AUTHORIZED
DISTRIBUTOR

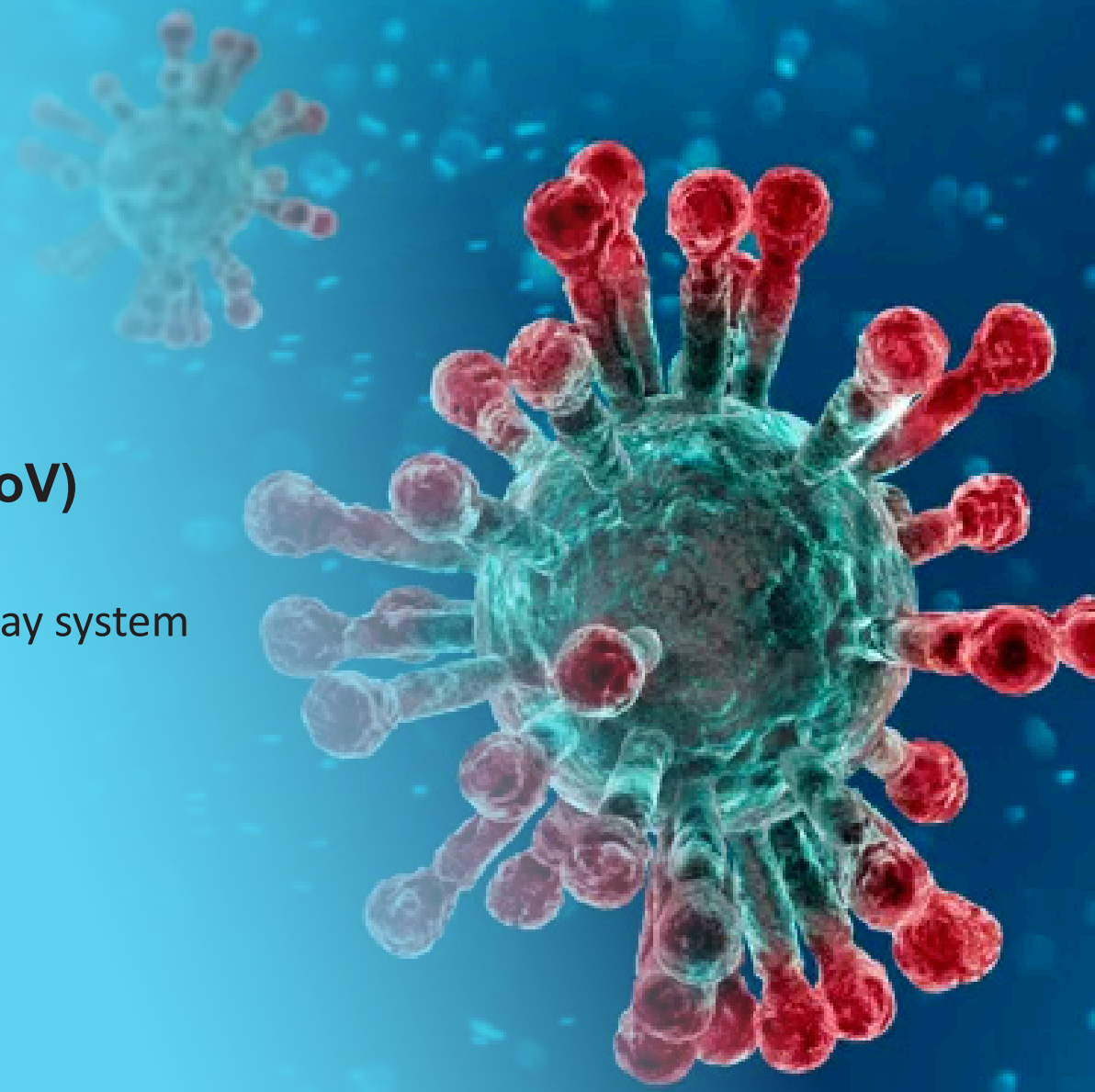
HERCULES
CARES...

Let's care for
our loved ones

SolGent DiaPlexQ™
Novel Coronavirus (2019-nCoV)
Detection Kit (CE-IVD)

Real-Time OneStep RT-PCR based assay system
for detection of 2019-nCoV (CE-IVD)

(For Local Dealer Information Confidential)



HERCULES ENGINEERING (SEA) SDN. BHD.
(324486 T)

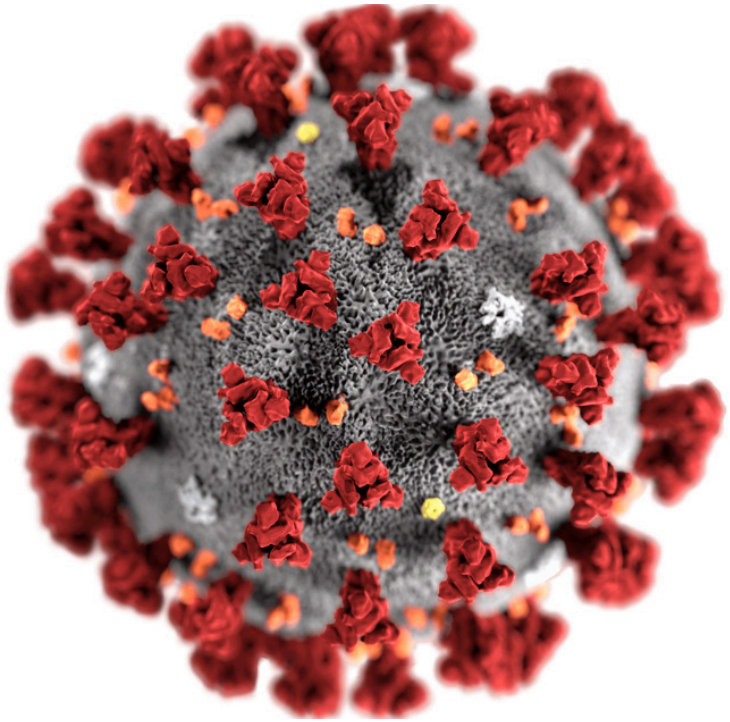
Introduction

Coronavirus Disease 2019 (COVID-19)

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Common symptoms include fever, cough, and shortness of breath.

This disease is getting worse and created a major impact to people around the world.

In order to contain and slow down the spread of coronavirus, testing is one of the most efficient way. Infected patients can be quarantined by detecting the people who tested positive. It also lets public health workers build a more accurate picture of the number of cases and how the virus is spreading in the population.



Introduction

Hercules has taken the initiative to distribute the COVID-19 test kits by collaborating with Korean company, SolGent Co., Ltd.

This DiaPlexQTM 2019-nCoV Detection Kit is CE-IVD reagent.

It is a screening kit to detect Novel Corona Virus as 2019-nCoV from isolated total RNA. This test kit has obtained regulatory agency approval from European CE-IVD and Korean CDC's Emergency Use Approval.

1. KIT Introduction

Regulatory Agency Approval

European CE-IVD
(Issued on 26th Feb. 2020)

DE/CA70/40838-153776

EC DECLARATION OF CONFORMITY

SolGent Co., Ltd.
Head Office : 3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Korea
Factory : 1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
Tel : +82-42-864-5695, Fax: +82-42-864-5690, global@solgent.com

CE IVD

Declares that the medical device(s) described hereafter

Other Virology – NA Reagents, 15 04 40 90 00 (EDMA code)

Model Name: **DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit**

Catalogue Number: **SQD52-K100, SQD52-K020**

Has been classified as Others not covered by Annex II and self-testing according to Directive 98/79/EC.

Is in conformity with the applicable requirements of the following documents

Ref. No.
EN ISO 15223-1 : 2016
ISO 13485 : 2016
EN 13612 : 2002
EN ISO 17511 : 2003
EN 23640 : 2015
EN 13641 : 2002
EN ISO 14971 : 2012
EN ISO 18113-1 : 2011
EN ISO 18113-2 : 2011
IEC 62366-1:2015
IEC 62366-2:2016

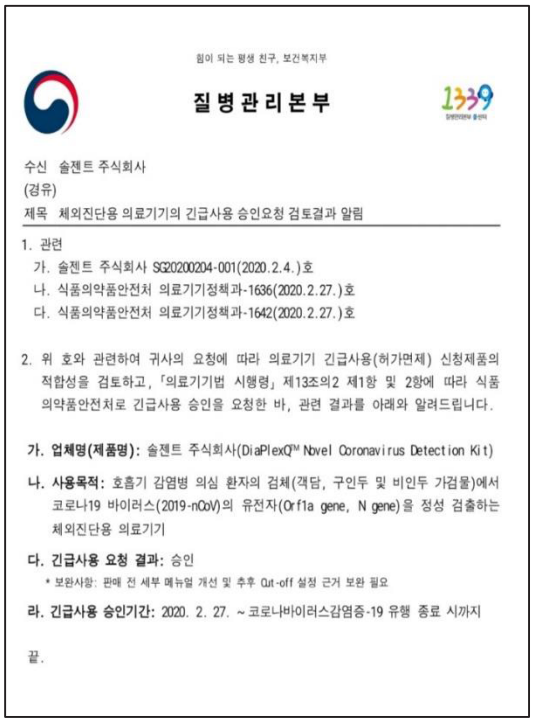
Is subject to the conformity assessment procedure set out in Annex III of Directive 98/79/EC

26th, February, 2020 Signature: Chanmajeong

SolGent Co., Ltd.
Solutions for Genetic Technologies

F-QP-21-2(2) SolGent Co., Ltd 02/2020 V2.0

Korea CDC's Emergency Use Approval
(Issued on 27th Feb. 2020)



힘이 되는 평생 친구, 보건복지부

질 병 관 리 본 부

1339

수신 솔젠트 주식회사
(경유)
제목 체외진단용 의료기기의 긴급사용 승인요청 검토결과 알림

1. 관련
가. 솔젠트 주식회사 SG20200204-001(2020.2.4.)호
나. 식품의약품안전처 의료기기정책과-1636(2020.2.27.)호
다. 식품의약품안전처 의료기기정책과-1642(2020.2.27.)호

2. 위 호와 관련하여 귀사의 요청에 따라 의료기기 긴급사용(허가면제) 신청제품의 적합성을 검토하고, 「의료기기법 시행령」 제13조의2 제1항 및 2항에 따라 식품의약품안전처로 긴급사용 승인을 요청한 바, 관련 결과를 아래와 알려드립니다.

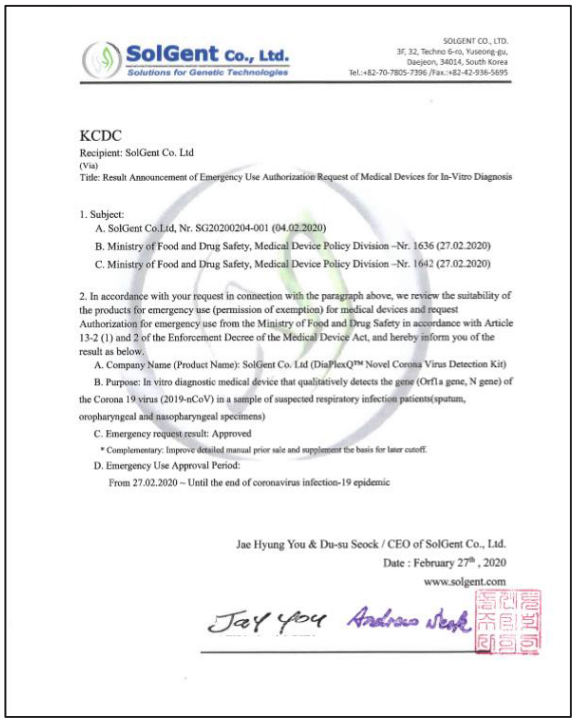
가. 업체명(제품명): 솔젠트 주식회사(DiaPlexQ™ Novel Coronavirus Detection Kit)

나. 사용목적: 호흡기 감염병 의심 환자의 검체(객담, 구인두 및 비인두 가검물)에서 코로나19 바이러스(2019-nCoV)의 유전자(Orf1a gene, N gene)을 정성 검출하는 체외진단용 의료기기

다. 긴급사용 요청 결과: 승인
* 보완사항: 판매 전 세부 메뉴얼 개선 및 추후 Cut-off 설정 근거 보완 필요

라. 긴급사용 승인기간: 2020. 2. 27. ~코로나바이러스감염증-19 유행 종료 시까지

끝.



SolGent Co., Ltd.
Solutions for Genetic Technologies

SOLGENT CO., LTD.
3F, 32, Techno 6-ro, Yuseong-gu,
Daejeon, 34014, South Korea
Tel.:+82-70-7805-7306 /Fax.:+82-42-936-5695

KCDC
Recipient: SolGent Co. Ltd
(Via)
Title: Result Announcement of Emergency Use Authorization Request of Medical Devices for In-Vitro Diagnosis

1. Subject:
A. SolGent Co.Ltd, Nr. SG20200204-001 (04.02.2020)
B. Ministry of Food and Drug Safety, Medical Device Policy Division –Nr. 1636 (27.02.2020)
C. Ministry of Food and Drug Safety, Medical Device Policy Division –Nr. 1642 (27.02.2020)

2. In accordance with your request in conneection with the paragraph above, we review the suitability of the products for emergency use (permission of exemption) for medical devices and request Authorization for emergency use from the Ministry of Food and Drug Safety in accordance with Article 13-2 (1) and 2 of the Enforcement Decree of the Medical Device Act, and hereby inform you of the result as below.
A. Company Name (Product Name): SolGent Co. Ltd (DiaPlexQ™ Novel Corona Virus Detection Kit)
B. Purpose: In vitro diagnostic medical device that qualitatively detects the gene (Orf1a gene, N gene) of the Corona 19 virus (2019-nCoV) in a sample of suspected respiratory infection patients(sputum, oropharyngeal and nasopharyngeal specimens)
C. Emergency request result: Approved
* Complementary: Improve detailed manual prior sale and supplement the basis for later cutoff.
D. Emergency Use Approval Period:
From 27.02.2020 – Until the end of coronavirus infection-19 epidemic

Jae Hyung You & Du-su Seock / CEO of SolGent Co., Ltd.
Date : February 27th, 2020
www.solgent.com

Jay You Andrew Seok

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

DiaPlexQ™ 2019-nCoV Detection Kit

DiaPlexQ™ Novel Coronavirus(2019-nCov) Detection Kit is CE-IVD reagent. It is screening kit to detect Novel Corona Virus as 2019-nCoV from isolated total RNA.
Basic principal of this kit is Real-time PCR method, which is able to detect specific target gene into total RNA.
It provides every necessary contents for PCR reaction, Therefore customer don't need to purchase additional reagent. One step RT-PCR contents are progressively apply for one tube RT(Reverse Transcription) reaction and PCR amplification. You can monitoring the nucleic acid amplification result based on real time condition through the amplification plot.
The Control Template (2019-nCov) is provide as positive control to assist the clinical sample data comparison analysis.

SQD52-K100

▶ Contents

Components	SQD52-K020	SQD52-K100
2X OneStep qRT-PCR Buffer (2019-nCoV)	200 μℓ x 1 ea	1.0 mL x 1ea
OneStep qRT-PCR Enzyme mix (2019-nCoV)	40 μℓ x 1 ea	200 μℓ x 1 ea
Primer & Probe Mixture (R,E,N)	60 μℓ x 1 ea	300 μℓ x 1 ea
Control Template (R,E,N)	20 μℓ x 1 ea	100 μℓ x 1 ea
RNase Free Water	200 μℓ x 1 ea	1.0 mL x 1 ea

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

Specification & Feature

▶ Specification

Item	Specification
Detection target	2019-nCoV (COVID-19)
Target region	Orf1a, N gene
Detection technology	Real-Time OneStep RT-qPCR
Specimen type	Nasopharyngeal swab, Oropharyngeal swab, Sputum
Compatible instruments*	CFX96™ Real-Time PCR System (Bio-Rad) ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems)
PCR running time	105 ~ 120 mins

▶ Feature

- Simple & Rapid detection system: OneStep Multiplex RT-qPCR based detection
- HotStart PCR: high-specificity
- Reliable system: automatic PCR control (not Internal control)
- Easy-to-use master mix: just adding template and Primer/Probe Mix
- Positive control included (Plasmid)

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

Process & Reaction Time

Sample collection	Nucleic acid isolation	Multiplex OneStep RT-qPCR	Data analysis
Sample collection according to sample type	• Manual Method • Auto extraction Method	***DiaPlexQ™ 2019-nCoV(RdRp, E, N) Detection Kit***	Use of software for each instrument

- HotStart PCR: high-specificity
- OneStep PCR : multiple targets in a single reaction
- Reliable system: automatic PCR control
- Easy-to-use master mix: just adding template and Primer/Probe Mix
- Rapid detection: OneStep RT-qPCR

PCR Reaction Time: 2 hours

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

Kit Composition & PCR Condition

Sample collection

Sample collection according to sample type

Nucleic acid isolation

- Manual Method
- Auto extraction Method

Multiplex OneStep RT-qPCR

DiaPlexQ™ 2019-nCoV(RdRp,E, N) Detection Kit

Data analysis

Use of software for each instrument

Cap color	Reaction Mixture	Vol.
Red ●	2X OneStep RT-qPCR Buffer	10 ㎕
Blue ●	OneStep RT-qPCR Enzyme mix	2 ㎕
Violet ●	Primer/Probe Mixture (2019-nCoV)	3 ㎕
	Sample template	5 ㎕
	Total	20 ㎕

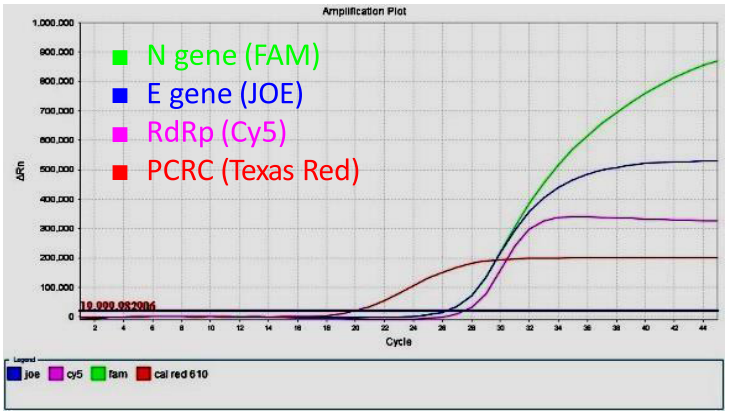
PCR Condition				
	Reverse Transcription	50 ℃	15 min	X 1
	Initial PCR activation	95 ℃	15 min	X 1
	Denaturation	95 ℃	20 sec	X 45
	Annealing / Extension	60 ℃	40 sec	

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

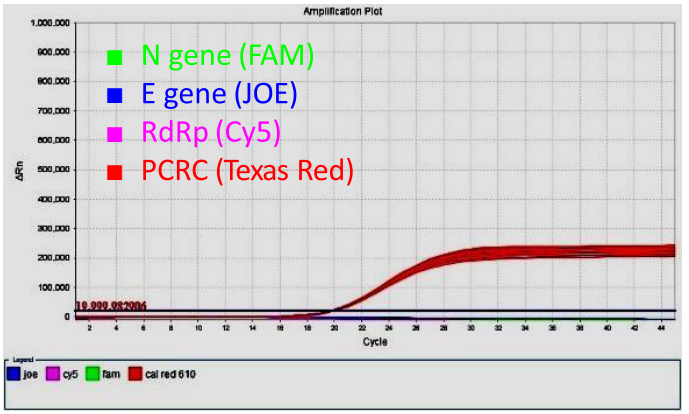
Experimental

COVID-19
Positive (Using Control Templet)



Control Transcripts RNA
(Orf1a(RdRp), E, N)

COVID-19
Negative (NTC)



22 negative strains

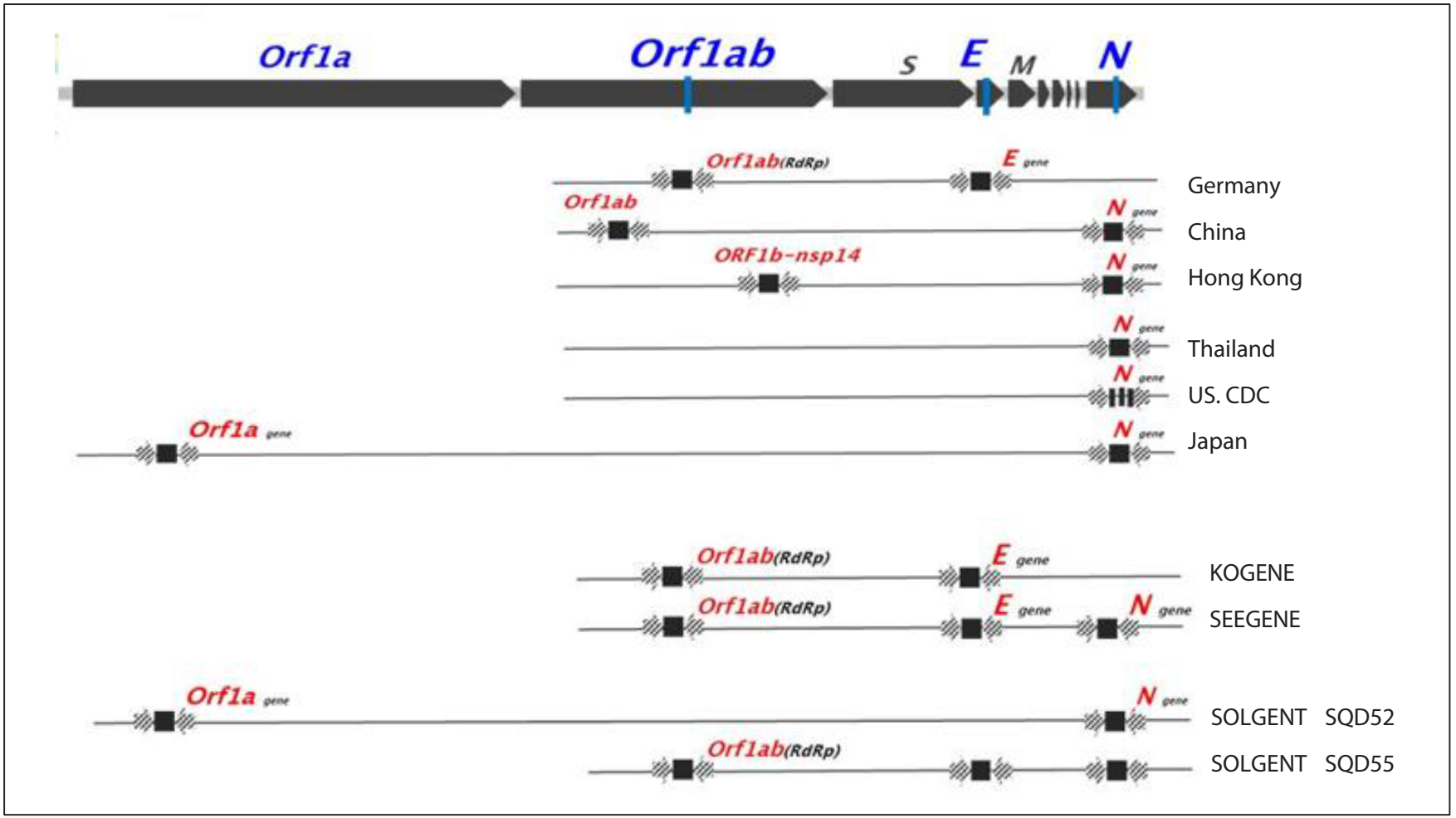
Target	5' Fluorophore	3' Quencher
N gene	FAM	BHQ1
E gene	JOE / VIC	BHQ1
Orf1ab(RdRp)	Cy5	BHQ3
PCR Control	*Texas Red / Cal Fluor Red 610	BHQ2

*ABI 7500 / 7500 Fast: JOE, Texas Red | Bio Rad CFX96™: VIC, Cal Fluor Red 610

1. KIT Introduction

SolGent Co., Ltd.
솔젠트(주)

Detection Criteria by Country / Product



1. KIT Introduction

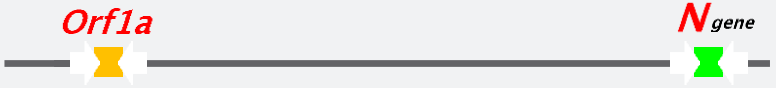
SolGent Co., Ltd.
솔젠트(주)

Comparison with the other product in KOREA

Korea CDC's Emergency Use Approval

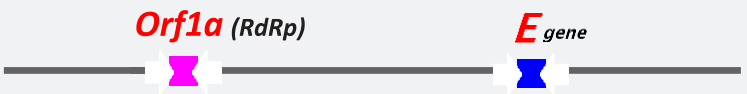
'SOLGENT'

Emergency Approval(3rd):
Detects Orf1a and N genes at the same time



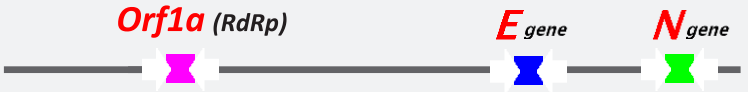
'KOGENE'

Emergency Approval(1st):
Detects RdRp and N genes separately



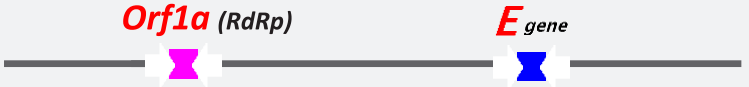
'SEEGEN'

Emergencu Approval(2nd):
Detects RdRp and N genes at the same time



'SD Biosensor'

Emergencu Approval(2nd):
Detects RdRp and N genes at the same time



1. KIT Introduction

Comparison with the other KIT's Spec.

Spec.	KOGENE	SEEGENE	SD Biosensor	SOLGENT
Product Name	PowerChek™ 2019-nCoV Real-time PCR Kit	Allplex™ 2019-nCoV Assay	STANDARD M nCoV Real-Time Detection kit	*DiaPlexQ™ Novel Coronavirus(2019-nCoV) Detection Kit*
Cat. No.	R6900T	RP10243X	M-NCOV-01	SQD52-K100
Target gene	RdRp, E gene (따로PCR)	RdRp, E gene, N gene	RdRp, E gene	Orf1a, N gene
IC	Control to Check PCR Performance	Internal control applied to nucleic acid extraction Control to Check PCR Performance	Internal control applied to nucleic acid extraction Control to Check PCR Performance	Control to Check PCR Performance
KIT Spec.	50test/kit	100test/kit	100test/kit	100test/kit

PCR Condition

Temperature (℃)	Time	Cycles
50 ℃	30 min	1
95 ℃	10 min	1
95 ℃	15 sec	40
60 ℃	1 min	

Step	No. of cycles	Temperature	Duration
1	1	50℃	20 min
2	1	95℃	15 min
3	45	94℃	15 sec
4*		58℃	30 sec
5	GOTO Step 3, 44 more times		

No.	Step	Temperature	Acquisition	Time	Cycles
1	Reverse transcription	50℃	-	15 min	1
2	Initial PCR activation	95℃	-	15 min	1
3	Denaturation	95℃	-	20 sec	45
4	Annealing/Extension	60℃	√	40 sec	

No.	Step	Temperature	Acquisition	Time	Cycles
1	Reverse transcription	50℃	-	15 min	1
2	Initial PCR activation	95℃	-	15 min	1
3	Denaturation	95℃	-	20 sec	45
4	Annealing/Extension	60℃	√	40 sec	

2. Manufacturer

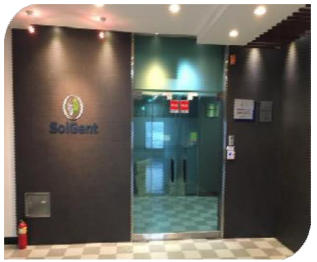
SolGent Co., Ltd

SolGent Co., Ltd Company Profile

SolGent

" Professional developer of diagnostic reagents and diagnostic kits for over 20 years in Korea"

Item	Contents
Company Name	SolGent Co.,Ltd
Address	3F, 32 Techno 6-ro, Yuseong-gu, Daejeon, 34014, South Korea
TEL	1544-5698
CEO	Do-Su, Seok, Jae-Hyung You
Employee	62
Clients	26 Companies in 20 Contries
Foundation	Aug. 2000
Homepage	www.soglent.com

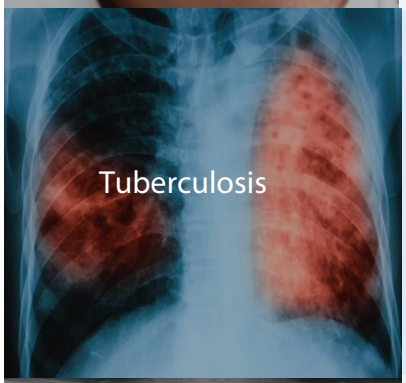
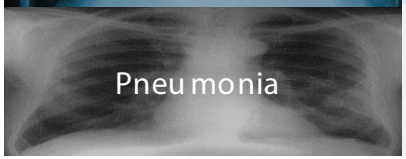


2. Manufacturer

SolGent Co., Ltd.
솔젠트(주)

SolGent's Diagnostics Kits List

SolGent

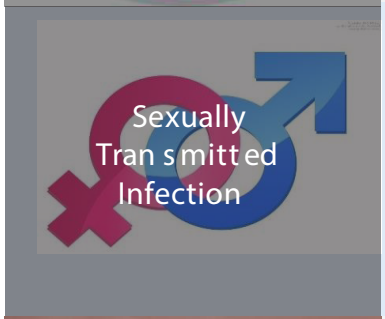
 Respiratory disease	▪ 2019-nCoV Detection kit	CE-IVD
	▪ DiaPlexC™ Influenza Virus A/B Detection Kit	CE-IVD
	▪ DiaPlexQ™ Influenza Virus A/B & A Subtype Detection Kit	CE-IVD
	▪ DiaPlexC™ RV13 Detection Kit	CE-IVD
	▪ DiaPlexQ™ RV16 Detection Kit	
	▪ DiaPlexQ™ MERS Virus Detection Kit I (upE only)	
	▪ DiaPlexQ™ MERS Virus Detection Kit II (upE / ORF1a / ORF1b)	
 Tuberculosis	▪ DiaPlexC™ MTB/M.bovis Detection Kit	CE-IVD
	▪ DiaPlexC™ M.Avium/M.Intracellulare Detection Kit	CE-IVD
	▪ DiaPlexC™ MTC/NTM Detection Kit	CE-IVD
	▪ DiaPlexQ™ MTC/NTM Detection Kit	CE-IVD
	▪ DiaPlexQ™ MTC/NTM / MDR Detection Kit	
	▪ DiaPlexQ™ MTC/NTM Detection Kit – ver 3.0	CE-IVD
	▪ DiaPlexQ™ MTC/NTM Detection Kit – ver 4.0	CE-IVD
 Pneumonia	▪ DiaPlexQ™ PneumoPatho 6 Detection Kit	
	▪ DiaPlexQ™ PneumoPatho 13 Detection Kit	

2. Manufacturer

SolGent Co., Ltd.
솔젠트(주)

SolGent's Diagnostics Kits List

SolGent

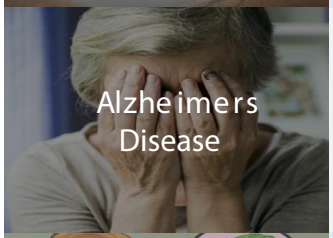
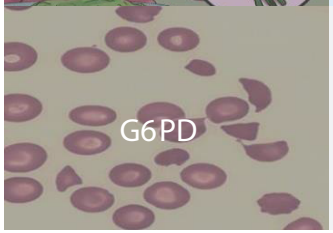
	▪ DiaPlexQ™ MTC/NTM / MDR Detection Kit ▪ DiaPlexC™ CRE Detection Kit *CRE(Carbapenem-Resistant Enterobacteriaceae)	CE-IVD
	▪ DiaPlexC™ CT/NG Detection Kit ▪ DiaPlexQ™ CT/NG Detection Kit ▪ DiaPlexQ™ STI 6 Detection Kit ▪ DiaPlexQ™ STI 12 Detection Kit ▪ DiaPlexC™ HPV Screening / genotyping kit	
	▪ DiaPlexQ™ Ebola Virus Detection Kit – Zaire ▪ DiaPlexC™ Malaria Detection Kit ▪ DiaPlexQ™ Dengue Virus Detection Kit ▪ DiaPlexQ™ ZCD Detection Kit(ZIKV, CHIV, DENV)	CE-IVD CE-IVD CE-IVD CE-IVD

2. Manufacturer

SolGent Co., Ltd. 솔젠트(주)

SolGent

SolGent's Diagnostics Kits List

	▪ DiaPlexC™ Avellino Corneal Dystrophy (ACD) Genotyping Kit ▪ DiaPlexQ™ Avellino Corneal Dystrophy(ACD) Genotyping Kit ▪ DiaPlexQ™ 5 type Corneal Dystrophy(5CD) Genotyping Kit	CE-IVD CE-IVD CE-IVD
	▪ DiaPlexQ™ ApoE Genotyping Kit ▪ DiaPlexQ™ ApoE Genotyping Kit	CE-IVD CE-IVD
	▪ DiaPlexC™ MTHFR Genotyping Kit ▪ DiaPlexQ™ MTHFR Genotyping Kit	CE-IVD CE-IVD
	▪ DiaPlexC™ G6PD Genotyping Kit (Asian type) ▪ DiaPlexC™ G6PD Genotyping Kit (African type)	CE-IVD CE-IVD

3. Global Distributor

CAREMILLE INC. & HERCULES ENGINEERING (SEA) SDN. BHD.

Global Distributor of SolGent Co., Ltd

SolGent Co., Ltd.
Solutions for Genetic Technologies

Letter of Sales Authorization

2020 March 16

Dear Sir/Madam,

Subject : Letter of Sales Authorization for Caremille Inc. (General Director : Alex Cheon)

We, SolGent Co., Ltd (3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, South Korea), as the Product Owner and Supplier, hereby authorize, Caremille Inc. (1318, West Wing, Hanshin InterValley, 322 Teherean-ro, Gangnam-gu, South Korea), as the General Distributor of DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit on our behalf in the Global market. The term of authorization shall be negotiated with us from the date of signing the power of attorney. And, We confirm that Caremille Inc. is transferred to all rights and goodwill of the Global Distributorship Agreement between SolGent Co., Ltd and Medi & Korea Co., Ltd, which was signed on March 2, 2020.

No	Catalog Number	Product
1	SQD52-K100	DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

We declared that given information on above records are true and correct to the best of our knowledge.

Yours Sincerely,

Jae Hyung You & Du-su Seock / CEO of SolGent Co., Ltd.
Date : March 16, 2020
www.solgent.com

Authorized Distributor

SolGent CAREMILLE Authorized Distributor

Letter of Sales Authorization

Dear Sir/Madam,

Subject : Letter of Sales Authorization for Hercules Engineering (SEA) Sdn Bhd

We, CAREMILLE Inc. (30F ASEM Tower, 517 Youngdongdae-ro, Gangnam-gu, Seoul (06164) South Korea) as the Global Authorization Distributor of SolGent Co.Ltd, hereby authorized Hercules Engineering (SEA) Sdn Bhd (12A, Jalan SB Jaya 1, Taman Industri SB Jaya, 47000 Sungai Buloh), as the Sub-Dealer of CAREMILLE Inc. for DiaPlexQ™Novel Coronavirus (2019-nCoV) Detection Kit on our behalf. The term of authorization shall be negotiated with us from the date of signing the power of attorney.

No	Catalog Number	Product
1	SQD52-K100	DiaPlexQ™Novel Coronavirus (2019-nCoV) Detection Kit

Dealership Term: 1month of period starting as of March 21, 2020
If the Sub-dealer sells more than 50kits in the designated territory within 1 month, this authorization will be extended automatically until the end of this year.
Territory: Malaysia

We declared that given information on above records are true and correct to the best of our knowledge.

Yours Sincerely,
Date : March 20, 2020

CARE MILLE INC.
PRESIDENT. ALEX CHEON

Alex Cheon
President of CAREMILLE Inc.

㈜ 케어미일 (www.caremille.com)

4. Sales Information

PT-PCR Detection KIT

Our diagnostic kit is a One Step RT-PCR Multiplex Kit using Real Time qPCR machine.

The diagnosis process involves taking samples from the upper respiratory tract runny nose (oral pharynx, nasopharynx) and lower respiratory sputum from patients with suspicion. The laboratory prepares the sample, adds the nucleic acid separation reagent, and extracts the nucleic acid using manual or automatic extraction equipment. If you put the gene amplification reagent in the tube containing the extracted nucleic acid and put the kit in the Real Time qPCR machine, the RNA gene will be amplified, and in this process, it is specific only to the COVID-19 virus parasitic to the RNA gene. Viruses are detected using primers / probes. Higher detection levels indicate the presence of the COVID-19 virus in the suspect's body.

Typically, 30 minutes to 1 hour preparation of nucleic acid extraction reagent for each sample, nucleic acid extraction process is 1 hour to 2 hours, depending on the method, RNA gene amplification reagent.
It takes about 4 ~ 6 hours for 30 minutes to prepare, 2 hours for gene amplification equipment, and 30 minutes for confirmation. Examination time varies according to the inspection equipment status, experts and proficiency of the hospital.

This diagnostic test product, used to confirm COVID-19, is not a simple test for the public like a pregnancy diagnostic kit. You need a diagnostic laboratory, a specialist, a laboratory, a Negative Pressure isolation room that can handle clinical samples, and a PCR test equipment (Real Time qPCR machine) in a large hospital or specialized testing center. Sensitive and specificity that only detects COVID-19 are detailed in the product introduction.

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

COVID-19 Detection Process (Real Time PT-PCR System)

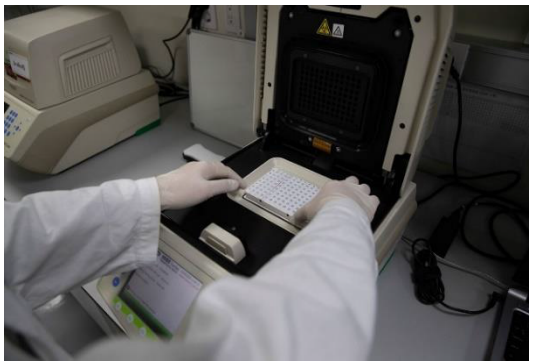
1) Sampling Collection

2) Transportation (4°C, Sealing)

3) Nucleic acid isolation

4) Diagnostic reagent injection

5) Real Time PCR Detection System



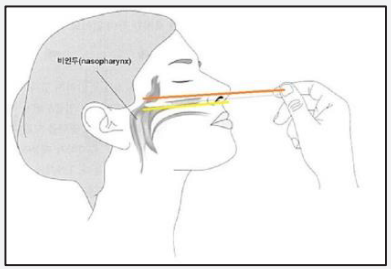
6) Data Analysis

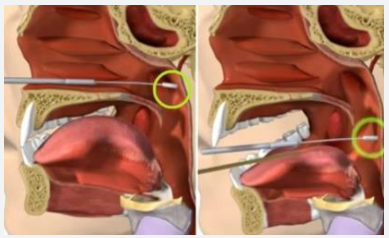
4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Sampling Collection & Transportation (Before Diagnostics)

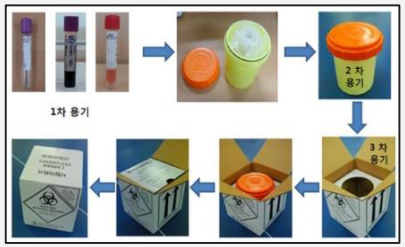
1) Push a 20 cm swab deep into your nose and mouth and collect a sufficient sample.

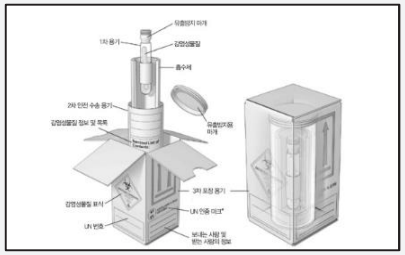




2) 1st Container: The middle kit contains sputum, and the two kits contain cotton swabs from the mucous membranes of the nose and throat.

3) 2nd ~3rd Containers: 3EA 1stcontainers are placed in 2nd Containers, sealed in 3rd paper box, and placed in an ice box to the test room.





4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

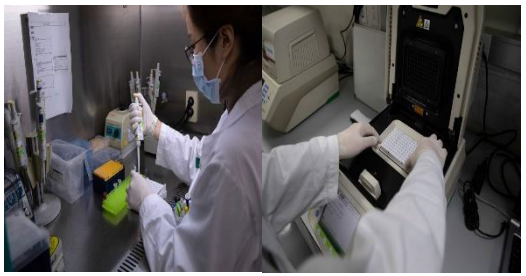
Nucleic Acid Isolation & RT-PCR Process (4~6 Hours in Laboratory)

Nucleic Acid Isolation
(1 ~ 3 hours)

A) Manual Method (2~3 hour)
1. Preparation of Isolation reagents (30min.)
2. Nucleic Acid Extraction (1~2hour)

B) Auto Extraction Method (30~80min)
*Hamilton 'STARlet'
(96 sample : 1hour 40min)
*Hamilton 'NimBUS'
(48 sample : 1hour 20min)
*Roche 'Magna Pure'
(96 sample : 1hour)
*Genolution 'NX48' (made in Korea)
(48 sample : 20min+@)

Real Time RT-PCR System
(2H ~ 2H 30min.)



1. Preparation of amplification reagents (30min.)

2. Amplification PCR (in 2hours)
A) SOLGENT PCR Kit
'DiaPlexQ™ 2019-nCoV'
(1 tube, 1hour 45min)
B) KOGENE BIOTECH PCR Kit
'PowerCheck 2019-nCoV'
(2 tubes, 2 hours)
C) SEEGENE PCR Kit
'Allplex 2019-nCoV'
(1 tube, 2hours)

Data Analysis & Report to CDC
(30min.~ 1hour)

1. Data Analysis using SW of the PCR equipment (30min.~1hour)

2. Report to CDC

*Recommended PCR Machine
-ABI 7500 / 7500 Fast
-Bio Rad CFX96

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486T)

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Frequent Q & A

1) Commercial Prices in other export countries ?

Please contact **Hercules Engineering (SEA) Sdn. Bhd.**

2) Packaging unit and weight ?

Type A) Small Styrofoam Box : 6 kits (6 kg) 27 x 27 x 26 cm
Type B) Medium Styrofoam Box : 20 kits (10 kg) 37 x 32 x 32 cm
Type C) Medium-Large Styrofoam Box : 40 kits (18 kg) 45 x 42 x 35 cm
Type D) Large Styrofoam Box : 80kits (25 kg) 50 x 50 x 55 cm
* Packing stability evaluation was safe up to 5 days when we shipped in ice pack packaging.

3) Is there a minimum order quantity?

: MOQ (Minimum Order Quantity) is 50 kits per order.

4) Payment terms ?

-Buying Immediately : 100% T.T Advance Payment
-Booking in weekly base : 50% Deposit (Basis on Min. 1,000kit) Before 1~2week

5) Storage

: Please contact us for inventory in Korea.

4. Sales Information

Frequent Q & A

6) Production Capacity in Manufacturer, Korea
: 3,000kits (300,000test) / Week

7) Does the kit require special storage ?
: Required refrigeration (-15 ~ -20 degree)

8) Storage expiration length : Validity 1 year

9) Kit Specification :
-Kit Box Size : 10cm * 6cm * 6cm
-Kit Unit : Available 100 Test per Kit
-Required Instrument for Kit : Real Time PCR Machine
-Recommended PCR Machine by SolGent
a) Applied Biosystems™ 7500 Real-Time PCR Instrument System
b) Applied Biosystems™ 7500 Fast Real-Time PCR Instrument System
c) Bio-Rad CFX96™ System

10) Accuracy
: When SolGent develops its products, it cross-reacts with 38 other viruses and bacteria. Results showed that only coronavirus-19 was detected.

4. Sales Information

Frequent Q & A

11) Time to extract results

: You can check the result in about 1 hour 45 minutes.

12) Comparison of data other COVID-19 kits ?

: Currently, there are no comparison results with the other kit.

13) Regulatory agency approval :

-Europe CE-IVD (Issued on 26th Feb. 2020)

-Korea CDC's emergency use approval (Issued on 27th Feb. 2020)

14) Specimens :

-Nasopharyngeal swab

-Oropharyngeal swab

-Sputum

15) Other Details

: Please contact us for detailed explanations and quotations for diagnosis kit's detail data.

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Comparison of Corona19 Test Methods (only for Sales Information)

Segment	Immune diagnosis		Molecular Diagnostics (Biochip, Biosense, PCR)	
Method of inspection	Antigen Diagnosis	Antibody Diagnosis	PanCorona Virus Test	COVID-19 Detection Test
Inspection equipment	Antigen Diagnostic Kit	Antibody Diagnostic Kit	Conventional RT-PCR	Real-Time RT-PCR
Pathogen	Corona 19 Detection (Low accuracy / sensitivity)	Corona 19 Detection (Low accuracy / sensitivity)	Whole Corona Virus Detection	Corona19 Detection
Accuracy	50~85%	50~85%	80 ~ 95%	95 ~ 99%
Inspection Difficulty	Low	Low	High (High false positive rate)	Middle
Corona19 Diagnostic method	Put a runny nose or sputum in the kit and check for the presence of N protein of Corona 19 (Not likely to respond within 10 days of onset)	Antibodies (IgG, IgM) to defend against the viral antigens of Corona 19 through the blood Check for infection by presence (Likely not responding within 10 days of onset)	1) Nucleic Acid Extraction 2) Conventional RT-PCR 3) Electrophoresis 4) Transfer CDC at the first positive decision 5) Request for Gene Sequence Analysis 6) Confirmation of final positivity	1) Nucleic Acid Extraction 2) Real-Time RT-PCR 3) Pathogen Identification 4) Confirmation of Positive Status
Diagnostic time	10 ~ 40 minutes	10 ~ 40 minutes	1 ~ 2 days	4 ~ 6 hours
Modification	Easy Kit Development	Easy Kit Development	Sequencing / Genotyping DNA amplification for cloning	• Quantitative Analysis of Gene Expression • Pathogen detection • Virus Quantitative Analysis
Feature	Low response early in infection Inadequate for infectious disease confirmation	RT-PCR test required for final confirmation	Complementary measures until development of the diagnostic kit	Specialized Kit for corona19 confirmation (WHO recommended)

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Selling Point (only for Sales Information)

1. Diagnostic Kit Accuracy (More than 99%)

1) **Sensitivity**: When the sensitivity of this product is confirmed in artificially synthesized RNA (In vitro transcripts), it has a detectable sensitivity up to 10 copies.
(Very small amount of corona19 can be detected, early diagnosis possible)

2) **Feature** : Multiple simultaneous detection of specific genes of ORF1a / N Gene
The new coronavirus confirmed the specificity of detection in 38 respiratory viruses, pneumonia and tuberculosis-associated bacteria. High specificity not detected in other viruses and fungi.
(Prevention of dust and low false positive rate)

3) **Result of test** : Three samples tested by the Korean Centers for Disease Control and Prevention showed very high accuracy.
(Unofficial, Only Sales Information)

2. Double the efficiency of PCR diagnostic equipment due to the Multiplex One-Tube method

: Introduced Multiplex One-Tube method, and can double inspection compared to Kogene Biotech's Two-Tube method when using the same PCR equipment.

3. Kit Production Stability: Direct Amplification Enzyme Production from SolGent

4. Common Use: Diagnosis is possible with commonly available RT-PCR equipment

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Selling Point (only for Sales Information)

Korea CDC's Emergency Use Approval (only 4 companies)

No.	Company Name	Detection Method	Target gene
1	솔젠트(SOLGENT Co.,Ltd.)	Real-Time OneStep RT-qPCR	Orf1a / N gene
2	코젠바이오텍(KOGENE BIOTECH)	Real-Time OneStep RT-qPCR	Orf1a / N gene
3	씨젠(SEEGENE)	Real-Time OneStep RT-qPCR	E gene / Orf1a / N gene
4	SD바이오센서(SD BIOSENSOR Co.,Ltd.)	Real-Time OneStep RT-qPCR	

China NMPA's Emergency Use Approval (only 7 companies)

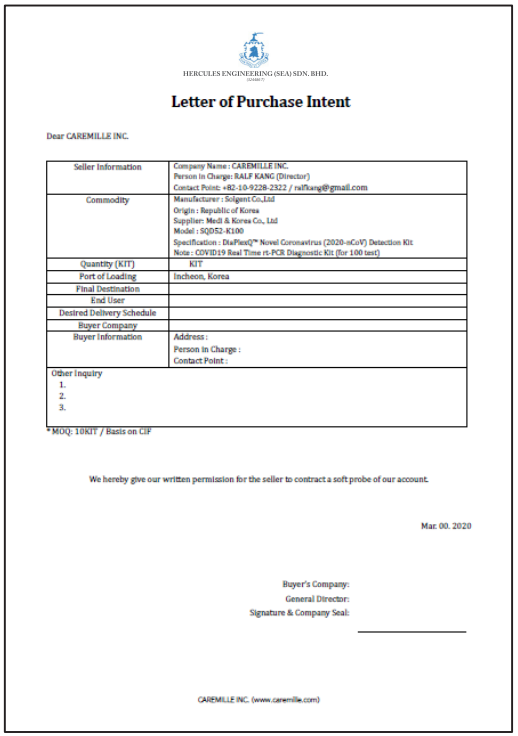
No.	Company Name	Detection Method	Target gene
1	Shanghai ZJ Bio-Tech Co.,Ltd (上海之江生物科技股份有限公司)	Real-Time RT-qPCR	E gene / Orf1a / N gene
2	BGI Biotechnology (WuHan) Co.,Ltd (华大生物科技（武汉）有限公司)	Real-Time RT-qPCR	ORF1ab
3	BGI Biotechnology (WuHan) Co.,Ltd (华大生物科技（武汉）有限公司)	cPAS with BGISEQ-500	
4	Shanghai GeneoDx Biotech Co.,Ltd (上海捷诺生物科技有限公司)	Real-Time RT-qPCR	Orf1a / N gene
5	Sandure Biotech Inc. (圣湘生物科技股份有限公司)	Real-Time RT-qPCR	Orf1a / N gene
6	DAAN Gene Co.,Ltd of Sun Yat-sen University (中山大学达安基因股份有限公司)	Real-Time RT-qPCR	Orf1a / N gene
7	Shanghai BioGerm Medical Biotechnology Co.,Ltd (上海伯杰医疗科技有限公司)	Real-Time RT-qPCR	Orf1a / N gene

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Ordering Process

1) Letter of Purchase Intent to Hercules Engineering (SEA) Sdn. Bhd.



HERCULES ENGINEERING (SEA) SDN. BHD.

Letter of Purchase Intent

Dear CAREMILLE INC.

Seller Information	Company Name : CAREMILLE INC. Person in Charge: RALF KANG (Director) Contact Point: +82-10-9228-2322 / ralfkang@gmail.com
Commodity	Manufacturer : Solgent Co.,Ltd Origin : Republic of Korea Supplier: Medi & Korea Co., Ltd Model : SQD52-K100 Specification : DiaPlexQ™ Novel Coronavirus (2020-nCoV) Detection Kit Note : COVID19 Real Time rt-PCR Diagnostic Kit (for 100 test)
Quantity (KIT)	KIT
Port of Loading	Incheon, Korea
Final Destination	
End User	
Desired Delivery Schedule	
Buyer Company	
Buyer Information	Address : Person in Charge : Contact Point :
Other Inquiry 1. 2. 3.	

* MOQ: 10KIT / Basis on CIF

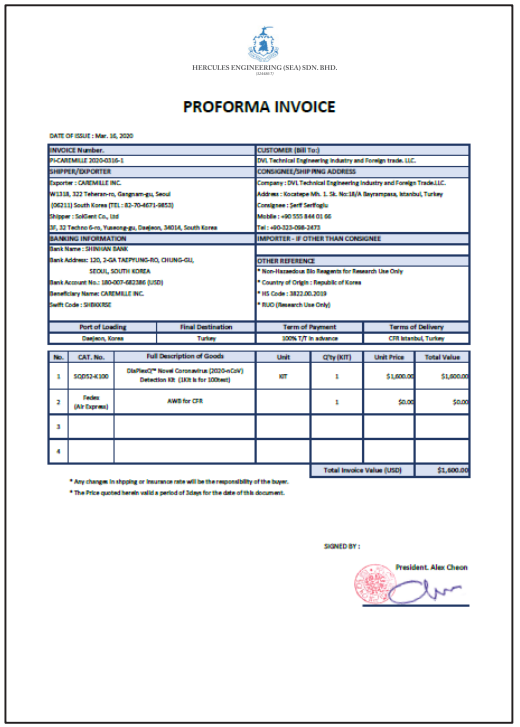
We hereby give our written permission for the seller to contract a soft probe of our account.

Mar. 00. 2020

Buyer's Company:
General Director:
Signature & Company Seal:

CAREMILLE INC. (www.caremille.com)

2) Contract & Invoice to Buyer



HERCULES ENGINEERING (SEA) SDN. BHD.

PROFORMA INVOICE

DATE OF ISSUE : Mar. 16, 2020

INVOICE Number.	CUSTOMER (Bill To:)
Pi-CAREMILLE 2020-0316-1	DVL Technical Engineering Industry and Foreign trade. LLC.
SHIPPER/EXPORTER	CONSIGNEE/SHIPPING ADDRESS
Exporter : CAREMILLE INC. W1318, 322 Teheran-ro, Gangnam-gu, Seoul (06211) South Korea (TEL : 82-70-4671-9853) Shipper : SolGent Co., Ltd 5F, 32 Techno 6-ro, Yuseong-gu, Daejeon, 34014, South Korea	Company : DVL Technical Engineering Industry and Foreign Trade.LLC. Address : Kocatepe Mh. 1. Sk. No:18/A Bayrampaşa, Istanbul, Turkey Consignee : Serif Serifoglu Mobile : +90 555 844 01 66 Tel : +90-323-098-2473
BANKING INFORMATION	IMPORTER - IF OTHER THAN CONSIGNEE
Bank Name : SHINHAN BANK Bank Address: 120, 2-GA TAEPYUNG-RO, CHUNG-GU, SEOUL, SOUTH KOREA Bank Account No.: 180-007-682386 (USD) Beneficiary Name: CAREMILLE INC. Swift Code : SHBKKRSE	OTHER REFERENCE * Non-Hazardous Bio Reagents for Research Use Only * Country of Origin : Republic of Korea * HS Code : 3822.00.2019 * RUO (Research Use Only)

Port of Loading	Final Destination	Term of Payment	Terms of Delivery
Daejeon, Korea	Turkey	100% T/T in advance	CFR Istanbul, Turkey

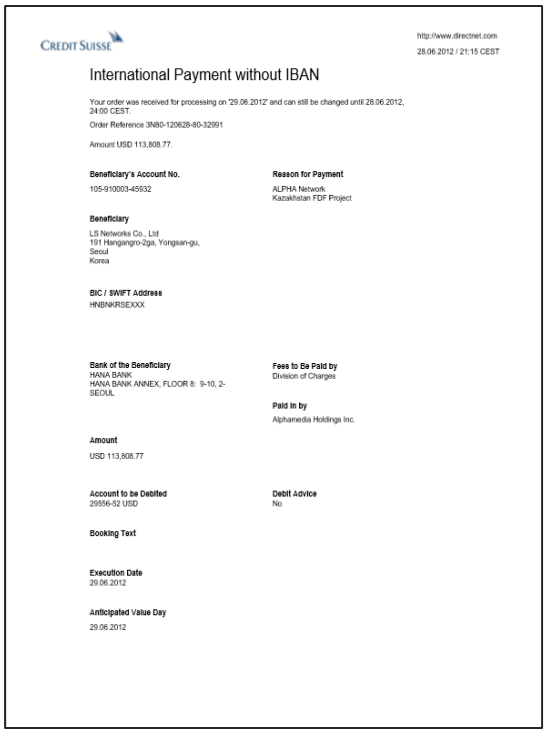
No.	CAT. No.	Full Description of Goods	Unit	Q'ty (KIT)	Unit Price	Total Value
1	SQD52-K100	DiaPlexQ™ Novel Coronavirus (2020-nCoV) Detection Kit (1EA is for 100test)	KIT	1	$1,600.00	$1,600.00
2	Fedex (Air Express)	AWB for CFR		1	$0.00	$0.00
3						
4						
					Total Invoice Value (USD)	$1,600.00

* Any changes in shipping or insurance rate will be the responsibility of the buyer.
* The Price quoted herein valid a period of 3days for the date of this document.

SIGNED BY :

President. Alex Cheon

3) TT copy receipt and shipping date notice



CREDIT SUISSE

http://www.directnet.com
28.06.2012 / 21:15 CEST

International Payment without IBAN

Your order was received for processing on '29.06.2012' and can still be changed until 28.06.2012, 24:00 CEST.

Order Reference 3N80-120628-80-32991

Amount USD 113,808.77.

Beneficiary's Account No.
105-910003-45932

Reason for Payment
ALPHA Network
Kazakhstan FDF Project

Beneficiary
LS Networks Co., Ltd
191 Hangangro-2ga, Yongsan-gu,
Seoul
Korea

BIC / SWIFT Address
HNBNKRSEXXX

Bank of the Beneficiary
HANA BANK
HANA BANK ANNEX, FLOOR 8: 9-10, 2-
SEOUL

Fees to Be Paid by
Division of Charges

Paid in by
Alphamedia Holdings Inc.

Amount
USD 113,808.77

Account to be Debited
29556-52 USD

Debit Advice
No

Booking Text

Execution Date
29.06.2012

Anticipated Value Day
29.06.2012

4. Sales Information

SolGent Co., Ltd.
솔젠트(주)

Ordering Information for Relative Products

Name of kits	CAT. No.	Detection Method
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection kit	SQD52-K100	Real-Time PCR
	SQD52-K020	
DiaPlexQ™ 2019-nCoV(RdRp, E, N) Detection kit	SQD55-K100	
	SQD55-K020	
DiaPlexQ™ RV16 Detectio kit	SQD50-K100	
	SQD50-K020	
DiaPlexQ™ PneumoPatho16 Detectio kit	SQD80-K100	
	SQD80-K020	
DiaPlexQ™ MTC/NTM Detection Kit – Ver 3.0	SQD25-K100	
DiaPlexQ™ MTC/NTM Detection Kit(w/Ext) – Ver 3.0	SQD26-K100	

SQD52-K100

▶ Kit Contents

Components	SQD52-K020	SQD52-K100
2X OneStep qRT-PCR Buffer (2019-nCoV)	200 μℓ x 1 ea	1.0 mL x 1ea
OneStep qRT-PCR Enzyme mix (2019-nCoV)	40 μℓ x 1 ea	200 μℓ x 1 ea
Primer & Probe Mixture (R,E,N)	60 μℓ x 1 ea	300 μℓ x 1 ea
Control Template (R,E,N)	20 μℓ x 1 ea	100 μℓ x 1 ea
RNase Free Water	200 μℓ x 1 ea	1.0 mL x 1 ea

5. Distributor Qualification & Competency

Hercules Medicare is managed by Dr. **Mohd Fauzi Hj Hassan** who has gained his MBBS from the University of Malaya in 1997.

With over 20 years of experience as medical practitioner, he has experienced SARS outbreak in 2003.

Dr. Fauzi's medical clinic has been appointed by the Ministry of Health (MOH) in managing Yellow Fever vaccine for state of Terengganu, Malaysia since 2018.

In addition, his medical clinic is currently also collaborating with QUALITAS Medical Group (appointed by the Malaysian Ministry of Health - MOH) in sample taking and transporting the sample of Covid-19 to laboratory for further tests and analyse using Polymerase Chain Reaction (PCR) method.

HERCULES

SolGent DiaPlexQ™
Novel Coronavirus (2019-nCoV)
Detection Kit (CE-IVD)

HERCULES

CUM MANU ET CORDE

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486T)

THANK YOU

AUTHORIZED
DISTRIBUTOR

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486 T)

(HERCULES Group Of Companies)

SolGentDiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit (CE-IVD)

Office : No. 12A, Jalan SB Jaya 1, Taman Industri SB Jaya, 47000 Sungai Buloh, Selangor, Malaysia.
Factory: Lot 3691, Kampung Jaya Industri Area, 47000 Sungai Buloh, Selangor, Malaysia.
Tel: 603-6156 6388 • H/P: 6016-336 7138 • Fax: 603-6156 4399 • Homepage: www.hercules-engineering.com • e-mail: medicare@hercules-engineering.com

HERCULES CARES...

Let's care for our loved ones

Ezplex®

2019-nCoV Real-time PCR Kit

MFDS certified (No.20-211)

(For Local Dealer Information Confidential)

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486 T)

AUTHORIZED DISTRIBUTOR

1. Introduction

Coronavirus Disease 2019 (COVID-19)

COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Common symptoms include fever, cough, and shortness of breath.

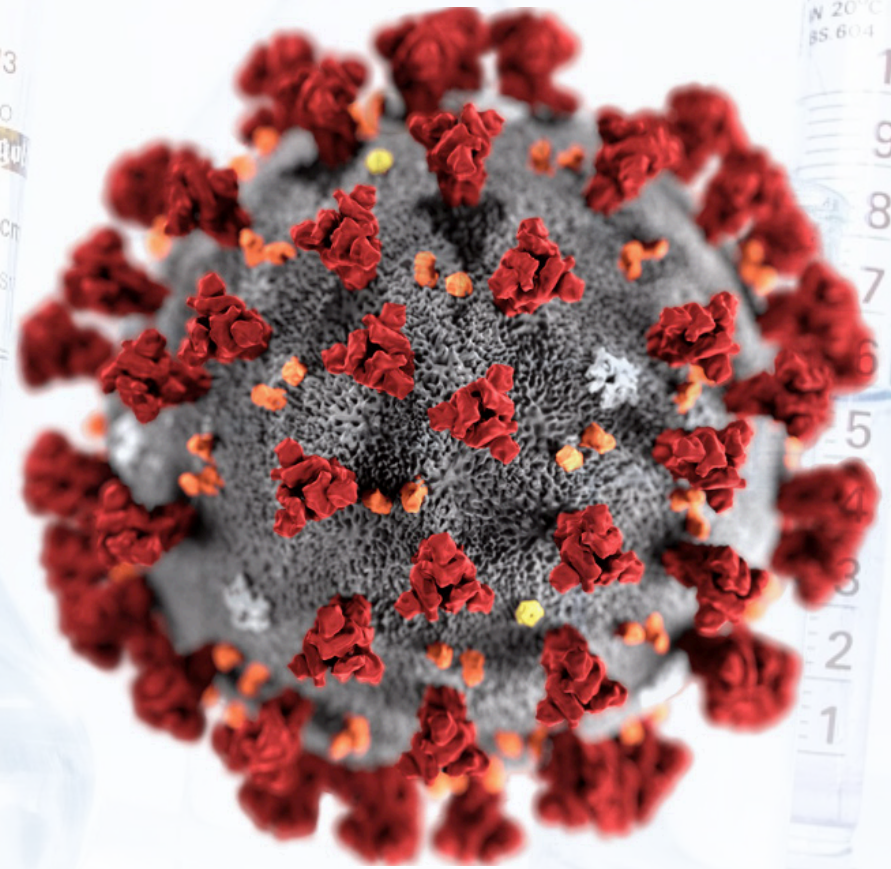
This disease is getting worse and created a major impact to people around the world.

In order to contain and slow down the spread of coronavirus, testing is one of the most efficient way. Infected patients can be quarantined by detecting the people who tested positive. It also lets public health workers build a more accurate picture of the number of cases and how the virus is spreading in the population.
Hercules has taken the initiative to distribute the COVID-19 test kits by collaborating with Korean company, SML Genetree.

1. Introduction

It is a screening kit to detect Novel Corona Virus as 2019-nCoV from isolated total RNA.

This test kit has obtained regulatory agency approval from European CE-IVD and Korean CDC's Emergency Use Approval.



2. Kit Introduction

Ezplex® 2019-nCoV Real-time PCR Kit

Sensitivity

This kit includes *RdRp, E, and N* gene assays. It allows for sensitive detection of SARS-CoV2 regardless of virus mutation.

Convenience

It comes with the analysis software, so users can conveniently check test results.

Stability

Long-term storage tests prove that this kit remains stable for 2 months

Reproducibility

High reproducibility was proved through repeated testing of standard substance.

Specificity

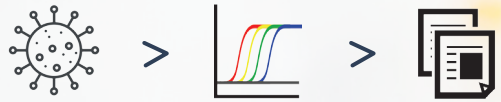
It specifically detects SARS-CoVs without cross-reactivity with other viruses that cause respiratory diseases such as pneumonia.

2. Kit Introduction

The Ezplex® 2019-nCoV Real-time PCR Kit is devised for qualitative detection of SARS-CoV2 virus using RNA extracted from oropharynx and nasopharynx specimens of patients through Real-time Polymerase Chain Reaction.

The real-time PCR allows for rapid and easy testing of 96 samples and users can check test results conveniently with the software included in this kit.

Workflow



Analytical Sensitivity

Repeated tests of serial-diluted standard substance demonstrated that Ezplex® 2019-nCoV Real-time PCR Kit has a high analytical sensitivity.

Target	Limit of Detection(copies/uL)
RdRp	1.842
E	0.467
N	1.842

Analytical Specificity

Fifteen kinds of standard substance of the virus were all tested negative, which represents a high analytical specificity of the Ezplex® 2019-nCoV Real-time PCR Kit.

Reproducibility

Reproducibility tests using standard substance produced stable results with all CV values less than 5%.

Target	Concentration	Mean	CV(%)
RdRp	Medium	27.60	0.75
	Low	32.40	0.42
E	Medium	28.61	0.68
	Low	33.63	0.44
N	Medium	27.58	0.50
	Low	33.47	0.27

2. Kit Introduction

Stability

Repeated tests of Ezplex® 2019-nCoV Real-time PCR Kit at the initial point and each storage point for 2 months showed that the kit remained stable with all CV values less than 5%.

Target	Concentration	Initial Mean	Ending Mean	Total CV(%)
RdRp	Positive	26.74	26.55	1.46
	Negative	Negative	Negative	-
E	Positive	23.45	23.54	0.46
	Negative	Negative	Negative	-
N	Positive	25.28	25.45	1.19
	Negative	Negative	Negative	-

② Result

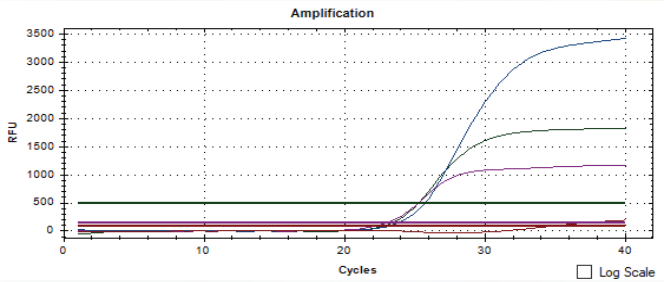
No.	Sample ID	Well	Content	RdRp	E	N	IC	Result
1	0324-1001	A04	Unkn-01	30.99	30.59	28.30	35.19	Positive
2	0324-1002	B04	Unkn-02	26.08	25.93	23.81	39.43	Positive
3	0324-1003	C04	Unkn-03	30.58	30.78	28.68	34.57	Positive
4	0324-1004	D04	Unkn-04	22.77	22.79	20.94	36.68	Positive
5	0324-1005	E04	Unkn-05	28.40	28.62	26.87	36.29	Positive
6	0324-1006	F04	Unkn-06	N/A	N/A	N/A	34.26	Negative
7	0324-1007	G04	Unkn-07	35.07	35.34	32.95	35.19	Positive
8	0324-1008	H04	Unkn-08	N/A	N/A	N/A	36.26	Negative

2. Kit Introduction

Analysis Software

Users can easily analyze test results using the software included in the kit.

① **Raw data**



Ordering Information

The Ezplex® 2019-nCoV Real-time PCR Kit is consisted of Taq Polymerase, Primer & Probe, Positive Control, and Negative Control.

Product Type	Product size
Ezplex® 2019-nCoV Real-time PCR Kit	**100 reaction**
Ezplex® 2019-nCoV Real-time PCR Kit	**200 reaction**

3. Introduction for Use

Instructions for Use

(Ezplex® 2019-nCoV Real-time PCR kit)

1. Product Name

Ezplex® 2019-nCoV Real-time PCR Kit

2. Manufacturer (Name and Address)

- Name: SML Genetree Co., Ltd. / 82-2-2057-7900
- Address: 6F, Hanmaeum Bldg., 225 Baumoe-ro, Seocho-gu, Seoul, South Korea.

3. Intended Use

The product is an in-vitro diagnostic medical device that is used for qualitative detection of SARS-CoV-2 Virus by extracting ribonucleic acid (RNA) from Nasopharyngeal and Oropharyngeal swab specimens from patients suspected of having the COVID-19 infection and by using the Real-time Reverse Transcription Polymerase Chain Reaction.

4. Instructions for use

4.1. Specimen Preparation and Storage
A. Nasopharyngeal and Oropharyngeal swab specimens shall be used for the test.
B. It is recommended that swab specimens shall be used immediately after collection. However, the specimens can be stored maximum 4 days at 2-8℃ in a fridge or maximum 2 months at –20℃ in a freezer if immediate use is not achievable.
C. Specimens shall be divided into amounts required for one testing and stored at –20℃ in a freezer so as to avoid from thawing repeatedly.
D. Specimens that are no longer needed shall be put in a container for liquids and disposed as liquid medical waste.
E. Specimen collection
- Specimens shall be collected in a dedicated container which shall be sealed to prevent leakage.
- Adequate protective gears such as gloves and gowns shall be used to handle the specimens.
- Protective glasses, masks, or aprons shall be worn if protection is required against specimen splatter.

4.2. Pre-test Preparations

A. Reagents shall be stored at –20℃ and shall avoid from repeated freezing and thawing.
B. Reagents shall be used after completely thawed.
C. Since RNA can be degraded from the positive control, it is recommended that the reagents shall be divided into amounts required for 1-2 tests and stored in a freezer.
D. Equipment required for testing: **CFX96 Real-time PCR (Bio-Rad)**

4.3. Test Procedure

A. Specimen Pretreatment
While it is possible to use various ways and kits adopted in laboratories to extract RNA and apply on this product, it is recommended that QIAamp DSP Virus Spin Kit (Qiagen GmbH) shall be used for RNA extraction and users shall follow the protocol included in the Kit Handbook. After being extracted, RNA shall be stored at –20 ± 2℃ in a freezer and shall be divided into amounts required for 1-2 tests since RNA can be degraded.

B. Real-time PCR Amplification
1) Making reagent master mix solution

① Refer to the tables below and make PCR master mix solution according the number of samples to be tested (See Table 1, 2).

Table 1. In case a separate IC is included in specimen extraction (unit: uL)

Component	Capacity
RQ Mixture	10
nCoVP+P	5
Total	15

Table 2. In case a separate IC is not included in specimen extraction (unit: uL)

Component	Capacity
RQ Mixture	10
nCoVP+P	5
IC	0.1
Total	15.1

② Divide 15㎕ of PCR mater mix solution in PCR tubes, add 5㎕ of the RNA specimen in each tube, and mix them well.

③ Both positive control and negative control shall be tested for accuracy.

2) Set up the device with below conditions.

Step	Temperature / Time	Cycle
Hold	25 ℃ / 2 min	1 Cycle
	50 ℃ / 30 min	
	95 ℃ / 5 min	
Cycle	95 ℃ / 15 sec	40 cycles
	60 ℃ / 45 sec	

4.4. Results

4.4.1 Fluorescent thresholds for detection targets were set **'500' for FAM, HEX, '150' for Cy5**, and, **'100' for Quasar705,** after which Ct value was checked to decide the results according to the below table.

FAM (RdRp)	HEX (E)	Cy5 (N)	Quasar 705(IC)	Result*	Remark
<40	<40	<40	Any	**Positive**	
<40	≥40 or Neg	<40	Any	**Inconclusive***	
<40	<40	≥40 or Neg	Any	**Inconclusive***	
≥40 or Neg	<40	<40	Any	**Inconclusive***	
<40	≥40 or Neg	≥40 or Neg	Any	**Negative****	
≥40 or Neg	<40	≥40 or Neg	Any	**Negative****	
≥40 or Neg	≥40 or Neg	<40	Any	**Negative****	
≥40 or Neg	≥40 or Neg	≥40 or Neg	<38	Negative	
≥40 or Neg	≥40 or Neg	≥40 or Neg	≥38 or Neg	Invalid	Retest after re-extraction

*** The result is judged as Positive only when it is detected all of RdRp, E and N gene. Further confirmatory test shall be necessary if the result is judged as "Inconclusive".**
**** If single gene is detected alone, regardless of the gene, the result is judged as Negative.**

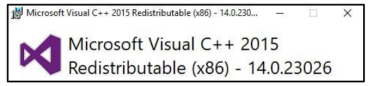
4.4.2 Positive&Negative control range
Due to PCR instruments managing in all different conditions, the individual fluorsence thresholds are changeable if controls are deviated from measured ranges as below table.

Control	RdRp Ct (FAM)	E Ct (HEX)	N Ct (Cy5)	IC Ct (Quasar 705)
PC	24.5 ~ 26.5	25.0 ~ 27.0	22.0 ~ 24.0	Any
NC	Neg	Neg	Neg	26.5 ~ 28.5

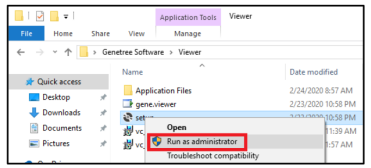
4.4.3 Software analysis(Genetree Viewer)

4.4.3.1 Software installation

1) Before installing analysis software, the 'Microsoft Visual C++ 2015 Redistributable(x86)' shall be installed in advance.



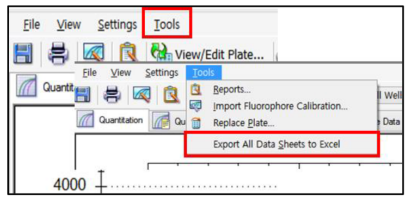
2). After pre-installation step, click on 'Run as administrator' of file 'Setup.exe' in the installation folder of 'Genetree Viewer'.
NOTE : Please contact 'genetree@genetree.co.kr' to acquire 'Genetree viewer' software.



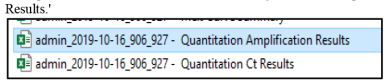
3) If the installation is completed, the run file of analysis software can be found in the 'Start menu' as below.

4.4.3.2 Software Analysis

1) Check that PCR is finished and click 'Export All Data Sheets to Excel' from CFX96 Manager software's 'Tool' menu to convert the test data into an excel spreadsheet (Create a folder and save the file in it).
NOTE : The Genetree Viewer software is only compatible with CFX96 Manager version 1.6. If other version is used for PCR running, manual analysis shall be performed referring to '4.4.1'.

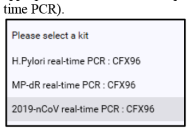


2) Run the analysis software (Genetree Viewer), press 'Open' on the upper left to navigate the folder where the converted excel file is saved, and open the file with name that ends with 'Quantitation Amplification Results.'



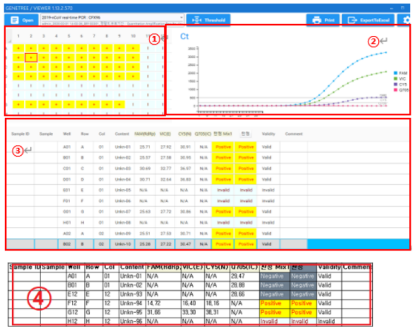
3. Introduction for Use

3) Click 'Please select a kit' menu at the top of the screen and select an appropriate item for the tested panel as in the below figure (2019-nCoV real-time PCR).



4) As it is shown in the below image, results for each well can be checked according to the selected Kit component.
Note: Refer to the below table for description of the results.

No.	Description
①	Positive/Negative results by well are indicated in '+', '-' respectively.
②	Ct and fluorescent values of the results for each well are plotted on a graph.
③	Ct values of the results for each well are indicated numerically and qualitative results are printed.
④	Analysis results are converted into an excel spreadsheet.



5. Warnings and Precautions

1) This product is intended for diagnostic use, and shall be used by clinical expert such as clinical pathologist and medical technologist.
2) Insufficient test results, such as inconclusive result, through this product shall be confirmed together with additional diagnostic measures.
3) All product components shall be taken out just before use and shall be stored in a freezer (below –20°C) immediately after use they are exposed as little as possible to the ambient temperature.
4) Beware of carry-over contamination since the Real-time PCR has a high sensitivity.
5) Repeated freezing and thawing of reagent and specimen shall be avoided because they may affect the test sensitivity.
6) Beware of microbe contamination when dividing the reagent and it is recommended to use a sterilized disposable filter tip.
7) Beware not to touch the reagent container cap or the inner side of PCR tube cap with your hands.
8) It is prohibited to mix the products from different Lots even in case of the same product's reagent.
9) Do not use the product if the use authorization is expired.
10) Tests shall be performed in accordance with the Guideline for Laboratory Biosafety and the Laboratory Safe Management Manual.
11) While handling the specimen, beware of infection through skin or inhalation. In case of human exposure, the part shall be immediately cleansed with running tab water and medical attention shall be sought immediately for symptoms including high fever and rashes.
12) Tests shall be performed in accordance with the Guideline for Laboratory Biosafety and the Laboratory Safe Management Manual, and all spaces shall be thoroughly sterilized using 70% Ethanol or 0.5% sodium hypochlorite.

6. Performance

No	Test Name	Test method
1	Analytical Sensitivity (Limit of Detection)	Using synthesized RNA of RdRp, E and N gene, it was serially spiked in both of nasopharyngeal and oropharyngeal swab specimens, and RNA were extracted from those prepared specimens. The test was performed ten times on every diluted concentrations and the limit of detection is calculated as below using probit analysis of 95% positive rate. Target / Limit of detections(copies/μℓ) RdRp: 1.842 E: 0.467 N: 1.842
2	Analytical Specificity (Cross reactivity)	The fifteen species of DNA and RNA materials, which are expected of cross reactivity, are chosen for the test and the test repeated three times on every chosen species. As a result of test, there were no cross reactivity as those were observed as all negative result. No. / Marterials 1 Influenza A H3 2 Influenza B 3 Respiratory Syncytial Virus A 4 Respiratory Syncytial Virus B 5 Parainfluenza virus 1 6 Parainfluenza virus 2 7 Parainfluenza virus 3 8 Coronavirus OC43 9 Coronavirus 229E 10 Coronavirus NL63 11 Enterovirus 71 12 Adenovirus 13 Rhinovirus 14 *Chlamydophila pneumoniae* 15 *Legionella pneumophila*
3	Analytical Specificity (Interference)	The interference materials were prepared with Albumin (0.24g/mL), Hemoglobin (0.2g/mL) and Billirubin (0.05mg/mL), those were tested three times with and without positive materials of RdrRp, E and N genes diluted in 2 copies/uL, which are the lowest detection concentration in LoD test. As a result of the test, there were no interference by observing the coefficient of variation(CV) value which were less than 5% in all cases.
4	Precision (Reproducibility, Repeatability)	The test materials were prepared as positive and negative control, positive divided into high and mid-concentration of the synthesized RNA materials, and D.D.W was used as negative control. Those materials were tested totally ten times each, repeating five times daily for two days. As a result of the test, the high precision has been confirmed by observing the coefficient of variation(CV) value which were less than 5% in all cases.
5	Clinical Performance	The clinical performances of 53 oropharyngeal and nasopharyngeal swab samples, in which confirmed through a certified another IVD reagent, were collected and performed as below. Specimens / Clinical sensitivity (95 % CL) / Clinical specificity (95 % CL) Nasoparyngeal: 100 % (47.8 ~100%) / 100 % (84.6 ~100%) Oropharyngeal: 100 % (47.8 ~100%) / 100 % (83.9 ~100%)

7. Storage

A. Storage

Reagent Name	Before/After opening the container	Storage Condition	Shelf life
RQ Mixture	Before opening	-20°C	64 days from date of manufacture
nCoV P+P	Before opening	-20°C	
Positive control	Before opening	-20°C	
Negative control	Before opening	-20°C	
Internal control	Before opening	-20°C	

B. Storage and transport conditions

1) Products that are packaged shall be stored in a storage freezer.
2) To transport the products to a client, the products shall be put in a cooler with dry ice so that the products are not exposed to the ambient temperature.
3) When sending the products via a courier service, product boxes shall be wrapped with bubble wraps before putting in a cooler, ices packs shall be stacked on the products, and then dry ice shall be filled to cover more than 1/3 of the entire box so that temperature change during delivery is minimized.

8. Packing Unit

* 100 Test Kits

No	Component	Presentation
1	RQ Mixture	1 vial, 1000 uL
2	nCoV P+P	1 vial, 500 uL
3	Positive control	1 vial, 50 uL
4	Negative control	1 vial, 50 uL
5	Internal control	1 vial, 20 uL

* 200 Test Kits

No	Component	Presentation
1	RQ Mixture	2 vials, 1000 uL
2	nCoV P+P	2 vials, 500 uL
3	Positive control	2 vials, 50 uL
4	Negative control	2 vials, 50 uL
5	Internal control	2 vials , 20 uL

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486 T)

3. Manufacturer

SML Genetree

SML genetree keeps on competing with the best companies in the world for healthy life of mankind.

About us

Since the establishment, SML genetree is one of the fastest-growing companies in molecular diagnostics. As being of remaining of the balance between fundamental research in molecular biology and relative applied study, SML genetree has been recognized as best partner to be able to serve our advanced technology to our customer in right time. Especially, it has succeeded in commercializing Ezplex® HPV 100 NGS Kit, which is the first in the world. It is highly evaluated among the research institutes in and out of the country and is becoming the exemplary bio-venture company in Korea.

Vision

SML genetree will be the top-notch company based on continuous challenge, innovation, and customer value.

SML genetree has the world-class genome research competence and abundant experience leading to research and customer value. It is already considered as the top molecular diagnostics company in Korea through efficiency and value-based business system establishment and performance in global market, but furthermore, it will be the top-notch company through developing new driving force in bio-industry.

Value

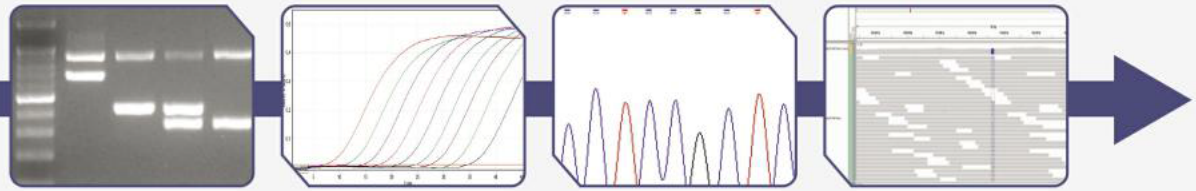
SML genetree will always be with the customers and the society.

SML genetree wii share the love from the customers to the society with the attitude that 'healthy life of mankind' is our fate. As the scientific fruit that we enjoy isn't the effort and contribution of just one man, SML genetree will play the role as the business citizen so that all members of the society can enjoy healthy and happy life.

SML Genetree

3. Manufacturer

Methods



Benefit

- Conveniently supplied with viewer software.
- Monitoring system from specimen extraction state to the result analysis.
- Validated Clinical performance.
- The analysis software also provided, makes the work easier.
- Simultaneous processing ability for the large scale samples, not only for single sample.

Bacterial disease

Viral disease

Drug resistance

Precision medicine for cancer

Human leukocyte antigen (HLA) typing

3. Global Distributor

Samkwang Genetree

LETTER OF AUTHORIZATION

Date: 03 April 2020

TO WHOM IT MAY CONCERNS:

We, **SML GENETREE CORP**., a corporation established and duly existing under the laws of Republic of Korea, with main office located at **6F, Hanmaeum Bldg., 225 Baumoe-ro, Seocho-gu, Seoul, Korea** hereby duly appoint and authorize **HERCULES ENGINEERING (SEA) SDN BHD**., a corporation established and duly existing under the laws of Malaysia, with main office located at **2A, Jalan SB Jaya 1, Taman Industrial SB Jaya, 47000 Sungai Buloh, Selangor, West Malaysia** represented by Izral Mafti Director (the "Agent"), as our authorized sales agent for the sales promotion of **COVID19 Diagnostic Kit 'Ezplex® 2019-nCoV Realtime PCR Kit'** manufactured by **SML GENETREE CORP.,**("Products") in the territory (none exclusive right) Republic of Malaysia until the end of 2020 from this date written hereinafter.

Please acknowledge and understand that:

a. we authorized the Agent to provide us with the counsel, guidance, liaison assistance, facilities and information as shall be reasonably necessary and required for the promotion of the sale of Products;
b. the Agent agreed to do their best efforts to promote and further the sale of the Products;
c. Agent's authority under this Instrument is to assist us in the promoting of the sales of the Products and we shall not authorize the Agent to enter into any commitment of any kind on behalf of us and shall not make any contractual offers on behalf of us unless the Agent obtains prior written instructions from us concerning the terms of such commitment and/or offers;
d. the Agent will assume and discharge for their own account all costs, expenses and charges necessary or incidental to its marketing functions and operations hereunder, and will indemnify and save us harmless from and against all such costs, expenses and charges, and all claims, disputes, actions, judgments and liabilities of every kind which are made, contracted, suffered or incurred by the Agent; and
e. the official Agent Agreement regulating rights and obligations of the Agent and us will be separately made and entered into between the Agent and us after verifying the marketability of the Products.

IN WITNESS WHEREOF, we have duly caused this Instrument to be executed by our duly authorized representatives as of the date and year first above written.

SML GENETREE CORP.,

AHN JI HOON
C.E.O.

HERCULES ENGINEERING (SEA) SDN. BHD.
(3244867)

4. Sales Information

Osong Health Technology Administration Complex,
187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea, 28159
Tel: +82-43-719-2342, Fax: +82-43-719-2300

열람용

No. of Certificate : 20200032745 Date : 2020/03/26

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. : 4937)

SML GENETREE Inc.

225, Baumoe-ro, Seocho-gu, Seoul, 06740, Rep. of Korea

Product-License No.	Classification
20-211	IVD reagents for infectious disease marker(Diagnosis of Sexually transmitted disease, Legally designated infectious pathogens other than 'high-risk pathogens', Infectious agents with moderate infectivity), nucleic acid test [3]

※Attached : List of Product Classification and Model

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

4. Sales Information

Ezplex® 2019-nCoV Real-time PCR Kit

INTENDED USE

- *IN VITRO* USE

This product is intended for diagnostic use of COVID-19, and shall be used by trained clinical personnel.

- DESCRIPTION

The product is an in-vitro diagnostic medical device that is used for qualitative detection of SARS-CoV-2 Virus(RdRp, E, N gene) by extracting ribonucleic acid (RNA) from Nasopharyngeal and Oropharyngeal swab specimens from patients suspected of having the COVID-19 infection and by using the Real-time Reverse Transcription Polymerase Chain Reaction.

MATERIALS PROVIDED

Name	Description
RQ Mixture	1000 uL of PCR mixture containing Taq, dNTP and UNG.
nCoV Probe Primer	500 uL of Probe Primer mixture containing Primer and Probe fluorescence
Positive control	50 uL of Positive control containing synthesized DNA of SARS-CoV-2 virus
Negative control	50 uL of Negative control containing double distilled water
Internal control	20 uL of Internal control containing synthesized DNA of housekeeping gene

PERFORMANCE

- ANALYTICAL SENSITIVITY

RdRp (copies/uL)	E (copies/uL)	N (copies/uL)
1.842	0.467	1.842

- CLINICAL PERFORMANCE

Specimens	Sensitivity	Specificity
Nasopharynge	**100% (47.8-100%)**	**100% (84.6-100%)**
Oropharynge	**100% (47.8-100%)**	**100% (84.6-100%)**

- ANALYTICAL SPECIFICITY (CROSS-REACTION)

All Negative results have been confirmed on below 15 organisms;
Influenza A H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Parainfleunza Virus 1, Parainfluenza Virus 2, Parainfluenza 3, Coronavirus OC43, 229E, NL63, Eneterovirus 71, Adenovirus, Rhinovirus, *Chlamydophila pneumoniae, Legionella pneumophila*

- ANALYTICAL SPECIFICITY (INTERFERENCE)

No interference effect has been confirmed on below materials;
Albumin(0.24g/mL), Hemoglobin(0.2g/mL), Billirubin(0.05mg/mL)

Ezplex® 2019-nCoV Real-time PCR Kit

METHOD AND PROCEDURES

RNA EXTRACTION	Extract RNA from Nasopharyngeal and Oropharyngeal swab from suspcted patient of COVID-19. **(Extraction kit is not included in the product)**
PCR RUNNING	Apply this product with extracted RNA using CFX96 Real-time PCR instrument.
RESULT ANALYSIS	The Analysis can be carried out with manually using instrument's software or automatically using Genetree Viewer software.

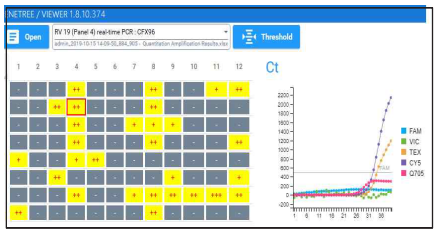
STORAGE AND STABILITY

The product is stable stored at -20 ℃ in freezer. Do not thaw and freeze more than 3 times and do not use after expiration date indicated on lable of the product.

EXTERIOR

PRODUCT

SOFTWARE



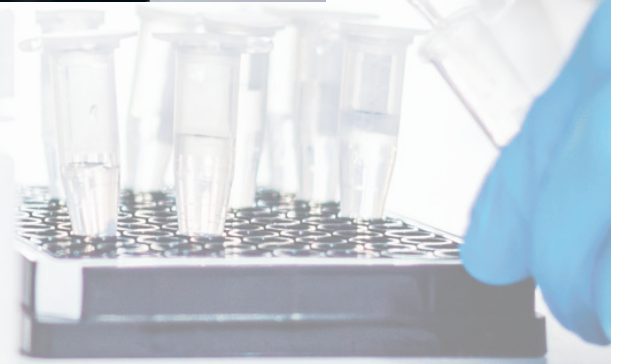
5. Distributor Qualification & Competency

Hercules Medicare is managed by Dr. **Mohd Fauzi Hj Hassan** who has gained his MBBS from the University of Malaya in 1997.

With over 20 years of experience as medical practitioner, he has experienced SARS outbreak in 2003.

Dr. Fauzi's medical clinic has been appointed by the Ministry of Health (MOH) in managing Yellow Fever vaccine for state of Terengganu, Malaysia since 2018.

In addition, his medical clinic is currently also collaborating with QUALITAS Medical Group (appointed by the Malaysian Ministry of Health - MOH) in sample taking and transporting the sample of Covid-19 to laboratory for further tests and analyse using Polymerase Chain Reaction (PCR) method.



SML Genetree

Ezplex® 2019-nCoV Real-time PCR Kit

HERCULES

CUM MANU ET CORDE

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486-T)

THANK YOU

AUTHORIZED DISTRIBUTOR

HERCULES ENGINEERING (SEA) SDN. BHD.
(324486 T)

(HERCULES Group Of Companies)

Ezplex® 2019-nCoV Real-time PCR Kit, MFDS certified (No.20-211)

Office : No. 12A, Jalan SB Jaya 1, Taman Industri SB Jaya,
47000 Sungai Buloh, Selangor, Malaysia.
Factory: Lot 3691, Kampung Jaya Industri Area,
47000 Sungai Buloh, Selangor, Malaysia.

• Tel: 603-6156 6388 • H/P: 6016-336 7138 • Fax: 603-6156 4399
• Homepage: www.hercules-engineering.com
• e-mail: medicare@hercules-engineering.com