triamcinolone, budesonide, mometasone, fluticasone; Histamine hydrochloride; Interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, litonavir; Mupiroxacin, levofloxacin, azithromycin, cephalosporins, minocycline, aridol, tobramycin.

3.2 Cross Reaction

Inactivated pathogen cultures or nucleic acids that are the same as the sampling site or cause respiratory tract infection were used for testing, and the following pathogens had no effect on the test results of this kit: coronavirus (HKU1, OC43, NL63 and 229E), SARS coronavirus and MERS coronavirus;

H1N1 (new influenza A (H1N1) virus (2009), the seasonal H1N1) and H3N2, H5N1, H7N9, Hib, B, BV, respiratory syncytial virus type A, B, parainfluenza 1/2/3, nasal virus, adenovirus, intestinal virus, human pulmonary virus, Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, such as virus, parotitis virus, varicella - zoster virus; Mycoplasma pneumoniae, chlamydia pneumoniae, legionella, whooping cough bacillus, Hemophilus influenzae, Staphylococcus aureus, streptococcus pneumoniae, streptococcus pyogenes, klebsiella pneumoniae, mycobacterium tuberculosis; Aspergillus fumigatus, candida albicans, candida smooth, cryptococcus neoformans.

4. Clinical Performance

Clinical testing was performed at five clinical Institution of China, 859 effective cases were included in the assessment reagent and comparison reagent statistics, including 606 throat swab samples, 118 nasopharyngeal swab samples and 135 sputum samples.

All specimens were tested with the Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR) produced by Shanghai GeneoDx Biotechnology Co., Ltd. as well as the Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing) (National Device Registration Permission No. 20203400063, approved by NMPA) produced by Da An Gene Co., Ltd. of Sun Yat-sen University used as a comparator.

The calculation of sensitivity and specificity of the 859 effective specimens as following.

Result Description of the Assessment and Comparison Reagent

		Comparison Reagent		Total
		Positive	Negative	
Assessment Reagent	Positive	317	7	324
	Negative	12	523	535

Total	329	530	859
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Statistics of the Assessment and Comparison Reagent

Statistical Indicator	Estimated Value	Standard Error	95%CI	
			Lower Limit	Upper Limit
PPA	96.35%	0.0103	93.73%	97.90%
NPA	98.68%	0.0050	97.30%	99.36%
OPA	97.97%	0.0050	96.57%	98.58%

[Information]



Shanghai GeneoDx Biotechnology Co., Ltd.

Address: Room 236, Area A, 2nd Floor, No. 420, Fenglin Road, Xuhui District, Shanghai, China

Tel: 021-64960972

Postcode: 200231

Fax: 021-64960972

Website: www.geneodx.com

Name of after-sales service: Shanghai GeneoDx Biotechnology Co., Ltd.

Contact:

Tel: 021-64960972

Postcode: 200231

Fax: 021-64960972

Website: www.geneodx.com

Production address: 1st Floor, Building 3, Juke Bio-Park, 466 Yindu Road, Xuhui District, Shanghai, China 200231

Room 201, 203, 2nd Floor, Building 1, Juke Bio-Park, 466 Yindu Road, Xuhui District, Shanghai, China 200231

Room 104, 106, 108, Building 1, 2715 longwu Road, Xuhui District, Shanghai, China 200231

Manufacturing License No.: Shanghai Food and Drug Administration Machinery Production No. 20202655

[Approval date and modification date of the manual] 25th November, 2020

EU representative

Name: Luxus Lebenswelt GmbH

Business Address Kochstr. 1, 47877, Willich, Germany

DIMDI Code: DE/0000047791

Tax Number DE305829099









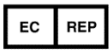

Contact Person Lin Sun

Telephone 0049-1715605732

Website <http://www.ringbio.com>

Email Info.m@luxuslw.de

Explanation of symbols

	CE Mark		Batch number
	Consult instruction for use		IVD product
	Store between -25--15°C		Catalog No.
	Manufacturer		Date of manufacture
	European representative	union	 Expire date