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

Product: PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay
EUL Number: EUL-0501-192-00
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.

PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay with product code SY580, CE-mark regulatory version manufactured by PerkinElmer Inc, SYM-BIO LiveScience Co., Ltd**,** 115 North Taiping Road, Taicang, China was listed as eligible for WHO procurement on 24 April 2020.

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the product listed under EUL 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 and closure of precision and specimen stability studies commitments for EUL.	22-Jul-2020

Intended use:

According to the claim of intended use from PerkinElmer Inc, "*the PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay is an in vitro nucleic acid amplification test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in human oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.*

SARS-CoV-2 RNA is generally detectable in human oropharyngeal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of presence of SARS-CoV-2 RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information."

Specimen type(s) that were validated:

Oropharyngeal swab and Nasopharyngeal swab specimens

Test kit contents:

Component	**48 tests (product code SY580)**
nCoV reagent A	1 vial x 950 µL
nCoV reagent B	1 vial x 230 µL
nCoV enzyme mix	1 vial x 170 µL
nCoV internal control	1 vial x 390 µL
nCoV positive control	2 vials x 1.4 mL
nCoV negative control	2 vials x 1.4 mL

Items required but not provided:

Extraction/Purification:

Extraction reagent: PerkinElmer Nucleic Acid Extraction Kits, with product code KN0212. If other nucleic acid extraction reagents are used, they must first be verified before use.

Extraction/purification instruments and software:

- Chemagic 360 instrument and software.
- Pre-NAT II Automated Workstation and Software.

Amplification and detection instruments:

Real Time PCR Instruments with FAM, HEX/VIC and ROX Channels,

- Applied Biosystems 7500 Real-Time PCR System (4351104 with Laptop, 4351105 with desktop) and software version 2.3.
- SLAN 96P/96S and supporting software.

Storage:
Store all reagents at -25 to -15°C.

Shelf-life upon manufacture:

12 months, real-time stability study is ongoing.

Warnings/limitations:

Refer to the instructions for use (IFU)

Product dossier assessment

PerkinElmer Inc submitted a product dossier for PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347 version 3)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external product evaluating committee (PEC) assessor appointed by WHO.

Post listing Commitments for EUL:

1. As a requirement to listing, the manufacturer is required to 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. A precision study report to be submitted to WHO by 30 June 2020. Commitment was fulfilled and closed on 16 July 2020.
3. A specimen stability study report to be submitted to WHO by 31 July 2020. Commitment was fulfilled and closed on 16 July 2020.
4. An analytical specificity study report to be submitted to WHO by 31 October 2020.
5. A robustness study report to be submitted to WHO by 31 October 2020.
6. For the on-going real time stability study: 3-month interim results and the final study report within one month of completion (expected August 2021).

Risk benefit assessment conclusion: acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, PerkinElmer Inc 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 and external technical experts (assessors), it was established that sufficient information was provided by PerkinElmer Inc to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_ 347 version 3)*".

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).*

PerkinElmer Inc 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 sales data will serve as denominator data to guide the frequency of re-inspection.

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

The PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay with product code SY580 manufactured by PerkinElmer Inc 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 2019 novel coronavirus (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, PerkinElmer Inc must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. PerkinElmer Inc is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days.

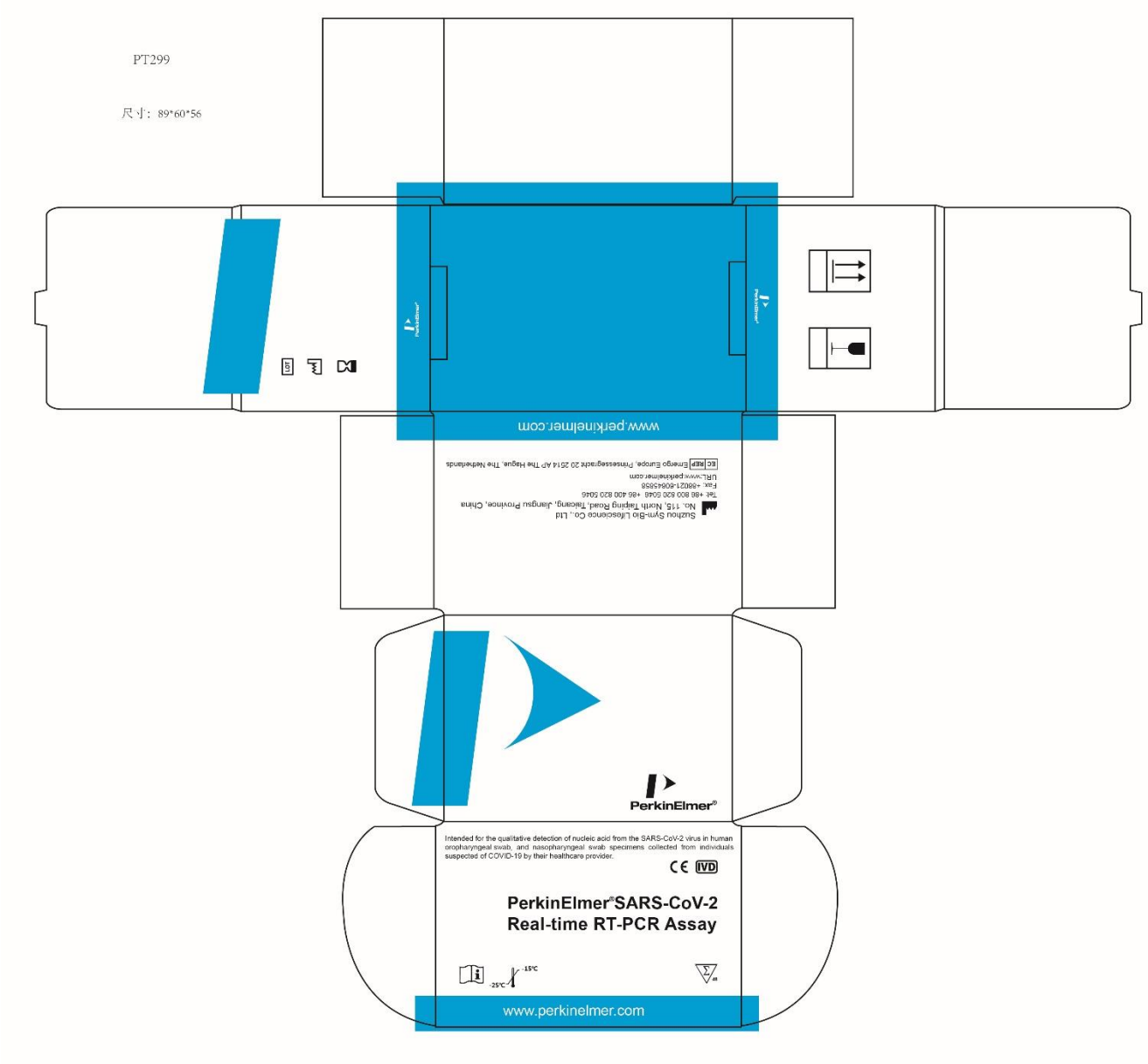
WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.

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

Labelling

1. Labels

Labelling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EC REP Emergo Europe, Prinsessegracht 20 2514 AP The Hague, The Netherlands
PerkinElmer®
Intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in human oropharyngeal swab, and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.
CE IVD
PerkinElmer® SARS-CoV-2
Real-time RT-PCR Assay
-25°C -15°C
www.perkinelmer.com

25*15mm

nCoV Reagent A

LOT

950μL

nCoV Reagent B

LOT

230μL

nCoV Enzyme Mix

LOT

170μL

nCoV Internal Control

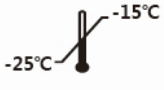
LOT

1.4mL

nCoV Negative Control

LOT

1.4mL



nCoV Positive Control

LOT

1.4mL

2. 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.

Instructions for **PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay**

Suzhou Sym-Bio LifeScience Co., Ltd

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*Sym-Bio is a PerkinElmer company

PerkinElmer Healthcare
Diagnostics (Shanghai) Co., Ltd.

1670 Zhangheng Road,
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Distributed by

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Prinsessegracht 20 2514 AP The Hague, The Netherlands

Key to symbols used

CE	European conformity
IVD	In vitro diagnostic medical device
-15℃ -25℃	Store at -25℃ to -15℃
	Consult instructions for use
	This way up
	Recyclable
Σ n	Contains sufficient for (n) test
REF	Catalogue number
LOT	Lot number
	Manufacturer
	Use by date
	Fragile
EC REP	Authorized Representative in the European Community
	Date of manufacture
D	Distributed by

Product Name

PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay

Kit Contents

48 Tests

Intended Use

The SARS-CoV-2 Real-time RT-PCR Assay is an *in vitro* nucleic acid amplification test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in human oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

SARS-CoV-2 RNA is generally detectable in human oropharyngeal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of presence of SARS-CoV-2 RNA. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Principles of the Assay

The SARS-CoV-2 Real-time RT-PCR Assay uses TaqMan-based real-time PCR technique to conduct *in vitro* transcription of SARS-CoV-2 RNA, DNA amplification and fluorescence detection.

The Assay targets at the specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene and ORF1ab. The TaqMan probes for the two amplicons are labeled with FAM and ROX fluorescent dyes respectively to generate target-specific signal.

The assay includes an RNA internal control (IC, bacteriophage MS2) to monitor the processes from nucleic acid extraction to fluorescence detection. The IC probe is labeled with VIC fluorescent dye to differentiate its fluorescent signal from SARS-CoV-2 targets.

The assay also uses a dUTP/UNG carryover prevention system to avoid contamination of PCR products and subsequent false positive results.

Kit Components

Component	Volume		Ingredients
nCoV Reagent A	950 µL	×1 tube	PCR Buffer, dNTPs, Mg^{2+}
nCoV Reagent B	230 µL	×1 tube	TE Buffer, primers, probes
nCoV Enzyme Mix	170 µL	×1 tube	Taq DNA polymerase, MMLV, RNasin, UNG
nCoV Internal Control	1.4 mL	×1 tube	TE Buffer, bacteriophage MS2
nCoV Positive Control	1.4 mL	×2 tube	SARS-CoV-2 RNA capsulated in bacteriophage
nCoV Negative Control	1.4 mL	×2 tube	TE Buffer

Notes: **1)** *The reference materials and other components in the kit should be treated as potential sources of infection.* **2)** *The use of this kit should be strictly in accordance with the nucleic acid amplification guidelines to operate in compliance with the requirements of the appropriate laboratories.* **3)** *The components in different batches of the kit cannot be used interchangeably.*

Materials Required but not Provided

1. **Extraction reagents**
   It is recommended to use PerkinElmer Nucleic Acid Extraction Kits (e.g. KN0212). If other nucleic acid extraction reagents are used, they must be verified before use.
2. **Instrument and software**
   Chemagic™ 360 instrument and software
   Pre-NAT II Automated Workstation and software
   Real-time PCR instruments with FAM, HEX/VIC and ROX channels (e.g. Applied Biosystems™ 7500 Real-Time PCR System, SLAN 96P/96S) and supporting software.

Storage and Handing Requirements

1. Store the reagents at -25℃ to -15℃.
2. Use the reagents within 12 months from its production, expiration date is stated on kit and component labels.
3. Use the reagents within 30 days once open.
4. Completely thaw the reagents before use, do not freeze-thaw the reagents more than 6 times, avoid excessive freeze/thaw cycles for reagents.
5. The reagents must be transported via cold chain and are stable while transportation time is within 6 days.

Collection, Storage and Shipment of Specimens

1. **Specimen Collection**
   Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 3 ml of viral transport media. For initial testing, nasopharyngeal swab specimens are recommended. Collection of oropharyngeal swabs is a lower priority and is acceptable if other swabs are not available.
   - Nasopharyngeal swab (NP): Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.
   - Oropharyngeal swab (OP): Swab the posterior pharynx, avoiding the tongue.
2. **Storage**
   Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.
3. **Shipping**
   Specimens PUI's must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation External Icon. Store specimens at 2-8°C and ship overnight to the lab on ice pack. If a specimen is frozen at -70°C ship overnight to the lab on dry ice. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).
4. **For more information, refer to:**
   - Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)
     https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
   - Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)
     https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html

Assay Procedure

1. **Nucleic acid extraction** (in Specimen Preparation area)

1.1 Take out nCoV Internal Control, nCoV Positive Control and nCoV Negative Control, completely thaw them at room temperature, vortex mix, then centrifuge the tubes at low speed for a few seconds to collect the liquid to the bottom of the tubes.

1.2 Add 5 µL Internal Control to 400 µL specimens, Positive Control and Negative Control, then proceed to nucleic acid extraction according to kit instructions.

2. **PCR setup** (in Pre-PCR area)

2.1 Take out nCoV Reagent A and nCoV Reagent B from the kit, and completely thaw them at room temperature before use. Votex mix the reagents and centrifuge them at low speed for a few seconds to collect the liquid to the bottom of the tubes.

2.2 Prepare PCR mix according to the following table. Positive and Negative Controls should be considered when preparing a batch of PCR mix.

Component	Volume
nCoV Reagent A	15 µL / test × n
nCoV Reagent B	3 µL / test × n
nCoV Enzyme mix	2 µL / test × n
Total	20 µL / test

2.3 Aliquot 20 µL of PCR mix into each PCR tubes.

2.4 Add 40 µL of extracted nucleic acid into each tube containing PCR mix, close the tube lids (or seal PCR plates with appropriate film), slightly vortex the tubes and briefly centrifuge them to get rid of bubbles. Transfer the tubes to PCR area.

3. Amplification (in PCR area)

3.1 Place the PCR tubes from step 2.4 in a real-time PCR instrument.

3.2 Set thermal cycling conditions as following for PCR amplification and fluorescence detection.

Step	Temperature	Time	Number of Cycles
1	37°C	2 minutes	1
2	50°C	5 minutes	1
3	42°C	35 minutes	1
4	94°C	10 minutes	1
5	94°C	10 seconds	45
	55°C	15 seconds	
	65°C *	45 seconds	

* Detect fluorescence signal during the final 65°C step.

Set fluorescence channels as below:

Analyte	IC	N	ORF1ab
Detection channel	VIC or HEX	FAM	ROX

IC: Internal Control;
ORF1ab: SARS-CoV-2 ORF1ab target;
N: SARS-CoV-2 N target.

4. Data Analysis

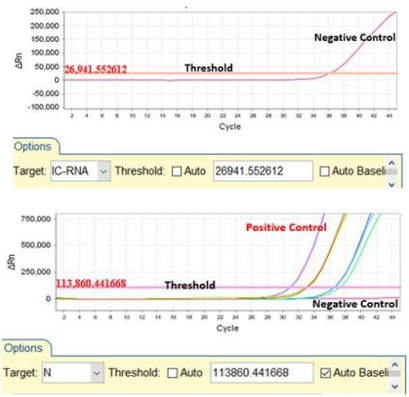
After the run completion, save and analyze the data according to PCR instrument instructions.

4.1 Set baseline for each target

View the baseline values, in the Graph Type drop-down list, select "Linear". Select the Baseline check box to show the start cycle and end cycle. The horizontal part of the baseline is used for the baseline range, which normally starts from 3-5 cycles and ends at 15-20 cycles. Baseline setting is normally automatically done by instrument. It can also be manually adjusted to choose the horizontal part of the curve.

4.2 Set threshold for each target

View the threshold values, In the Graph Type drop-down list, select "Linear". In the Target drop-down list, select N, ORF1ab or IC. Select the Threshold check box to show the threshold. Thresholds should be adjusted to fall within exponential phase of the fluorescence curves and above any background signal (refer to the two figures below). The threshold value for different instruments varies due to different signal intensities.



4.3 Perform data analysis by clicking "Analyze" button of the software.

4.4 Output the data to csv file by the "export" function of the software.

4.5 Interpret the results based on the tables listed in "Quality Control" and "Examination and Interpretation of Specimen Results".

5. Quality Control

The product provides negative control, positive control, and internal control to monitor the reliability of the results for the entire batch of specimens from sample extraction to PCR amplification. Test results from Positive Control and Negative Control should be examined prior to interpretation of specimen results. Positive control and negative control should meet the requirements listed in the below table to ensure valid results. If the controls are not valid, the specimen results cannot be interpreted.

Control	Ct		
	N (FAM)	ORF1ab (ROX)	IC (HEX/VIC)
Negative	Undet or > 42	Undet or > 42	Ct ≤ 40
Positive	≤ 35	≤ 35	/

Undet: Undetermined;
/: No requirements on the Ct value;
Negative Control: both ORF1ab and N of SARS-CoV-2 must be not detected, and the Ct value of internal control should be ≤40;
Positive Control: both ORF1ab and N of SARS-CoV-2 must be detected and their Ct values should be ≤35, the Ct value of internal control does not have to be ≤40 for positive control.

6. Examination and Interpretation of Specimen Results

Assessment of clinical specimen test results should be performed after the positive and negative controls have been examined and confirmed to be valid and acceptable. If the controls are not valid, the specimen results cannot be interpreted.

The table below lists the expected results for the kit with valid positive control and negative control:

Ct		Result interpretation
IC (VIC/HEX)	N (FAM), ORF1ab (ROX)	
≤40	Both targets Undet or >42	SARS-CoV-2 not detected
/	Both targets ≤ 42	SARS-CoV-2 detected
/	One of the targets ≤ 42	Specimen needs to be re-tested from re-extraction
>40 or Undet	Both targets Undet or >42	Invalid result, specimen needs to be re-tested from re-extraction or re-collected from patient for test.

Undet: Undetermined;
/: No requirements on the Ct value;

Limitations

1. This kit is used for qualitative detection of SARS-CoV-2 RNA from human oropharyngeal swab and nasopharyngeal swab. The results cannot directly reflect the viral load in the original specimens.
2. This kit is only applicable to specimen types described in the Intended Use section. Testing other types of specimen may cause inaccurate results. The specimens to be tested shall be collected, processed, stored and transported in accordance with the conditions specified in the instructions. Inappropriate specimen preparation and operation may lead to inaccurate results.
3. The PerkinElmer Nucleic Acid Extraction Kit (KN0212), Chemagic™ 360 instrument and Pre-NAT II Automated Workstation are recommended for nucleic acid extraction. If other nucleic acid extraction reagents or equipment are used, they must be verified before use.
4. Applied Biosystems® 7500 Real-Time PCR instrument and SLAN 96P/96S are recommended for nucleic acid amplification. Other nucleic acid amplification instruments should be verified before use.
5. The limit of detection (LoD) is determined based on a 95% confidence of detection. When SARS-CoV-2 presents at or above the LoD concentration in the test specimen, there will be a low probability that SARS-CoV-2 is not detected. When SARS-CoV-2 presents below the LoD concentration in the test specimen, there will also be certain probability that SARS-CoV-2 can be detected.
6. When determining LoD of this kit, encapsulated SARS-CoV-2 RNA particles were used, and the copy number of the RNA was determined by droplet digital PCR. The results are only applicable to this kit, and the copy numbers defined by other methods are not necessarily equivalent.
7. Primers and probes for this kit target highly conserved regions within the genome of SARS-CoV-2. Mutations occurred in these highly conserved regions (although this is rare) may result in RNA being undetectable.
8. This kit uses an UNG/dUTP PCR products carryover prevention system, it can effectively prevent contamination caused by PCR products. However, in the actual operation process, only by strictly

following the instructions of PCR laboratories can PCR contamination be avoided.

9. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other management decisions.
10. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutics or immunosuppressant drugs have not been evaluated.
11. Laboratories are required to report all positive results to the appropriate public health authorities.

Assay Performance

1. **Limited of Detection**
   LoD of this kit was determined to be 20 copies/mL**.**
2. **Precision**
   Two samples with encapsulated RNA targets at 7× LoD and 70× LoD were tested in 10 experiments over 5 days with 4 replicates of each sample in each experiment. the coefficient of variation (CV%) of the Ct values for these two samples are ≤5%.
3. **Analytical specificity**
   Human coronavirus (229E, OC43), SARS coronavirus (plasmid), MERS coronavirus (plasmid), adenovirus (type 2, 3, 31, 37 and 51), enterovirus (type A and D), rhinovirus (type A and B), influenza A virus (H1N1, H1N1-2009, H3N2), influenza B virus, respiratory syncytial virus, parainfluenza virus, measles virus, Mumps virus, human cytomegalovirus, Chlamydia pneumoniae, Mycoplasma pneumoniae, Hemophilus influenzae, Staphylococcus aureus, Streptococcus pyogenes, Streptococcus saliva, Hepatitis A virus, Hepatitis B virus, Hepatitis C virus, Epstein-Barr virus, herpes simplex virus type I, herpes simplex virus type II, human immunodeficiency virus type I (HIV-1), human immunodeficiency virus type II (HIV-2) and human genomic DNA were tested using this kit. The results were all negative for SARS-CoV-2, no cross-reactivity was found with these pathogens or DNA.
4. **Interfering substance**
   The following interfering substances were added to negative sample and positive sample with encapsulated target RNA at 3× LOD concentration: hemoglobin, bilirubin, human serum albumin, triglycerides, valacyclovir, entecavir, adefovir, ribavirin, and acyclovir, azithromycin, clarithromycin, ciprofloxacin, telbivudine, efavirenz, tenofovir, saline, beclomethasone propionate, dexamethasone acetate, flunisolide (USP Standard), triamcinolone tablets, budesonide, mometasone furoate, fluticasone propionate, oxymetazoline hydrochloride, sulfur ointment, pharyngitis lozenges, chlorhexidine benzocaine, menthol, zanamivir (USP standard substance), mupirocin, tobramycin, rheumatoid factor, systemic lupus erythematosus positive specimens, antinuclear antibodies, these samples were then tested using this kit. The positive samples with encapsulated RNA at 3× LOD all showed results of SARS-CoV-2 detected, while the negative samples all showed results of SARS-CoV-2 not detected, indicating that the above interfering substances do not affect the performance of the kit.

Precautions

1. This product is only used for in vitro diagnosis. Please read this instruction carefully before starting an experiment. The kit is limited to those who have been trained in PCR laboratory and who are proficient in PCR experimental skills.
2. Keep the kit upright during storage and transportation.
3. Before using the kit, check tubes for leakage or damage. Each component in the kit should be thawed at room temperature, thoroughly mixed and centrifuged before use.
4. Cross-contamination may occur when inappropriate handling of reference materials and specimens, which will cause inaccurate results. It is recommended to use sterile disposable filter-tips to aspirate reagents and specimens.
5. All specimen to be tested and the reference materials of the kits should be considered as infectious substances and processed strictly in accordance with laboratory biosafety requirements. Sterile centrifuge tubes and filter-tips should be used. After use, the tips should be disposed into a waste bin containing a 10% sodium hypochlorite solution. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% sodium hypochlorite solution, and then cleaned with 75% ethanol or pure water. Finally, turn on UV light to disinfect working surfaces for 30 minutes.
6. The PCR instrument used for this assay should be calibrated regularly according to instrument's instruction to eliminate cross-talks between channels.
7. This kit uses PCR-based technology and experiments should be conducted in three separate areas: reagent preparation area, specimen preparation area, amplification area. Protective equipment accessories (goggles, work clothes, hats, shoes, gloves, etc.) should be worn during operation and protective equipment accessories should be changed when entering and leaving different work areas. Protective equipment accessories in each work area must not be used crosswise.

References

1. Laboratory testing for 2019 novel coronavirus (SARS-CoV-2) in suspected human cases, World Health Organization, 2020.
2. Innis MA et al, PCR protocols – A guide to methods and applications,1990.
3. Mahony JB. Detection of respiratory viruses by molecular methods. Clinical Microbiology Reviews. 2008, 21 (4): 716-747.
4. China CDC Virus Disease Control and Prevention. Novel coronavirus nucleic acid detection primer and probe sequences (Specific Primers and Probes for Detection Novel coronavirus 2019) [EB / OL]., 2020-01-21.
5. Chinese Center for Disease Control and Prevention. Guidance for laboratory testing techniques for pneumonitis associated with novel coronavirus infection (the 7th edition).

Basic Information

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Approval Date and Revision Date of Package Insert

2020-03-29 V2

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