Supporting SMEs and Businesses during the COVID-19 Pandemic: Examples from the Republic of Korea

코로나19 관련 중소기업 지원 정책 및 기업 대응: 대한민국과 UNDP 사례

Jae-hyung You

CEO

SolGent, Korean SME & Producer of COVID-19 Test Kits

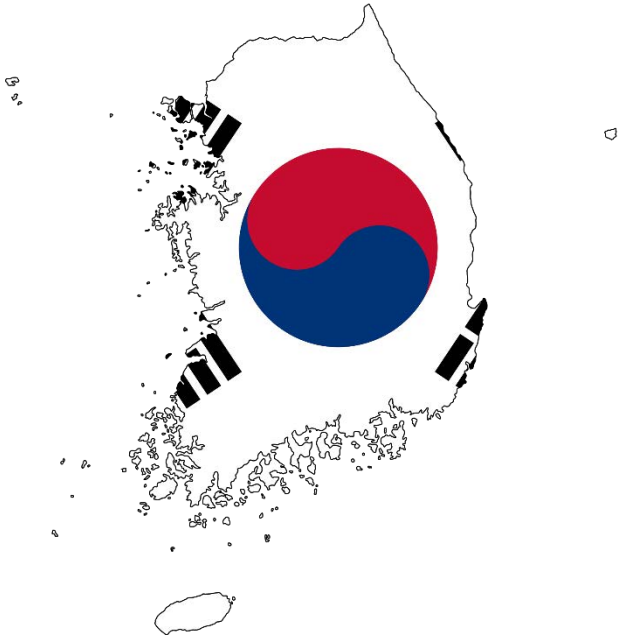
JULY 23, 2020

Ministry of Trade, Industry and Energy

KITA

UNDP

2020.07.23



Molecular Diagnostics Company (KOREA)

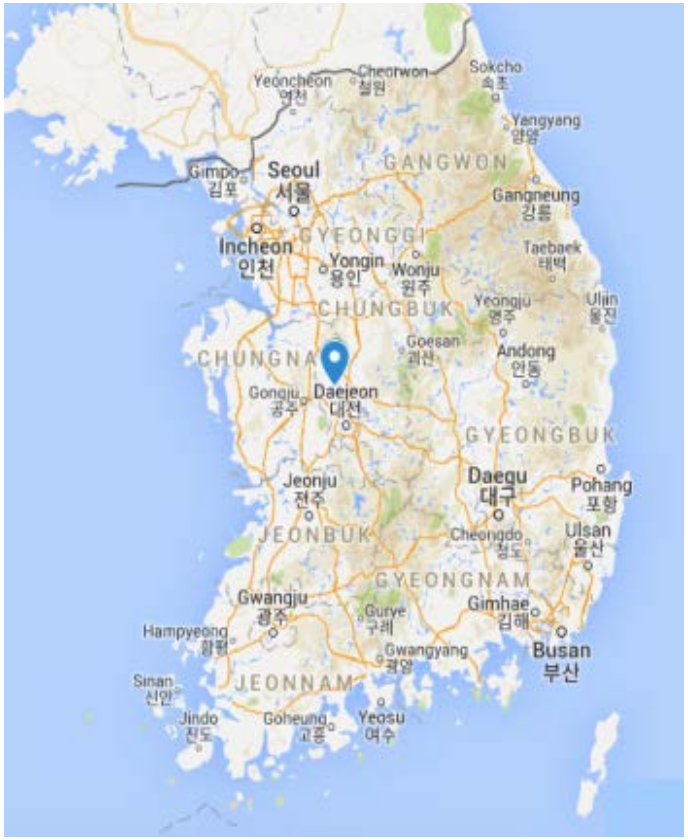
SolGent Co., Ltd.

Case of the Korean Government's Support
for Small and Medium Businesses
in COVID-19

SolGent Co., Ltd.
Solutions for Genetic Technologies

SolGent Overview

Since 2000, We have developed and produced research reagents, diagnostic reagents, and diagnostic kits for molecular diagnostics. We also provide genetic analysis services(+Sequencing) and test services for species and country of origin of agricultural, livestock and fisheries products.



- **CEO**
  - Jae hyung Yoo (Jay Yoo) *presenter
    - Doctor of Microbiology
      (Chungbuk National University Graduate School)
  - Do-su Seok

- **Head Office** (Number of employees: 60)

Located in Daejeon, the center of science in Korea

43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014,

- We have a branch in Seoul, the capital of Korea.

SolGent Business Field

NADPH Rapid Quantity Measurement System
G6PD Active Measurement
in the pipeline

Core
Reagents
Polymerase(Taq, Pfu), Buffer,
Ligase, Pre-Mix, Smart-Mix,
Cloning Kit, DNA extraction kit

Genetic characteristics, risk analysis Service
Human(Beauty, Cancer),
Animal(Telomere)
in the pipeline

Core
Human Diagnosis Kit
Infectious disease, Genetic disorder
<COVID-19>

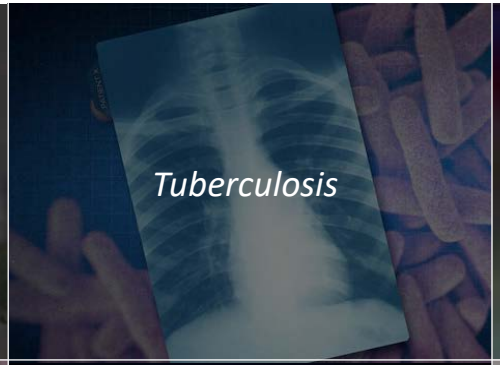
Customized Research Service
Bulk sample processing, Cloning,
Genotyping, PCR Set-up
Core

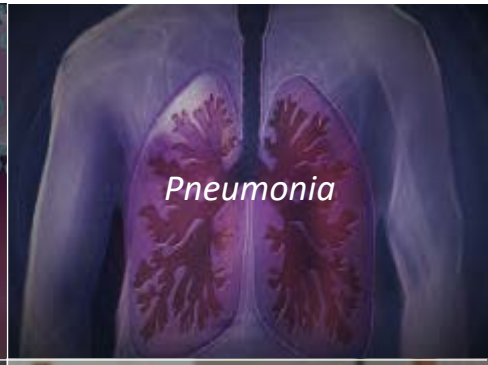
Core
Genome Analysis
Sequencing,
Rice variety test,
Hanwoo(Korea beef) authenticity test

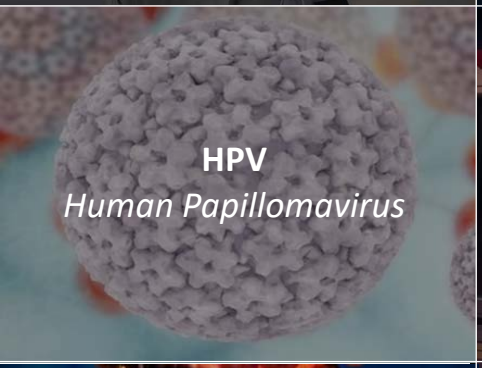
SolGent's PCR Kit

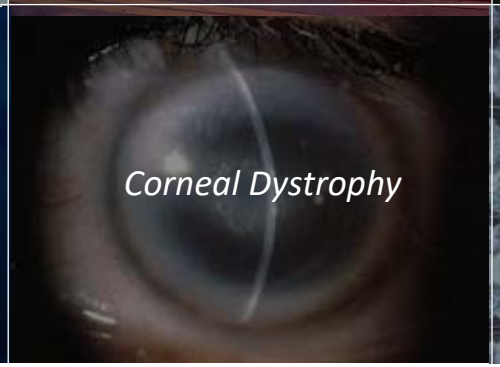
CE IVD : 33 KITS

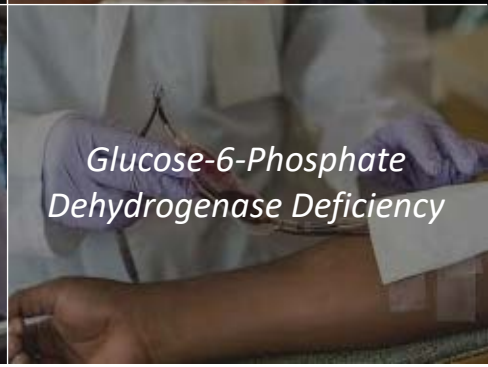
KGMP 우수의료기기품질인증 : 7 KITS











COVID-19 Detection Kit – R&D Decision

12. 2019 We heard of pneumonia caused by an unknown virus in Wuhan, China.

01. 2020 The cause of pneumonia turned out to be the new corona virus, and one of SolGent's Chinese agents had proposed the development of a diagnostic kit for the new virus.

COVID-19 R&D TF
Young-Joon.Ko/Sun-Mi.Sim/Ji-Yoon.Jo/Mee-Jeong.Cha

As a small and medium-sized company, the decision to study new products was not easy. Although we had confidence that our development capability would be able to complete the development as soon as possible, we had no choice but to worry about the development cost.

Recognizing the very high infectious power of COVID-19, we immediately embarked on the development and completed the development in three weeks.

COVID-19 Detection Kit – R&D History, Specification

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit	
mid-January	Select the target gene to detect (ORF1a gene, N gene)
early February	Prototype determination, Data Preparation for KFDA EUA Approval
early February	Apply for KFDA EUA approval
Mid-February	Apply for CE-IVD
02.27.20	KFDA EUA approved
02.28.20	CE-IVD Certified
22.05.21	U.S FDA EUA approved

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.

3. Kit HS Code

- 3822.00.10

4. Kit Specification

- Size(mm) : 95 * 55 * 60 mm (3. 7 * 2.1 * 2.3 inch)
- Weight(g) : 34 g (0.037 lb)

5. kit require special storage

- Required refrigeration -Storage Temperature(℃): -20℃ ± 5℃ (-4 ± 41℉)

6. Period of use

- 1 year

7. Real-time PCR time

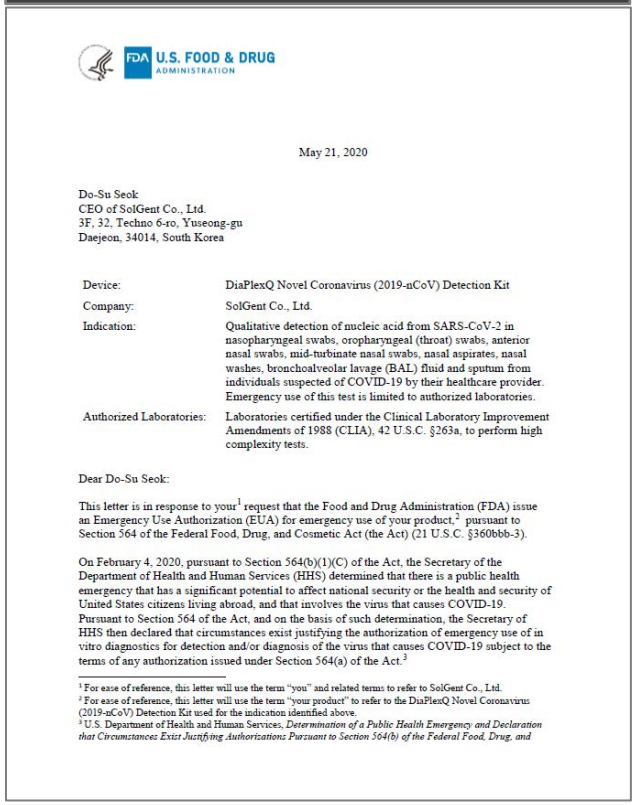
- 1 hour 45 minutes

SolGent Co., Ltd.
Solutions for Genetic Technologies

U.S. FOOD & DRUG ADMINISTRATION

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

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



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.

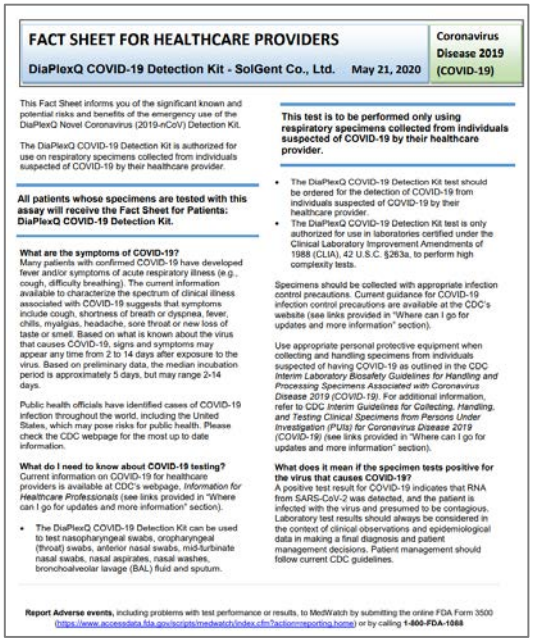
Dear Do-Su Seok:

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



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

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.

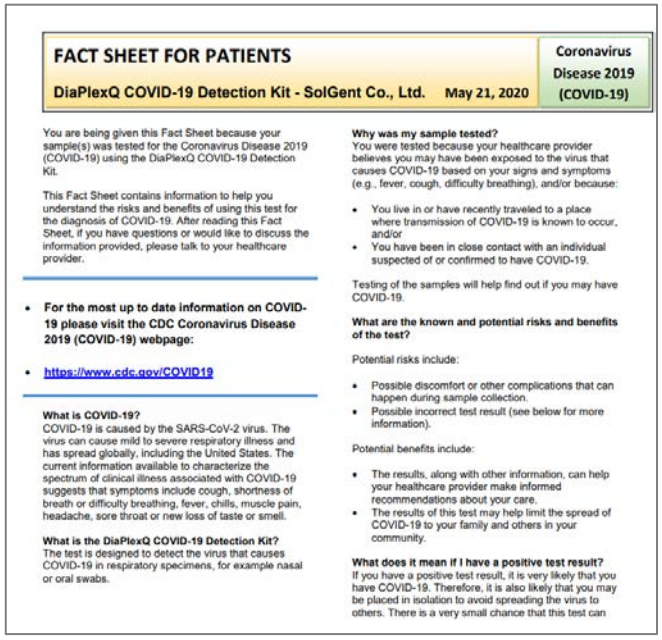
Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

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
DiaPlexQ COVID-19 Detection Kit - SolGent Co., Ltd. May 21, 2020
Coronavirus Disease 2019 (COVID-19)

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

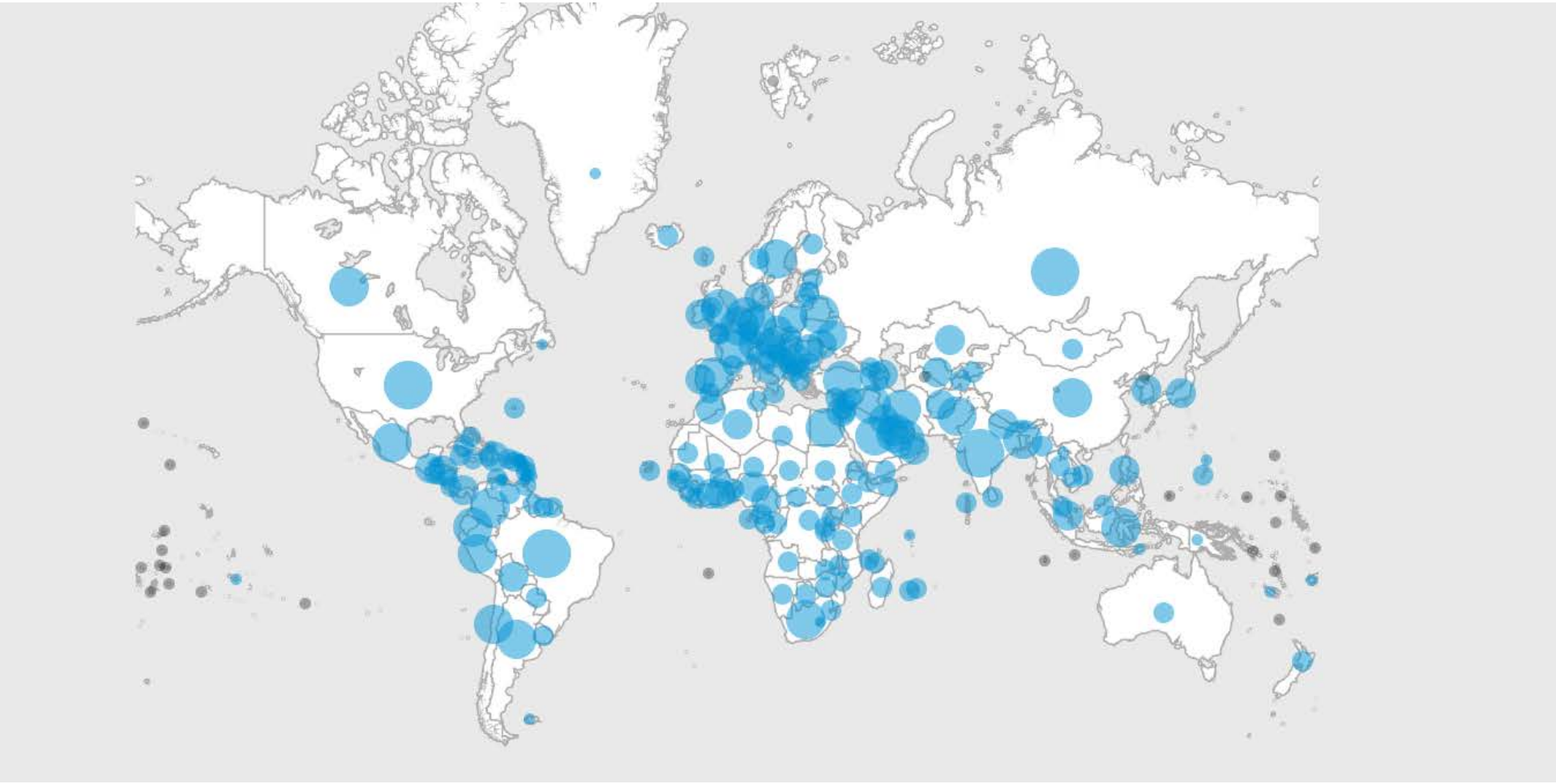
Fact Sheet for patients

SolGent Co., Ltd.
Solutions for Genetic Technologies

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

is being supplied around the world more than 50 countries.

We can quickly supply kits to your country. Additional supply is possible.



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

SolGent Co., Ltd.
Solutions for Genetic Technologies

COVID-19 Detection Kit – KOREA Government's Support(1)

Ministry of SMEs and Startups:

중소벤처기업부
Ministry of SMEs and Startups

Administrative Organization of Korea Supporting Small and Medium-sized Enterprises

In the early stages of COVID-19, Minister Park Young-sun of Ministry of SMEs and Startups visited SolGent in person to listen to the difficulties and resolve them.

Ministry of SMEs and Startups helped Samsung Electronics match its **Smart factory construction project** that can solve the inefficient part of SolGent through its technology, know-how and infrastructure.

SolGent Co., Ltd.
Solutions for Genetic Technologies

Smart factory construction project

04. Localization of tubes

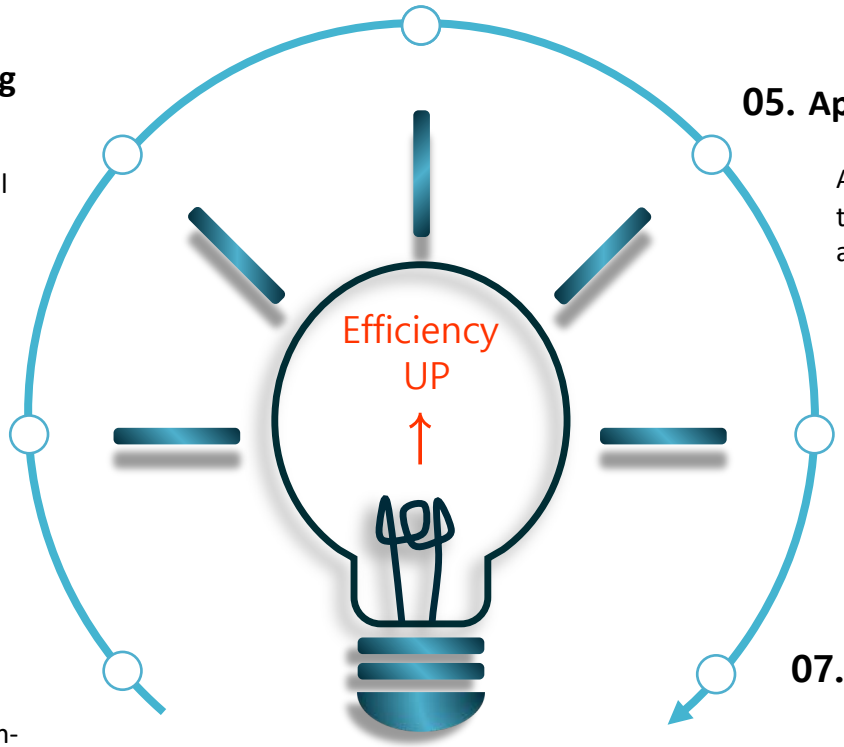
Tubes are essential packaging materials for commercializing reagents, making it difficult to complete kits as purchasing German tubes became increasingly difficult, and Samsung Electronics developed tubes with subcontractors and made them available to SolGent.

03. Improvement of working environment

Installation of air curtain, removal of disused goods

05. Application of automation

Application of automated facilities to tasks such as labeling, capping, and spreading



02. Minimize work flow

Changing the layout to reduce movement by 34%

06. Apply Barcode System

Application of Barcode System for Storage and Forwarding Materials

01. Relocation according to character

Relocation of raw materials, work-in-processes, and products → Systematization

07. Real-time management of resources

Operate computerized systems with APP-based tablets

Production Capacity:

3000 KIT per week (March, 2020)→

15,000 KIT (=15 million test) per week (present)

Up to MAX 250,000 kits per week by the end of October

COVID-19 Detection Kit – KOREA Government's Support(2)

Public Procurement Service:

조달청
Public Procurement Service

The central administrative agency of the Republic of Korea, which oversees the government's affairs concerning the purchase, supply and management of materials and the government's contracts for major facilities construction.

UNITED NATIONS
GLOBAL MARKETPLACE

Public Procurement Service supports registration with the United Nations as a vendor. Registration completed.

SolGent is eligible to bid on UNGM.

COVID-19 Detection Kit – KOREA Government's Support(3)

Export-Import Bank of Korea:

한국수출입은행
THE EXPORT-IMPORT BANK OF KOREA

Providing mid- to long-term financing necessary for Korean companies' export of capital goods and overseas investment, development of overseas resources, import of key resources, etc.

기획재정부
Ministry of Economy and Finance

Public institutions under the Ministry of Economy and Finance.

- low-interest loan support

Thanks for your attention and time!

It would be appreciated if you could visit our homepage.

www.solgent.com

- e-mail: global@solgent.com
- Tel: +82-70-7893-7831

Donation to Daejeon City