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
Molecular Diagnostics Company (KOREA)

SolGent Co., Ltd.

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

**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.

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

![Map of South Korea with Daejeon location marked]
SolGent Business Field

Polymerase Chain Reaction

Core

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

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

Genetic characteristics, risk analysis Service
- Human (Beauty, Cancer), Animal (Telomere)

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

NADPH Rapid Quantity Measurement System
- G6PD Active Measurement

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

in the pipeline
SolGent’s PCR Kit

**COVID-19**
Respiratory Disease

**Tuberculosis**

**Influenza**

**Pneumonia**

**HPV**
Human Papillomavirus

**Sexually Transmitted Infection**

**Zika**
Chikungunya

**Dengue**

**MERS**

**MTHFR**
Methylenetetrahydrofolate Reductase

**Corneal Dystrophy**

**Alzheimer’s disease**
<ApoE>

**Glucose-6-Phosphate Dehydrogenase Deficiency**

**SolGent’s PCR Kit**

- IVD: 33 KITS
- KGMP: 7 KITS

[Logo and certifications]
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.

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

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°F)

6. Period of use
   - 1 year

7. Real-time PCR time
   - 1 hour 45 minutes
3rd Company approved by S. Korea & U.S FDA-EUA

Letter of Authorization

HCP Fact Sheet

Fact Sheet for patients

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

May 21, 2020

Do-Su Seok
CEO of Solgent Co., Ltd

JF, 52, Teheran 6-6, Yuseong-gu
Daejeon, 305-141, South Korea

Device: DiaPrex® 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), sputum from individuals suspected of COVID-19 by their healthcare provider.

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 request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product in accordance with Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On February 6, 2020, pursuant to Section 564(a)(2)(A) 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 it is necessary to issue the EUA under Section 564 of the Act.

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

For ease of reference, this letter will use the term “you” and related terms in reference to Solgent Co., Ltd.

For ease of reference, this letter will use the term “your product” in reference to the DiaPrex® Novel Coronavirus (2019-nCoV) Detection Kit used for the detection of SARS-CoV-2.


Coronavirus Disease-2019 (COVID-19)

Fact Sheet for Healthcare Providers

DiaPrex® COVID-19 Detection Kit - Solgent Co., Ltd. May 21, 2020

What is the Coronavirus Disease-2019 (COVID-19)?

Coronavirus Disease-2019 (COVID-19) is an infection caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus is a member of a family of viruses that typically cause respiratory infections.

Symptoms of COVID-19:

Symptoms can include fever, cough, shortness of breath, fatigue, muscle aches, new loss of taste or smell, or sore throat. If you have any of these symptoms, please contact your healthcare provider for further evaluation.

Factors that increase the risk of severe COVID-19:

People with heart conditions, lung disease, diabetes, kidney disease, chronic obstructive pulmonary disease (COPD), or other serious lung conditions may be at increased risk for severe COVID-19.

Pregnant people are also considered to be at increased risk for severe COVID-19.

Pregnant people with severe COVID-19 may be at risk of losing their baby.

People with severe COVID-19 are at risk of death.

What is the severity of COVID-19 in children:

Children with COVID-19 often experience mild or no symptoms. Children who get COVID-19 can get severe outcomes, but children are generally not at increased risk for severe COVID-19 or death.

What to do if you think you have COVID-19:

If you think you have COVID-19, you should contact your healthcare provider to discuss your symptoms and receive recommendations.

Remember: COVID-19 is spread mainly through respiratory droplets when an infected person coughs, sneezes, or talks. It is possible to spread the virus even if you do not have symptoms.

Fact Sheet for Patients

DiaPrex COVID-19 Detection Kit - Solgent Co., Ltd. May 21, 2020

What is the Coronavirus Disease-2019 (COVID-19)?

COVID-19 is a contagious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It can cause serious illness, including pneumonia, in some people.

Symptoms:

COVID-19 symptoms may include fever, cough, shortness of breath, fatigue, muscle aches, new loss of taste or smell, or sore throat. If you have any of these symptoms, please contact your healthcare provider for further evaluation.

Factors that increase the risk of severe COVID-19:

People with heart conditions, lung disease, diabetes, kidney disease, chronic obstructive pulmonary disease (COPD), or other serious lung conditions may be at increased risk for severe COVID-19.

Pregnant people are also considered to be at increased risk for severe COVID-19.

Pregnant people with severe COVID-19 may be at risk of losing their baby.

People with severe COVID-19 are at risk of death.

What is the severity of COVID-19 in children:

Children with COVID-19 often experience mild or no symptoms. Children who get COVID-19 can get severe outcomes, but children are generally not at increased risk for severe COVID-19 or death.

What to do if you think you have COVID-19:

If you think you have COVID-19, you should contact your healthcare provider to discuss your symptoms and receive recommendations.

Remember: COVID-19 is spread mainly through respiratory droplets when an infected person coughs, sneezes, or talks. It is possible to spread the virus even if you do not have symptoms.
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/
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.
Efficiency

01. Relocation according to character
Relocation of raw materials, work-in-processes, and products → Systematization

02. Minimize work flow
Changing the layout to reduce movement by 34%

03. Improvement of working environment
Installation of air curtain, removal of disused goods

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.

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

06. Apply Barcode System
Application of Barcode System for Storage and Forwarding Materials

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
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.

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

SolGent is eligible to bid on UNGM.
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.

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