SKANDA
GROUP OF INDUSTRIES

presents

1copy™

Molecular Diagnostics

1copy™ COVID-19 qPCR Multi kit

Global Mobile Healthcare Leader through Innovative Technology

1copy™

www.1copy.com

1copy™

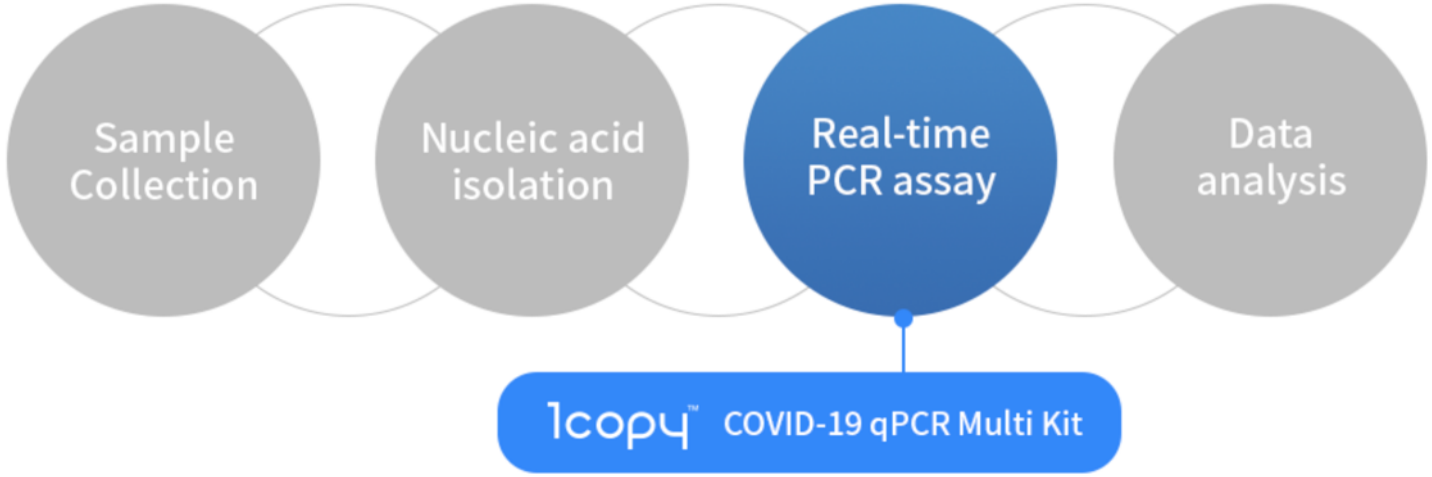
Molecular Diagnostics

1copy™ COVID-19 qPCR Multi kit

www.1copy.com

1Copy™ Technology

COVID-19 qPCR Multi Kit?



This kit allows qualitative detection of genes (E gene and RdRp gene) of COVID-19 with real-time qPCR (including reverse-transcription reaction) via RNA extracted from a specimen(Nasopharyngeal swab, Oropharyngeal swab) of suspected respiratory infectious disease patient.

www.1copy.com

1Copy™ Technology

SKANDA
GROUP OF INDUSTRIES

Single virus level Limit of detection

1copy™ COVID-19 qPCR Multi Kit can reduce the risk of asymptomatic and latent infection of COVID-19 by a single virus level limit of detection.

	RdRp gene Detection rate	E gene Detection rate
10^3 copies	100%	100%
10^2 copies	100%	100%
10 copies	100%	100%
8 copies	100%	100%
4 copies	98%	97%
2 copies	90%	87%
1 copy	78%	64%
0 copy	0%	0%

www.1copy.com

Short measurement time

1copy™ COVID-19 qPCR Multi Kit has a short measurement time that less than 2 hours.

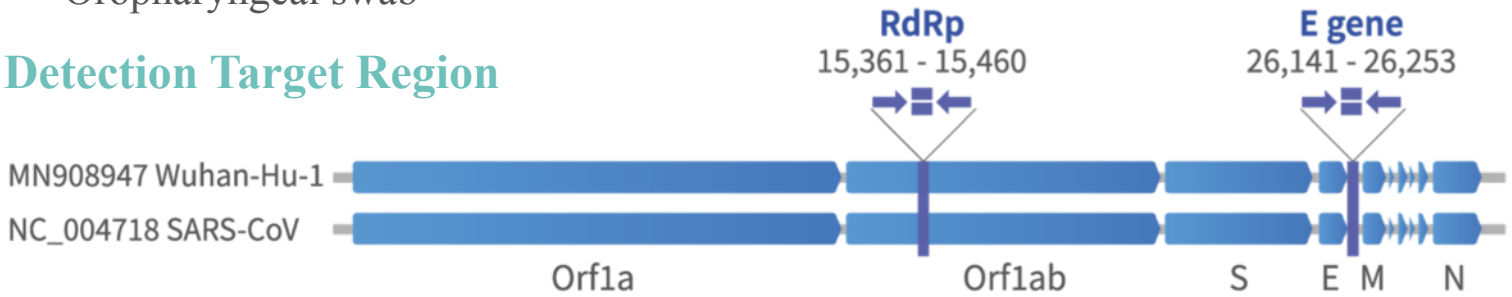
	1copy™ COVID-19 qPCR Multi Kit
Total measurement time	1hour 50minutes
Hands-on time	20 minutes

COVID-19 Detection System

Specimen Type

- Nasopharyngeal swab
- Oropharyngeal swab

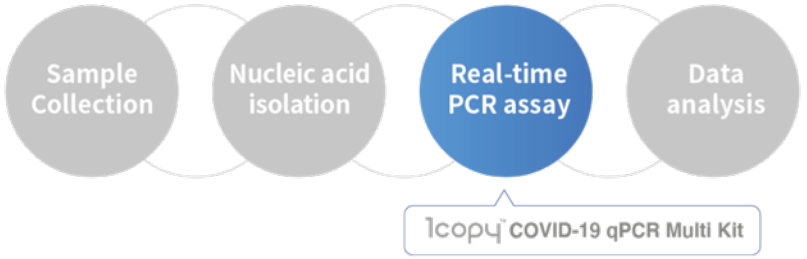
Detection Target Region



Real-time PCR instruments

- Roche Light Cycler® 480
- Qiagen Rotor-Gene® Q 5plex HRM
- Applied Biosystems® Quantstudio5
- Applied Biosystems® 7500 Real-Time PCR system
- Bio-Rad CFX96™ Real-Time PCR Detection system

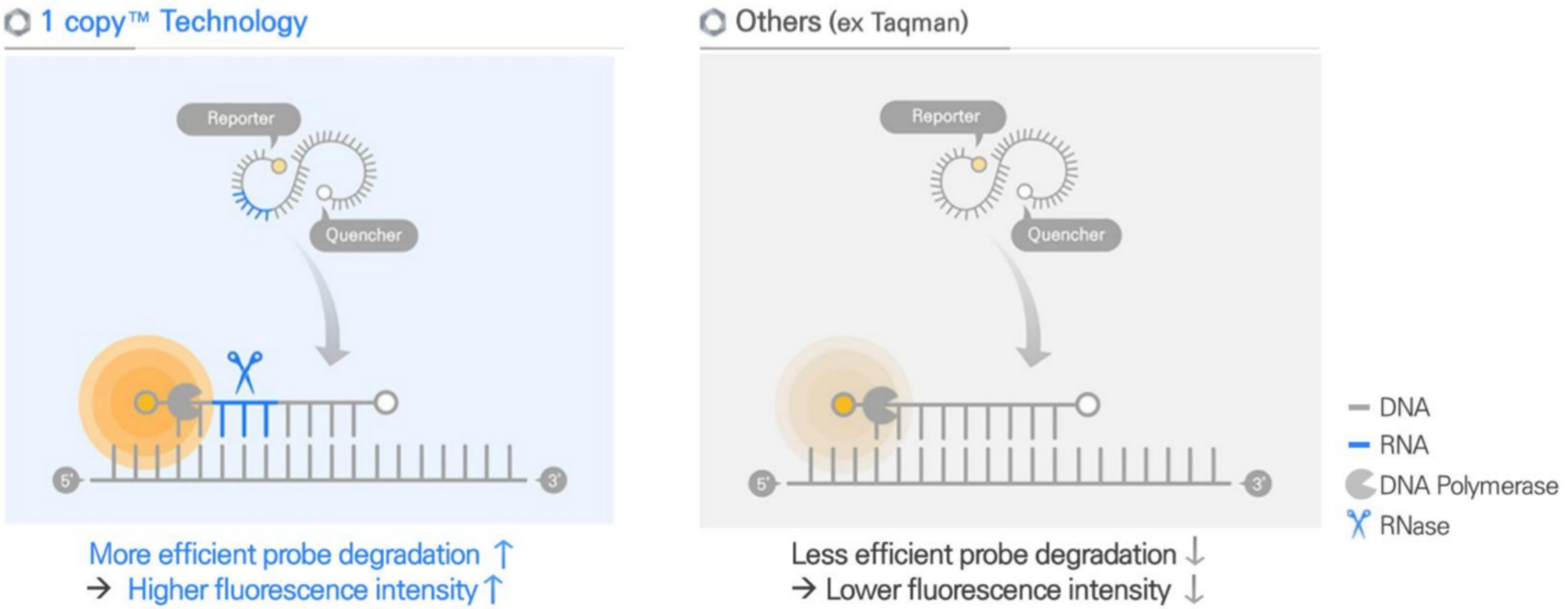
Process



www.1copy.com

1Copy™ Technology

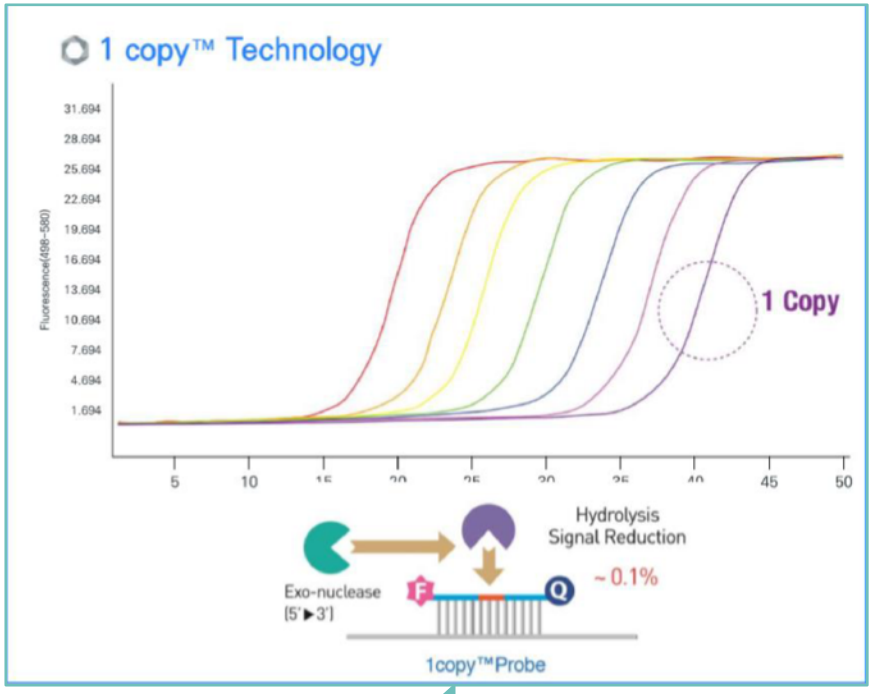
Catacleave (DNA-RNA-DNA Hybrid probe) + RNase(Thermo-stable, Hot-start)

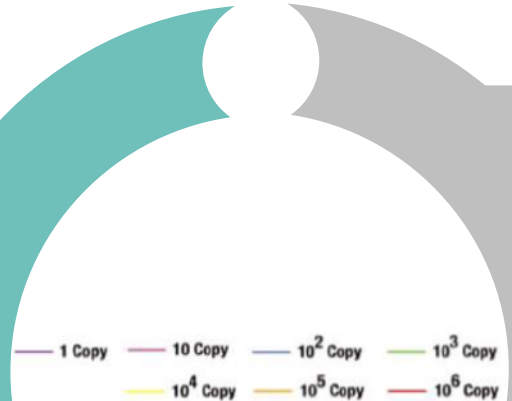


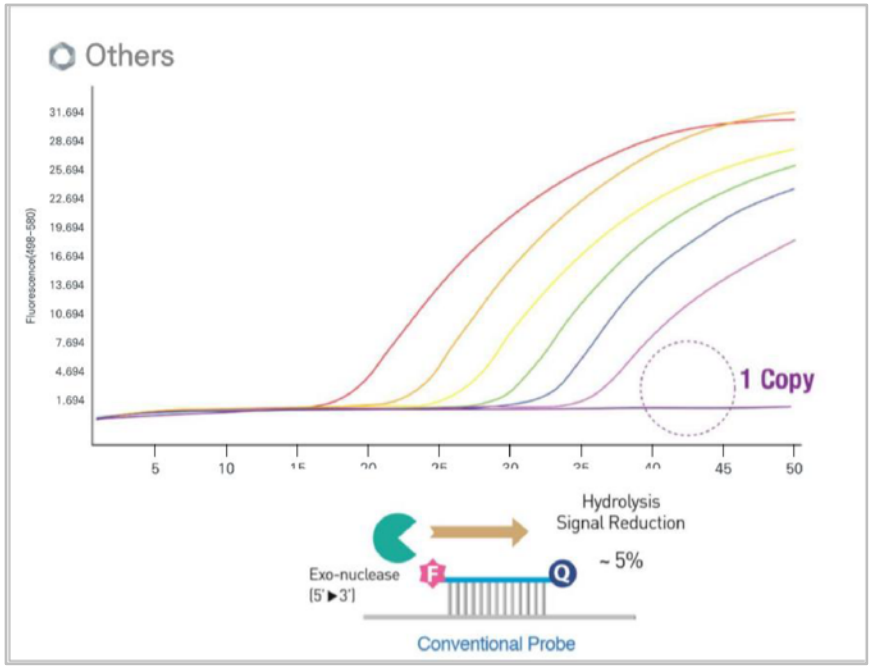
www.1copy.com

1Copy™ Advantage : High Sensitivity

Single Molecule RNA Detection





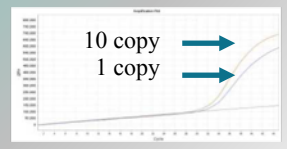


www.1copy.com

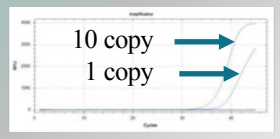
1Copy™ Advantage : High Compatibility

High compatibility with commercial PCR machines

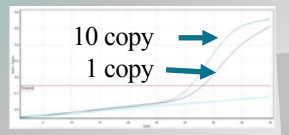
ABI7500 (ABI)



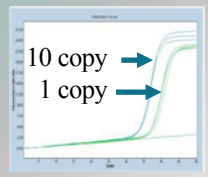
CFX96 (Bio-Rad)



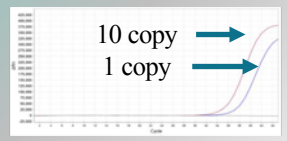
Rotor gene Q (Qiagen)



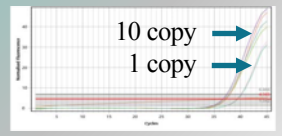
LC480 (Roche)



Quantstudio5 (ABI)

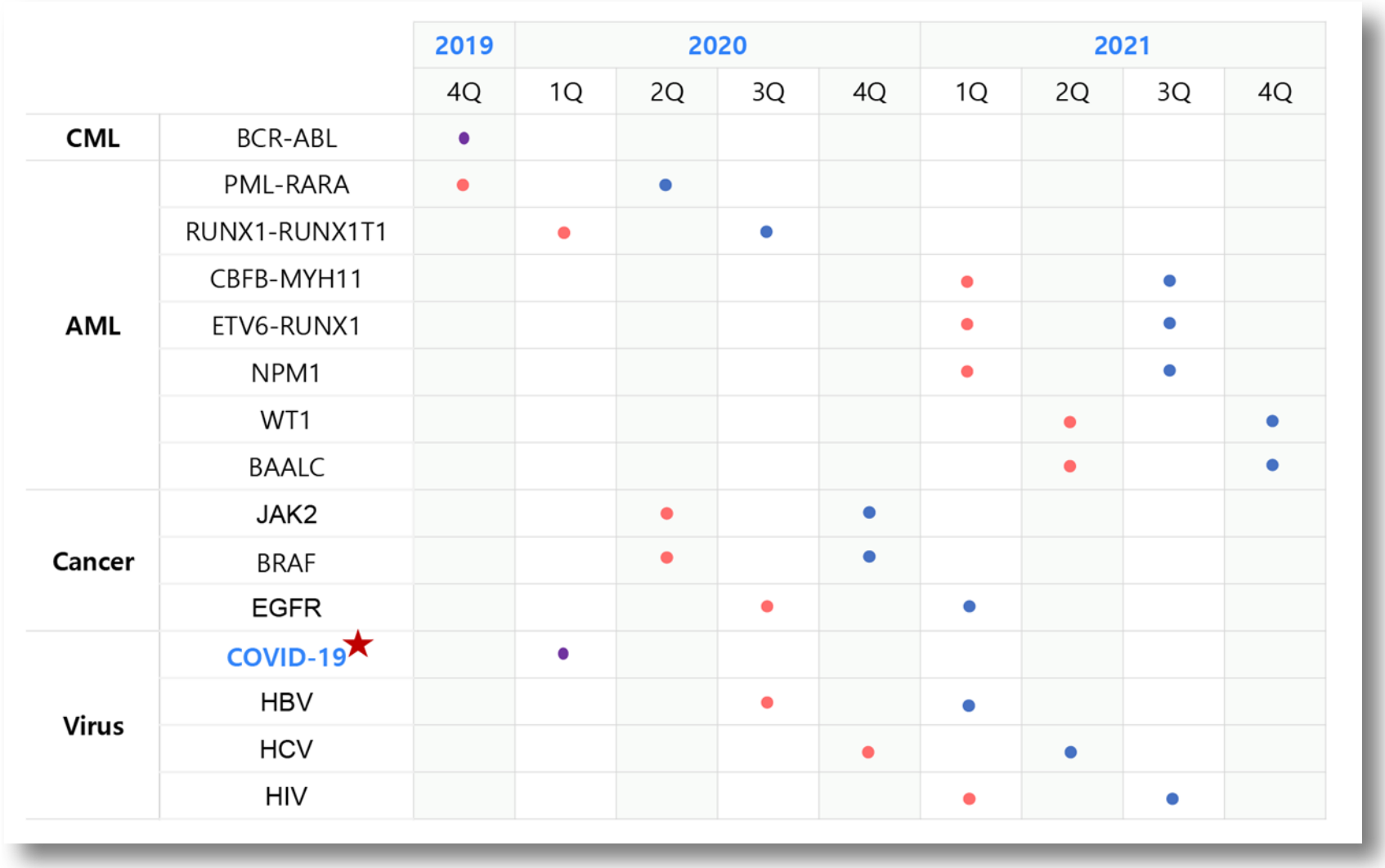


Mic qPCR cycler (BMS)



1Copy™ Pipeline

Product Pipeline



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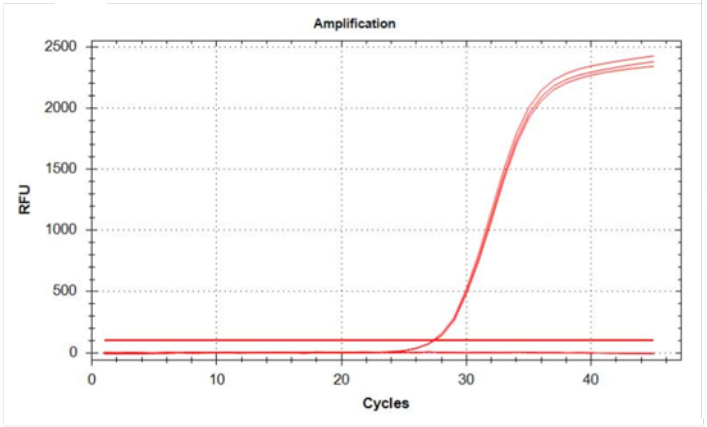
1Copy™ COVID-19

Internal Positive Control (IPC)

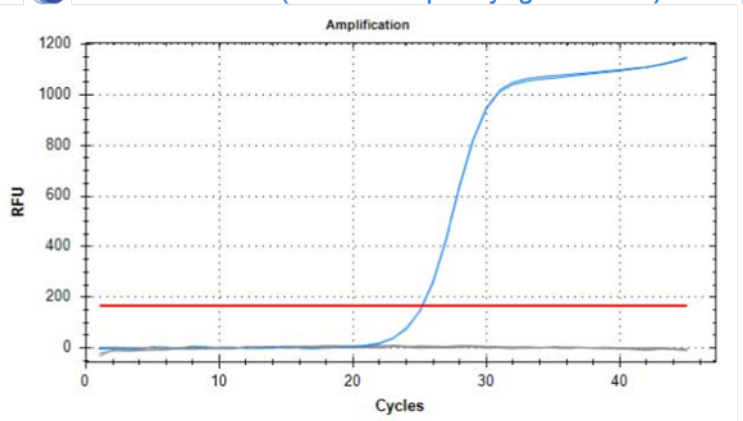
Measurement method : RT-qPCR / Target gene : Human GAPDH

K-562 : 100pg/reaction



Raw data(Ct)	
27.46	27.35
27.52	26.98
27.28	27.37
27.23	27.3
27.3	27.39
average	**27.32**

Extraction RNA (from nasopharyngeal swab) : sample 4ul/reaction



Raw data(Ct)	
24.93	25.35
25.49	25.17
25.51	25.39
25.23	25
25.38	25.18
average	**25.26**

- IPC originated from specimens is used as an extraction control and internal control.
- The IPC is needed to evaluate, whether the extraction and amplification procedure is valid or not.

1Copy™ COVID-19 qPCR Specification

Specification	
Steps	Single step
LoD	0.2copy/㎕ (4copies/reaction)
Target	RdRp, E gene
Turn-around time	1hour 30minutes

Contents (100 Test/Kit)
Master mix : 2ea
Primer/Probe mix (E gene) : 1ea
Primer/Probe mix (RdRp gene) : 1ea
Control 1 (E gene) : 1ea
Control 2 (RdRp gene) : 1ea
DEPC Water

www.1copy.com

1Copy™ COVID-19 qPCR

Certifications

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

TÜV SÜD Product Service

Certificate
No. Q5 102612 0002 Rev. 00

Holder of Certificate: 1drop Inc.
A-203, Keumkang Penterium IT Tower
215, Galmachi-ro, Jungwon-gu
Seongnam-si, Gyeonggi-do 13217
REPUBLIC OF KOREA

Facility(ies): 1drop Inc.
A-203, Keumkang Penterium IT Tower, 215, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do 13217, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: Design, Development, Production and Distribution of In Vitro Diagnostic Medical Devices - Reagents and Software Application for Blood Testing System and Molecular Diagnostics Reagent Kits

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74955478

Valid from: 2020-03-27
Valid until: 2022-04-29

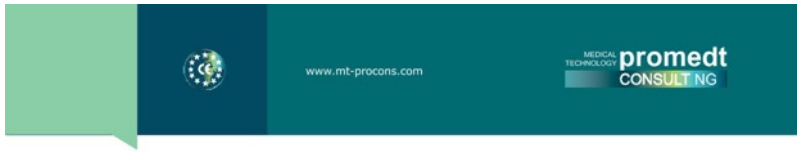
Date, 2020-03-27

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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



www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULT NG

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

1Drop Inc.
A-203, Keumkang Penterium IT Tower
215, Galmachi-ro, Jungwon-gu,
Gyeonggi-do, Seongnam-si
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

6 March 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

www.mt-procons.com

MEDICAL TECHNOLOGY promedt CONSULT NG

1Drop Inc.

Annex I
to "Certificate of EU Product Notification"
(List of CE marked Products)

Page 1 / 1 of Annex I

Internal Number	Registration Number (at the German CA/ DIMDI)	Product Category (EDMS)	EDMS Code Description	Classification Annex
DRO-01	DE/CA70/40838-151378	16 01 01 90 00	Other Monogenetic Disorders Test	III
DRO-02	DE/CA70/40838-151379	13 01 70 01 00	Haemoglobin (Hb)	III
DRO-03	DE/CA70/40838-151380	13 01 20 04 00	Haemoglobin Control	III
DRO-04	DE/CA70/40838-151381	42 03 01 01 (notified as 27 02)	Data Management Software/Consumables	III
DRO-05	DE/CA70/40838-151382	11 70 01 90 00	Other Blood Test Strips	III
DRO-06	DE/CA70/40838-151383	11 70 01 50 00	Calibrators and Controls (Blood Test Strips)	III
DRO-07	DE/CA70/40838-151385	11 70 01 01 00	Glucose Test Strips	III
DRO-09	DE/CA70/40838-151386	11 70 01 02 00	Cholesterol Test Strips	III
DRO-10	DE/CA70/40838-153851	16 90 90 01 90	Other Other Genetic Tests	III

6 March 2020

Dr. Michael Rinck
- Managing Director -

1Copy™ COVID-19 qPCR

Certifications

Health Canada / Santé Canada — Medical Devices Directorate / Direction des instruments médicaux

COVID-19 Medical Device Authorization for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

Authorization Reference Number : 312777 **Numéro de référence de l'autorisation**

Issue Date: 2020-03-29 **Date de délivrance:**

Device Class/Classe de l'instrument : 3

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

1COPY COVID-19 QPCR MULTI KIT

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

1DROP INC.
A-203 KEUMKANG PENTERIUM IT TOWER 215, GALMACHI-RO, JUNGWON-GU
SEONGNAM-SI, GYEONGGI-DO
REPUBLIC OF KOREA
13217

David Boudreau, ing., Interim Director General, Medical Devices Directorate
Directeur général par intérim, Direction des instruments médicaux

David Boudreau

Application Number: / Numéro de la demande: 312777 Manufacturer ID: / Identificateur du fabricant: 151664

Health Canada / Santé Canada — Medical Devices Directorate / Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

1COPY COVID-19 QPCR MULTI KIT

Device ID/No de l'instrument: 1020660
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
M22MD100M

Application Number: / Numéro de la demande: 312777 Manufacturer ID: / Identificateur du fabricant: 151664

Document Number : RQAI-SF3S-IV8H-KCL0

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2346, Fax: +82-43-719-1000

No. of Certificate : 20200039088 Date : 2020/04/13

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No. : 6385)

1drop Inc.

A-203, Keumkang Penterium IT Tower, 215, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do

Product-License No.	Classification
20-259	IVD (reagents for Infectious disease market(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high risk pathogens', infectious agents with moderate infectivity), nucleic acid test (3) Product Name : 1copy™ COVID-19 qPCR Multi Kit

※Attached : List of Product Classification and Model

Jiyeh Lee

Director of High-Tech Medical Devices Division
Department of Medical Device Evaluation
National Institute of Food and Drug Safety Evaluation
Ministry of Food and Drug Safety

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr).
Furthermore, You can also check it by barcode exploiting document check program for scanner

www.1copy.com

1Copy™ COVID-19 qPCR

Certifications

DECLARATION OF CONFORMITY

MANUFACTURER : **1drop Inc.**
A-203, Keumkang Penterium IT Tower, 215, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13217, REPUBLIC OF KOREA

EUROPEAN REPRESENTATIVE : **MT Promedt Consulting GmbH**
Altenhofstr. 80
66386 St. Ingbert, Germany

PRODUCT : **1copy™ COVID-19 qPCR Multi Kit**

CATALOG NO. : M22MD100M

EDMA code/ Term : **16 90 90 01 90 Other Other Genetic Tests**

Registration Number : **DE/CA70/40838-154617**

CLASSIFICATION : Others (Neither listed in Annex II of IVDD Nor self-testing)

CONFORMITY ASSESSMENT ROUTE : IVDD ANNEX III

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED : EN ISO 13485:2016, EN 15223-1:2016, EN 13612:2002/AC:2002, EN 13975:2003, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015

START DATE OF CE MARKING: 2020-03-27

PLACE, DATE OF ISSUE : Seongnam-si, 2020-03-27

SIGNATURE :

CE

FDA U.S. FOOD & DRUG ADMINISTRATION

May 11, 2020

Ahmad Bayat MD,
Director, Regulatory Affairs
Amarex Clinical Research, LLC
Representing: 1drop Inc.
20201 Century Boulevard, 4th Floor
Germantown, MD 20874

Device:	1copy COVID-19 qPCR Multi Kit
Company:	1drop Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal swab specimens as well as nasopharyngeal wash/aspirates and nasal aspirate specimens collected from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Dr. Bayat:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to 1drop Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the 1copy COVID-19 qPCR Multi Kit used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and,
3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal swab specimens as well as nasopharyngeal wash/aspirates and nasal aspirate specimens collected from individuals suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 nucleic acid is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal swab specimens as well as nasopharyngeal wash/aspirates and nasal aspirate specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

1Copy™ COVID-19 qPCR

Certifications

real-time (RT) PCR instrument. The 1copy COVID-19 qPCR Multi Kit includes the following materials or other authorized materials: Master mix, Primer/Probe mix 1(E gene), Primer/Probe mix 2(RdRp gene), Control 1 (E gene), Control 2 (RdRp gene) and DEPC DW.

Your product requires the following control materials, or other authorized control materials, that are processed in the same way as the specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control - endogenous human GAPDH mRNA in clinical samples: The GAPDH primer and probe set is included in each run to test for human GAPDH mRNA, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Control 1 (E gene) - Positive Control - contains E genomic regions targeted by the kit The positive control is used to monitor for failures of PCR reagents and reaction conditions.
- Control 2 (RdRp gene) - Positive Control - contains RdRp genomic regions targeted by the kit. The positive control is used to monitor for failures of PCR reagents and reaction conditions.
- DEPC DW - Negative Control - Diethylpyrocarbonate-treated water; nuclease-free water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product, is authorized to be accompanied with labeling entitled "1copy COVID-19 qPCR Multi Kit Instructions for Use" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: 1copy COVID-19 qPCR Multi Kit
- Fact Sheet for Patients: 1copy COVID-19 qPCR Multi Kit

The above described product, when accompanied by the instructions for use (identified above) and the two Fact Sheets (collectively referred to as "authorized labeling") is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used for the qualitative detection of SARS-CoV-2 and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific

evidence available to FDA, that it is reasonable to believe that your product may be effective i diagnosing COVID-19, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth ir Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

1drop Inc. (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropr limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) will make your product available with the authorizec labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

C. You and authorized distributor(s) will make available on your website(s) the Fact

[5] "Authorized Distributor(s)" are identified by you, 1drop Inc., in your EUA submission as an entity allowed to distribute your device.

Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, authorized labeling and authorized Fact Sheets.

E. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

1drop Inc. (You)

H. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You will provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You may request to make available additional authorized labeling, including fact sheets, specific to an authorized distributor. Such additional labeling and fact sheets may use another name for the product, but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

1Copy™ COVID-19 qPCR

Certifications

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M. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You will evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, You will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You will evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

Authorized Laboratories

U. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

V. Authorized laboratories using your product will use your product as outlined in the "1copy COVID-19 qPCR Multi Kit Instructions for Use." Deviations from the

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

W. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

X. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

Y. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (sales@1drop.co.kr, +82 31 747 0109) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

Z. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

1drop Inc. (You), Authorized Distributors and Authorized Laboratories

AA. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

BB. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

CC. No descriptive printed matter, including advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

DD. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S3

Digitally signed by Denise M. Hinton -S3
Date: 2020.05.11 13:29:43 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

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