VITA ASSIST
HEALTH LIMITED

SUPPLY OF LABORATORY REAGENTS, EQUIPMENT AND CONSUMABLES TO BOTH PRIVATE AND PUBLIC HEALTH SECTOR

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@ vitaassisthealth@gmail.com
www.vitaassist.com

About Us

We have the pleasure of introducing our company VITA ASSIST HEALTH LIMITED, an indigenous Limited Liability Company incorporated in Nigeria on 2016. The company with registration number, RC1230412 is aimed at supplying medical equipment, laboratory equipment and consumables as well as motor vehicles to pharmaceutical companies.

Our Main Business:

Vita assist Health Ltd has participated in the supply of Laboratory reagents, equipment and consumables to both private and public health sector to meet the healthcare needs in all six geopolitical zones in the country.

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PROJECTS EXECUTED

I. Supply of Lassa fever and Yellow fever PCR reagents by Altona to Nigeria Center for Disease and Control (NCDC): Total contract value: N274,232,000

II. Supply of Emergency reagents and consumbles (Thermofisher, Biorad, Nimagen, Sigma Aldrich, New England Biomedical, Eppendorf, Qiagen) for COVID-19: Total Contract value: N99,975,161

III. Supply of Genefinder COVID-19 Fast PCR kits to Private laboratories: Total current value: N247,500,000

IV. Supply of Liferiver extraction kits (ME-0078 and ME-0044) to Private laboratories and NCDC: Total contract value: N321,000,000

V. Supply of Lassa fever PCR reagents by Altona to MSF: Total contract value: N4,879,500

VI. Supply of Zika virus PCR by Altona to University of Ibadan Teaching hospital: Total contract value: N940,000

VII. Supply of Lassa fever PCR reagents by Altona to Nigerian Institute of Medical Research (NIMR): Total contract value: N1,999,310

VIII. Supply of 10 Vehicles to Servier Pharmaceuticals: Total contract value: N39,000,000

IX. Supply of Altona COVID-19 PCR reagents (S-gene and E gene only) to Zaine Lab: Total contract value: N6,244,000

X. Supply of Hospital Equipment under the CaCOVID project to 6 different states: Total Contract value: N262,000,000

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Management

Vita Assist Health Limited is managed by seasoned Administrators, skilled and qualified Medical Laboratory Technologists right from its inception.
The company has in her employ staff who by virtue of their education and training are professionals in the fields of Biomedical Engineering, Medical Doctors, Pharmacists, Instrumentation, Medical Engineering, Administration, Accounting, Systems Analysis and Programming, Laboratory Science and Marketing.

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EX9600

Automated Nucleic Acid Extraction System

Small Size

High Throughput

High Efficiency

EX9600
Technical Principles

With nano magnetic bead technology, EX9600 Automated Nucleic Acid Extraction System automatically completes nucleic acid extraction and purification through collecting, releasing, and transferring magnetic beads.

Product Features

Smaller Size

With＜0.15m², EX9600 can fit into bio-safety cabinet, with 3 stacked so as to expand the throughput to 288

Simpler Operation

Touchscreen with one-click operation makes EX9600 highly efficient with preloaded extraction reagent.

Faster Extraction

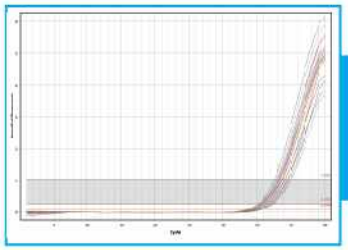
Extraction of 96 specimens in only 10 minutes.

Contamination Control

- Equipped with UV lamp for disinfection
- Optimal amplitude and frequency stettings
- Pyrolysis under room temperature to prevent aerosol contamination

Safe & Reliable

Fully automated & completely enclosed system with high stability.



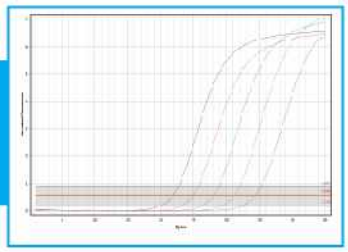
EX9600 Reliable Extraction Result

Precision

Repeated extraction and detection results of the same specimen for 20 times (concentration: 300 copies/mL)

Linearity

Extraction and detection results of the same specimen of different concentrations (concentrations: E7/E6/E5/E4/E3 copies/mL)



EX9600 Technical Specifications

Parameters	Specifications
Throughput	1-96
Sample Volume Processed	200-1,000μL
Extraction Time	Up to 10 min/run (96 samples)
Magnetic Bead Recycle Rate	>98%
Mixture Mode	Adjustable frequency and amplitude
Contamination Control	UV disinfection lamp
Interface	8-inch color LCD touchscreen, and windows operating system
Number of Programs Stored	>5,000
Interface Mode	USB
Dimensions(L*W*H)	564mm*250mm*397mm
Weight	14.6kg
Environment	Humidity: 30%~80%, Temperature: 10℃~40℃
Power	AC 220V±20V, 50Hz/60Hz, 120W

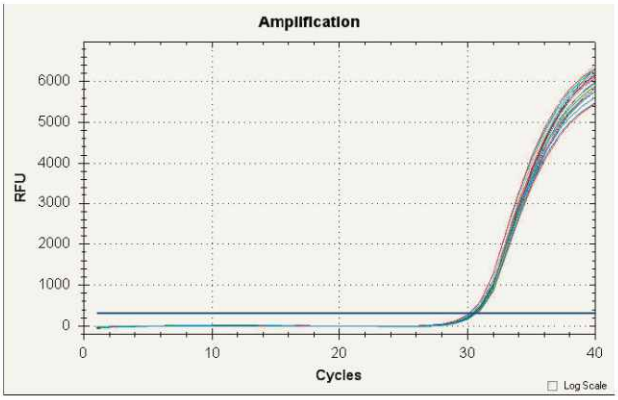
EX2400/EX3600 Automated Nucleic Acid Extraction System

Features

- **Automation solution**
  The fully automated system provides a streamlined workflow to avoid tedious manual operation.
- **Simple operation**
  After samples are added, the entire process can be initiated with the push of a button.
- **Multiplexing capability**
  The system can process 24 to 36 samples per run.
- **Fast process**
  Purification only takes 20 minutes.
- **Reliable quality**
  The automation system improves purification quality compared to manual operation.
- **Safety measurement**
  The system runs in a closed environment which reduces potential risks for the contamination from pathogens or chemicals.
- **Prevention of sample contamination**
  The build-in UV lamp destroys the residual nucleic acids after each run to prevent potential nucleic acid contamination in the next run.

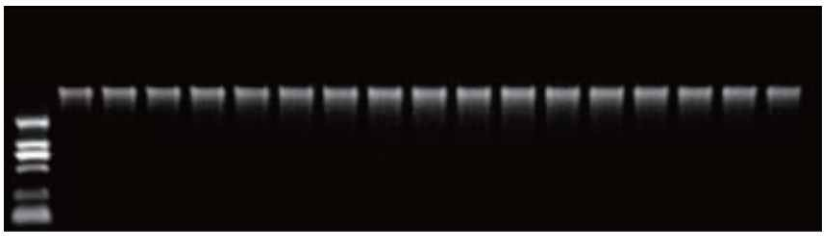
Case studies

- Real Time PCR assay using 24 DNA templates purified from one sample by one operation. The result showed that similar amplification curves were observed.



Fluorescent Amplification Curves (n=24)

- Agarose Gel Electrophoresis using 17 DNA templates purified from one sample by one operation. The result showed that 17 similar DNA bands were observed.



Agarose Gel Electrophoresis (n=17)

Parameters and Specifications

Product Name	EX2400 Automated Nucleic Acid Extraction	EX3600 Automated Nucleic Acid Extraction
Cat. #	IE-0001	IE-0002
Sample Volume	20-200ul	20-200ul
Sample Quantity	24 units/time	36 units/time
CMOD	1	1
Sample Handling Time	20 min	20 min
Magnetic Bead Collection Efficiency	≥99%	≥99%
96 Well Plate	2	3
Magnetic Bar	24	36
Magnetic Cap (disposable)	2 strips (12 well/strip)	3 strips (12 well/strip)
Keypad	Start/ Stop/ Direction Keys	Start/ Stop/ Direction Keys
Monitor	LCD (text display)	LCD (text display)
UV lamp	Available	Available
Boundary dimension (L*W*H)	45*38*43cm	53*50*45cm
Net weight	20 kg	30 kg
Operation Condition	Room temperature	Room temperature

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Immuno-compromised

Real-Time Efficiency in Monitoring Immunocompromised Patients

RealStar® Immunocompromised Testing Panel

Persons with congenital or acquired immunodeficiency cannot respond properly to an infection due to an impaired or weakened immune system. There are various causes that can affect the human immune system such as the infection with certain viruses, like the human immunodeficiency virus (HIV), antitumor treatments in cancer patients, immunosuppressing drugs given to transplant recipients but also genetic disorders. Immunocompromised patient management highly leans on the reliable monitoring of the viral load of so-called indicator viruses, like different herpes- and polyomaviruses.

The RealStar® Immunocompromised PCR Panel facilitates the monitoring of viruses and other pathogens with possible clinical relevance for patients with immunodeficiency and can be used to control the status of the immune system.

RealStar® kits are CE-IVD marked tests, based on real-time PCR technology, utilizing polymerase chain reaction (PCR) for the amplification of specified target sequences, as well as target-specific probes linked to fluorescence dyes used for the detection and quantification of specific amplification products.

The key advantages: The harmonized design of the RealStar® kits allows the simultaneous detection and quantification of multiple viruses and pathogens in a single run. Due to the composition of the RealStar® Immunocompromised PCR Panel a flexible combination of the assays depending on the specific needs of the individual patient is possible.

Thanks to their sensitive, specific and reliable performance and their ease of use, the real-time PCR assays of the RealStar® Immunocompromised PCR Panel are widely used in a large variety of laboratories, worldwide.

RealStar®

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RealStar® real-time PCR kits (RUO)

Product name	Detection of	Rxns	Order No.
Human adenovirus, human herpesviruses and human polyomaviruses			
RealStar® Adenovirus PCR Kit 1.0	Human adenovirus (quantitative)	96	301003
RealStar® CMV PCR Kit 1.0	Cytomegalovirus (quantitative)	96	021003
RealStar® CMV PCR Kit 1.2*	Cytomegalovirus (quantitative)	48	021202
RealStar® EBV PCR Kit 1.0	Epstein-Barr virus (quantitative)	96	131003
RealStar® EBV PCR Kit 2.0	Epstein-Barr virus (quantitative)	96	132003
RealStar® EBV PCR Kit 1.2*	Epstein-Barr virus (quantitative)	48	131202
RealStar® HHV-6 PCR Kit 1.0	Human herpesvirus 6A and 6B (quantitative)	96	311003
RealStar® HHV-4 /-5 /-6 PCR Kit 1.0	Human herpesvirus 4, 5, 6A and 6B	96	371003
RealStar® HSV PCR Kit 1.0	Herpes simplex virus 1 and 2 (quantitative)	96	061003
RealStar® HSV PCR Kit 1.1**	Herpes simplex virus 1 and 2 (quantitative)	48	061102
RealStar® VZV PCR Kit 1.0	Varicella zoster virus (quantitative)	96	071003
RealStar® VZV PCR Kit 1.2*	Varicella zoster virus (quantitative)	48	071202
RealStar® *alpha* Herpesvirus PCR Kit 1.0	HSV-1, HSV-2 and VZV	96	081003
RealStar® BKV PCR Kit 1.0	BK virus (quantitative)	96	031003
RealStar® BKV PCR Kit 1.2*	BK virus (quantitative)	48	031202
RealStar® JCV PCR Kit 1.0	JC virus (quantitative)	96	041003
RealStar® JCV PCR Kit 1.2*	JC virus (quantitative)	48	041202
Respiratory viruses, bacteria and fungi			
RealStar® Adenovirus PCR Kit 1.0	Human adenovirus (quantitative)	96	301003
RealStar® Enterovirus RT-PCR Kit 1.0	Enterovirus and rhinovirus	96	571003
RealStar® Influenza S & T RT-PCR Kit 4.0	Human influenza A and B and swine flu (H1N1)pdm09	96	164003
RealStar® MERS-CoV RT-PCR Kit 1.0	Middle East respiratory syndrome coronavirus	48	391002
RealStar® MERS-CoV (N gene) RT-PCR Kit 1.0	Middle East respiratory syndrome coronavirus (N gene)	96	651003
RealStar® SARS-CoV-2 RT-PCR Kit 1.0	Severe acute respiratory syndrome coronavirus 2	384	821005
RealStar® hMPV RT-PCR Kit 2.0	Human metapneumovirus A and B	96	252003
RealStar® Parechovirus RT-PCR Kit 1.0	Human parechovirus	96	781003
RealStar® PIV RT-PCR Kit 2.0	Human parainfluenza virus 1 – 4	96	262003
RealStar® RSV RT-PCR Kit 3.0	Respiratory syncytial virus A and B	96	193003
RealStar® Bordetella PCR Kit 1.0	*Bordetella pertussis* and *Bordetella parapertussis*	96	531003
RealStar® Pneumocystis jirovecii PCR Kit 1.0	*Pneumocystis jirovecii* (quantitative)	96	551003
Enteric viruses and bacteria			
RealStar® Adenovirus PCR Kit 1.0	Human adenovirus (quantitative)	96	301003
RealStar® Norovirus RT-PCR Kit 3.0	Norovirus genogroup I and II	96	053003
RealStar® Rotavirus RT-PCR Kit 1.0	Rotavirus	96	561003
RealStar® Clostridium difficile PCR Kit 2.0	*Clostridium difficile* toxin A and B	96	172003
RealStar® EHEC PCR Kit 2.0	Shiga toxin 1 and Shiga toxin 2 and ipaH	96	292003

Product name	Detection of	Rxns	Order No.
Blood borne viruses			
RealStar® HDV RT-PCR Kit 1.0	Hepatitis D virus (quantitative)	96	401003
RealStar® HEV RT-PCR Kit 2.0	Hepatitis E virus (quantitative)	96	272003
RealStar® Parvovirus B19 PCR Kit 1.0	Parvovirus B19 (quantitative)	96	101003
RealStar® Parvovirus B19 PCR Kit 1.2*	Parvovirus B19 (quantitative)	48	101202
Tropical viruses and parasites			
RealStar® AHFV / KFDV RT-PCR Kit 1.0	Alkhurma virus and Kyasanur Forest disease virus	96	771003
RealStar® CCHFV RT-PCR Kit 1.0	Crimean-Congo hemorrhagic fever virus	96	181003
RealStar® Chagas PCR Kit 1.0	*Trypanosoma cruzi*	96	611003
RealStar® Chikungunya RT-PCR Kit 2.0	Chikungunya virus	96	012003
RealStar® Dengue RT-PCR Kit 3.0	Dengue virus	96	283003
RealStar® Dengue Type RT-PCR Kit 1.0	Dengue virus 1 – 4 and serotype differentiation	2×48	621003
RealStar® Filovirus Screen RT-PCR Kit 1.0	Human pathogenic filovirus species	96	441003
RealStar® Filovirus Type RT-PCR Kit 1.0	Filoviruses and species differentiation	4×24	451003
RealStar® Lassa Virus RT-PCR Kit 2.0	Lassa virus	2×48	642003
RealStar® RVFV RT-PCR Kit 1.0	Rift Valley fever virus	96	541003
RealStar® WNV RT-PCR Kit 2.0	West Nile virus	96	322003
RealStar® Yellow Fever Virus RT-PCR Kit 1.0	Yellow fever virus	96	671003
RealStar® Zika Virus RT-PCR Kit 1.0	Zika virus	96	591003
RealStar® Malaria PCR Kit 1.0	Human pathogenic *Plasmodium* species	96	341003
RealStar® Malaria S & T PCR Kit 1.0	*Plasmodium* and species differentiation	2×48	351003

Real-time PCR instruments:

ABI Prism® 7500 SDS and 7500 Fast SDS, m2000rt, LightCycler® 480 Instrument II, Rotor-Gene® 6000, Rotor-Gene® Q5/6 plex Platform, Mx 3005P™ QPCR System, VERSANT® kPCR Molecular System AD, CFX96™ Deep Well Dx System (previous designation: CFX96™ Deep Well Real-Time PCR Detection System), CFX96™ Dx System (previous designation: CFX96™ Real-Time PCR Detection System)

* LightCycler® 1.2/1.5/2.0, SmartCycler® II | ** LightCycler® 1.2/1.5/2.0

Kits not available in all countries. For research use only. Not for use in diagnostic procedures.

Product Name	Detection of	Order No.
RealStar® Immunocompromised Testing Panel		
RealStar® Adenovirus PCR Kit 1.0	Human Adenovirus (quantitative)	301013
RealStar® CMV PCR Kit 1.0	Cytomegalovirus (quantitative)	021013
RealStar® EBV PCR Kit 1.0	Epstein-Barr Virus (quantitative)	131013
RealStar® EBV PCR Kit 2.0	Epstein-Barr Virus (quantitative)	132013
RealStar® HHV-6 PCR Kit 1.0	Human Herpesvirus 6A and 6B (quantitative)	311013
RealStar® HSV PCR Kit 1.0	Herpes Simplex Virus 1 and 2 (quantitative)	061013
RealStar® VZV PCR Kit 1.0	Varicella Zoster Virus (quantitative)	071013
RealStar® *alpha* Herpesvirus PCR Kit 1.0	HSV-1, HSV-2 and VZV	081013
RealStar® BKV PCR Kit 1.0	BK Virus (quantitative)	031013
RealStar® JCV PCR Kit 1.0	JC Virus (quantitative)	041013
RealStar® Pneumocystis jirovecii PCR Kit 1.0	*Pneumocystis jirovecii* (quantitative)	551013

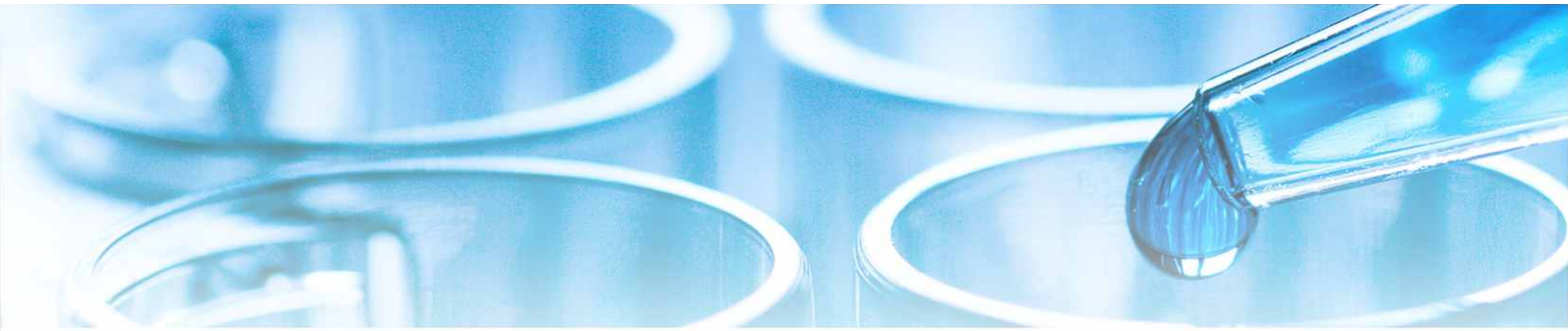
The RealStar® PCR assays are CE-IVD marked diagnostic kits according to the European *in vitro* diagnostic directive 98/79/EC.
Each RealStar® real-time PCR kit contains components sufficient for 96 rxns.

The RealStar® Immunocompromised Testing Panel includes assays for the detection of all relevant herpes- and polyomaviruses like CMV, EBV, HHV–6 (A and B), BKV, JCV and others, but also of adenovirus and *Pneumocystis jirovecii.* The panel also comprises the RealStar® *alpha* Herpesvirus PCR Kit 1.0 for the detection and differentiation of herpes simplex virus 1 and 2 and varicella zoster virus in one single reaction. All assays are developed and validated to be used on a wide range of real-time PCR cyclers.

Uniform PCR Setup | Real-Time PCR Cycler | Result

Supported Cyclers: ABI Prism® 7500 (Fast), m2000rt, LightCycler® 480, Rotor-Gene®, Mx 3005 P™ QPCR, VERSANT® kPCR, CFX96™ (DW)

In addition to the CE-IVD marked PCR kits of the RealStar® Immunocompromised Testing Panel, altona® offers assays that can be combined to panels of respiratory and enteric agents as well as blood borne viruses. A particular focus of altona Diagnostics is in the field of emerging and tropical infectious diseases. Depending on the respective kit, analytical methods can include: detection, differentiation and quantification methods.



Product Introduction

EX2400 and EX3600 are two fully automated platforms for nucleic acid extraction. Using the latest magnetic bead technology, the system provides high efficiency with simple operation. Multiple nucleic acid samples can be processed simultaneously. The entire process only takes 20 minutes. The system can extract nucleic acids from various samples including whole blood, plasma, serum, cells, milk, feces, etc.

EX3600

EX2400

Reagents

Consumable Items

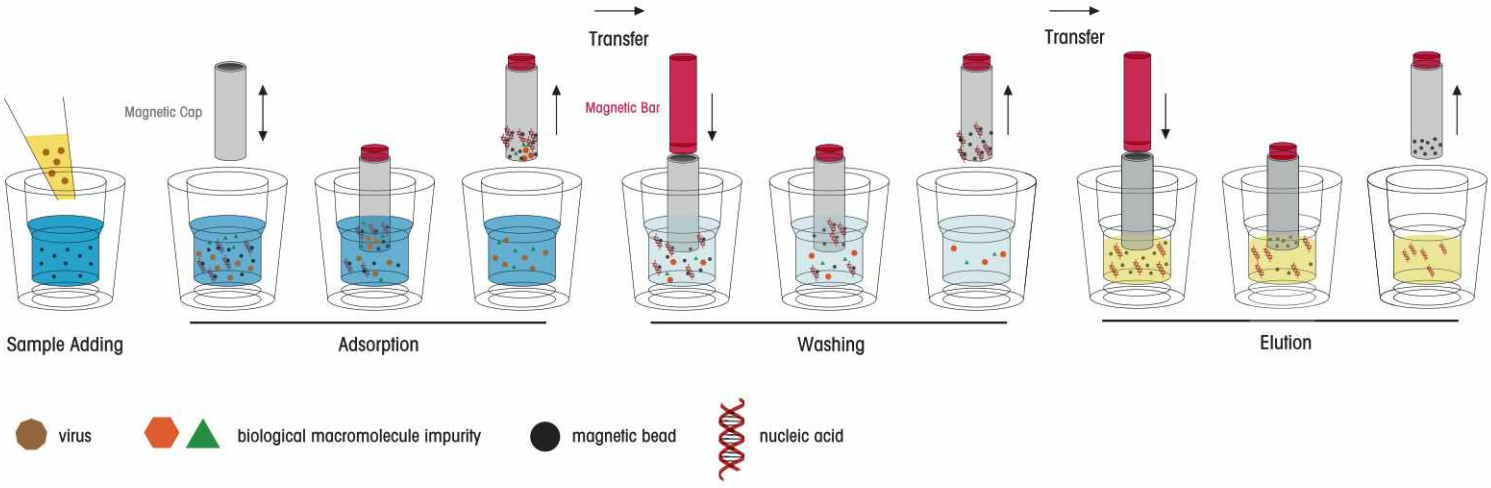
Principle of the System

The principle underlying magnetic bead procedures involves negatively-charged nucleic acids binding to magnetic beads reversibly, washing and elution as follows -

(1) Binding: nucleic acids released from the sample are binded to the magnetic beads

(2) Washing: non-nucleic acid components are removed

(3) Elution: purified nucleic acids are released from beads into the elution buffer



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

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GeneFinder™ COVID-19 Plus RealAmp Kit – Kit Component

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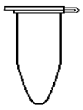
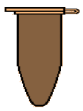
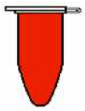
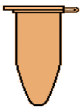
GeneFinder™ COVID-19 Plus			
COVID-19 Plus Reaction Mixture	COVID-19 Plus Probe Mixture	COVID-19 Plus Positive Control	COVID-19 Plus Negative Control
1050 uL / kit	550 uL / kit	50 uL / kit	50 uL / kit
			

	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 RealAmp Kit– Test Procedure

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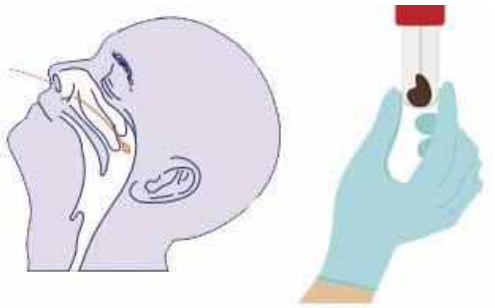
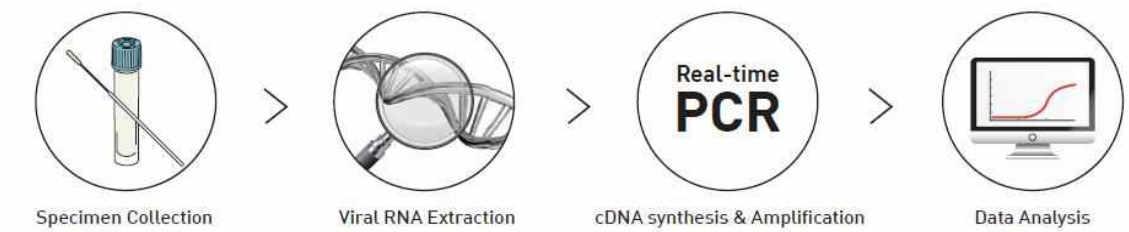
Specimen - viral RNA samples extracted from human respiratory specimens such as alveolar lavage fluid, nasopharyngeal swabs (NPS), sputum etc.



Test Procedure



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

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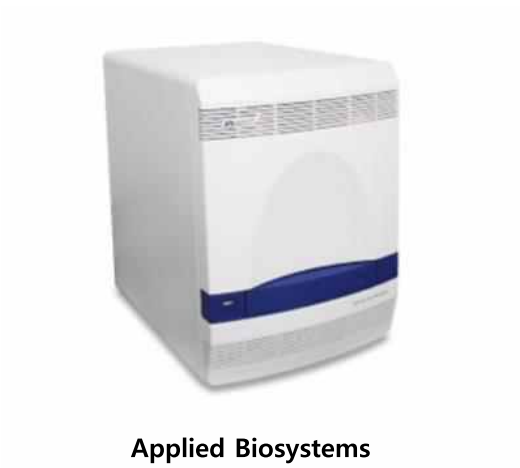
Bio-Rad/CFX96



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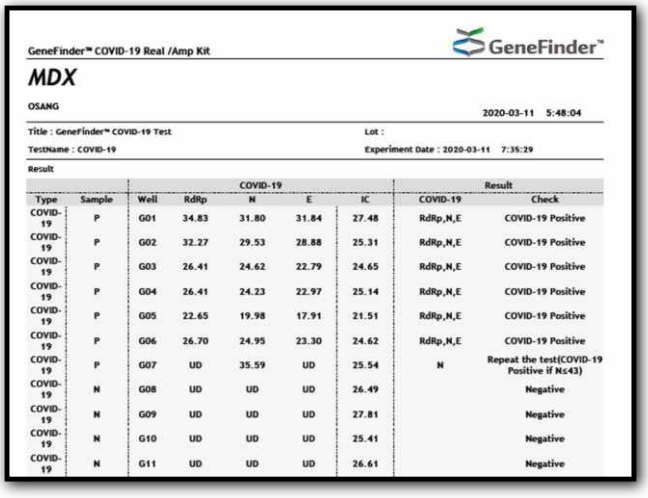
Results can be exported as either PDF and/or Excel format



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 Ns<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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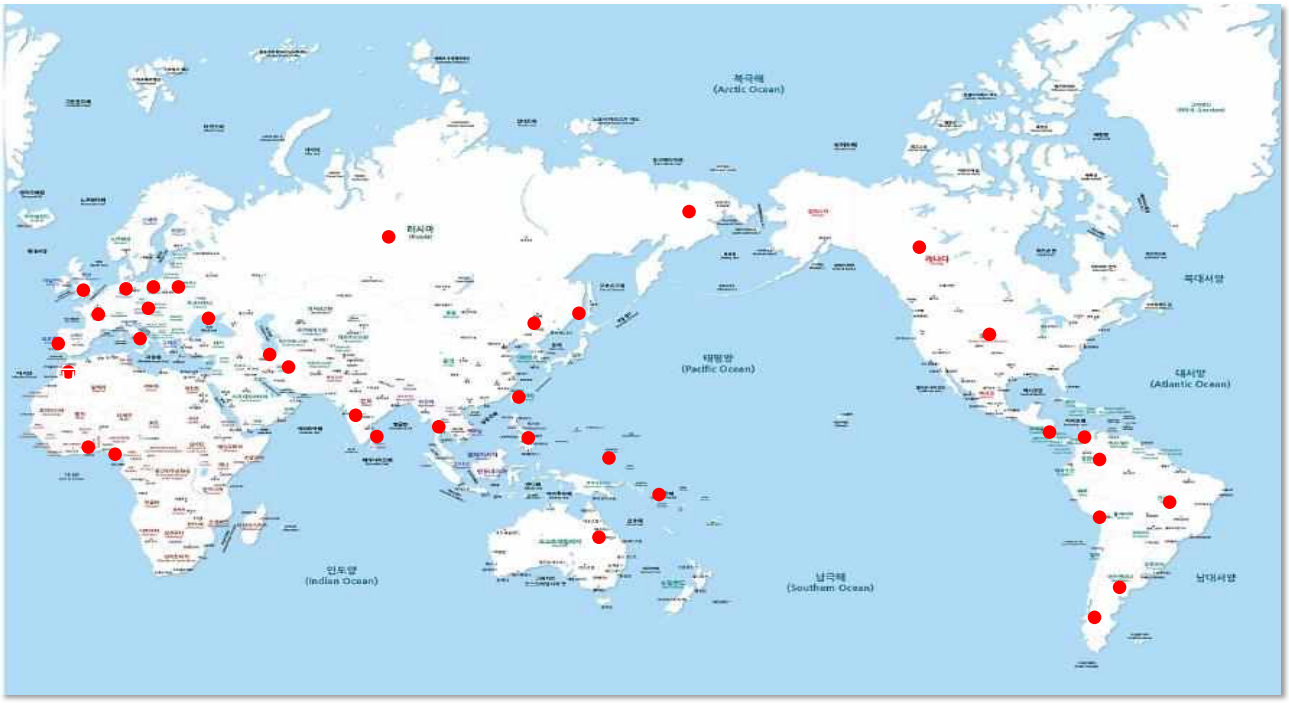

Most of countries suffering from Corona Impact are adopting GeneFinder™ COVID-19 Plus Real*Amp* Kit. Several CDCs are using GeneFinder™ COVID-19 Plus Real*Amp* Kit to control Corona infection in their countries.

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

VITA ASSIST
HEALTH LIMITED

GeneFinder™ COVID-19 Plus RealAmp Kit – Certification

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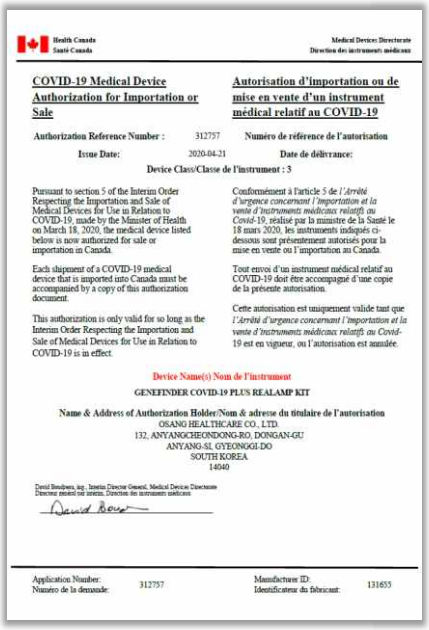


Health Canada

Health 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.

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

GENEFINDER COVID-19 PLUS REALAMP KIT

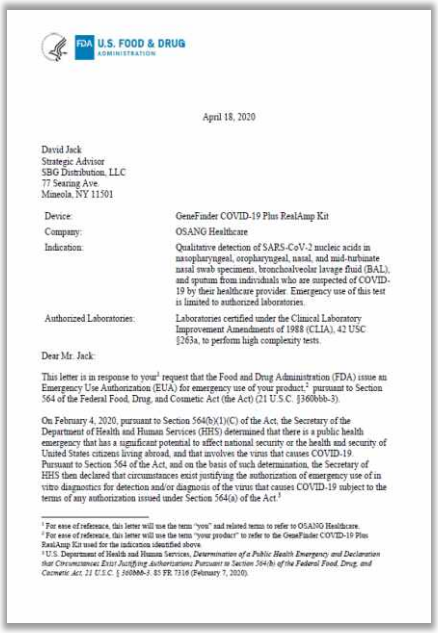
Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

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

David Boudreau, Inc., 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:



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 indications 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).

Russia

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

Производитель:
"ОСАНГ Хелскэр 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 № РЗН-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 № 3[illegible]
допущено к обращению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения

А.Ю. Самойлова

0048896

GeneFinder™ COVID-19 Plus RealAmp Kit – Certification

OHC
OSANG HEALTHCARE

ISO13485

DAkkS
TÜV SÜD

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

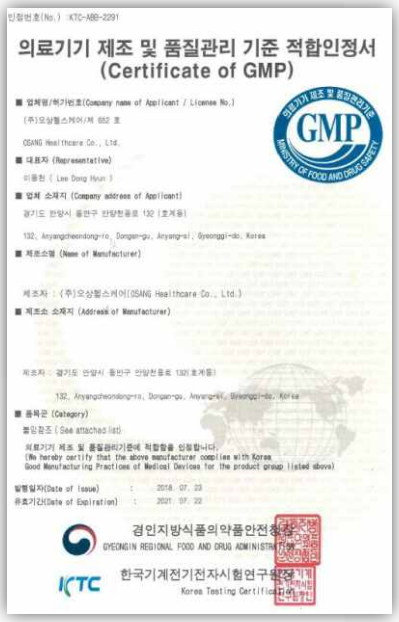
Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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 Preß

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



GMP

인정번호(No.) KTC-MB-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

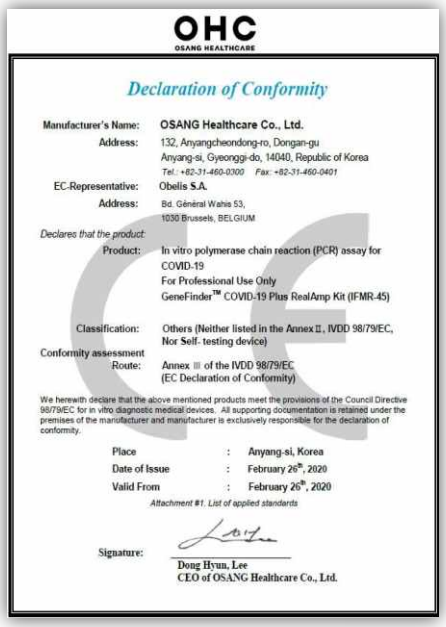
■ 품목군 (Category)
별첨참조 (See attached list)

(No 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 한국기계전기전자시험연구원
Korea Testing Certification



CE

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.

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Off Awolowo Road
Ikoyi Lagos State

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