GeneFinder™ COVID-19 Plus RealAmp Kit *CE-IVD*

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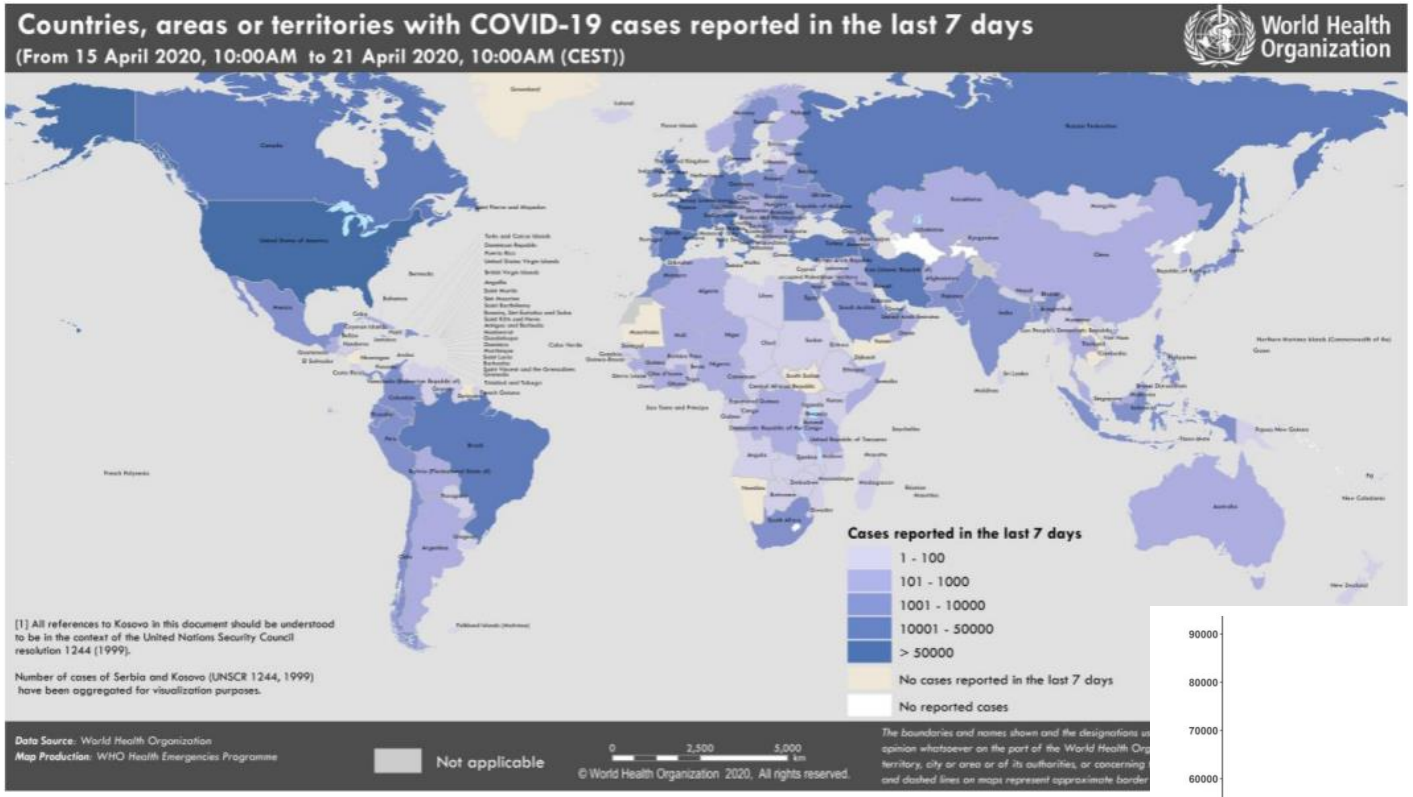
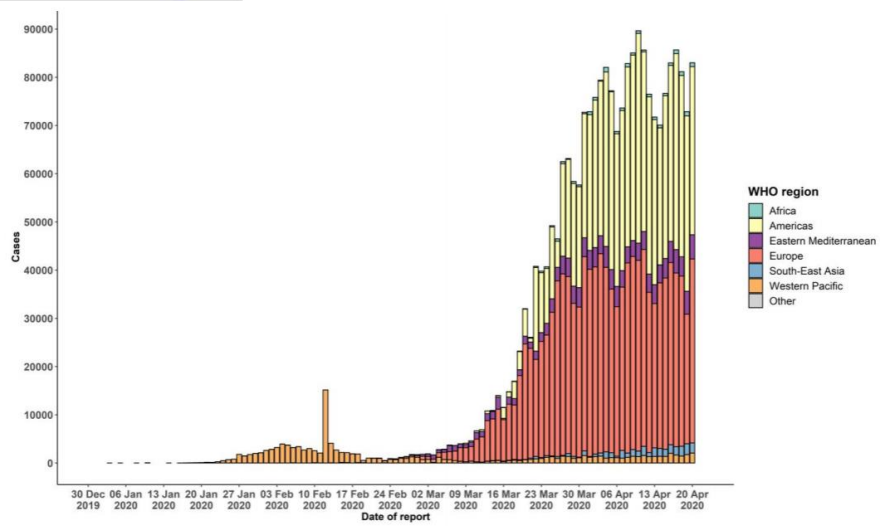
Presented by Osang Heathcare Co., Ltd / Mar 17, 2020

COVID 19 WW Situation / Outbreaks





중국 우한 → 아시아 → 유럽 → 미국/중남미 → 아프리카로

전세계 확산

COVID 19 WW Situation / Outbreaks

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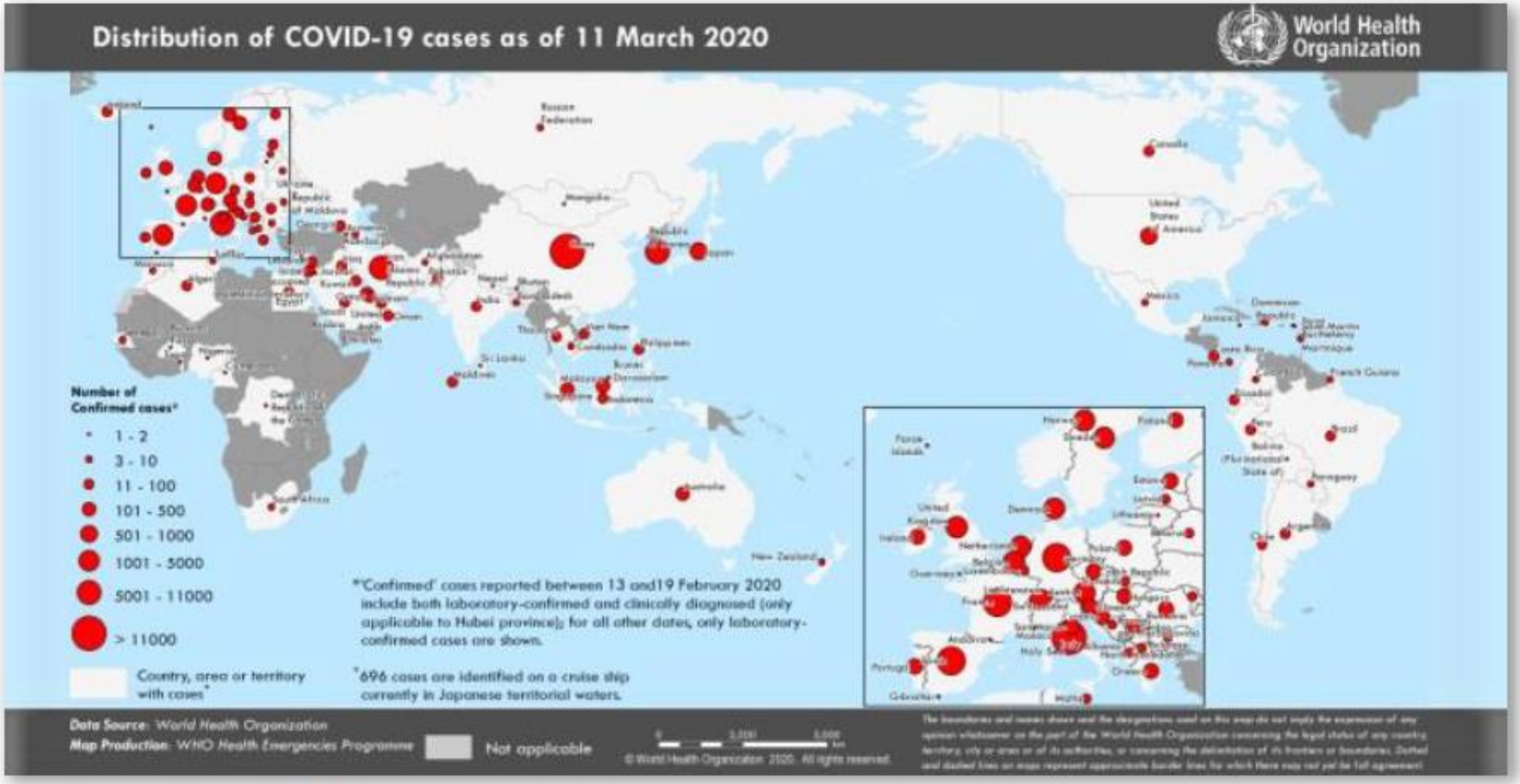

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). A novel coronavirus (nCoV) is a new strain that has not been previously identified in humans.

GeneFinder™ COVID-19 Plus Real*Amp* Kit - Overview

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GeneFinder™ COVID-19 Plus Real*Amp* Kit is the **One-Step Reverse Transcription Real-Time PCR Kit** designed to detect Novel Corona virus (COVID-19) qualitatively through Reverse Transcription reaction and Real-Time Polymerase Chain Reaction

Main Features

- Target Genes : RdRp, N, E
- 120 minutes detection for COIVD-19
- Reverse Transcription reaction and Real-Time Polymerase Chain Reaction
- Easy-to-use(One-Tube) and interpretation
- Reliable result by internal/Positive/ Negative Control

GeneFinder™ COVID-19 Plus Real*Amp* Kit – Kit Component

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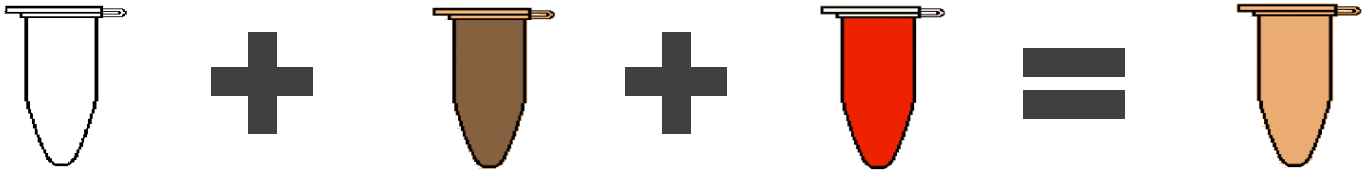
GeneFinder™ COVID-19 Plus			
COVID-19 Plus Reaction Mixture	COVID-19 Plus Probe Mixture	COVID-19 Plus Positive Control	COVID-19 Plus Negative Control
1050 uL / kit	550 uL / kit	50 uL / kit	50 uL / kit
			

10 µl 5 µl 5 µl **Total 20 µl**

1 Sample



COVID-19 Plus Reaction Mixture

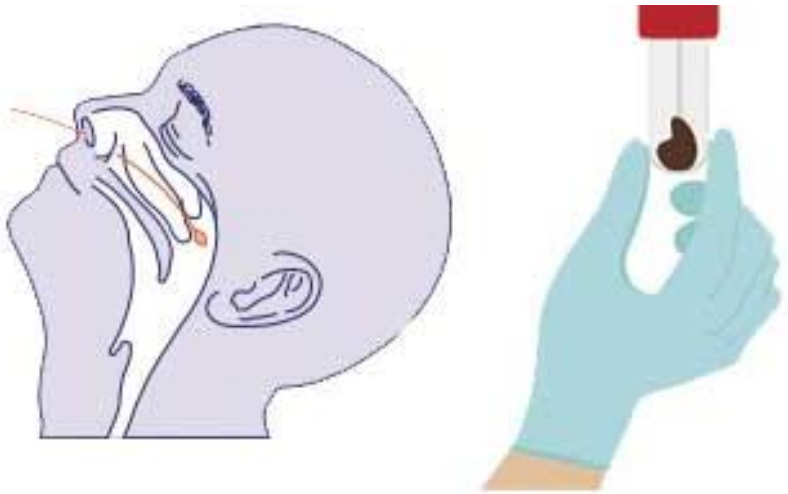
COVID-19 Plus Probe Mixture

Sample RNA

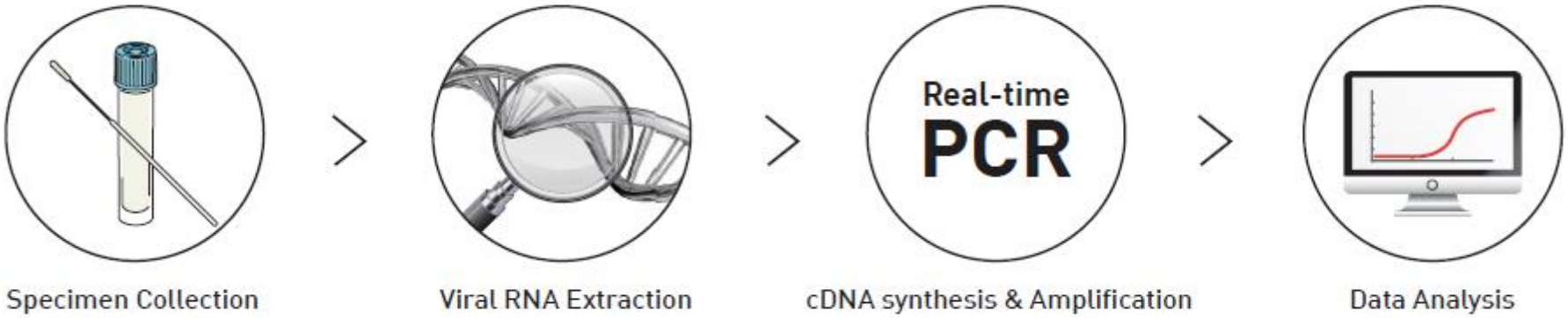
Mixtrue / 1sample

GeneFinder™ COVID-19 Plus Real*Amp* Kit– Test Procedure

Specimen - viral RNA samples extracted from human respiratory specimens such as alveolar lavage fluid, nasopharyngeal swabs (NPS), sputum etc.



Test Procedure



GeneFinder™ COVID-19 Plus Real*Amp* Kit – Instruments

Bio-Rad/CFX96

Applied Biosystems
7500 Real-time PCR System (ST/FAST)

GeneFinder ™ COVID-19 Plus RealAmp Kit is validated on Bio-Rad CFX96 and Thermo Fisher's AB7500 system (Standard/Fast).

If you are using other RT-PCR instruments, please contact OHC Technical Team.

GeneFinder™ COVID-19 Plus Real*Amp* Kit – Analysis(Software)

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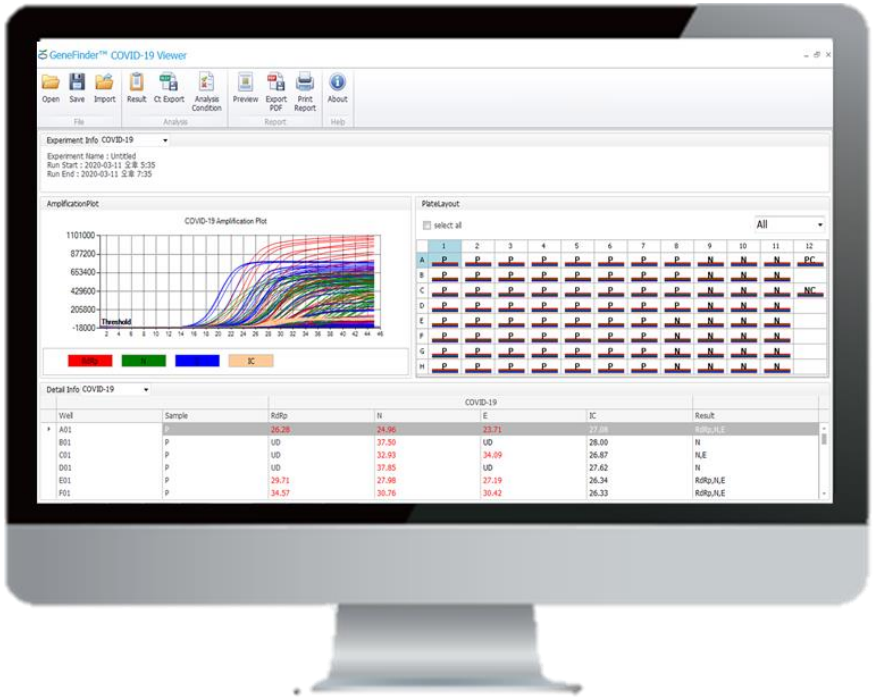

Results can be exported as either PDF and/or Excel format

GeneFinder™ COVID-19 Real /Amp Kit

GeneFinder™

MDX

OSANG

2020-03-11 5:48:04

Title : GeneFinder™ COVID-19 Test

Lot :

TestName : COVID-19

Experiment Date : 2020-03-11 7:35:29

Result

		COVID-19					Result	
Type	Sample	Well	RdRp	N	E	IC	COVID-19	Check
COVID-19	P	G01	34.83	31.80	31.84	27.48	RdRp,N,E	COVID-19 Positive
COVID-19	P	G02	32.27	29.53	28.88	25.31	RdRp,N,E	COVID-19 Positive
COVID-19	P	G03	26.41	24.62	22.79	24.65	RdRp,N,E	COVID-19 Positive
COVID-19	P	G04	26.41	24.23	22.97	25.14	RdRp,N,E	COVID-19 Positive
COVID-19	P	G05	22.65	19.98	17.91	21.51	RdRp,N,E	COVID-19 Positive
COVID-19	P	G06	26.70	24.95	23.30	24.62	RdRp,N,E	COVID-19 Positive
COVID-19	P	G07	UD	35.59	UD	25.54	N	Repeat the test(COVID-19 Positive if N≤43)
COVID-19	N	G08	UD	UD	UD	26.49		Negative
COVID-19	N	G09	UD	UD	UD	27.81		Negative
COVID-19	N	G10	UD	UD	UD	25.41		Negative
COVID-19	N	G11	UD	UD	UD	26.61		Negative

GeneFinder™ COVID-19 Viewer automatically analyze raw data when imported.

*Import file for ABI series is ABI(eds) file and CFX96 exported excel files for CFX96

GeneFinder™ COVID-19 Plus Real*Amp* Kit – Analytic performance

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✓ **Analytical Sensitivity**

LOD(Limit of Detection)

Target	LoD
RdRp gene	10 copies/test
E gene	10 copies/test
N gene	10 copies/test

✓ **Analytical Specificity**

No.	Name
1	Influenza A (H1N1/09)
2	Influenza A (H3N2)
3	Influenza A (H5N1)
4	Influenza B
5	Rhinovirus
6	Respiratory syncytial virus (A/B)
7	Parainfluenza 1 virus
8	Parainfluenza 2 virus
9	Parainfluenza 3 virus
10	Parainfluenza 4 virus
11	Adenovirus
12	Human Bocavirus
13	Measles virus
14	Mycoplasma spp.

A total 14 DNA/RNA samples extracted from reference strains were tested on three batches of the GeneFinder™ COVID-19 Plus RealAmp Kit in order to evaluate the possibility of cross-reactivity.
The Negative control was detected as Not applicable (N/A) (or undetermined, U.D) which means there was no testing, contamination and instrument errors.
14 DNA/RNA samples which have no concern with the detection target of the kit were negative.

GeneFinder™ COVID-19 Plus Real*Amp* Kit –Clinical performance

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✓ Samples : Residual test samples from Laboratories with which the COVID-19 test was completed.

✓ Type of sample: Extracted RNA from Nasopharyngeal swab, sputum.

COVID-19		Compared reagent	
		Positive	Negative
Test reagent	Positive	60	0
	Negative	0	60

Overall percent agreement (%) = 100 x [(120+0)/120] = 100%

Clinical Sensitivity = 60/60×100 = 100%

Clinical Specificity = 60/60×100 = 100%

GeneFinder™ COVID-19 Plus Real*Amp* Kit - Business

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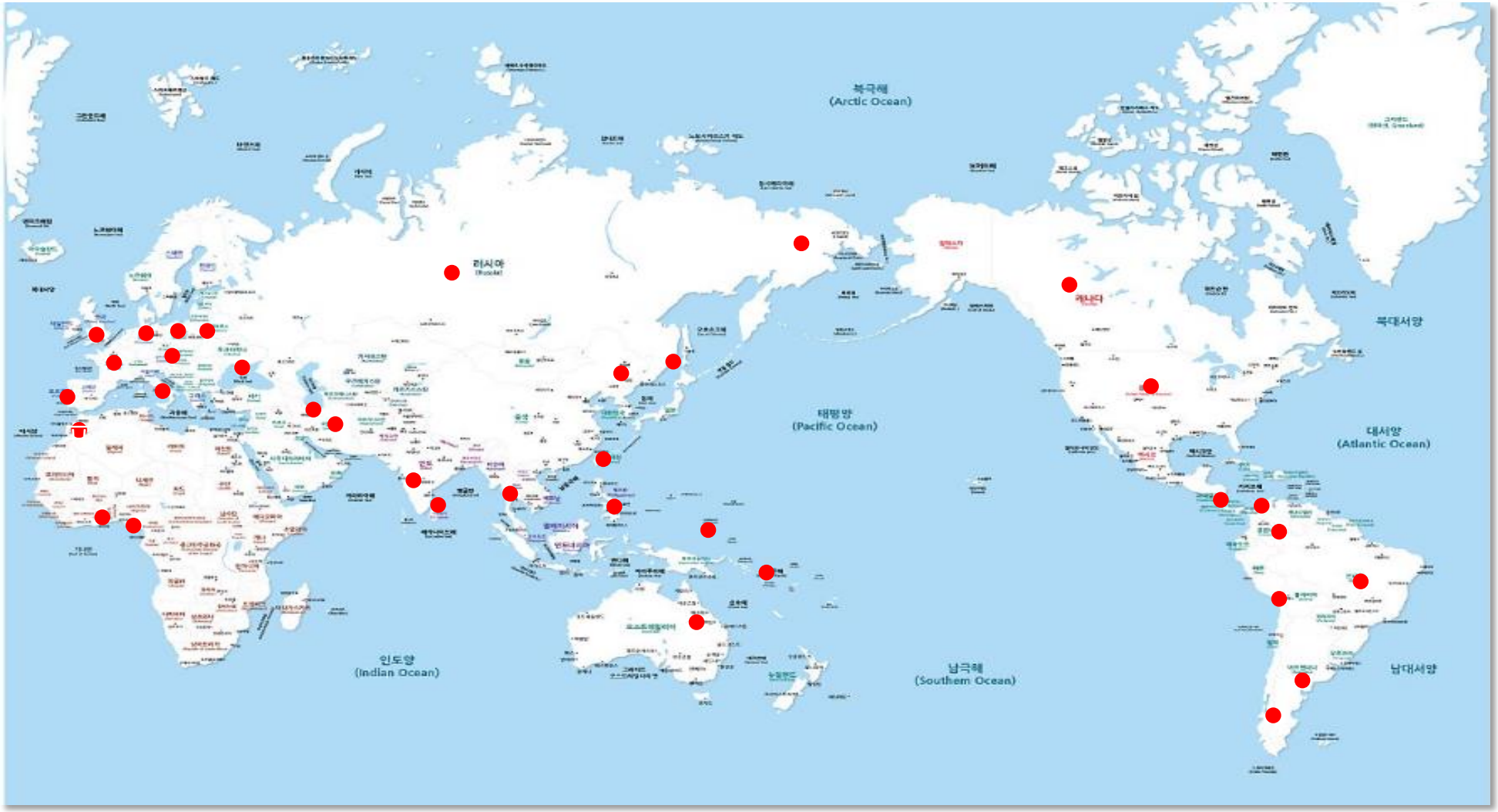

Most of countries suffering from Corona Impact are adopting GeneFinder™ COVID-19 Plus Real*Amp* Kit. Several CDCs are using GeneFinder™ COVID-19 Plus Real*Amp* Kit to control Corona infection in their countries.

Product Comparison

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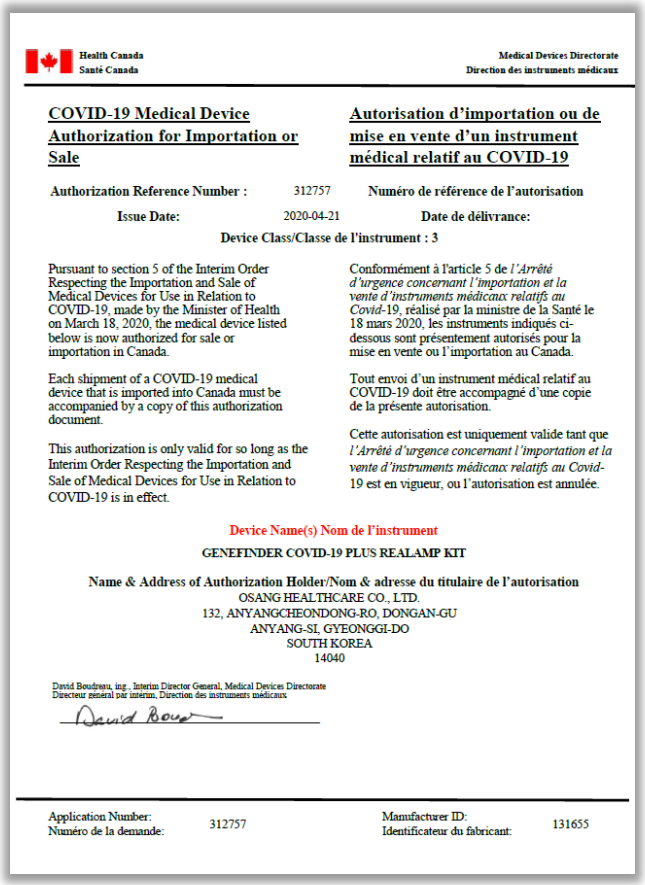
	WHO	Korea CDC	S****	K*****	GeneFinder™
Target Gene	RdRp	RdRp	RdRp	RdRp	RdRp
	E	E	E	E	E
	-	-	N	-	N
Internal Control	-	-	I.C (Exogenous)	I.C	I.C (Endogenous)
Tube #	2 tubes	2 tubes	1 tube	2 tubes	1 tube
	RdRp / E	RdRp / E	RdRp, E, N, IC	RdRp, IC / E, IC	RdRp, E, N, IC

GeneFinder™ COVID-19 Plus Real*Amp* Kit – Certification



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 : 312757 **Numéro de référence de l'autorisation**

Issue Date: 2020-04-21 **Date de délivrance:**

Device Class/Classe de l'instrument : 3

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

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

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

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

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

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

Device Name(s) Nom de l'instrument

GENEFINDER COVID-19 PLUS REALAMP KIT

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

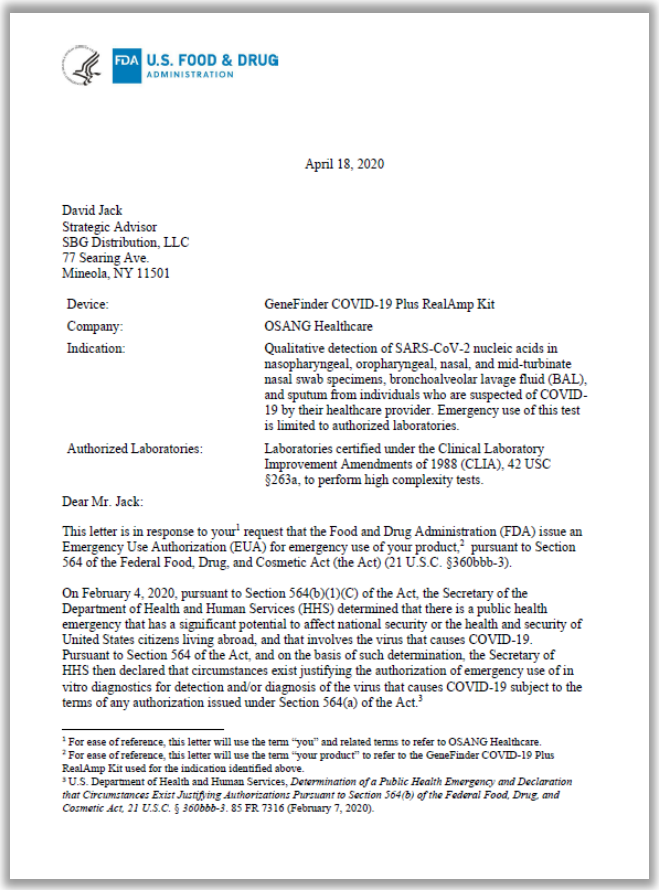
OSANG HEALTHCARE CO., LTD.
132, ANYANGCHEONDONG-RO, DONGAN-GU
ANYANG-SI, GYEONGGI-DO
SOUTH KOREA
14040

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

Application Number: 312757
Numéro de la demande:

Manufacturer ID: 131655
Identificateur du fabricant:

Health Canada



FDA U.S. FOOD & DRUG ADMINISTRATION

April 18, 2020

David Jack
Strategic Advisor
SBG Distribution, LLC
77 Searing Ave.
Mineola, NY 11501

Device:	GeneFinder COVID-19 Plus RealAmp Kit
Company:	OSANG Healthcare
Indication:	Qualitative detection of SARS-CoV-2 nucleic acids in nasopharyngeal, oropharyngeal, nasal, and mid-turbinate nasal swab specimens, bronchoalveolar lavage fluid (BAL), and sputum from individuals who are 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 USC §263a, to perform high complexity tests.

Dear Mr. Jack:

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 OSANG Healthcare.
[2] For ease of reference, this letter will use the term "your product" to refer to the GeneFinder COVID-19 Plus RealAmp 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 Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

FDA

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 23 апреля 2020 года № РЗН 2020/10152

Действительно до 1 января 2021 г.

На медицинское изделие
Набор реагентов для выявления РНК коронавирусов SARS/COVID-19 методом ПЦР GeneFinder COVID-19 Plus RealAmp Kit (IFMR-45), серия LOT 2003-R45-20, серия LOT 2003-R45-22, серия LOT 2003-R45-27

Настоящее регистрационное удостоверение выдано
"ОСАНГ Хелскеар Ко., Лтд.", Республика Корея,
OSANG Healthcare Co., Ltd., 132, Anyangcheondong-ro, Dongan-Gu, Anyang-si, Gyeonggi-do, Republic of Korea

Производитель
"ОСАНГ Хелскеар Ко., Лтд.", Республика Корея,
OSANG Healthcare Co., Ltd., 132, Anyangcheondong-ro, Dongan-Gu, Anyang-si, Gyeonggi-do, Republic of Korea

Место производства медицинского изделия
OSANG Healthcare Co., Ltd., 132, Anyangcheondong-ro, Dongan-Gu, Anyang-si, Gyeonggi-do, Republic of Korea

Номер регистрационного досье **№ РД-32557/26557 от 23.04.2020**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции по видам экономической деятельности **21.20.23.110**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

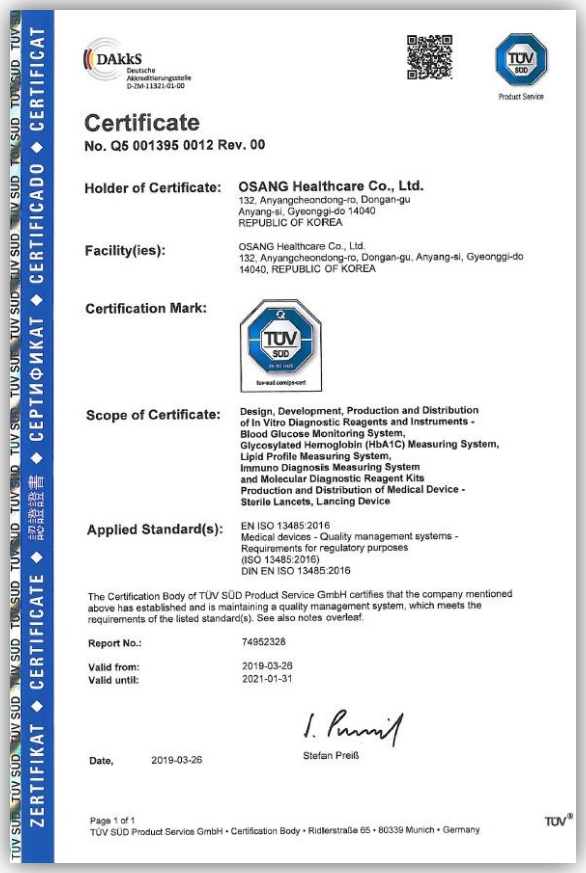
приказом Росздравнадзора от 23 апреля 2020 года № 3519
допущено к обращению на территории Российской Федерации

Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0048896

Russia

GeneFinder™ COVID-19 Plus Real*Amp* Kit – Certification



DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 001395 0012 Rev. 00

Holder of Certificate: **OSANG Healthcare Co., Ltd.**
132, Anyangcheondong-ro, Dongan-gu
Anyang-si, Gyeonggi-do 14040
REPUBLIC OF KOREA

Facility(ies): OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do
14040, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of In Vitro Diagnostic Reagents and Instruments - Blood Glucose Monitoring System, Glycosylated Hemoglobin (HbA1C) Measuring System, Lipid Profile Measuring System, Immuno Diagnosis Measuring System and Molecular Diagnostic Reagent Kits Production and Distribution of Medical Device - Sterile Lancets, Lancing Device**

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

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

Report No.: 74952328

Valid from: 2019-03-26
Valid until: 2021-01-31

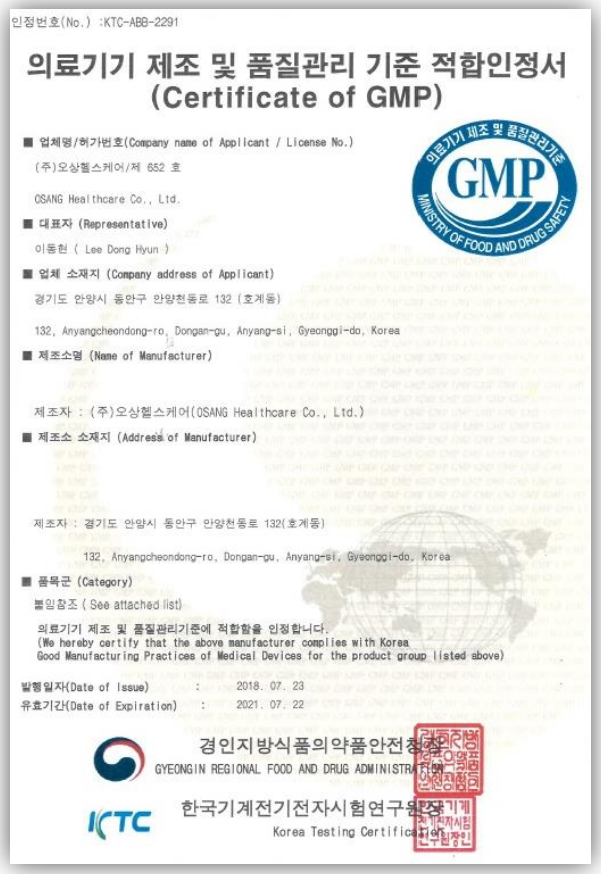
Date, 2019-03-26

Stefan Preiß

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

TÜV®

ISO13485



인정번호(No.) :KTC-ABB-2291

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)오상헬스케어/제 652 호
OSANG Healthcare Co., Ltd.

■ 대표자 (Representative)
이동현 (Lee Dong Hyun)

■ 업체 소재지 (Company address of Applicant)
경기도 안양시 동안구 안양천동로 132 (호계동)
132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea

■ 제조소명 (Name of Manufacturer)
제조자 : (주)오상헬스케어(OSANG Healthcare Co., Ltd.)

■ 제조소 소재지 (Address of Manufacturer)
제조자 : 경기도 안양시 동안구 안양천동로 132(호계동)
132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea

■ 품목군 (Category)
붙임참조 (See attached list)

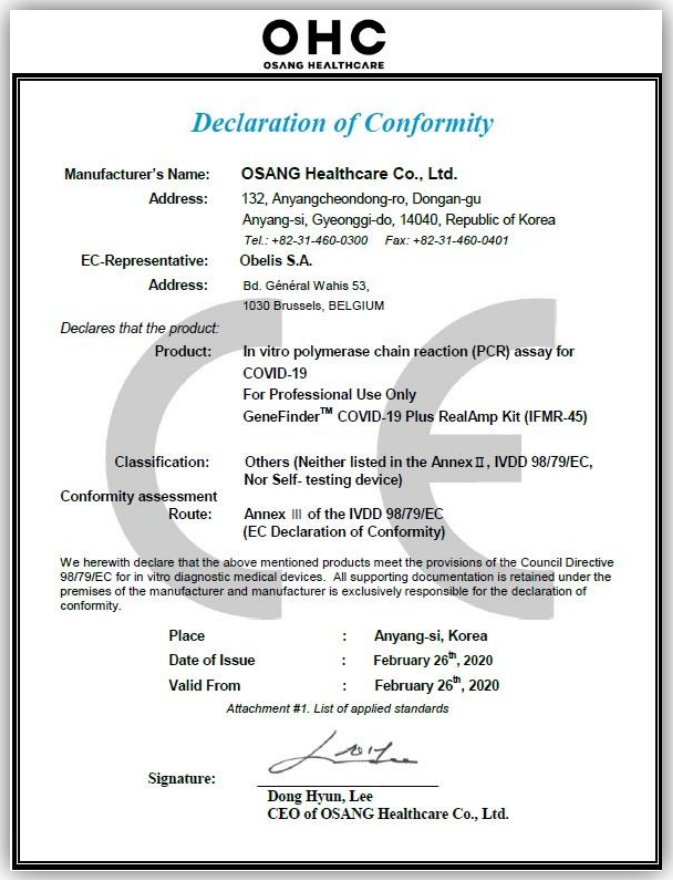
의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2018. 07. 23
유효기간(Date of Expiration) : 2021. 07. 22

경인지방식품의약품안전청장
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATOR

KTC 한국기계전기전자시험연구원장
Korea Testing Certification

GMP



OHC OSANG HEALTHCARE

Declaration of Conformity

Manufacturer's Name: **OSANG Healthcare Co., Ltd.**
Address: 132, Anyangcheondong-ro, Dongan-gu
Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: +82-31-460-0300 Fax: +82-31-460-0401
EC-Representative: **Obelis S.A.**
Address: Bd. Général Wahis 53,
1030 Brussels, BELGIUM

Declares that the product:
Product: In vitro polymerase chain reaction (PCR) assay for COVID-19
For Professional Use Only
GeneFinder™ COVID-19 Plus RealAmp Kit (IFMR-45)

Classification: Others (Neither listed in the Annex Ⅱ, IVDD 98/79/EC, Nor Self- testing device)
Conformity assessment Route: Annex Ⅲ of the IVDD 98/79/EC (EC Declaration of Conformity)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Place : **Anyang-si, Korea**
Date of Issue : **February 26th, 2020**
Valid From : **February 26th, 2020**

Attachment #1. List of applied standards

Signature:

Dong Hyun, Lee
CEO of OSANG Healthcare Co., Ltd.

CE

OSANG HEALTHCARE Co., Ltd

Company Overview

Presented by Osang Heathcare Co., Ltd / Revised by Mar 12nd, 2020

OHC
OSANG HEALTHCARE

Group OSANG Family

OHC
OSANG HEALTHCARE

OSANG
The global network company

IT & Advanced Materials

OSANG JAIEL
- KOSDAQ listed
- Advanced Materials (Boehmite & Alumina)
- IT Solution Service (PLM, System Integration)

OSANG NEWEL
- Thermal Plasma Application – Urban mining

Biotechnology & Agriculture

OSANG Healthcare
- IVD Diagnostic Medical Devices (POCT)
  - Biochemical
  - Immunoassay
  - Molecular Diagnostics
  - Digital Healthcare

OSANG BIO
- Agricultural Biotech

KINSECT
- Insect Business
- Natural Enemy
- Bio Business
- Nature Eco System Restoration & Sustainable Agricultural Technology

Fruit Packaging

OBIT
- Premium Fruit Packaging
- Pancap (Brand)
- Functional Films

Environmental Engineering

(주)GEO환경
(GEO Environment)
- Environmental Engineering
- Natural River Method
- Greenscaping
- Plasma Heat Recycling

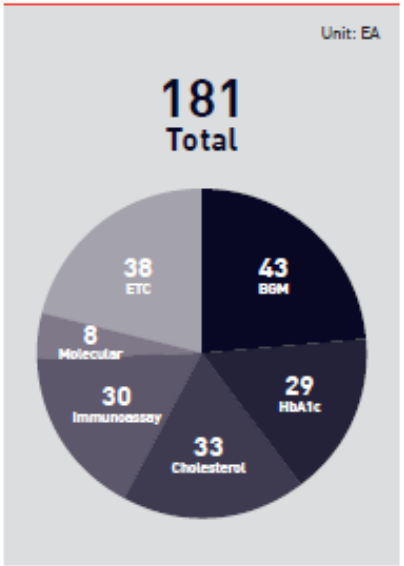
OSANG HEALTHCARE

OSANG Healthcare (formerly known as "Infopia") has been a leader in the Korean IVD (In-Vitro Diagnosis) industry since its founding in 1996, ever expanding a wide array of medical devices for Biochemical, Immunoassay and Molecular Diagnostics.
Giving the first priority to our customers and partners, we will further develop powerful synergies with other affiliates in the group, each an industry leader.

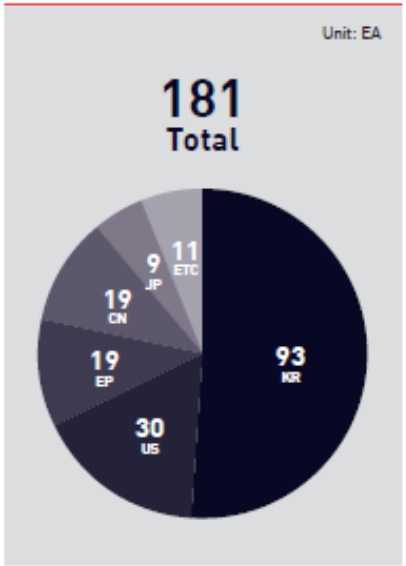
Core Technologies

- BGM
- POCT (HbA1c, Cholesterol, Immunoassay)
- Molecular Diagnostics
- Digital Healthcare Platform

Patents by Technology

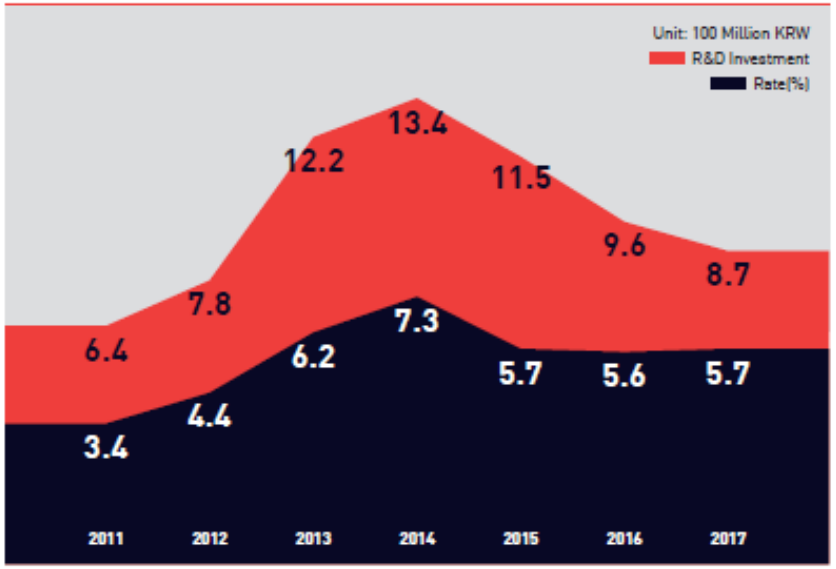


Patents by Country



R&D Investment & Employees

- Total Employees: 315
- R&D Employees: 52 (16.5%)
  - Doctorate/Master's Degree Holders: 27 / 52 (51.9%)



OHC Products Portfolio

OHC
OSANG HEALTHCARE

BGM

The blood glucose meter is an easy way to collect and manage blood samples and to screen for diseases.


Oh'Care


Oh'Care Lite


GluNEO


GluNEO Smart


GluNEO Lite


GluNEO Plus

HbA1c

An HbA1c measuring device gauges average blood glucose over 3 months by detecting hemoglobin (HbA1c, or hemoglobin A1c) combined with glucose for an accurate measure of blood glucose level.


Clover A1c


Clover A1c Plus

Cholesterol

A cholesterol measuring device enables quick and efficient measurement of Total Cholesterol, Triglycerides and HDL.


LipidPro


Element Multi


Landmark

Immunoassay

Through antigen-antibody reactions, SelexOn screens for diseases by extracting markers created by cardiac disorders, thyroid conditions, cancer and infectious diseases.


SelexOn


SelexOn-V

Molecular Diagnostics

Molecular diagnosis can detect human papilloma virus (HPV), and enable testing for histocompatibility (HLA) and infectious diseases, by examining nucleic acid (DNA and RNA) for genetic information (e.g., on a virus or human body).


PCR Kits


Nucleic Acid Extractor

OHC Molecular Diagnostic Products Portfolio

OHC
OSANG HEALTHCARE

Product Overview

- GeneFinder for diagnostic kits
- EX-MATE32 Plus for DNA extractor

Competitiveness

S.M.A.R.T. Solution	**S**imple and Convenient **M**ultiplex Assay **A**utomation **R**eliable Result **T**ime-saving & Cost-effective
Turn-key Set-up	DNA Extractor + Diagnostic Kits + Real-time PCR Machine

GeneFinder Kits


HLA-B*27 RealAmp Kit


HLA-B*51 RealAmp Kit


HLA-ABDR RealAmp Kit


HPV PCR Kit


TB&NTM Multiplex Real-time PCR Kit


HPV Liquid Bead Microarray

EX-MATE 32 Plus DNA Extractor

Specifications

Type	Stand-alone desktop
Number of Samples	1 ~ 32 samples
Processing Time	6~25 minutes
Dimensions (W x D x H)	350 x 370 x 400 mm
Power Requirements	100 ~ 240v / 3A

Thank You

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