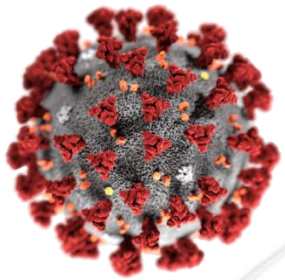


SolGent *DiaPlexQ*™ Novel Coronavirus (2019-nCoV)Detection Kit

Real-Time One-Step RT-PCR based assay system for detection of SARS-CoV-2

WHY CHOOSE SOLGENT FOR YOUR DETECTION KIT?

PANDEMIC : GLOBAL STATUS OF COVID-19 DETECTION KITS

1. Insufficient supply due to few numbers of production countries

- Only about 10 countries manufacture detection kits worldwide
- Most countries depend on import

2. Global supply shortage of detection kits

- Tests for symptoms are challenging due to lack of supply
- Shortcomings of diagnosis and quarantine measures
- Implementing detection kits ration : priority use for high-risk group

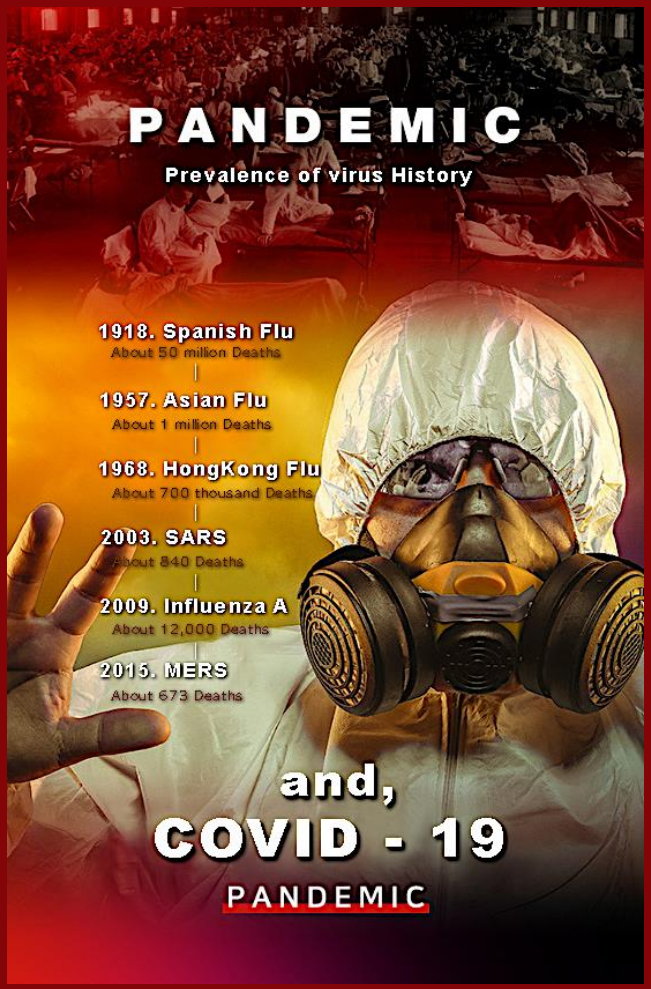
3. US CDC's detection kits show faulty results

- US CDC reputation for 74 years of history plunged. "even plain water tested positive to COVID-19"

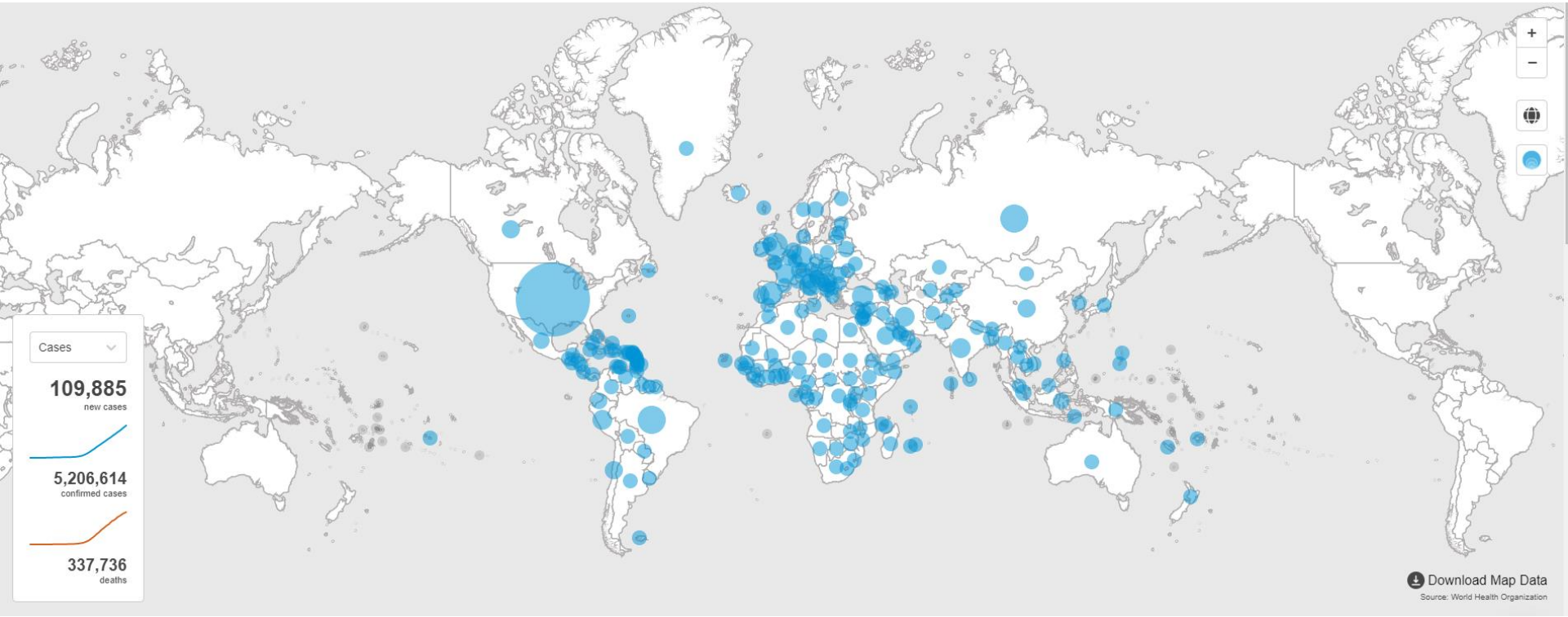
4. Chinese detection kits, 'piles of faulty products'

- Over 50% of detection kit manufacturers worldwide is Chinese company
- Severely inaccurate results from contaminated reagents caused by poor management and production
- Chinese detection kits rejected overseas including Czech, Spain, Turkey, Philippines, UK, USA and others

- Czech : 200,000 of faulty detection kits
- Slovakia : 1.2 mil of faulty detection kits
- Spain : Only 30% of accuracy showed by Chinese imported kits
- Turkey : Only 35% of accuracy showed by Chinese imported kits
- Italy : 75% of Chinese relief goods were defective
- Netherlands : withdraw 600,000 of Chinese masks



WHO Coronavirus Disease (COVID-19) Dashboard



Globally, as of **7:07pm CEST, 24 May 2020**, there have been **5,206,614 confirmed cases** of COVID-19, including **337,736 deaths,** reported to WHO.

Supply of "SolGent COVID-19 Test Kit"

is **urgent** worldwide

Ref: https://covid19.who.int/

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

1. Features

- Multiplex OneStep qRT-PCR
- Hot Start PCR system by using optimized Hot Start polymerase
- Commercial Real-time PCR Instrument available
- High specificity: simultaneous detection of **ORF1a and N gene.**

2. Detection Targets

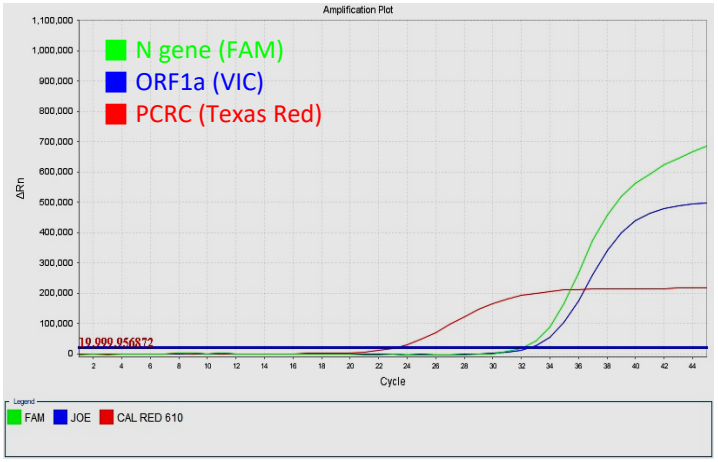
- Simultaneous Detection of ORF1a / N gene
- CDC 2019-Novel Coronavirus (2019-nCoV) Real-time qRT-PCR Panel Primers and Probes

High specific targets were selected based on the Chinese CDC and US CDC.

1. KIT HS Code : 3822.00.10
2. Kit Specification : Kit Box (100test) Size : 95 * 55 * 60mm
3. kit require special storage : Required refrigeration (-25 ~ -15 °C)
4. Expiration Length : Validity 1 year
5. Time to extract results : 1 hour 45 minutes

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

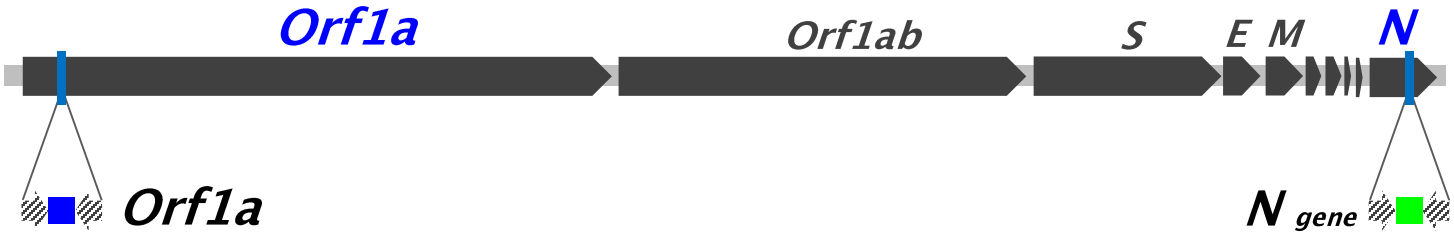
Amplification Plot information



Fluorescence information

Target	5` Fluorophore	3` Quencher
N gene	***FAM***	***BHQ1***
ORF1a	***VIC / JOE****	***BHQ1***
PCR control	***Texas Red/ Cal Fluor Red 610****	***BHQ2***

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



2019-nCoV Detection region **2** of **SolGent**

2019-nCoV Detection region **1** of **SolGent**

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

Interpretation of Results

Ct Value			Interpretation
N Gene	ORF1a	PCRC	
≤ 40	Any	Any	Positive
Any	≤ 40	Any	Positive
≤ 40	≤ 40	Any	Positive
> 40	None	Any	Inconclusive[1]
None	> 40	Any	Inconclusive[1]
> 40	> 40	Any	Inconclusive[1]
None	None	≤ 26	Negative
None	None	> 26 or None	Invalid[2]

Result Interpretation for Patient Samples

1 Repeat RT-PCR

2 Repeat extraction and RT-PCR

Note:

•Even if the target is detected (Ct ≤40) and the PCRC is not detected, the result is still valid because:

1.If the sample is high concentration, PCRC may not amplify.

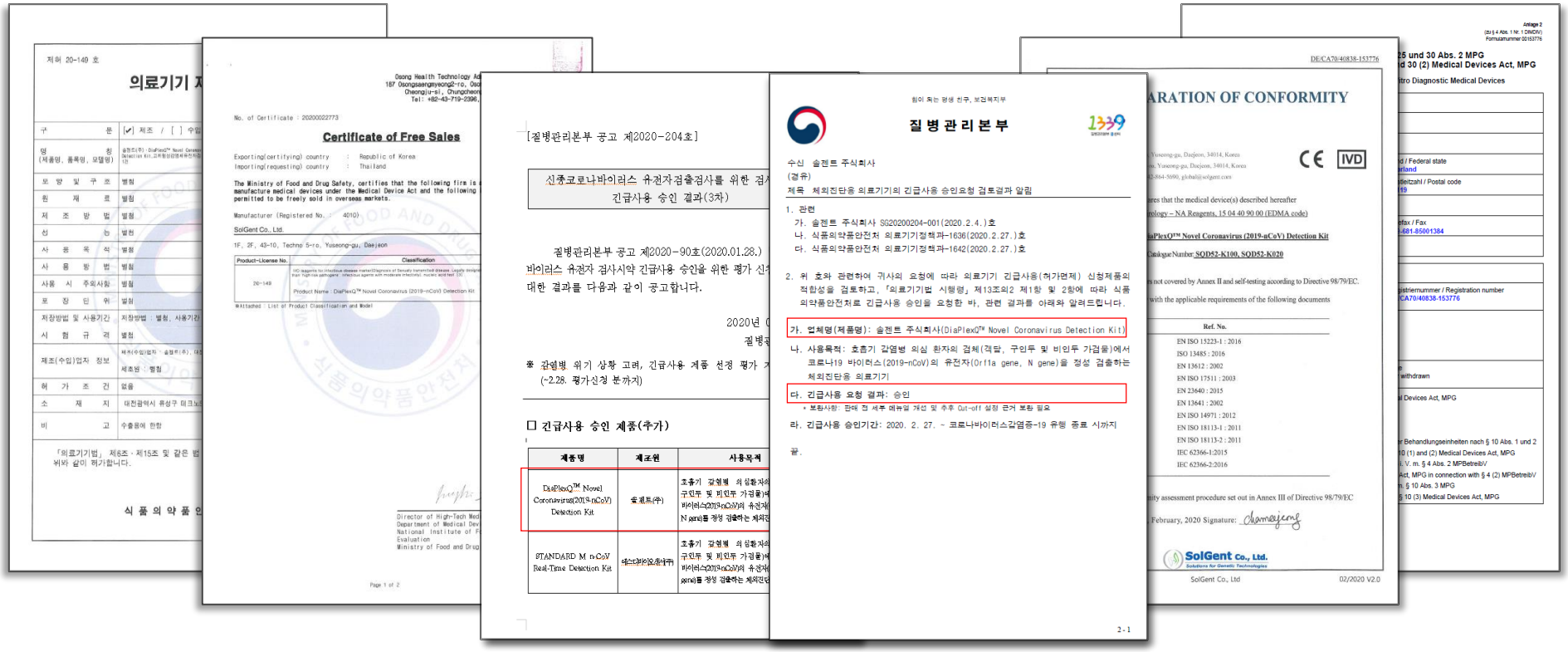
2.If PCR inhibitors are present, the PCRC may not amplify.

•When the Non-Template Control test result is positive, all samples must be retested.

※ PCRC (PCR Control)

Erroneous results may occur due to a variety of factors - for example, PCR mixture mix error, PCR condition error, PCR equipment use error etc. The PCR control is intended to monitor for the success of the PCR process. If the PCRC fails unexpectedly all experimental procedures and steps should be checked.

Certifications of DiaPlexQ™ Novel Corona Detection kit



CFS of KFDA

Approved at third by KFDA-EUA (Issued on 27th Feb.2020)

CE-IVD (Issued on 27th Feb.2020)

U. S FDA- Emergency Use Authorizations (EUA) Approval

U.S FDA EUA
(Issued on 21th May. 2020)

FDA U.S. FOOD & DRUG ADMINISTRATION

May 21, 2020

Do-Su Seok
CEO of SolGent Co., Ltd.
3F, 32, Techno 6-ro, Yuseong-gu
Daejeon, 34014, South Korea

Device:	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit
Company:	SolGent Co., Ltd.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes, bronchoalveolar lavage (BAL) fluid and sputum 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 Do-Su Seok:

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 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]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to SolGent Co., Ltd.
[2] For ease of reference, this letter will use the term "your product" to refer to the DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit used for the indication identified above.
[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*

Letter of Authorization

3rd Company approved by S. Korea & U.S FDA-EUA

FACT SHEET FOR HEALTHCARE PROVIDERS — Coronavirus Disease 2019 (COVID-19)
DiaPlexQ COVID-19 Detection Kit - SolGent Co., Ltd. May 21, 2020

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit.

The DiaPlexQ COVID-19 Detection Kit is authorized for use on respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: DiaPlexQ COVID-19 Detection Kit.

What are the symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The DiaPlexQ COVID-19 Detection Kit can be used to test nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirates, nasal washes, bronchoalveolar lavage (BAL) fluid and sputum.

This test is to be performed only using respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The DiaPlexQ COVID-19 Detection Kit test should be ordered for the detection of COVID-19 from individuals suspected of COVID-19 by their healthcare provider.
- The DiaPlexQ COVID-19 Detection Kit test is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

HCP Fact Sheet

FACT SHEET FOR PATIENTS — Coronavirus Disease 2019 (COVID-19)
DiaPlexQ COVID-19 Detection Kit - SolGent Co., Ltd. May 21, 2020

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the DiaPlexQ COVID-19 Detection Kit.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the DiaPlexQ COVID-19 Detection Kit?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can

Fact Sheet for patients

Ref: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev

License Approval status by country

European , CANADA, Thailand, Philippines

European CE-IVD (Issued on 27th Feb. 2020)	FDA Canada (Issued on 5th Apr. 2020)	FDA Thailand (Issued on 27th Mar. 2020)	FDA Philippines (Issued on 19th Mar. 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

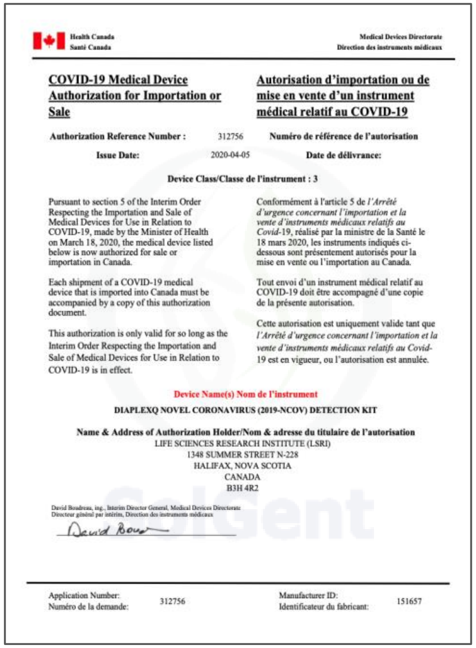
Ref. No.
EN ISO 15223-1 : 2016
ISO 13485 : 2016
EN 13612 : 2002
EN ISO 17511 : 2003
EN 23640 : 2015
EN 13641 : 2002
EN ISO 14971 : 2012
EN ISO 18113-1 : 2011
EN ISO 18113-2 : 2011
IEC 62366-1:2015
IEC 62366-2:2016

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

26th, February, 2020 Signature:

SolGent Co., Ltd.

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



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 : 312756 Numéro de référence de l'autorisation

Issue Date: 2020-04-05 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.

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.

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

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

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.

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
DIAPLEXQ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation
LIFE SCIENCES RESEARCH INSTITUTE (LSRI)
1348 SUMMER STREET N-228
HALIFAX, NOVA SCOTIA
CANADA
B3H 4R2

Application Number: / Numéro de la demande: 312756
Manufacturer ID: / Identificateur du fabricant: 151657

รับรองบางส่วน
หนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์
สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

KOR 6302287

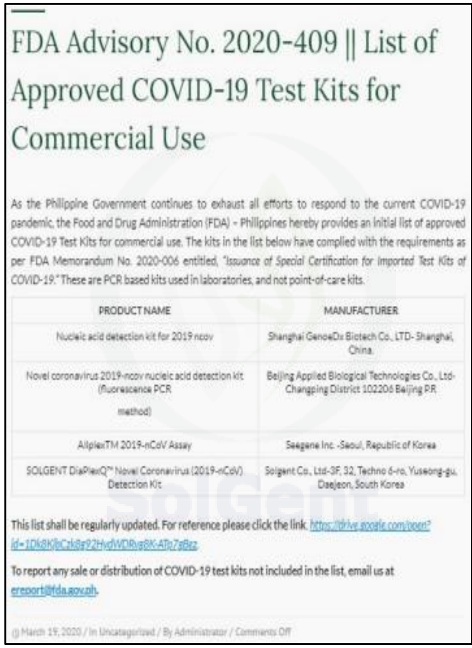
27 มีนาคม 2563

SOLGENT CO., LTD. (KOREA)

20200022773

Republic of Korea

3 มีนาคม 2568



FDA Advisory No. 2020-409 || List of Approved COVID-19 Test Kits for Commercial Use

As the Philippine Government continues to exhaust all efforts to respond to the current COVID-19 pandemic, the Food and Drug Administration (FDA) – Philippines hereby provides an initial list of approved COVID-19 Test Kits for commercial use. The kits in the list below have complied with the requirements as per FDA Memorandum No. 2020-006 entitled, "Issuance of Special Certification for Imported Test Kits of COVID-19." These are PCR based kits used in laboratories, and not point-of-care kits.

PRODUCT NAME	MANUFACTURER
Nucleic acid detection kit for 2019 ncov	Shanghai GenoeDx Biotech Co., LTD- Shanghai, China
Novel coronavirus 2019-ncov nucleic acid detection kit (fluorescence PCR method)	Beijing Applied Biological Technologies Co., Ltd- Changping District 102206 Beijing P.R.
AllplexTM 2019-nCoV Assay	Seegene Inc. -Seoul, Republic of Korea
SOLGENT DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	Solgent Co., Ltd-3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, South Korea

This list shall be regularly updated. For reference please click the link.

To report any sale or distribution of COVID-19 test kits not included in the list, email us at ereport@fda.gov.ph.

March 19, 2020 / In Uncategorized / By Administrator / Comments Off

In Progress

USA (FDA EUA), Brazil (ANVISA), Australia (TGA), Malaysia, Indonesia etc.

Registration status by Country

Malaysia, India, Mexico, Taiwan

Malaysia

INSTITUT PENYELIDIKAN PERUBATAN
(Institute For Medical Research)
Jalan Pahang
50588 KUALA LUMPUR
MALAYSIA

Telefon : 03-2616 2666
Faks : 03-2693 9335
http : //www.imr.gov.my

Ruj.kami: IMR/P/15/1501/0046/03 (/)
Tarikh : 16 April 2020

Medical Apparatus Supplies Sdn. Bhd.
909, Blok A, Pusat Dagangan Phileo Damansara II
No. 15, Jalan 16/11, Off Jalan Damansara
46350 Petaling Jaya
Selangor
(U/P: Mohd Niza Md Azar)

Tuan,

LAPORAN UJIAN PENILAIAN KIT SOLGENT'S DIAPLEXQ™ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT

Dengan segala hormat merujuk kepada perkara di atas.

2. Adalah dimaklumkan bahawa pihak kami telah menjalankan ujian penilaian terhadap kit novel Coronavirus (2019-NCOV) test kit seperti yang dimohon oleh pihak tuan.

3. Bersama-sama ini dikemukakan laporan bertajuk *Performance of SolGent's DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit* untuk perhatian dan rujukan pihak tuan.

Sekian, terima kasih.

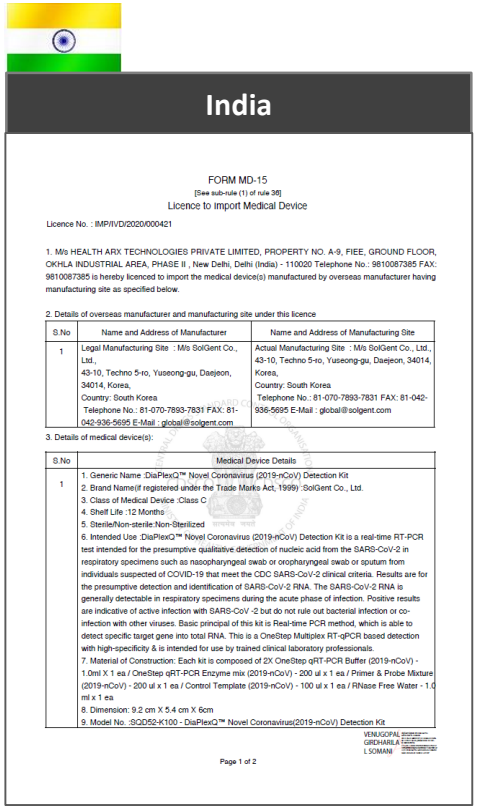
"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR. HAJI TAHIR BIN ARIS)
Pengarah
Institut Penyelidikan Perubatan (IMR)
☎ 03 – 3362 8906
✉ tahir.a@moh.gov.my

Quality approval (MDA)

India



FORM MD-15
[See sub-rule (1) of rule 38]
Licence to import Medical Device

Licence No. : IMP/IVD/2020/000421

1. M/s HEALTH ARX TECHNOLOGIES PRIVATE LIMITED, PROPERTY NO. A-9, FIEE, GROUND FLOOR, OKHLA INDUSTRIAL AREA, PHASE II , New Delhi, Delhi (India) - 110020 Telephone No.: 9810087385 FAX: 9810087385 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s SolGent Co., Ltd., 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea, Country: South Korea Telephone No.: 81-070-7893-7831 FAX: 81-042-936-5695 E-Mail : global@solgent.com	Actual Manufacturing Site : M/s SolGent Co., Ltd., 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea, Country: South Korea Telephone No.: 81-070-7893-7831 FAX: 81-042-936-5695 E-Mail : global@solgent.com

3. Details of medical device(s):

S.No	Medical Device Details
1	1. Generic Name :DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit 2. Brand Name(if registered under the Trade Marks Act, 1999) :SolGent Co., Ltd. 3. Class of Medical Device :Class C 4. Shelf Life :12 Months 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 in respiratory specimens such as nasopharyngeal swab or oropharyngeal swab or sputum from individuals suspected of COVID-19 that meet the CDC SARS-CoV-2 clinical criteria. Results are for the presumptive detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV -2 but do not rule out bacterial infection or co-infection with other viruses. Basic principal of this kit is Real-time PCR method, which is able to detect specific target gene into total RNA. This is a OneStep Multiplex RT-qPCR based detection with high-specificity & is intended for use by trained clinical laboratory professionals. 7. Material of Construction: Each kit is composed of 2X OneStep qRT-PCR Buffer (2019-nCoV) - 1.0ml X 1 ea / OneStep qRT-PCR Enzyme mix (2019-nCoV) - 200 ul x 1 ea / Primer & Probe Mixture (2019-nCoV) - 200 ul x 1 ea / Control Template (2019-nCoV) - 100 ul x 1 ea / RNase Free Water - 1.0 ml x 1 ea 8. Dimension: 9.2 cm X 5.4 cm X 6cm 9. Model No. :SQD52-K100 - DiaPlexQ™ Novel Coronavirus(2019-nCoV) Detection Kit

VENUGOPAL GIRDHARILAL SOMANI

Page 1 of 2

Import registered (CDSCO)

Mexico

SALUD | 2020 LEONA VICARIO

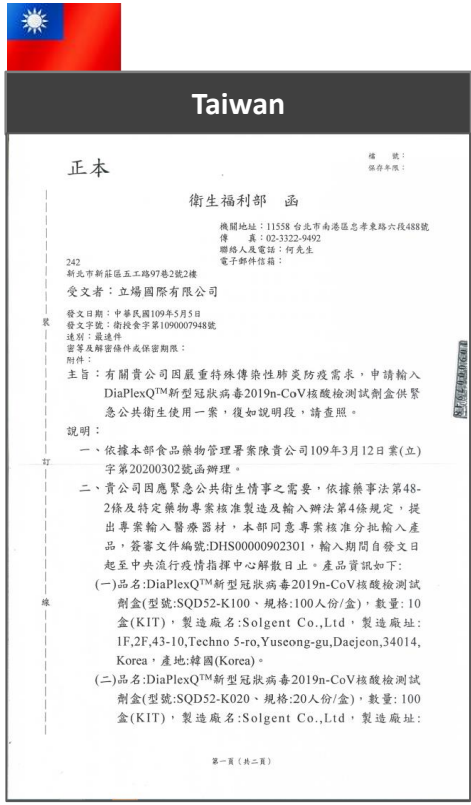
Subsecretaría de Prevención y Promoción de la Salud
Dirección General de Epidemiología
Instituto de Diagnóstico y Referencia Epidemiológicos
"Dr. Manuel Martínez Báez" (InDRE)

Listado de pruebas moleculares útiles para el diagnóstico de SARS-CoV-2 durante la contingencia de COVID-19 en México

Nombre Prueba	No Catálogo	Fabricante
BERLIN TEST-PRUEBA DE REFERENCIA REALIZADA EN EL INDRE Y EN LA RED NACIONAL DE LABORATORIOS DE SALUD PÚBLICA	NO DISPONIBLE COMERCIALMENTE	IMPLEMENTACIÓN INSTITUCIONAL
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	SQD52-K100	SolGent Co., Ltd.
RIDA® GENE SARS-CoV-2 RUO	PG6815RUO	R-Biopharm AG
COVID-19 Real Time PCR Kit	HBRT-COVID-19	Chaozhou Hybribio Biochemistry Ltd,
"Abbott Real Time SARS-CoV-2", Amplification Reagent Kit	09N77-080	Abbott Molecular Inc.
	09N77-090	
CDC 2019-Novel Coronavirus (2019-nCoV) (CDC)	10006606, 10006625, 10006626	Integrated DNA Technologies, Inc.
	A6121	Promega Corporation.
Accupower® SARS-CoV-2 Real Time RT-PCR Kit	SCV-2122	Bioneer Corporation
SARS-CoV-2, RealTime PCR Kit	RTPCR001	Vircell, S.L.
Allplex™ 2019-nCoV Assay	RP10244Y	Seegene INC
GeneFinder™ COVID 19 PLUS RealAmp Kit	IFMR-45	OSANG HEALTHCARE LTD
Kit para Coronavirus 2019 Logix Smart™ (COVID-19)	COVID-K-001	CO-DIAGNOSTICS, INC
LightMix® Modular SarbecoV E-gene EAV, SARS-CoV (COVID19) N-gene y SARS-CoV-2 (COVID-19) RdRP	40-0776-96, 53-0775-96 y 53-0777-96, respectivamente.	TIB MOLBIOL, LLC.

Quality approval (COFERIS)

Taiwan



正本

衛生福利部 函

機關地址：11558 台北市南港區忠孝東路六段488號
傳　　真：02-3322-9492
聯絡人及電話：何先生
電子郵件信箱：

242
新北市新莊區五工路97巷2號2樓

受文者：立場國際有限公司

發文日期：中華民國109年5月5日
發文字號：衛授食字第1090007948號
速別：最速件
密等及解密條件或保密期限：
附件：

主旨：有關貴公司因嚴重特殊傳染性肺炎防疫需求，申請輸入DiaPlexQ™新型冠狀病毒2019n-CoV核酸檢測試劑盒供緊急公共衛生使用一案，復如說明段，請查照。

說明：

一、依據本部食品藥物管理署案陳貴公司109年3月12日業(立)字第20200302號函辦理。

二、貴公司因應緊急公共衛生情事之需要，依據藥事法第48-2條及特定藥物專案核准製造及輸入辦法第4條規定，提出專案輸入醫療器材，本部同意專案核准分批輸入產品，簽審文件編號:DHS00000902301，輸入期間自發文日起至中央流行疫情指揮中心解散日止。產品資訊如下:

(一)品名:DiaPlexQ™新型冠狀病毒2019n-CoV核酸檢測試劑盒(型號:SQD52-K100、規格:100人份/盒)，數量:10盒(KIT)，製造廠名:Solgent Co.,Ltd，製造廠址:1F,2F,43-10,Techno 5-ro,Yuseong-gu,Daejeon,34014, Korea，產地:韓國(Korea)。

(二)品名:DiaPlexQ™新型冠狀病毒2019n-CoV核酸檢測試劑盒(型號:SQD52-K020、規格:20人份/盒)，數量:100盒(KIT)，製造廠名:Solgent Co.,Ltd，製造廠址:

第一頁（共二頁）

Import registered (FDA)

In Progress

UK, Vietnam, Peru, Singapore, Russia, Indonesia, Thai etc.

Long-term contract in progress

Supply to 50 countries other than the Poland, USA(Colorado), Saudi Arabia, Belgium, Estonia

https://www.youtube.com/watch?v=60l_OgR0Acg&feature=youtu.be

Media Article

NBC PALM SPRINGS | NEWS | CORONAVIRUS | YOU ASK. WE INVESTIGATE.® | LIFESTYLE | ABOUT US

CORONAVIRUS

US TO RECEIVE 750,000 CORONAVIRUS TESTS FROM SOUTH KOREA

Taylor Martinez

APRIL 13, 2020 4:40 PM

The United States is turning to South Korea — a country with an aggressive testing regime that President Donald Trump previously downplayed — to bring approximately 750,000 more coronavirus tests to the US, according to the Federal Emergency Management Agency.

FEMA, an agency within the US Department of Homeland Security, awarded contracts to manufacturers in South Korea last week to provide approximately 750,000 tests, according to a FEMA spokesperson and federal records.

Over the weekend, the first shipment of 150,000 tests were delivered to the US by SolGent. The next shipment of 600,000 tests will arrive by April 15. They are being provided by two South Korea-based companies, SD Biosensor and Osang Healthcare.

The intent, the FEMA spokesperson said, is to move the tests to a cold storage facility in Louisville, Kentucky, for distribution. Urgent needs will be given priority, according to a FEMA advisory obtained by CNN.

The Trump administration has waffled on its praise of South Korea's testing capabilities.

Pulse

Biz | Bio&Tech | Market | Economy | Seoul

S. Korea's COVID-19 testing kit maker SolGent picked as U.S. strategic supplier

2020.04.08 11:38:36 | 2020.04.08 16:04:18

[Photo provided by SolGent]

Kosdaq-listed EONE Diagnomics Genome Center Co. (EDGC) said on Wednesday that its Daejon-based affiliated COVID-19 detection kit developer SolGent has been registered with the U.S Federal Emergency Management Agency (FEMA) as a supplier to the federal government's strategic stockpile.

EDGC Shares gained 5.39 percent to finish at 17,600 won ($14.42) on Wednesday.

The registration grants the Korean company a license to provide its COVID-19 sampling kits as a national strategic stockpile. The initial shipments of the company's products are set at a volume for 150,000 persons.

SolGent hopes to seek a permanent supplier status from the federation government and build a local manufacturing site in the U.S. within two to three years.

SolGent's COVID-19 detection kit uses real-time polymerase chain reaction (RT-PCR) to sensitively and specifically detect the virus in patient samples by amplifying a specific region in a DNA strand.

The detection kit also was approved in Korea under the emergency use authorization.

The Korea Herald

Business | All | Industry | Technology | Transport | Retail

Caremile sees surge in quarantine goods orders from foreign governments

By Korea Herald | Published : Apr 15, 2020 - 11:20 | Updated : Apr 15, 2020 - 11:20

Ukrainian Ambassador Oleksandr Horin (second from right) checks a Caremile shipment with company officials. (Caremile)

Korean safety solution company Caremile said Tuesday it is seeing a rapid surge in orders of Korean-made diagnostic kits and quarantine goods from various countries, including Ukraine, Poland, Turkey, Uzbekistan, Mexico, Iraq and Malaysia, amid the COVID-19 pandemic.

Caremile, which has rights for Solgent's global special sale, for instance, exported the "Solgent COVID-19 DiaPlexQ Detection Kit" that can be used for 100,000 people on March 27 upon an emergency request from Ukrainian President Volodymyr Zelensky. On April 11, 25,000 sets of personal protective suits were sent to Ukraine.

Korea Biomedical Review

Hospital | Pharma | Bio | Device/ICT | Policy | People | Life science

HOME > Device/ICT

Solgent picked as supplier for US agency

By Shim Hyun-tai | Published 2020.04.08 18:31 | Updated 2020.04.08 18:31

Eone Diagnomics Genome Center (EDGC) said Wednesday that its affiliate test kit maker, Solgent, has been registered as the first Korean company for stockpile procurement by the U.S. Federal Emergency Management Agency (FEMA).

Solgent will initially export the new coronavirus test kits for 150,000 people and 40 other diagnostic kits, including the Middle East Respiratory Syndrome, as a procurement supplier for the U.S. government.

On top of that, Solgent submitted for the official approval for permanent use in the U.S., besides the emergency use approval from the Food and Drug Administration for its COVID-19 diagnostic kit developed until March 22.

"Our becoming the first test kit maker to supply to FEMA is a reaffirmation of the excellence and reliability of Korea's molecular diagnosis technology worldwide in the battle against the COVID-19 virus," Solgent CEO Yoo Jae-hyung said.

The company plans to promote supplying COVID-19 test kit procurements for FEMA, and also to provide stable supplies of its test kit, DiaPlexQ, for 51 U.S. state governments, including the Washington D.C.

Solgent's DiaplexQ is a real-time reverse transcription-polymerase chain reaction diagnostic kit that amplifies and tests a specific gene sequence of the COVID-19 virus.

Solgent began to export diagnostic kits to test 100,000 people to Ukraine on March 27 at the request of Ukrainian President Vladimir Zelensky.

UKRINFORM

Ukrainian multimedia platform for broadcasting

Some 100,000 PCR tests have been delivered to Ukraine from South Korea to detect coronavirus, the press service of the Office of the President of Ukraine has said.

"A plane carrying 100,000 PCR tests produced by SolGent to detect COVID-19 has arrived from Seoul (the Republic of Korea). Caremille has conducted the delivery for the needs of the health care system of Ukraine," the statement reads.

It notes that after passing the customs procedures on registration the test kits will be delivered to the infectious laboratories of all regions of the country, which have proper storage conditions.

According to the statement, the SolGent test kit contains all the necessary components for a polymerase chain reaction. Therefore, when used, there is no need for additional reagents. Testing lasts from 105 to 120 minutes.

The cargo was shipped to Ukraine on the initiative of the Office of the President. The delivery was coordinated by Ukraine's Ambassador to South Korea Oleksandr Horin.

Pulse by Maeil Business News Korea

Biz | Bio&Tech | Market | Economy | Seoul

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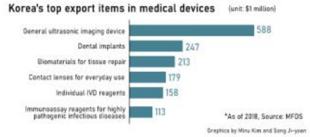
Korean-made COVID-19 testing kits over 100 countries

2020.04.09 15:35:39 | 2020.04.09 15:36:14

Exports of Korean-made COVID-19 testing kits

Seegene	90% of total production go to 45 countries
SolGent	Exports to 35 countries including Poland and Ukraine
Kogene Biotech	Exports to 37 countries including 7 Latin American countries
Gene Matrix	Exports to 4 countries including Italy, UAE and Chile
GenBody	Signs 4.8 bn won export contracts with 15 countries including Brazil & Ireland
LabGenomics	Exclusive supply to India through Germany's Siemens Healthineers
Bioneer	5 bn won export contract with Qatar's state oil company
Clinomics	Waits for MFDS export permission after 4.8 bn won contract with Hungary



COVID-19 testing kits are emerging as South Korea's No. 1 export items among medical devices as demand for quality and fast detection kits for coronavirus has spiked from more than 100 countries in recent months.

CNN politics | Donald Trump | Supreme Court | Congress | Facts First | 2020 Election

US to receive 750,000 coronavirus tests from South Korea

By Priscilla Alvarez and Katelyn Polantz, CNN

Updated 2119 GMT (0519 HKT) April 13, 2020

A member of the Brooklyn Hospital Center COVID-19 testing team calls in the next patient in line, Thursday, March 26, 2020, in the Brooklyn borough of New York.

Washington (CNN) — The United States is turning to South Korea -- a country with an aggressive testing regime that President Donald Trump previously downplayed -- to bring approximately

NEWS & BUZZ

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Trump touts new missile but Penta… confirm...

Reference Letter

Letter from clients as evidence for the performance

SYNLAB (Estonia)

SYNLAB

To: United Nations Registration Office

11.05.2020

Reference Letter

Herewith we confirm that SYNLAB Estonia has evaluated and thereafter been using DiaPlex TM Novel Corona virus (2019-nCOV) detection kit from Solgent in clinical practice for detection of SARS-CoV-2 in patient samples.

Use of Solgent's DiaPlex TM Novel Corona virus (2019 nCov) detection kit requires compliance with the manufacturer's instructions, suitable facilities and equipment as well as trained and competent personnel. By making the above statement SYNLAB does assume any liability related to Solgent's DiaPlex TM Novel Corona virus (2019 nCov) detection kit.

Sincerely

Rainar Aamisepp
CEO, SYNLAB Northern Europe and CEMEA

SYNLAB Eesti OÜ · Reg nr: 11107913 · Veerenni 53a, 13113 Tallinn
Tel: +372 640 8210 · Faks: +372 640 8218 · E-post: synlab@synlab.ee · www.synlab.ee

EONE Laboratories (Korea)

Letter of Test Evaluation Result

To whom it may concern,

As a result of evaluating SolGent's DiaPlexQ Novel Corona virus (2019-nCOV, SQD52-K100) detection kit at laboratory Medicine Division of EONE Laboratories.

This product was judged to be suitable for clinical use in terms of sensitivity, accuracy and specificity.

If you have any inquiry, please feel free contact us

Sincerely,

Laboratory Medicine Division of EONE Laboratories.

March 31th 2020

SQLab (Korea)

Letter of Test Evaluation Result

To whom it may concern,

As a result of evaluating Solgent's DiaPlexQ Novel Corona virus (2019-nCOV, SQD52-K100) detection kit at the Sure Quest Laboratory (SQLab)

This product was judged to be suitable for clinical use in terms of sensitivity, accuracy and specificity.

If you have any inquiry, please feel free contact us

Sincerely,

Nam Yong Kim, CEO

Sure Quest Laboratory (SQLab)

April 15th 2020

THANK YOU!

www.solgent.com

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