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

Product: Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)
EUL Number: EUL-0492-037-00
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.

Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR) with product code KH-G-M-574-48, Rest-of-World regulatory version manufactured by Shanghai Kehua Bio-engineering Co., Ltd., 1189 North Qinzhou Road, Shanghai, 200233, China was listed as eligible for WHO procurement on 8 June 2020.

Intended use:

According to the claim of intended use from Shanghai Kehua Bio-engineering Co., Ltd, "*the test is used for the manual qualitative detection of SARS-CoV-2 nucleic acid by targeting ORF1ab region, N and E proteins genes of the viral genome in nasopharyngeal specimens from patients with signs and symptoms suggestive of COVID-19 infection. The product is for aiding in the diagnosis of COVID-19 infection by clinical laboratory professionals trained in PCR techniques in a level 2 biosafety laboratory.*"

Specimen type that was validated:

Nasopharyngeal specimen.

Test kit contents:

Component	48 tests (product code KH-G-M-574-48)
SARS-CoV-2 Reagent A	300µL ×1 vial
SARS-CoV-2 Reagent B	400µL ×1 vial
SARS-CoV-2 Reagent C	300µL ×1 vial
SARS-CoV-2 Positive Control	3mL x 1 vial
SARS-CoV-2 Negative Control	3mL x 1 vial

Items required but not provided:

Extraction/Purification:

Extraction reagent:

- Nucleic Acid extraction kit (Catalatalogue No.: KH -G-M-565 -48 -CE) manufactured by Shanghai Kehua Bio-engineering Co., Ltd.

General laboratory equipment and consumables:

- PCR hood PCR.
- Benchtop centrifuge.
- Vortex mixer.
- Transparent Applied Biosystems 7500 Real-Time PCR System Multiwell Plate 96.
- Adjustable calibrated pipettes.
- Disposable gloves.
- RNAse/DNAse filtered pipette tips.
- RNAse/DNAse free microcentrifuge tubes.
- 8-tube strips for real time PCR.

Amplification and detection instruments:

- ABI 7500
- Bio Rad CFX96
- Tianlong Gentier 96 E.

Storage:
Store all reagents below -15°C away from direct light.

Shelf-life upon manufacture:

12 months, real-time stability study is ongoing.

Warnings/limitations:

Refer to the instructions for use (IFU)

Product dossier assessment

Shanghai Kehua Bio-engineering Co., Ltd submitted a product dossier for the Diagnostic kit for SARS-CoV-2 Nucleic Acid (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. Participate in the WHO collaborative study for the assessment of the suitability of an interim standard for SARS-CoV-2 virus nucleic acid amplification tests.
2. Validate a range of Ct values for the IC that mitigates the risk its partial inhibition that masks the inhibition of amplification of SARS-CoV-2 RNA from patient specimens by 31 July 2020.
3. Conduct a precision study that estimates product reproducibility and that includes both the extraction and amplification steps by 31 July 2020.
4. Conduct a further robustness study that investigates operator errors and other human factors like incorrect specimen types by 31 July 2020.
5. Provide a study reports for real time stability and shipping stability studies by 30 April 2021.

Risk benefit assessment conclusion: acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Shanghai Kehua Bio-engineering 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 Kehua Bio-engineering 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)*".

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 Kehua Bio-engineering 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]

Scope and duration of procurement eligibility

Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR) with product code KH-G-M-574-48 manufactured by Shanghai Kehua Bio-engineering 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 Kehua Bio-engineering Co., Ltd must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. Shanghai Kehua Bio-engineering 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.

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

Labelling

1.0 Labels

2.0 Instructions for Use (IFU)

1.0 Outer box label and vial labels

94x64x80mm

Shanghai Kehua Bio-engineering Co., Ltd.

Diagnostic Kit for SARS-CoV-2
Nucleic Acid (Real-time PCR)

REF KH-G-M-574-48

KHB®

KHB 科华生物

CONTENT
1. SARS-CoV-2 Nucleic Acid (Real-time PCR) x 48
2. Instructions for use x 1

/ Production date

LOT / Lot number:

/ Expiry date

-15°C / Store below –15°C

Shanghai Kehua Bio-engineering Co., Ltd.
1189 North Qinzhou Road，200233 Shanghai, P.R. China
Manufacturing address: 701 Guiping Road,200233，Shanghai，P.R. China
Tel: +86 -21-64850088
+86-8008203370
Fax: +86-21-64950975
Website:http://www.skhb.com

Please refer instructions for use IVD

KHB®

Diagnostic Kit for SARS-CoV-2
Nucleic Acid (Real-time PCR)

48 Tests/Kit

Shanghai Kehua Bio-engineering Co., Ltd.

Shanghai Kehua Bio-engineering Co., Ltd.
1189 North Qinzhou Road，200233 Shanghai, P.R. China
Manufacturing address: 701 Guiping Road,200233，Shanghai，P.R. China
Tel: +86 -21-64850088
+86-8008203370
Fax: +86-21-64950975
Website:http://www.skhb.com

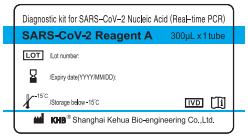
Please refer instructions for use IVD

Σ 48

Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)

20200313
29X17MM

■ K100
■ C100 M5



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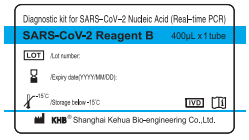

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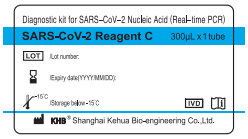

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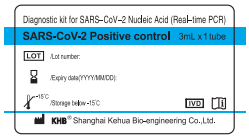

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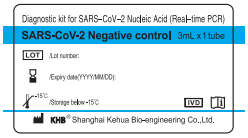

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2.0 Instructions for use[2]

[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.

KHB® IVD

Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)

Instructions for use

REF KH-G-M-574-48（48 Tests）

⚠ ***PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE***

[PRODUCT NAME]

Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)

[PACKING SPECIFICATIONS]

48 T/kit

[INTENDED USE]

The test is used for the manual qualitative detection of SARS-CoV-2 nucleic acid by targeting ORF1ab region, N and E proteins genes of the viral genome in nasopharyngeal specimens from patients with signs and symptoms suggestive of COVID-19 infection. The product is for aiding in the diagnosis of COVID-19 infection by clinical laboratory professionals trained in PCR techniques in a level 2 biosafety laboratory.

[PRINCIPLE OF TEST]

The 3 target sequences for the test are in ORF1ab region, in N and E protein genes of the SARS-CoV-2 genome. Specific primers were designed to amplify highly conservative segments of these 3 regions. Specific labeled probes were designed to hybridize to the amplicons, during the PCR extension step, 5'exonuclease activity of Taq polymerase cuts 5' end fluorophore from the probe, making it free in reaction system, so as to separate from the shielding of 3' end fluorescent quencher, which enables it to accept photo-stimulation to emit fluorescence that can be detected with instruments, so as to detect SARS-CoV-2 nucleic acid automatically in a fully closed reaction system.

Internal control (IC) is designed with a region from a housekeeping gene (beta-actin). Amplification of targets and IC takes place simultaneously in the same reaction. The IC is used for monitoring that the process has proceeded correctly for each specimen.

[WARNINGS AND PRECAUTIONS]

1. To ensure the accuracy and reliability of experimental result, please use a calibrated pipette, select qualified disposable PCR reaction tube, centrifugation tube, tip, etc. for specimen processing and dosing, and all apparatuses should be free of DNA enzyme and RNA enzyme.

2. PCR operators should be trained professionally, with certain experience.

3. During the testing procedure, lab coat, disposable gloves (latex without powder) is indispensable, gloves should be replaced frequently to avoid RNAse contamination and cross contamination between specimens.

4. Good practice of different function zones of the experiment should be strictly followed;

Zone 1: Reagent preparation area-prepare reagent for amplification;

Zone 2: Specimen processing area-process specimen to be detected and control

Zone 3: PCR detection area-PCR amplification detection, articles in each area are exclusive and should not be exchanged in case of cross examination, and upon completion of each experiment, clean the operation table immediately.

5. All reagent should be fully thawed in room temperature before use, vortexed thoroughly and centrifuged instantaneously at a low speed.

6. The specimen should be processed in a biosafety cabinet to protect the operator and prevent environmental contamination.

7. Negative control and positive control should be prepared for each test run, reagents of different lot numbers should not be mixed, and the kit should be used within the shelf life.

8. Avoid bubbles when dispensing extracted nucleic acid into PCR Master mix, and before loading in PCR instrument, check the reaction tubes or plates are correctly capped or sealed to avoid instrument contamination in case of leakage.

9. Once amplification completed, take out the reaction tube or plate, seal it in a plastic bag, and abandon it to the designated area.

10. The tips used during testing should be put in a waste cylinder with 10 % sodium chlorate and disposed with other wastes together.

11. The operation table and various testing equipment should be disinfected with 10 % sodium chlorate, 75 % alcohol and UV lamp.

12. The real time fluorescence PCR instrument should be calibrated frequently, and specimen loading plate orifices should be cleaned.

13. Specimens to be tested by the kit should be deemed to be infectious and be operated and treated according to laboratory inspection procedures for infectious diseases.

[MAIN COMPOSITIONS]

Component	Specifications	Main compositions
SARS-CoV-2 Reagent A	300μl ×1	Buffer, dNTPs, Mg^{2+}
SARS-CoV-2 Reagent B	400μl × 1	Taq polymerase, RNasin, Reverse transcriptase, UNGase
SARS-CoV-2 Reagent C	300μl × 1	Primers and probes
SARS-CoV-2 Positive control	3ml × 1	Armored RNA of ORF1ab/N/E targets
SARS-CoV-2 Negative control	3ml × 1	Storage buffer

Notes: Kit components of different lot numbers are not interchangeable.

[STORAGE CONDITIONS AND SHELF LIFE]

The kit must be stored at -15 °C or colder when not in use and keep away from the light. It has a shelf life of 12 months, and required to be used within the validity period.

[APPLICABLE INSTRUMENTS]

Fluorescent real-time PCR instruments with at least four detection channels (FAM, VIC /HEX, ROX/TEXAS RED, Cy5) such as ABI7500, Bio-Rad CFX96, Tianlong Gentier 96E.

Other ancillary equipment required which are not provided with the kit:

-PCR hood

-Benchtop centrifuge

-Vortex mixer

-Transparent Applied Biosystems® 7500 Real-Time PCR System Multiwell Plate 96

-Adjustable calibrated pipettes

-Disposable gloves

-RNAse/DNAse filtered pipette tips

-RNAse/DNAse free microcentrifuge tubes

-8-tube strips for real time PCR.

[SPECIMENS COLLECTION AND STORAGE REQUIREMENTS]

1. Specimens type: human Oropharyngeal and nasopharyngeal swabs.

2. Specimen collection:

1) Oropharyngeal swab: Wiping bilateral pharyngeal tonsils and posterior pharyngeal wall with two plastic rod swabs with polypropylene fiber head, and immerse the swab head in 3ml virus preservation solution tube, discard the tail, and close the tube.

2) Nasopharyngeal swab: Insert a plastic rod swab with a polypropylene fiber head into the nasal passage gently, turn it slowly then exit. Take another swab and collect from the other nostril in the same way. immerse the 2 swabs head in 3ml virus preservation solution. Discard the tail, and close the tube.

3. Specimen Storage: kept at 2-8 °C for no more than 72h, kept below -15 °C for no more than 3 months, long-term storage if kept below -70°C, but repeated freeze- thaw cycles should be avoided.

4. Specimen transportation: Oropharyngeal and nasopharyngeal swabs specimens can be transported at a storage temperature of 2-8 °C or below -18 °C.

[BIOSAFETY & BIOHAZARD]

Negative human plasma is used in Positive and Negative Controls of the kit. The negative human plasma has been tested by National Medical Products Administration licensed tests for HBV, HCV, HIV-1 nucleic acid, antibody to HCV, antibody to HIV-1, antibody to TP, HBsAg, HBsAb, HBeAg, HBeA and HBcAb, and found non-reactive for any of tested subject. However, no known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. All specimens to be tested and Controls in the kit should be considered infectious substances and operated in strict accordance with laboratory biosafety requirements and Processing, specimen handling and processing must comply with relevant regulatory requirements.

SARS-CoV-2 is considered as high contagious transmissible infection disease agent. During specimens collection, transportation and analysis, aerosol and droplets should be avoided.

Handling of material with high concentrations of live virus (such as when performing virus propagation, virus isolation or neutralization assays) or large volumes of infectious materials should be performed only by properly trained and competent personnel in laboratories capable of meeting additional essential containment requirements and practices, i.e. BSL-3.

SARS-CoV-2 may likely susceptible to disinfectants with proven activity against enveloped viruses,

including sodium hypochlorite (bleach) (e.g. 1,000 ppm (0.1%) for general surface disinfection and 10,000 ppm (1%) for disinfection of blood spills), 62-71% ethanol, 0.5% hydrogen peroxide, quaternary ammonium compounds and phenolic compounds, if used according to manufacturer's recommendations. Other biocidal agents such as 0.05-0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less effective.

[TEST METHOD]

1. For nucleic acid extraction, refer to the instructions of nucleic acid extraction reagent used in combination (For guaranteed optimum results, it is recommended to use the magnetic beads based Nucleic Acid Extraction Kit (Catalogue No.: KH-G-M-565-48-CE) of Shanghai Kehua bio-engineering Co., Ltd). Attention：Positive and negative controls of the Kit must be extracted.

2. Nucleic acid Amplification

2.1 Reagent preparation [reagent preparation area]

2.1.1 Thaw reagent A, B and C of the kit at room temperature, vortex each vial thoroughly, and then centrifuge at 2,000 rpm for 10sec.

2.1.2 Prepare the PCR master mix manually or using automatic liquid transfer platform, and then add the extracted nucleic acid template.

2.1.3 Each PCR Master mix is prepared as follows:

Reagent A	6μL
Reagent B	8μL
Reagent C	6μL
Final volume of PCR Master mix	20μL

2.2 Specimen adding [specimen processing area]

Add 20 μL extracted negative control, positive control and nucleic acid of each specimens into PCR Master mix respectively, with a final volume of 40 μL. Seal the PCR tubes or 96-well plate, centrifuge instantaneously, and then transfer to detection area.

2.3 PCR amplification and fluorescence detection [PCR detection area]

2.3.1 Place the reaction tubes or plate on PCR instrument, and perform PCR amplification according to the following procedures:

2.3.2 Detection fluorescence selection: ORF1ab (FAM), N gene (ROX), E gene (CY5), IC(VIC/HEX).

2.3.3 Specimen setting: Fill in the name and type of each specimen in the corresponding specimen

setting window of the software.

2.3.4 Perform PCR amplification according to the following procedures:

Step		Temperature (℃)	Time	No.of Cycles
1	UNG action	25℃	5min	1
2	Reverse transcription	50℃	25min	1
3	Taq polymerase activation	95℃	10min	1
4	degeneration	95℃	10 sec	5
	annealing	55℃	20 sec	
	extension	72℃	20 sec	
5	degeneration	95℃	10 sec	40
	Annealing, extension and fluorescence detection	60℃	45 sec	
Data acquired at 60℃ of 5th step				

[QUALITY CONTROL]

The SARS-CoV-2 Positive Control and SARS-CoV-2 Negative Control should be included in each run to evaluate run validity. The test run is valid when the 2 criteria listed below are met simultaneously, otherwise the test run is invalid and must be repeated.

1) Negative control: no detection of any of target genes, and the IC Ct value ≤40.

2) Positive control: detection of all 3 target genes, with Ct value ≤40.

For tested specimens without detection of any of 3 targets, the IC Ct value should be <40. If IC value is absent for specimens with negative detection, the specimen result should be qualified as **invalid**. Investigate the reason, and repeat testing the specimen.

[INTERPRETATION OF RESULTS]

1. If two or more targets of ORF1ab, N and E gene are detected, and the curve is of S shape, with a significant exponential growth stage, result can be interpreted as SARS-CoV-2 nucleic acid **positive**.

2. If only one of targets of ORF1ab, N and E gene is detected, the specimen detection should be repeated, and if the repeated detection result indicates more than two targets are detected, and the curve is of S shape, with a significant exponential growth stage, result can be interpreted as SARS-CoV-2 nucleic acid **positive**. If there is still one target detected to be positive, the result is **indeterminate**, and the sequence should be identified with other methods, such as sequencing.

3. If there is no detection of the three channels (ORF1ab, N and E gene), and the IC detection result is

positive. The result can be interpreted as SARS-CoV-2 nucleic acid **negative**.

[LIMITATION OF THE PROCEDURE]

1. The kit is used for qualitative detection of new coronavirus (SARS-CoV-2) nucleic acids in nasopharyngeal swabs specimens, and the results can not directly reflect the viral content in the original specimens.
2. The kit is recommended to be use together with the nucleic acid extraction reagents and supporting equipment from Shanghai Kehua bio-engineering Co., Ltd. If other nucleic acid extraction reagents are used, the whole procedure should be validated first.
3. The primers and probes located at the highly conserved domain of the novel coronavirus (SARS-CoV-2) genome. In rare cases mutations can appear in the virus genome where the primers or probes covered, it may lead to failure of detection of virus RNA.
4. Although the kit adopts UNG-dUTP anti carryover system, which can effectively prevent the contamination of PCR products. However, nucleic acid contamination from the positive controls, or specimens must be controlled by good laboratory practice and careful adherence to the procedures specified in this package insert.

[SPECIFIC PERFORMANCE CHARACTERISTICS]

1. 100 % compliance rate with manufacturer's negative reference QC material.
2. 100 % compliance rate with manufacturer's positive reference QC material.
3. Limit of detection: the LOD was determined at 10 copies/reaction with SARS-CoV-2 nucleic acid reference material from National Academy of Metrology. With 200μl input specimen volume, LOD at 150 copies/ml was validated for nasopharyngeal swab specimens.
4. Repeatability: two manufacturer's high and low positive reference QC materials tested 10 times consecutively, CV of Ct value≤ 5% for each specimens.
5. Reproducibility: 2 specimens constituted by dilution of SARS-CoV-2 nucleic acid reference material from National Academy of Metrology were tested by two operators, each operator perform one run per day for 5 days with 5 replicates of each specimen per run. Variabilities of Ct values were less than 5%.

Specimen	Target	Within day		Between day		Within operator		Between operator		Total	
		SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
J1	ORF1ab	0.33	1.1%	0.68	2.3%	0.76	2.6%	0.15	0.5%	0.77	2.7%
	N	0.19	0.7%	0.50	1.6%	0.54	1.7%	0.00	0.3%	0.54	1.8%
	E	0.19	0.7%	0.50	1.9%	0.54	2.0%	0.00	0.0%	0.54	2.0%
J2	ORF1ab	0.58	1.9%	0.66	2.1%	0.87	2.8%	0.23	0.7%	0.90	2.9%
	N	0.39	1.3%	0.27	0.9%	0.47	1.6%	0.06	0.2%	0.47	1.6%
	E	0.32	1.1%	0.44	1.5%	0.54	1.9%	0.00	0.0%	0.54	1.9%

6. Cross Reaction

The specimens containing following microorganisms or nucleic acids produced negative results when tested:

Microorganisms		
Adenovirus	*Candida albicans*	Human coronavirus 229E
Human Metapneumovirus	*Haemophilus influenzae*	Human coronavirus OC43
Parainfluenza virus	*Legionella pneumophila*	Human coronavirus HKU1
Rhinovirus	*Mycobacterium tuberculosis*	Human coronavirus NL63
Chlamydia pneumonia	*Staphylococcus aureus*	SARS-coronavirus
Influenza A virus (H1N1)	*S.pyrogenes*	MERS-coronavirus
Influenza B virus	HPV	*Streptococus pneumonia*
RSV	HSV	*Bordetella pertussis*
EV71	CMV	*Mycoplasma pneumoniae*
CA16	HEV	*Pneumocystis jirovecii* (PJP)
		Pooled human nasal wash
		MS2 phage RNA

7. Clinical performance

The clinical performance of Diagnostic Kit for SARS-CoV-2 Nucleic Acid (Real-time PCR) was established using 274 oropharyngeal swab specimens (in swab storage buffer) collected from 2 sites in Italy. The comparator method was an in-house real-time PCR method of Italian CDC for site A and the CE-Marked PCR kit from AB Analitica company for site B. The results are summarized in table below and demonstrated a PPA of 100% and NPA of 88.08%.

Specimens		Reference PCR result		Totals
		Positive	Negative	
KHB PCR result	Positive	123	18	141
	Negatives	0	133	133
Totals		123	151	274

Positive Agreement Rate: 123/123×100%＝100% (95% CI: 97.05% ~ 100.00%);

Negative Agreement Rate: 133/151×100%＝88.08 % (95% CI: 81.82% ~ 92.78%);

The limit of detection (LOD) and the clinical performance of Diagnostic Kit for SARS-CoV-2 Nucleic Acid (Real-time PCR) were also independently evaluated by FIND at the Hôpitaux Universitaires de Genève. The LOD analysis was performed using cultured viral stocks from a clinical isolate from Switzerland, and quantified using an E gene standard. The clinical performance analysis was conducted on extracted specimens from individuals suspected to have SARS-CoV-2 that were tested using an in-house PCR protocol that was optimized based on the Tib Molbiol assay. The evaluation results demonstrated 100% of both specificity and sensitivity for the Diagnostic Kit for SARS-CoV-2 Nucleic Acid (Real-time PCR).

Product name	Gene target	Verified LOD (copies / reaction)	Avg Ct (lowest dilution 10/10)	Clinical sensitivity (50 positives)	Clinical specificity* (100 negatives)	PCR platform
KHB Diagnostic kit for SARS-CoV-2 Nucleic Acid (Real-time PCR)	ORF1	1–10	30.39	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	BioRad CFX96 deep well
	N	1–10	32.95	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	
	E	1–10	31.72	100% (95%CI: 93, 100)	100% (95%CI: 96, 100)	

[REFERENCES]

1. Laboratory testing for 2019 novel coronavirus (SARS-CoV-2) in suspected human cases: World Health Organization; 2020.

2. Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV): Interim Recommendations WHO; 28 February 2020

3. PCR Protocols and Applications: A Laboratory Manual, Academic, New York, Innis, M.A., et al., 1989.

4. Detection of Respiratory Viruses by Molecular Methods. Clinical Microbiology Reviews. Mahony JB. 2008.21(4):716-747.

5. Administrative measures for clinical gene amplification Laboratory of medical institutions. NO.194 General Office of the Ministry of Health.

Key symbols used

	**Caution**		**Temperature limit (≤-15℃)**
	**Batch code**		**Date of manufacture**
	**In vitro Diagnostic use** **Medical device**		**Consult instructions for use**
	**Catalogue number**		**Do not use if package is damaged**
	**Use by**		**Contains sufficient for "n" tests**
	**Do not re-use**		**Biological risks**
	**Manufacturer**		**Keep away from sunlight**

Manufacturer：Shanghai Kehua bio-engineering Co., Ltd
Registered address： Qinzhou North Road 1189, 200233, Shanghai，P.R. China
Manufacturing address: Guiping Road 701, 200233, Shanghai，P.R. China
Postal code: 200233
Telephone：+86-21-64850088, +86-8008203370
FAX：+86-21-64950975
Service Hotline：+86-8008203370, +86-4009201238
Website: http://www.skhb.com