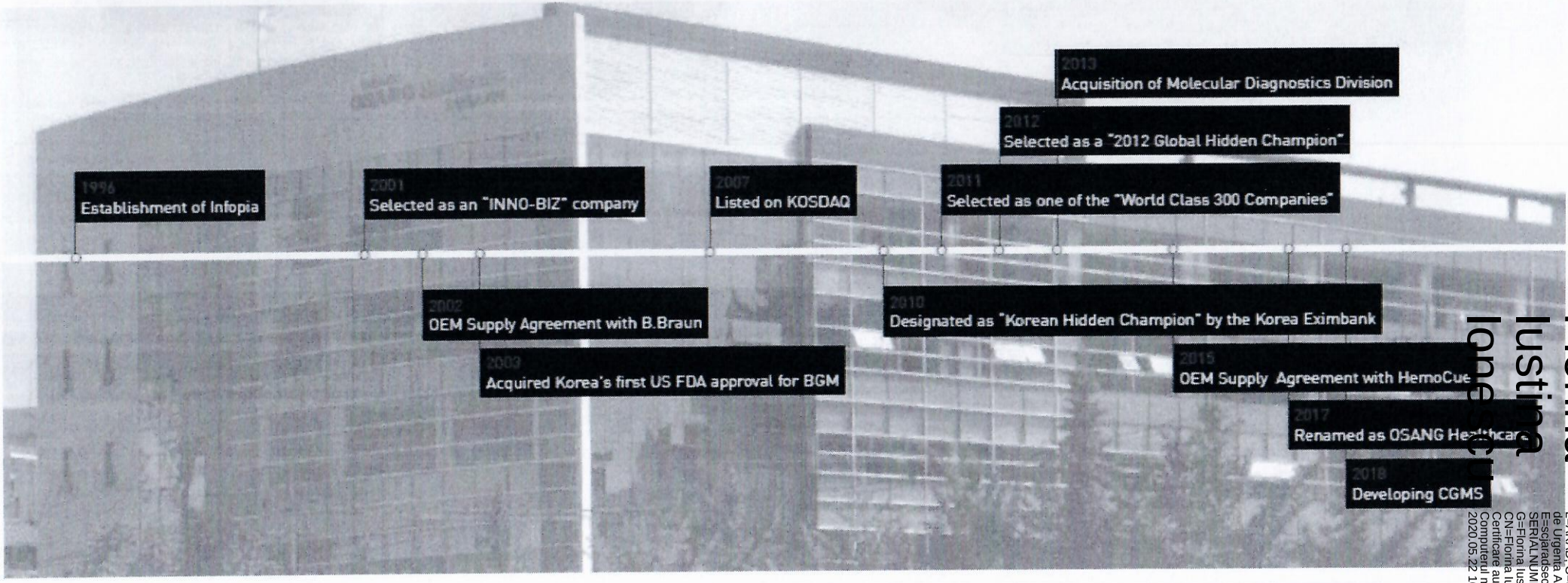
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OSANG Healthcare (formerly known as “Infopia”) has been a leader in the Korean IVD (In-Vitro Diagnosis) industry since its founding in 1996, ever expanding a wide array of medical devices for Biochemical, Immunoassay and Molecular Diagnostics.
Giving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



Florina Iustina Ionescu
Digitally signed by Florina Iustina Ionescu
T=Manager, C=RO, S=ARAD, L=ARAD, O=Spitalul Clinic Judetean de Urgenta Arad, OU=Administrativ, E=scpiaradsecretariat@yahoo.com, SERIALNUMBER=2011042609FII1, G=Florina Iustina, SN=Ionescu, CN=Florina Iustina Ionescu
Certificate autenticitate
Conținutul meu
2020.05.22 16:39

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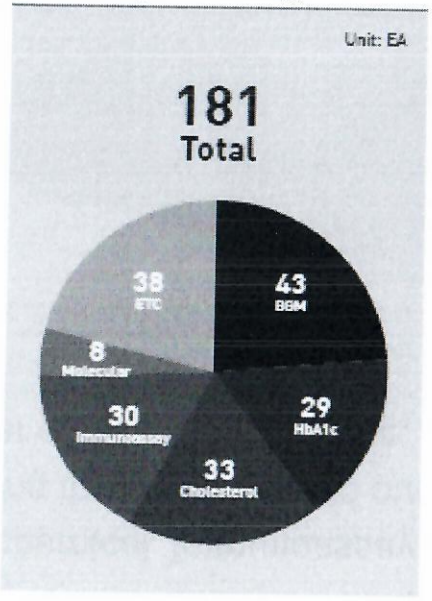
OHC Technology / R&D

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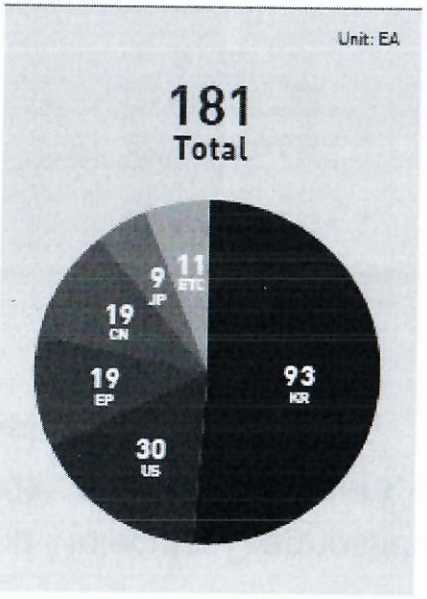
Core Technologies

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

Patents by Technology

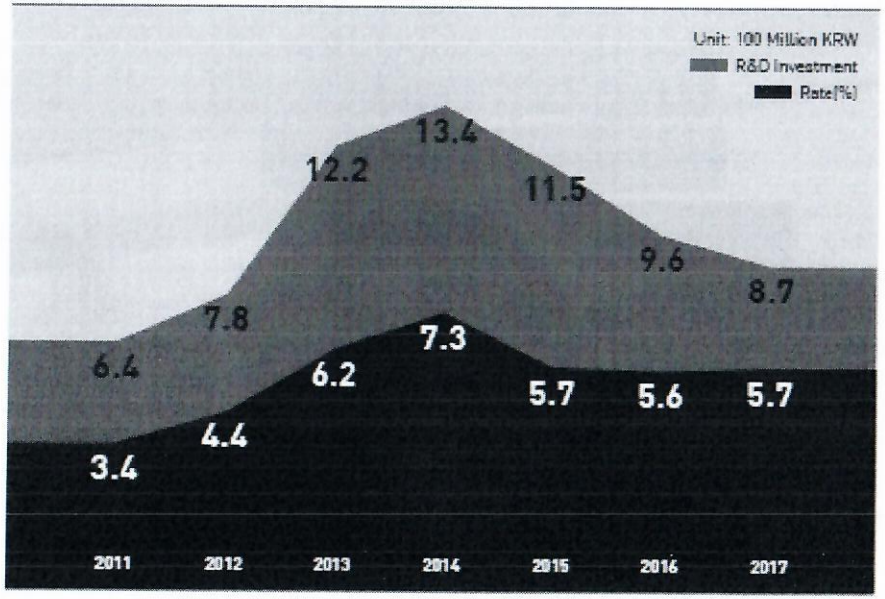


Patents by Country



R&D Investment & Employees

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



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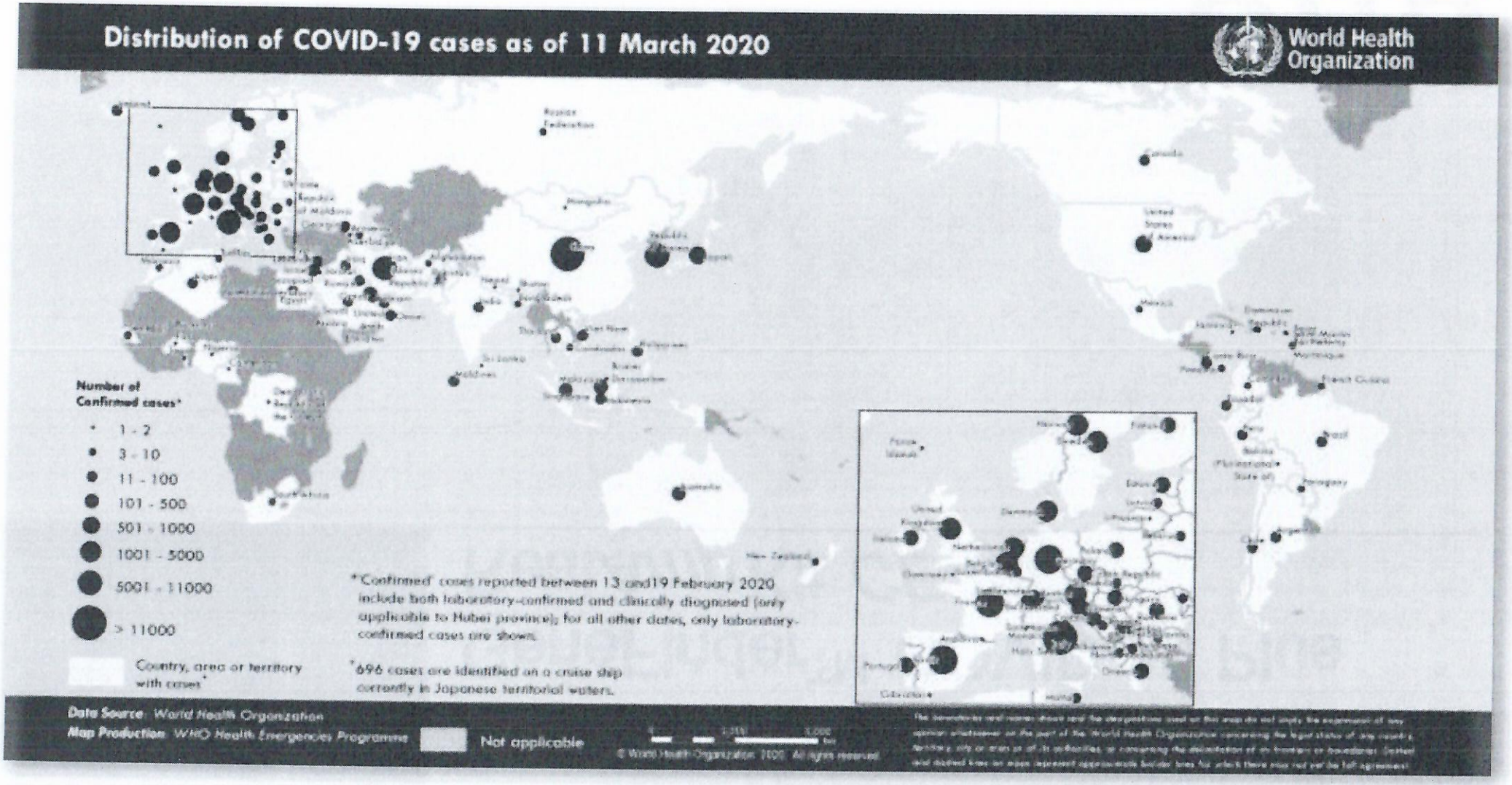
GeneFinder™ COVID-19 Plus RealAmp Kit *CE-IVD*

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Presented by Osang Heathcare Co., Ltd

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.

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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 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



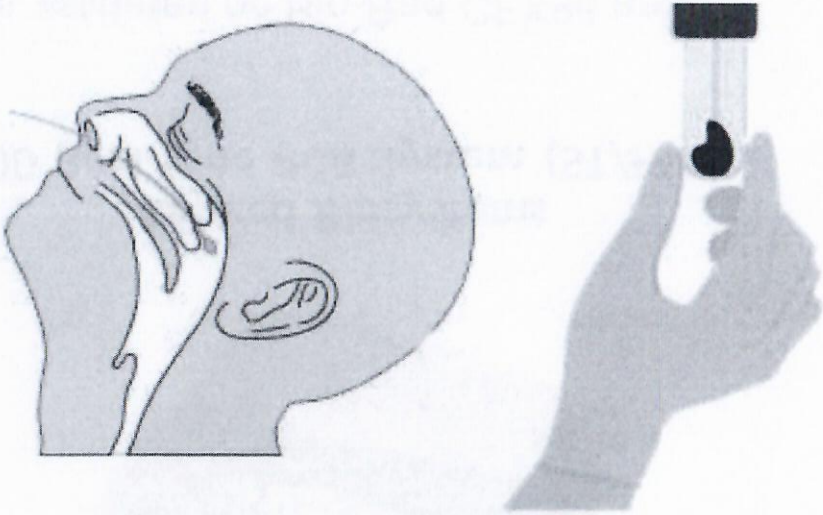
COVID-19 Plus Reaction Mixture + **COVID-19 Plus Probe Mixture** + Sample RNA = **Mixtrue / 1sample**

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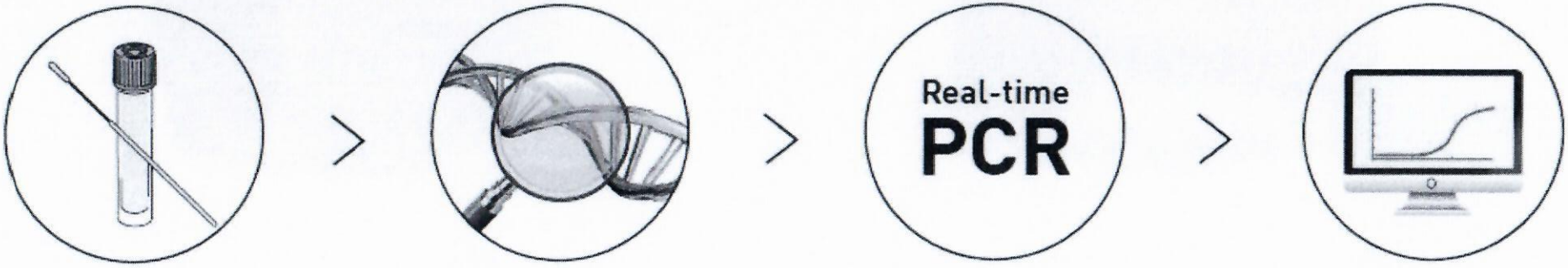
GeneFinder™ COVID-19 Plus Real*Amp* Kit– Test Procedure

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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



Specimen Collection > Viral RNA Extraction > cDNA synthesis & Amplification > Data Analysis

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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.

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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

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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.

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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%

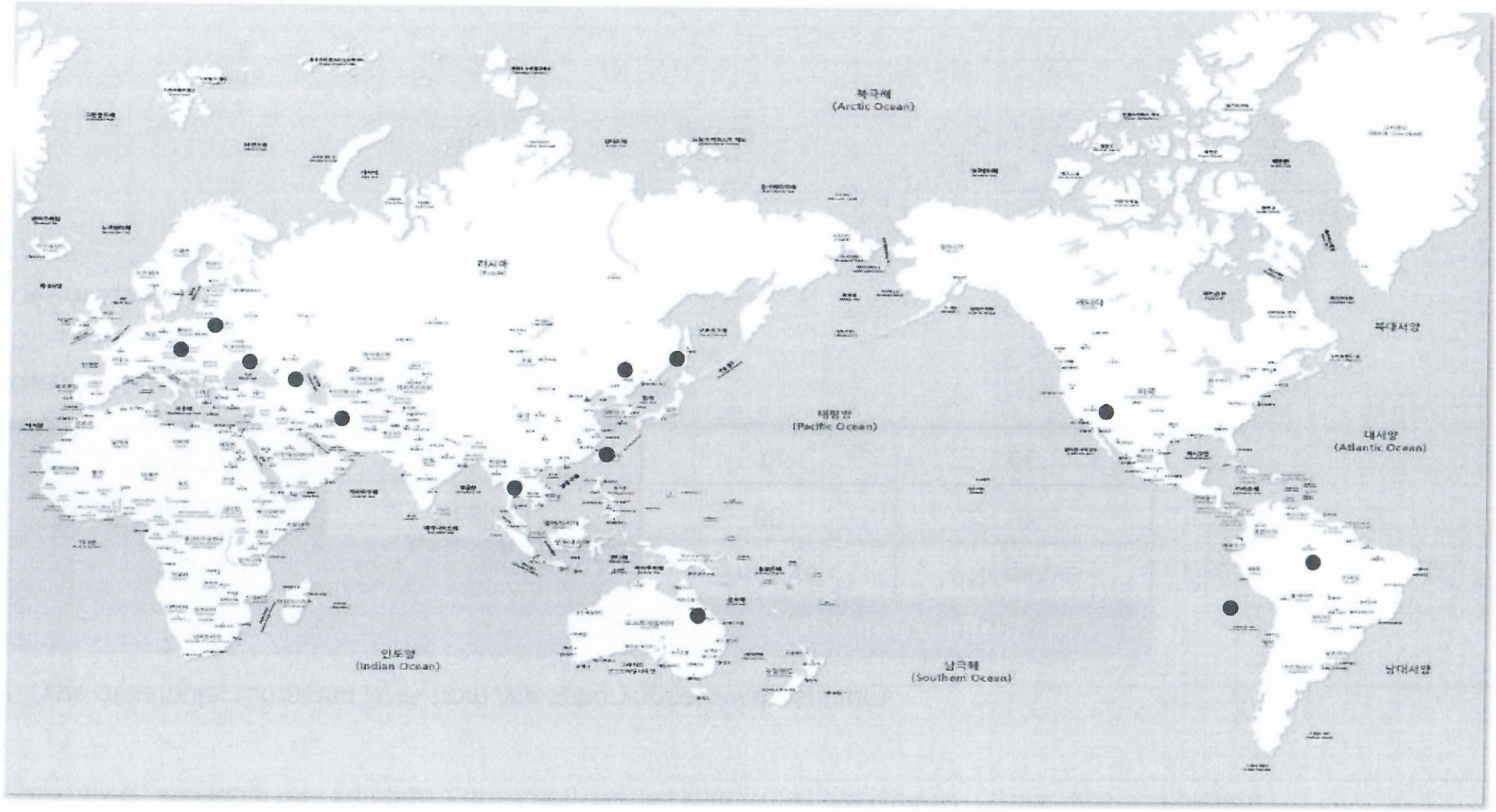
Clinical Sensitivity = 60/60×100 = 100%

Clinical Specificity = 60/60×100 = 100%

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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.**

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Product Comparison

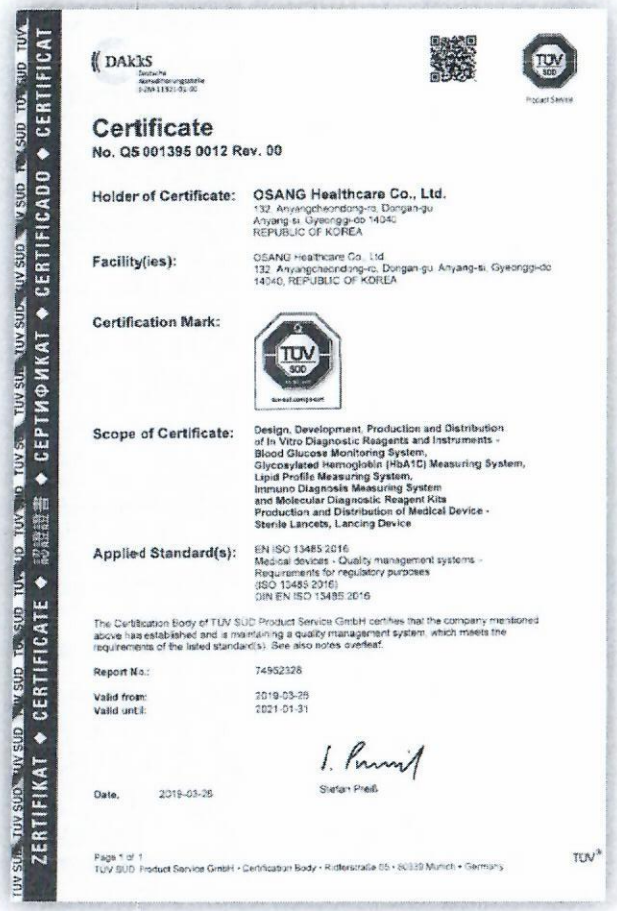
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	WHO	Korea CDC	S****	K*****	GeneFinder™
Target Gene	RdRp gene	RdRp gene	RdRp gene	RdRp gene	RdRp gene
	E gene	E gene	E gene	E gene	E gene
	-	-	N gene	-	N gene
Internal Control	-	-	I.C (Exogenous)	I.C	I.C (Endogenous)
Tube #	2 tubes	2 tubes	1 tube	2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

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

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DAkkS

Certificate
No. QS 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

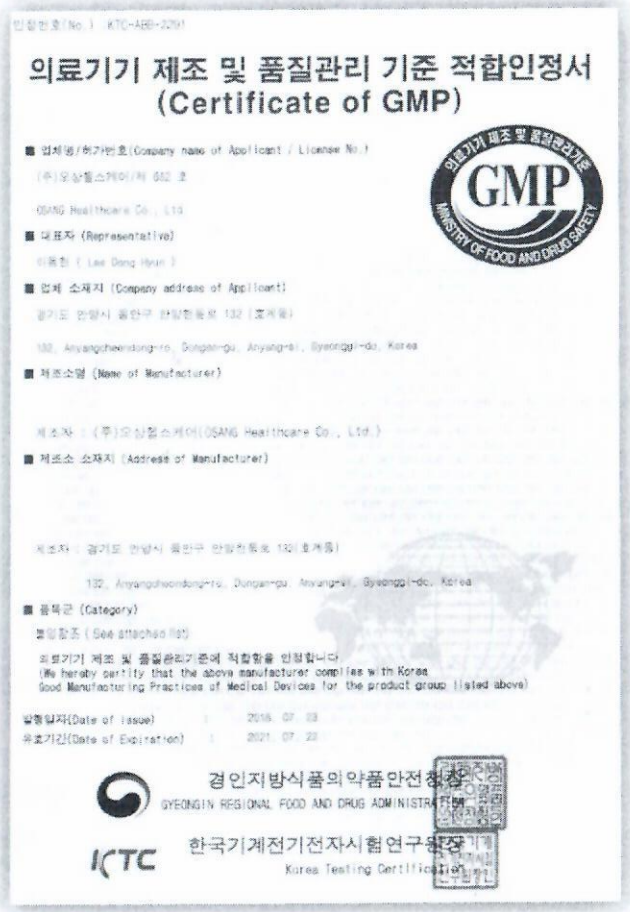
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

GMP
MINISTRY OF FOOD AND DRUG SAFETY

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)오상헬스케어/제 662 호
OSANG Healthcare Co., Ltd.

■ 대표자 (Representative)
이동현 (Lee Dong Hyun)

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

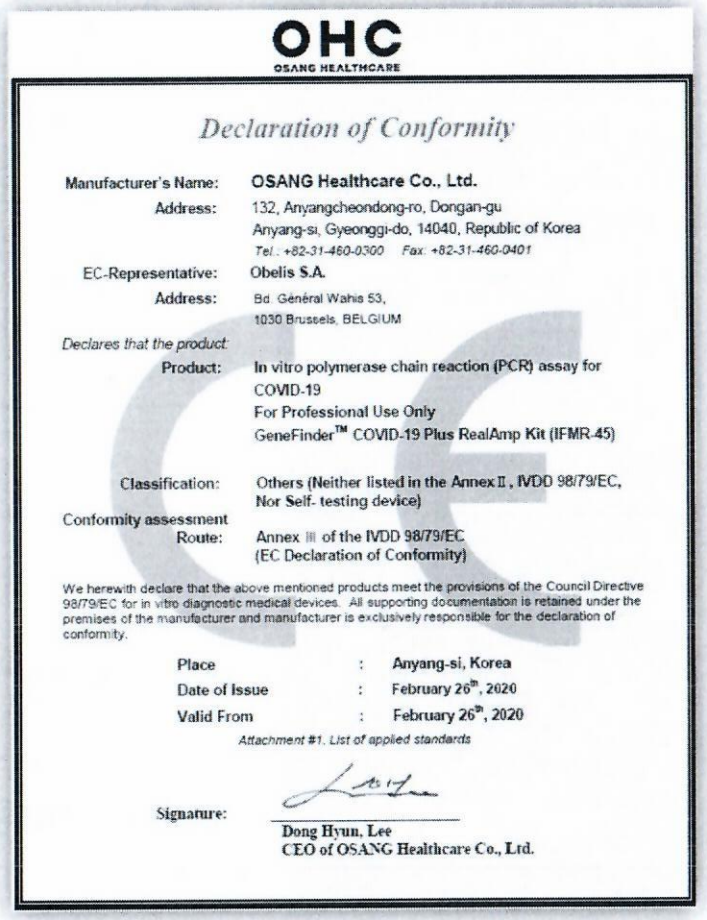
■ 품목군 (Category)
별첨참조 (See attached list)

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) : 2019. 07. 03
유효기간(Date of Expiration) : 2021. 07. 22

경인지방식품의약품안전청장
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATOR

KTC 한국기계전기전자시험연구원장
Korea Testing Certification



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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.

ISO13485 GMP CE

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OSANG HEALTHCARE Co., Ltd

Company Overview

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

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Group OSANG Family

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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

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OHC Products Portfolio

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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

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OHC Molecular Diagnostic Products Portfolio

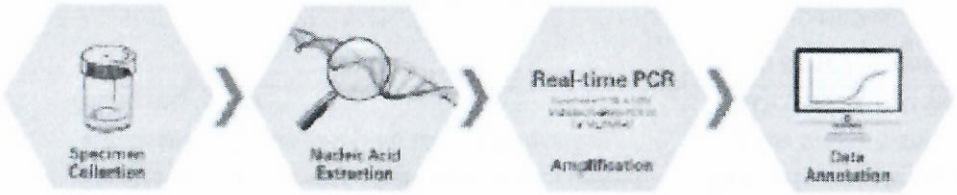
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Product Overview

- 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

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Thank You

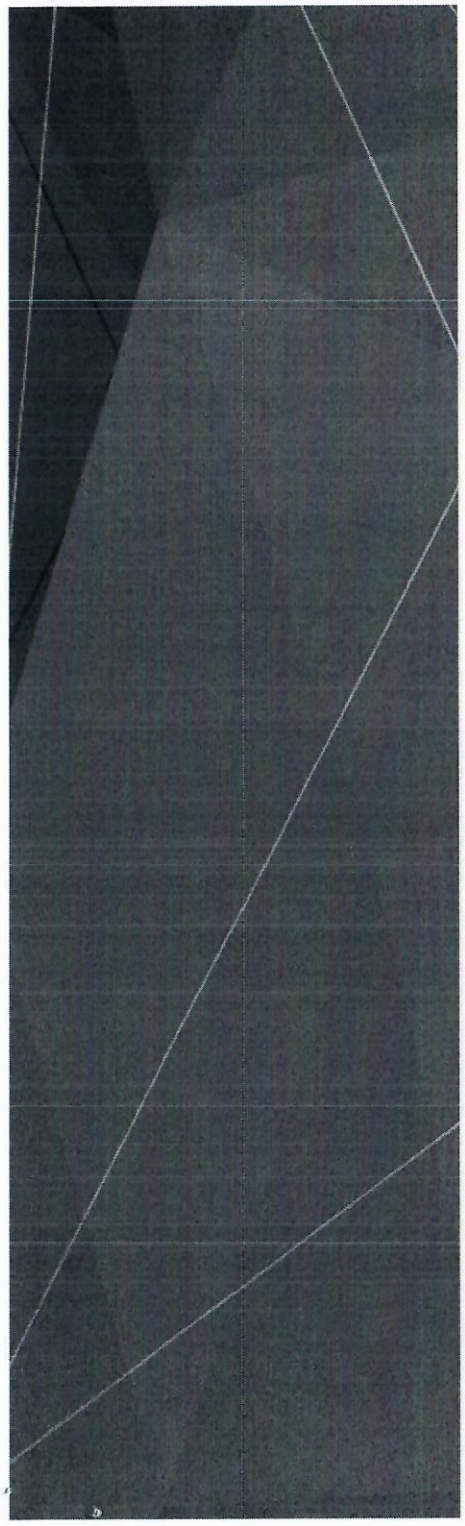
OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
www.osanghc.com

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Nucleic Acid Extraction System

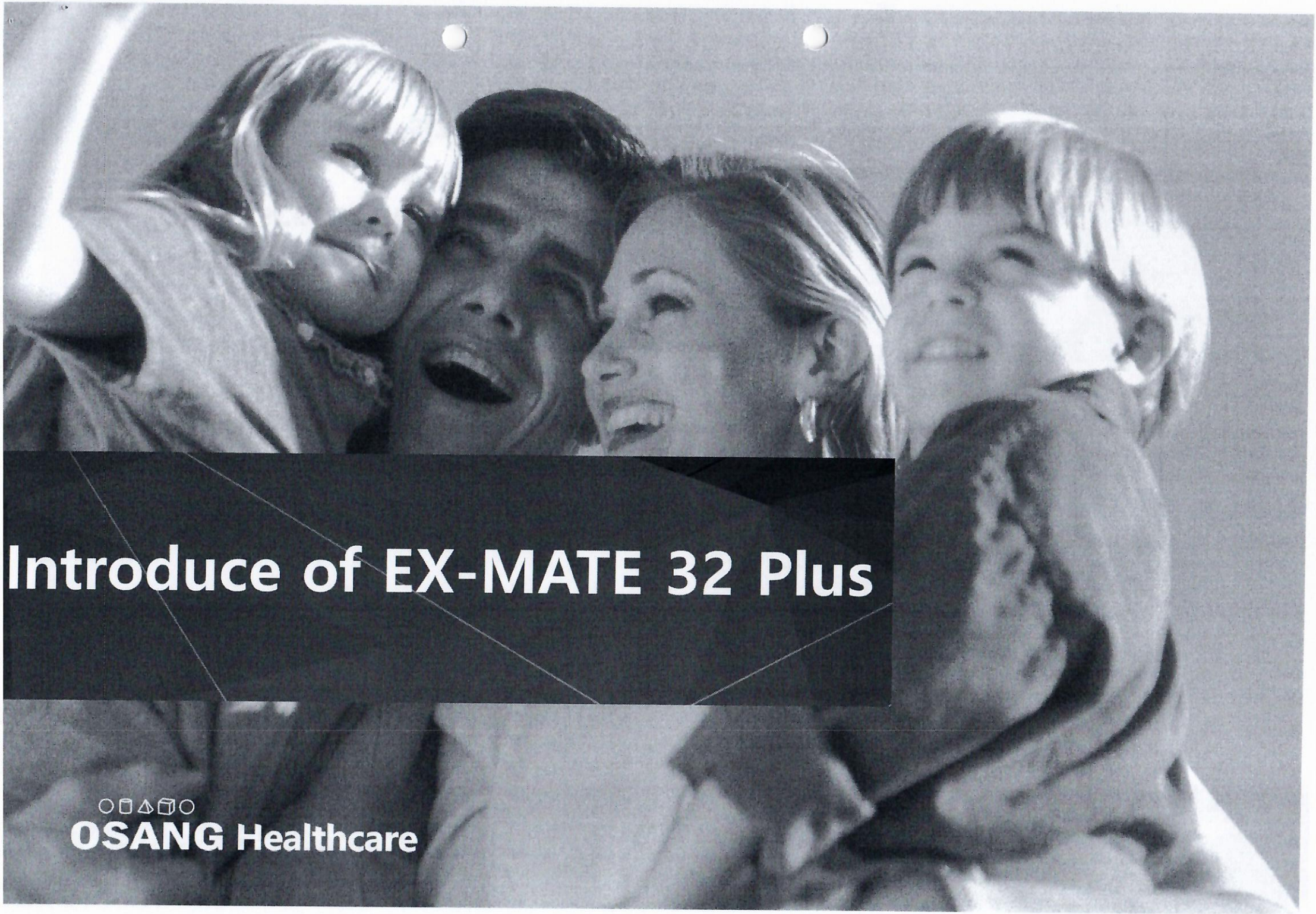
"GeneFinder™ EX-MATE32 PLUS"



1. Introduce of EX-MATE 32 Plus

2. GeneFinder™ Extraction kit

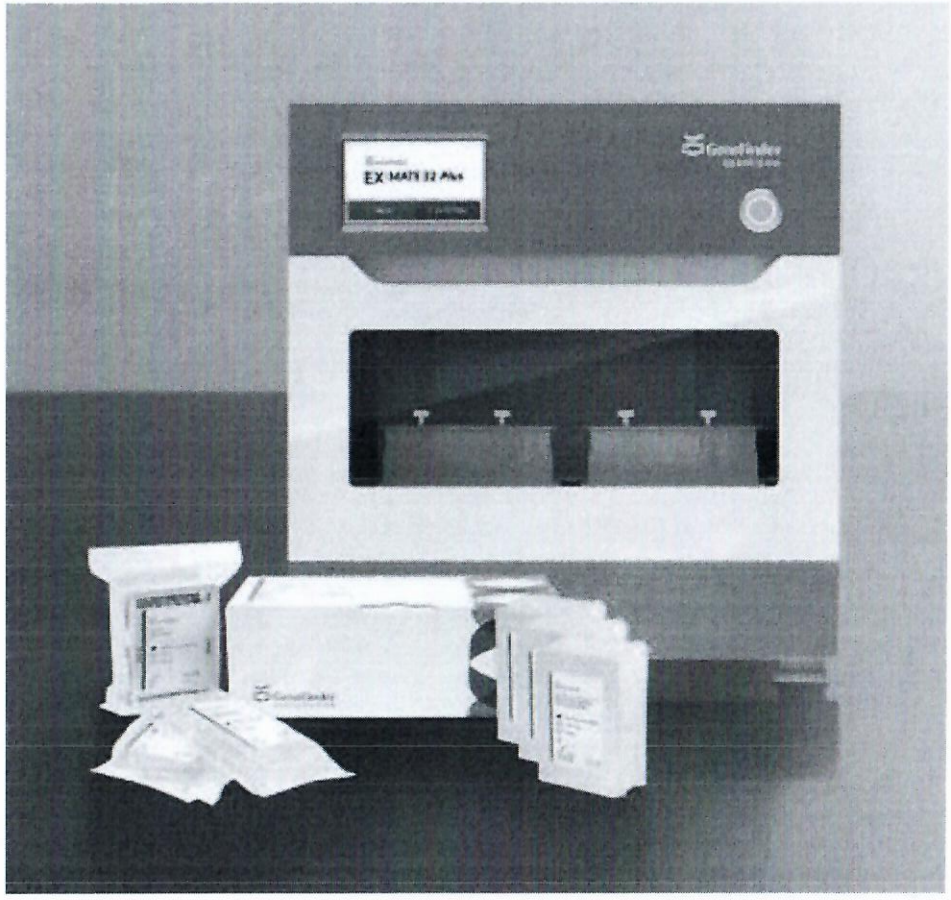
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Introduce of EX-MATE 32 Plus
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EX-MATE 32 Plus Extraction System

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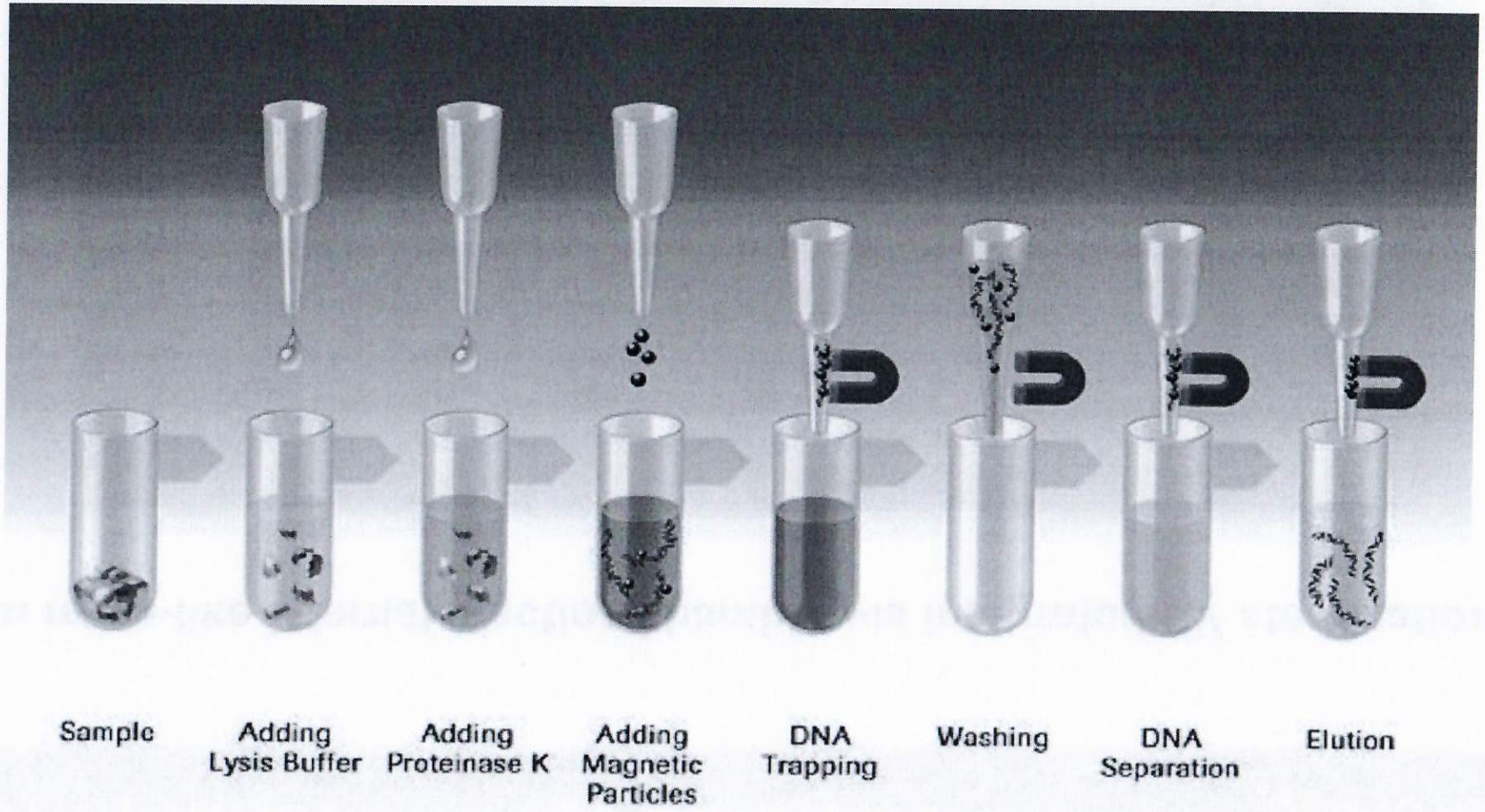
- Magnetic Bead type Extraction
- UV light
- 2 Modules
- Heating block
- 1~16 Tests per 1 run
- Internal SW
  Touch screen interface
- 21 inch carrier size



Principle of Extraction

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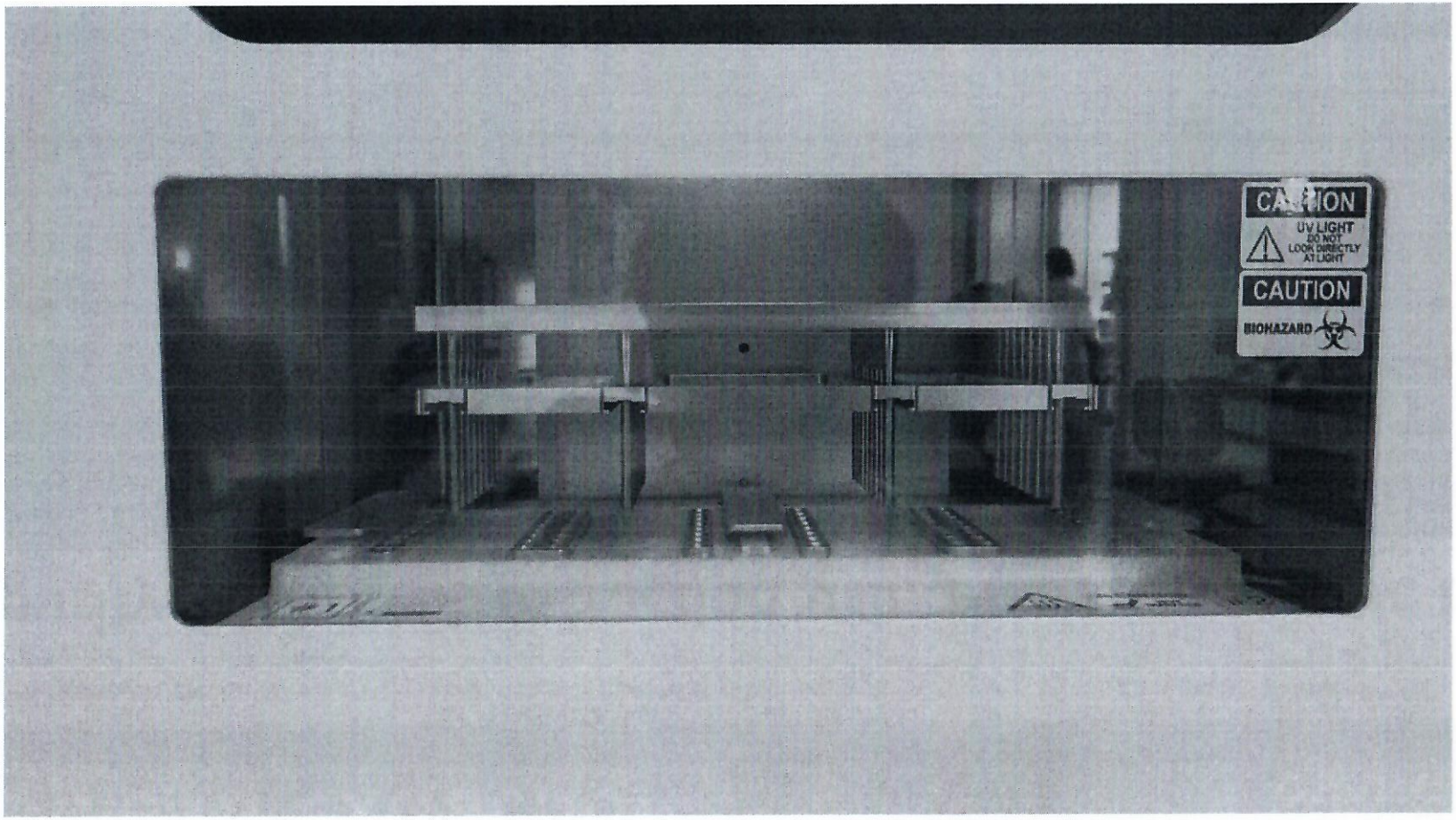
High purity DNA/RNA extraction using nano-magnetic beads



Contamination Free Analysis

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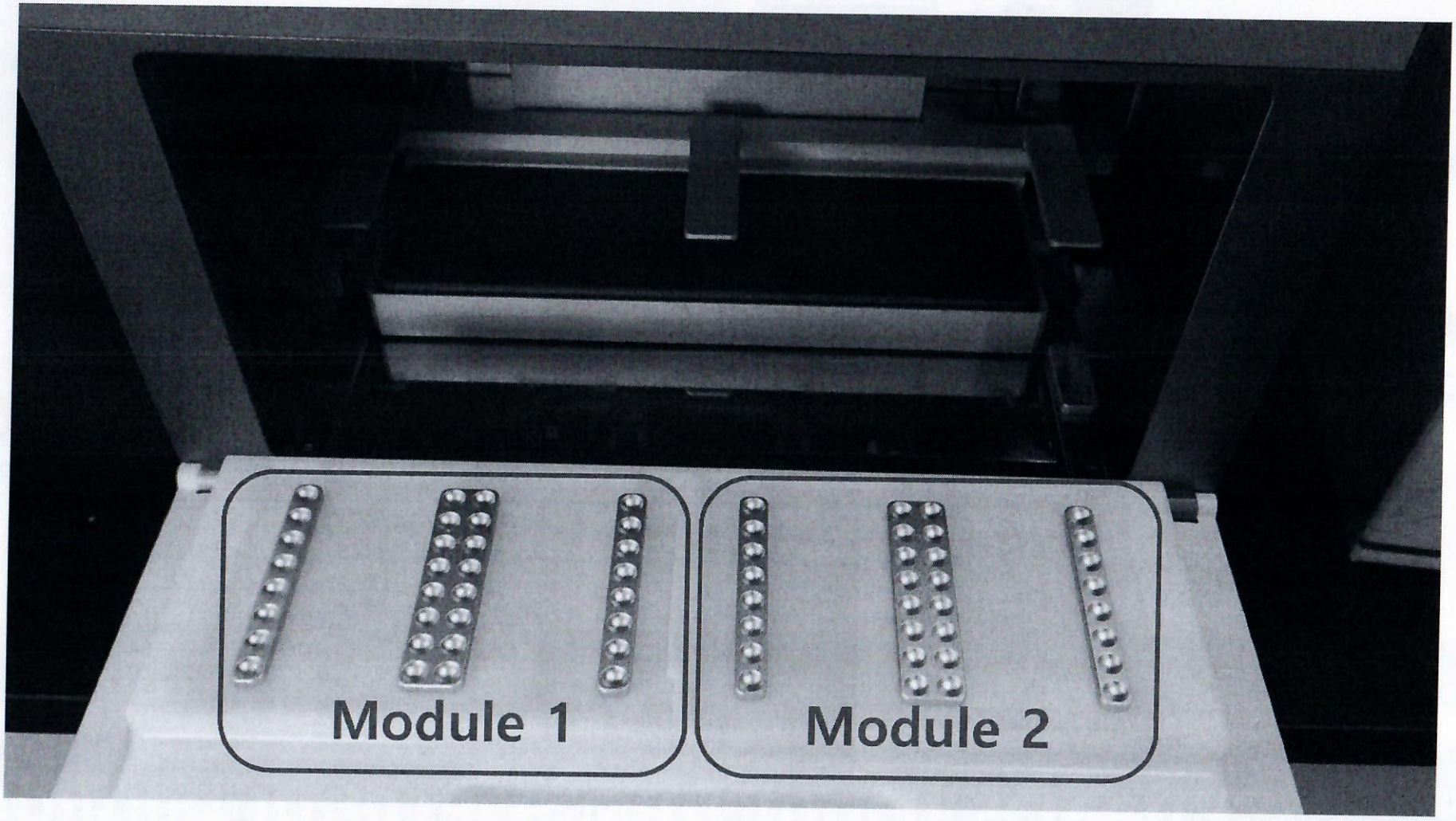
Clean room-like internal reaction chamber via integrated UV sterilization lamp



Accuracy, Efficiency

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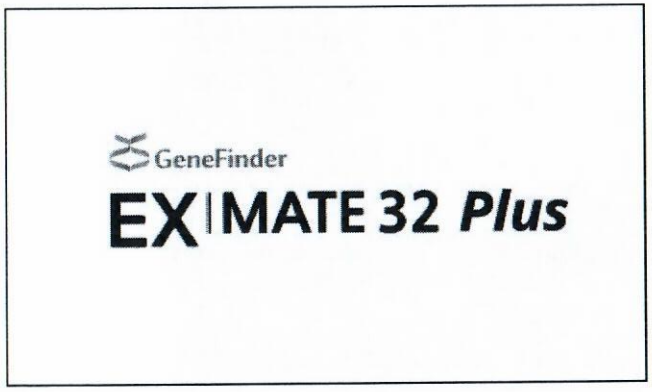
High purity DNA/RNA extraction using Heating block



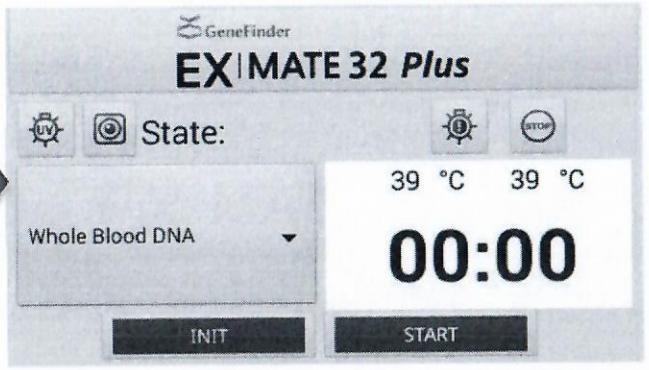
Simplified interface with touch screen

OSANG Healthcare

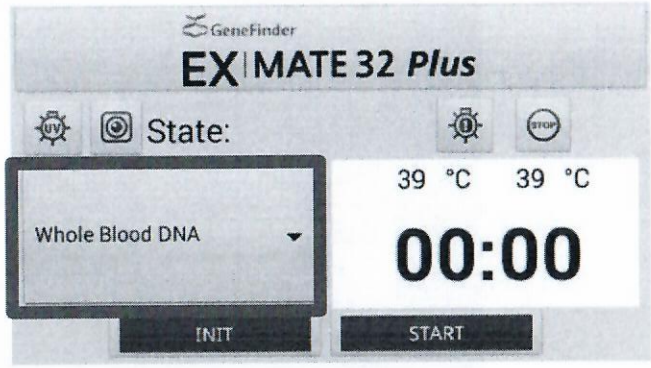
Start up

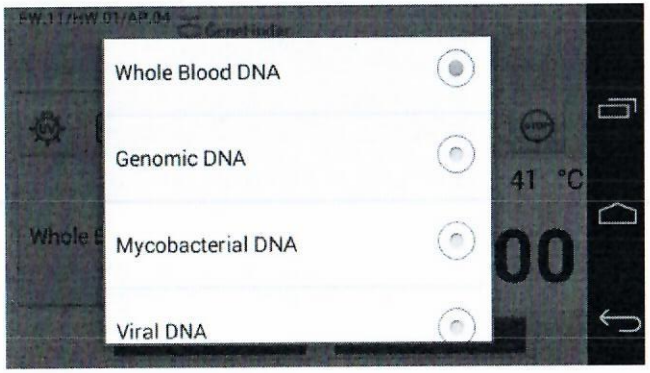


Pre-heating

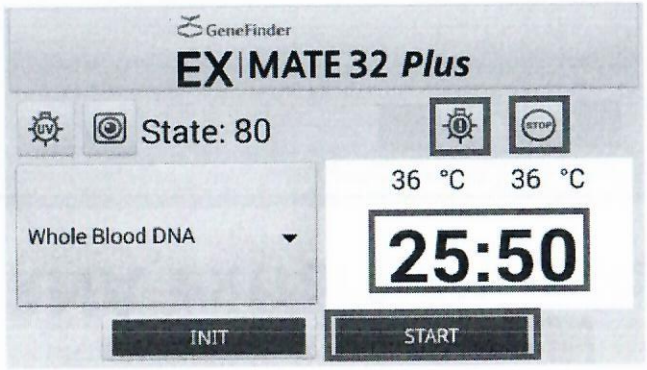


Protocol select

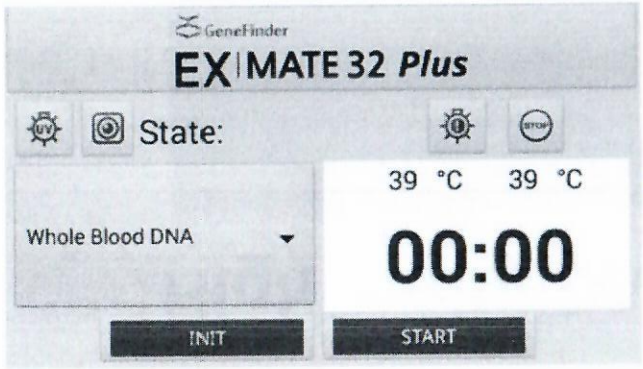




Protocol select



Running



Complete

Instrument specifications

OSANG Healthcare



Operating specifications	
Operating Temperature	10~40℃ (50~104℉)
Operating Humidity	10~80%
Number of Sample	At least 1 up to 32 samples
Processing Time	About 30 minutes
Physical specifications	
Dimensions (W x D x H)	365 x 433 x 390 mm
Weight	33.9 (kg)
Power Requirements	100-240VAC, 50/60Hz
UV Bulb	4800hours of lifetime, 135.9 x 16 mm(length, diameter) 4W, 0.166 A, Current



GeneFinder™ Extraction kit

Instrument Set-up

OSANG Healthcare

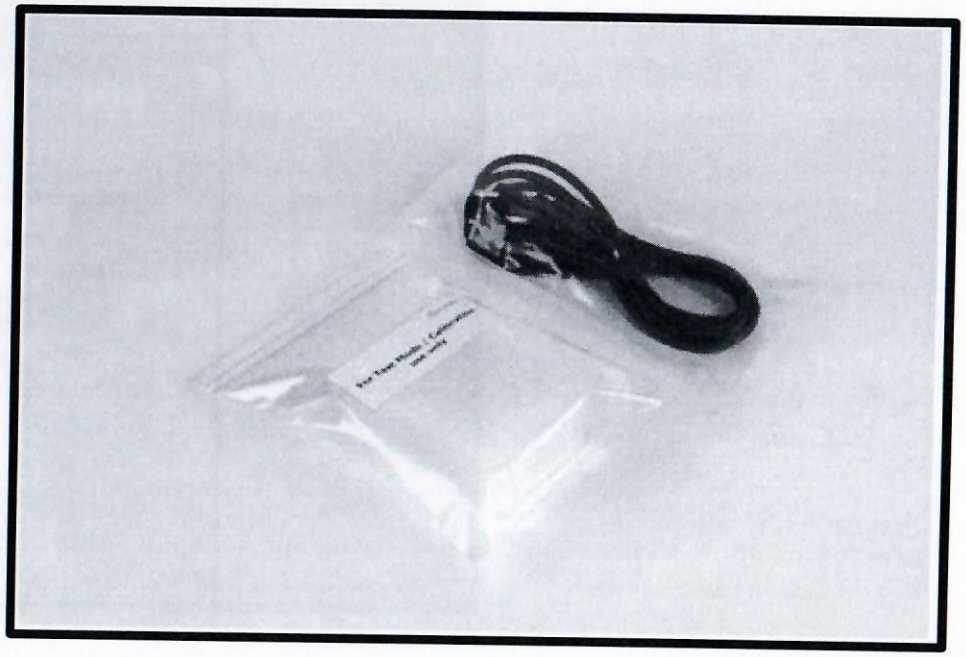
How to install the Instrument

OSANG Healthcare

1. Check the product components



GeneFinder™ EX-MATE 32 Plus

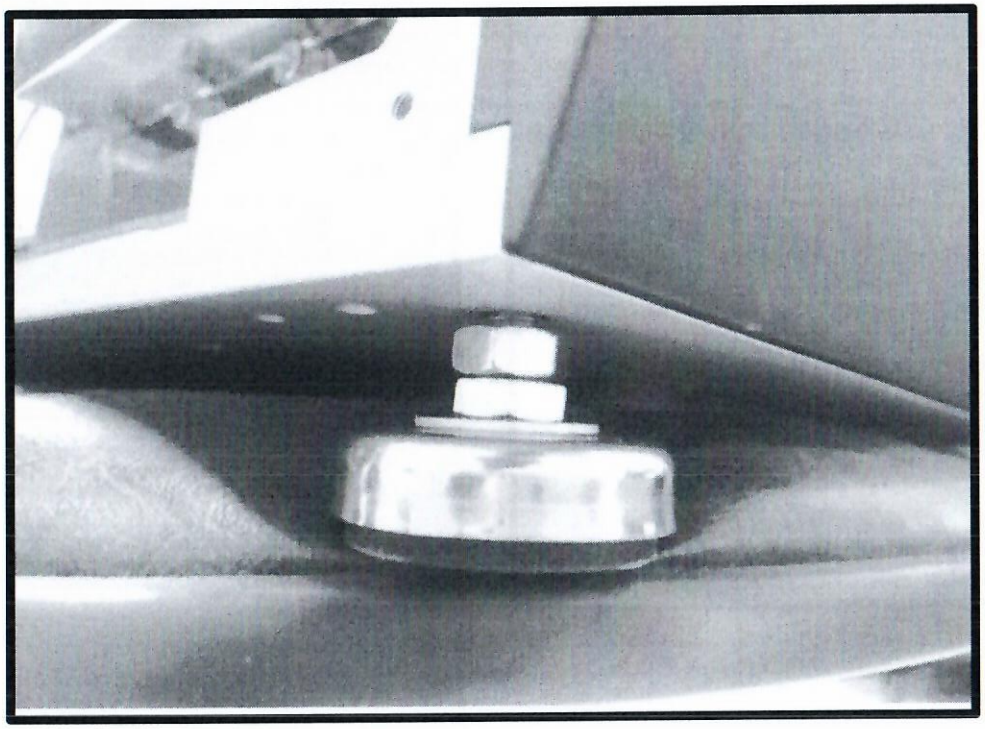


Other components
(Power code & Test Plate)

How to install the Instrument

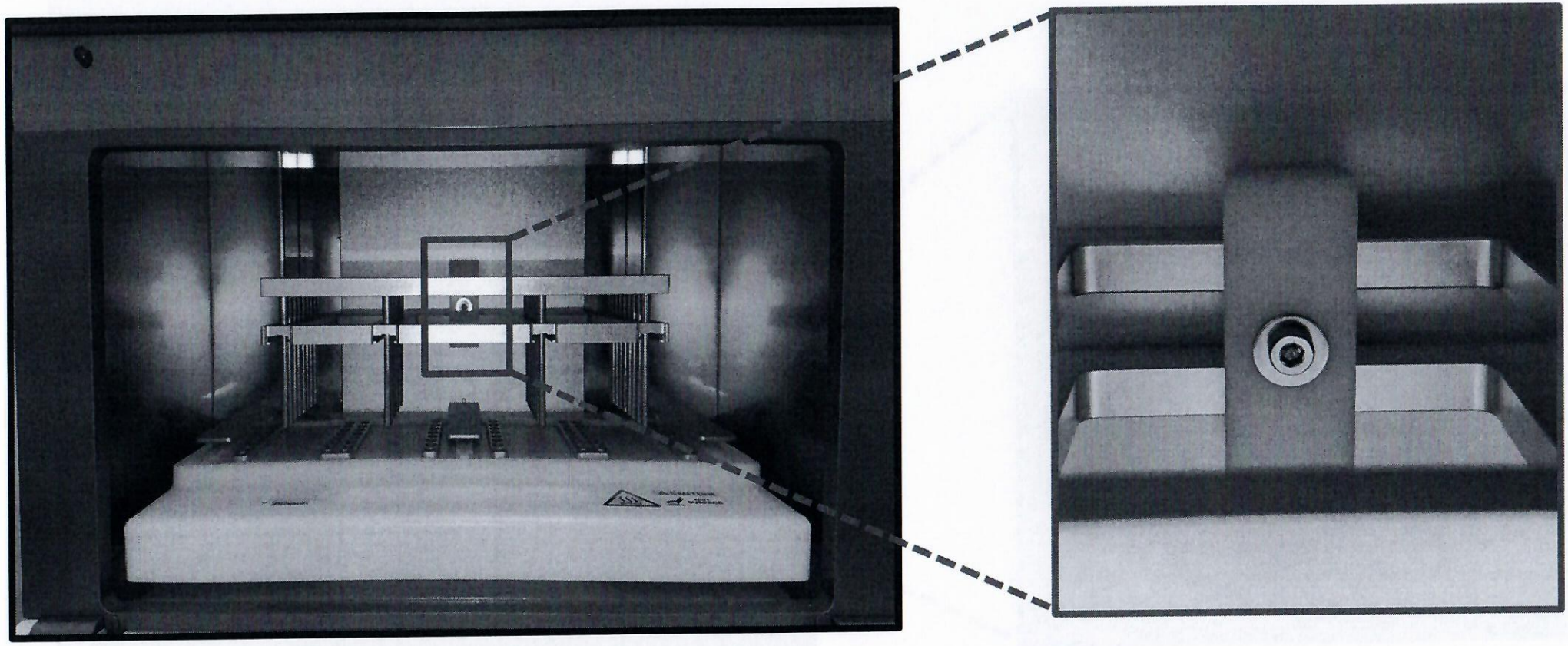
OSANG Healthcare

2. Set-up the instrument on site



Adjust horizontality by turning the rubber feet
(Bottom view)

3. Remove the fixture

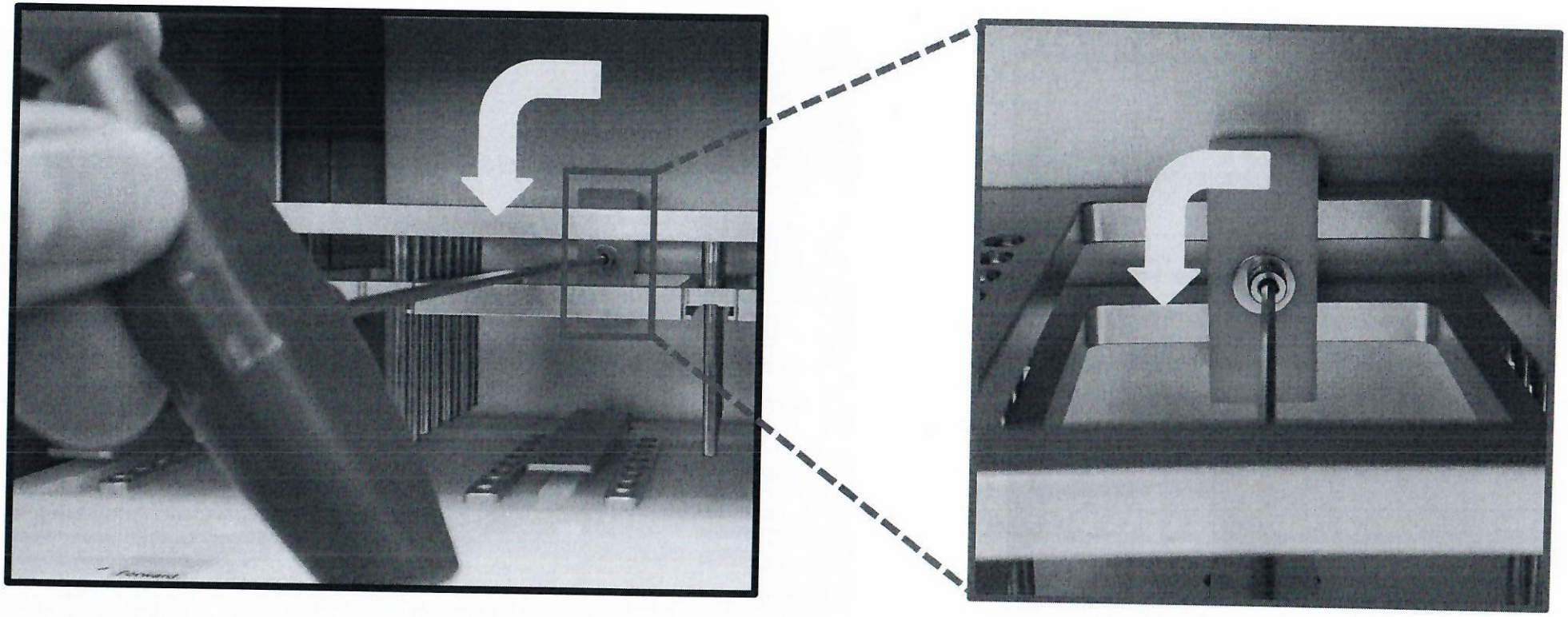


Open the door and check the fixture.
(Do not turn on the power)

How to install the Instrument

OSANG Healthcare

3. Remove the fixture

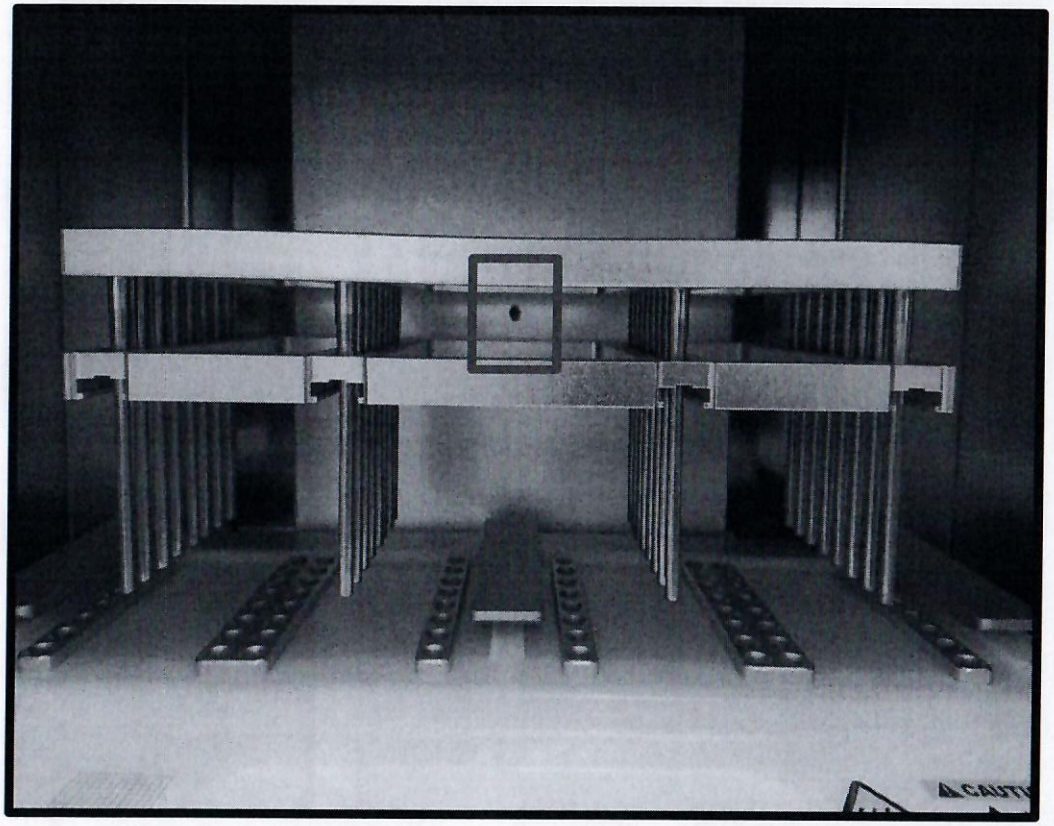


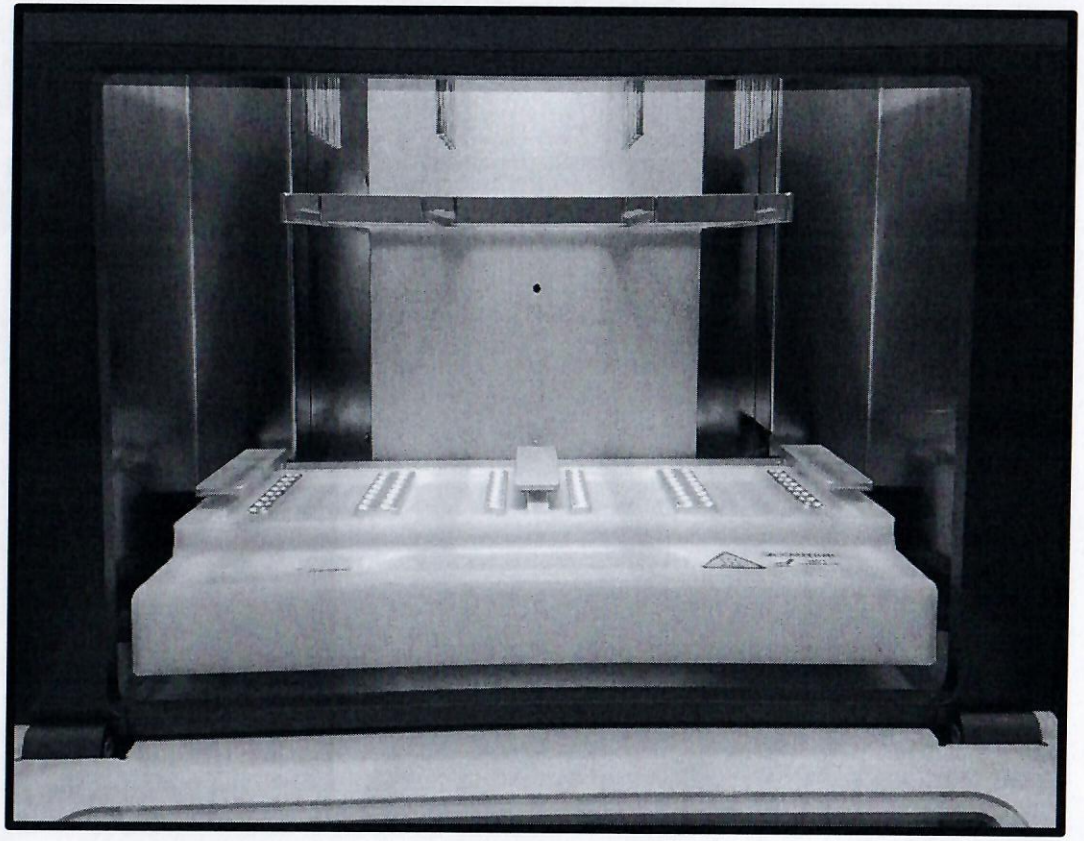
Use a hex wrench to remove the bolt

How to install the Instrument

OSANG Healthcare

3. Remove the fixture





Check the hole and close the door.
And Power on (Bars are automatically rise up)


GeneFinder™ Extraction kit
Flexible Format
OSANG Healthcare

Tube type of kit

OSANG Healthcare

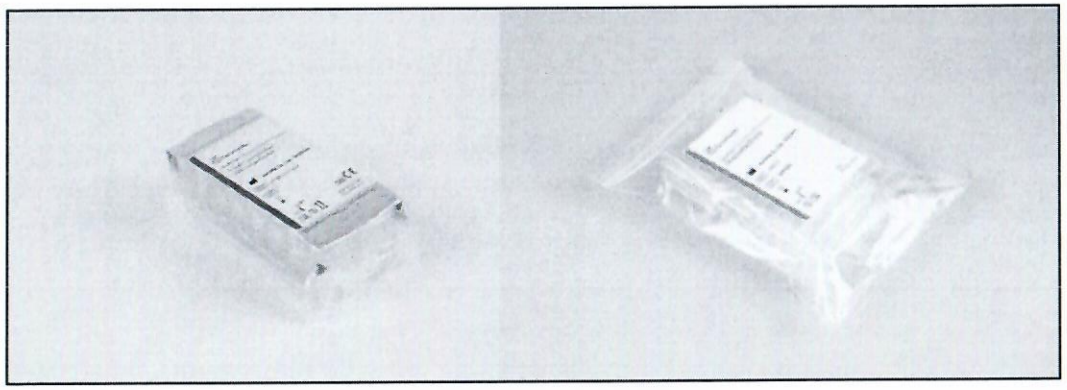
Tube type/32Test



Tube Type

OSANG Healthcare





6-well Tube

Disposable
8-Strip

Tube type

- 32 Tests / kit
- 1~16 samples Flexible
- 8 Tests Pack x 4
- Tube Rack
- 8 well Strip 12ea
- Pre-Treatment solutions(optional)

Variety of Extraction kit

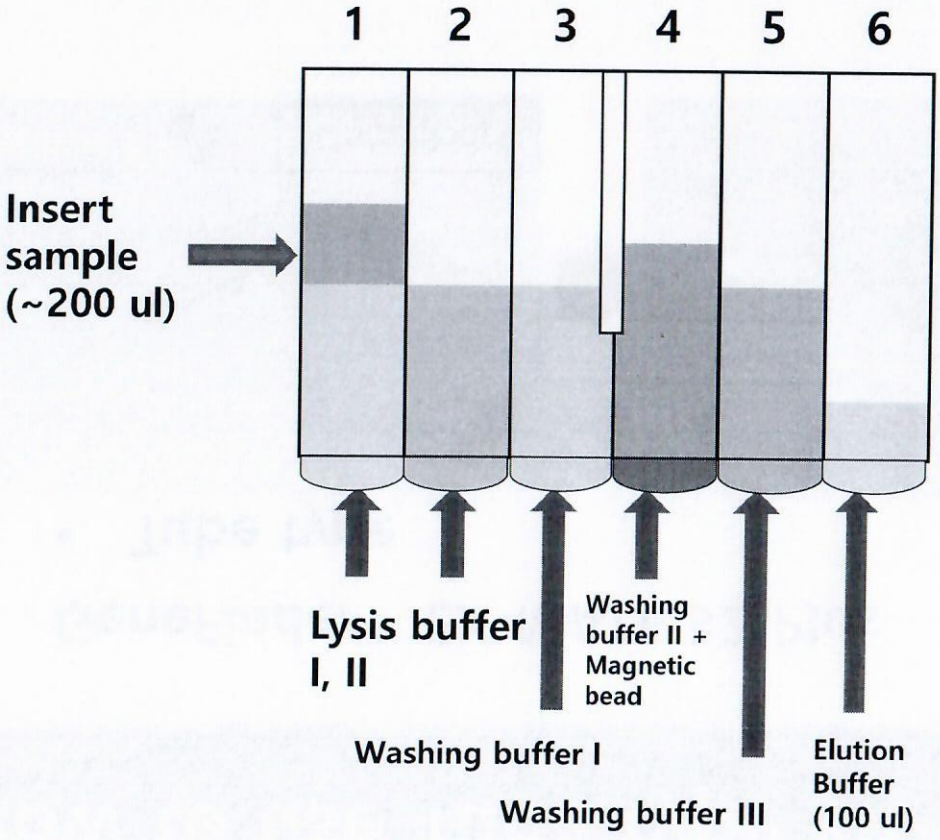
Whole Blood Extraction kit
Viral DNA/RNA Extraction kit
Genomic DNA Extraction kit

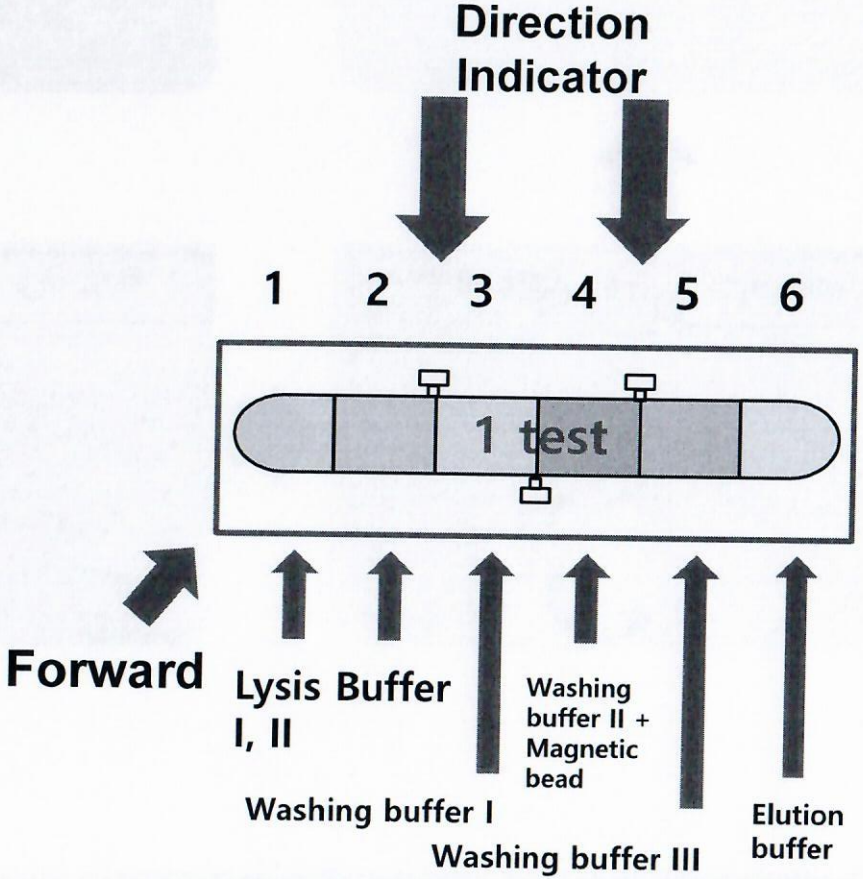
Configuration of Kits _ Tube Type

OSANG Healthcare

❖ GeneFinder™ Extraction Kits Contents

➢ Tube type



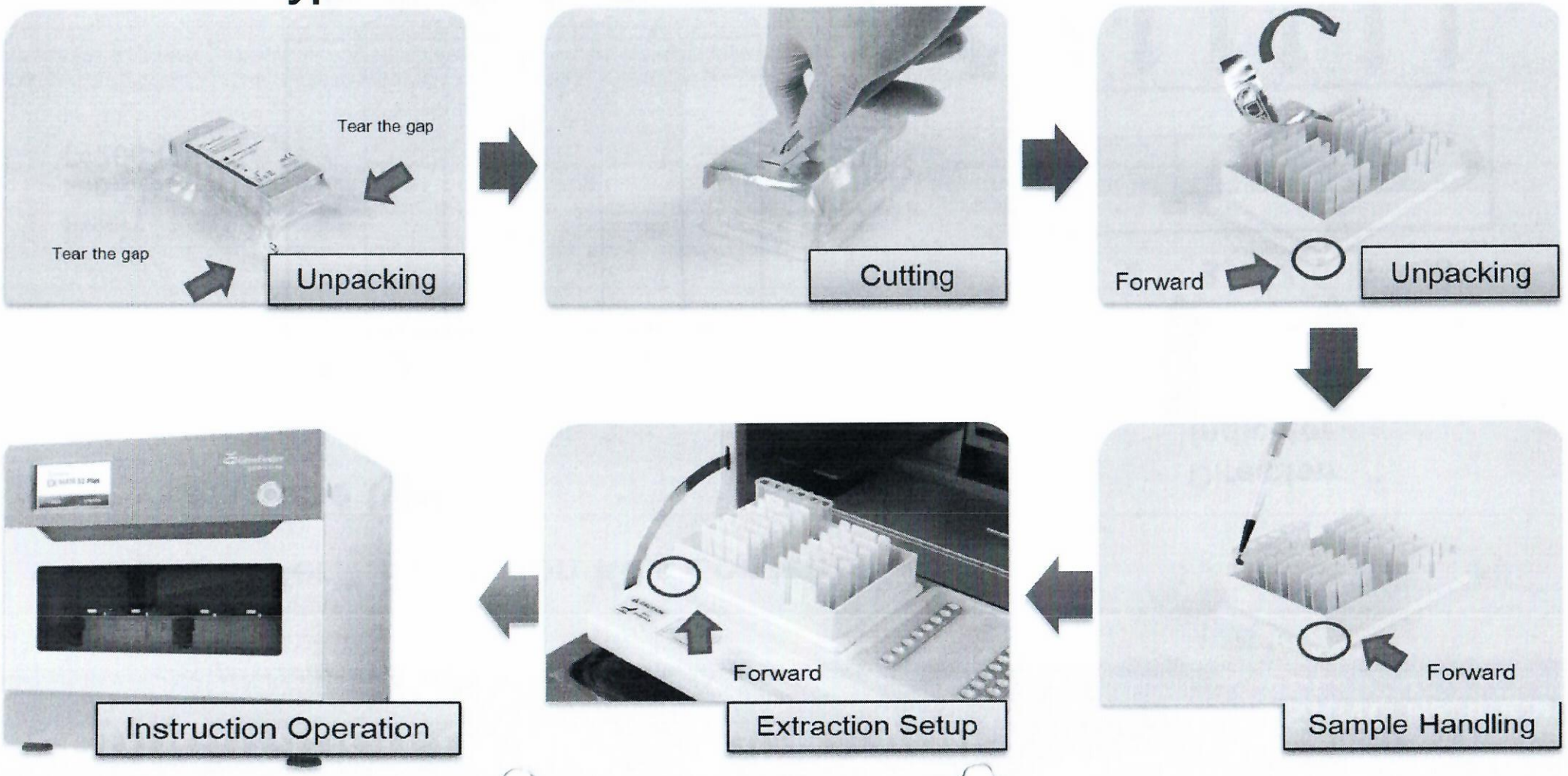


How to use Tube type kit

OSANG Healthcare

❖ GeneFinder™ EX-MATE 32 Plus

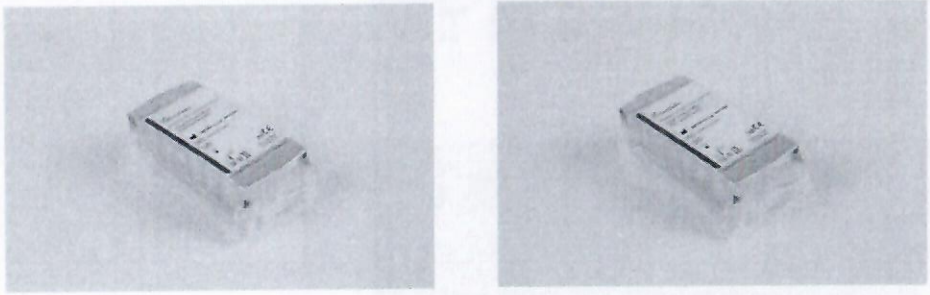
- **Tube type**



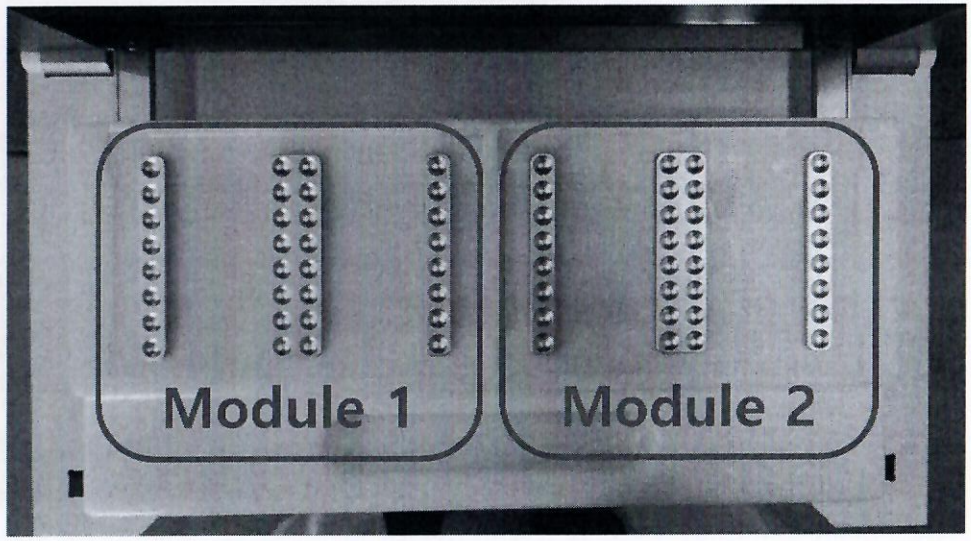
Operation Flexibility

OSANG Healthcare

➢ **Tube type**



1~8 samples / 1module



Number of cases, Enhanced usability

OSANG Healthcare

	Module 1	Module 2
1 to 8 samples		
9 to 16 samples		

GeneFinder Extraction kits

OSANG Healthcare

Extraction kit	Specimen	Target	Type
Whole Blood Extraction kit	Blood (WB, Serum, Plasma)	Human DNA	Tube type (32 Tests)
Viral DNA/RNA Extraction kit	Blood (WB, Serum, Plasma) Swab(PBS)	Viral DNA/RNA	
Genomic DNA Extraction kit	Swab, Urine, Body Fluid, Sputum	Genomic DNA (Bacteria)	

Sample	Target	Extraction kit	Down Stream Test
Blood (WB, Serum, Plasma)	Human DNA	Whole Blood Extraction kit	HLA Typing kit
	Viral DNA/RNA	Viral DNA/RNA Extraction kit	CMV, EBV
Swab	Viral DNA/RNA	Viral DNA/RNA Extraction kit	CMV, EBV
	Genomic DNA	Genomic DNA Extraction kit	HPV, STD I, II
Urine	Genomic DNA	Genomic DNA Extraction kit	STD I, II

GeneFinder™ Downstream Line

OSANG Healthcare

Extraction System

Product Name	규격	인증	
GeneFinder EX-MATE 32 Plus	1 EA	KFDA	CE-IVD
GeneFinder Viral DNA/RNA Extraction kit	Plate type 48 Reactions	KFDA	CE-IVD
GeneFinder Genomic DNA Extraction kit		KFDA	CE-IVD
GeneFinder Whole Blood DNA Extraction kit	Tube type 32 Reactions	KFDA	CE-IVD

Human Leukocyte Antigen

Product Name	규격	인증	
HLA-ABCDRB1DQ RealAmp kit	6 Tests		CE-IVD
HLA-ABDR RealAmp kit	20 Tests	KFDA	CE-IVD
HLA-C RealAmp kit	20 Tests		CE-IVD
HLA-DQB1 RealAmp kit	20 Tests		CE-IVD
HLA-B*27 RealAmp kit	100 Tests	KFDA	CE-IVD
HLA-B*51 RealAmp kit	100 Tests	KFDA	CE-IVD
HLA-B*57:01 RealAmp kit	100 Tests	Coming soon!	

Sexually Transmitted Infection

Product Name	규격	인증	
STD I Multiplex Real-time PCR kit (CT/NG/UU)	100 Tests	KFDA	CE-IVD
STD II Multiplex Real-time PCR kit (MG/MH/TV)	100 Tests	KFDA	CE-IVD
HPV PCR kit	100 Tests	KFDA	CE-IVD
HPV PCR Plus kit	100 Tests	KFDA	CE-IVD
HPV Liquid Bead MicroArray Genotyping kit	100 Tests	KFDA	CE-IVD

Microbial Infectious Disease

Product Name	규격	인증	
TB&NTM Multiplex Real-time PCR kit	100 Tests	KFDA	CE-IVD
Malaria RealAmp kit	100 Tests		CE-IVD
DENV/CHKN RealAmp kit	100 Tests		CE-IVD
DENV Typing RealAmp kit	100 Tests		CE-IVD


OSANG Healthcare

GeneFinder™ Viral DNA/RNA Extraction kit

Instruction for Use

For automated DNA/RNA extraction by using GeneFinder™ EX-MATE 32 Plus and EX-MATE 32

CE IVD

Σ 48 / 32

(Plate type /Single Tube type)

REF OSME-01-P48, OSME-01-T32

OSANG Healthcare Co., Ltd 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Korea
TEL. +82-31-460-0300 / FAX. +82-31-460-9933

EC REP Obelis S.A General Wahis 53,1030 Brussels, Belgium
TEL. +32-2-732-59-54 / FAX. +32-2-732-60-03 / E-mail. mail@obelis.net

For Professional Use Only

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10. Trouble Shooting 16

11. Symbols 18

12. Manufacturer 18

1. Intended use

GeneFinder™ Viral DNA/RNA Extraction kit is designed to extract and isolate DNA/RNA from human sample using automated GeneFinder™ EX-MATE 32 Plus and EX-MATE 32.

The GeneFinder™ EX-MATE 32 Plus, EX-MATE 32 and GeneFinder™ Viral DNA/RNA Extraction kits are intended for professional use only.

Any diagnostic result generated from the sample preparation procedure followed by any downstream diagnostic nucleic acid testing assay must be complemented by other clinical or laboratory finding.

2. Principle of the test

GeneFinder™ Viral DNA/RNA Extraction kit allows simultaneous extraction of up to 32 different samples at single run with GeneFinder™ EX-MATE 32 Plus and EX-MATE 32, a specialized extraction device for the kit.

The kit contains pre-filled 96-well plates/ 6-well tube and each of them is capable of extracting 16 samples as single extraction requires 6 consequent wells. 6 consequent wells are aligned horizontally and each well contains specific reagents for extraction. First well contains lysis buffer and binding buffer which destroy cell membrane along with disposable 8-strip and elute DNA/RNA with magnetic bead from fourth column. Magnetic bead may be damaged if stored in lysis buffer, hence it is located at fourth column until the extraction begins and moves to first column by device once initiated. Second well contains binding buffer that help magnetic bead hold DNA/RNA. Third, fourth and fifth column contains washing buffer I, II and III, respectively to remove unwanted cell component and buffers. Elution buffer in sixth column detaches DNA from magnetic bead and complete extraction process.

3. Kit Information

REF OSME-01-P48 (Plate type, 48 tests)

3.1. Materials provided

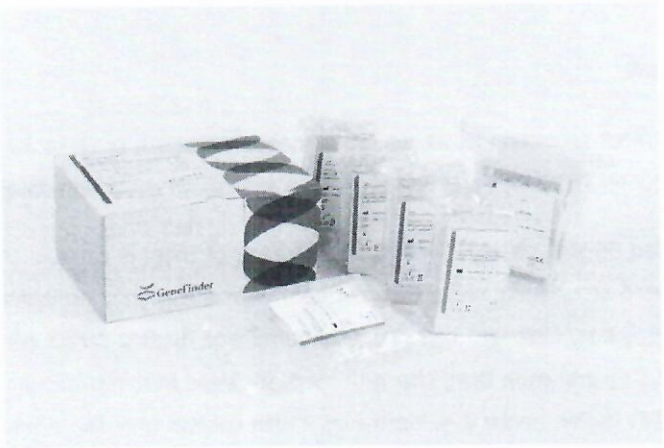


Components of GeneFinder™ Viral DNA/RNA Extraction kit

Materials	48 tests/kit
96-well plate pre-filled with reagent buffer	3 pouches
Disposable 8-strip	6 pcs (1 pouch)
Carrier RNA	1 tube
Nuclease-Free Water	1 tube

REF OSME-01-T32 (Tube type,32 tests)

3.1. Materials provided



Components of GeneFinder™ Viral DNA/RNA Extraction kit

Materials	32 tests/kit
6-well Tube pre-filled with reagent buffer	4 pouches
Disposable 8-Strip	12 pcs (2 pouches)
Tube Rack	2 pcs (1 pouch)
Carrier RNA	1 tube
Nuclease-Free Water	1 tube

3.2. Required but not provided

- Pipettes (1- 20 µl, 20-200 µl, 200-1,000 µl)
- Pipettes tips with aerosol barrier (RNase, DNase-free) or sterilization
- Powder-free gloves (disposable)
- Vortex mixer or equivalent
- 1.5 ml sterilized tube
- Clean Bench
- GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 (Extraction Instrument)

4. Reagent information

REF OSME-01-P48 (Plate type, 48 tests)

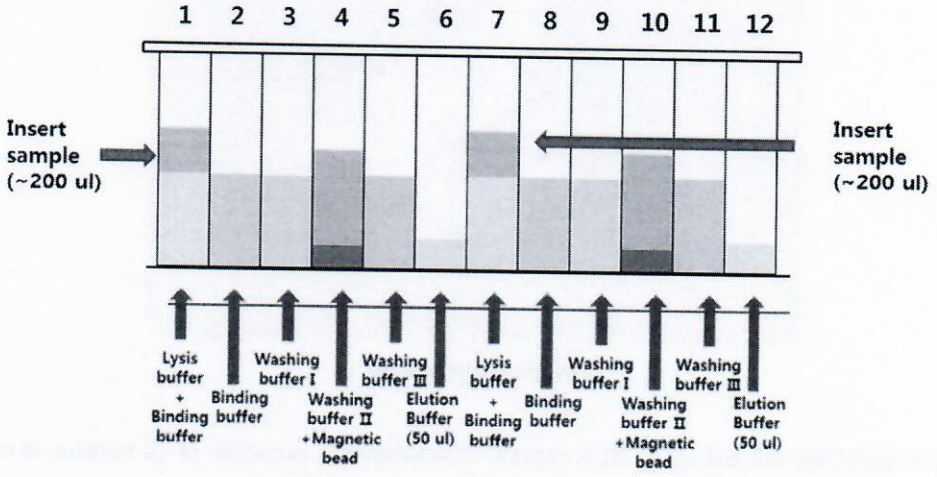
1) 96-well plate pre-filled with reagent buffer



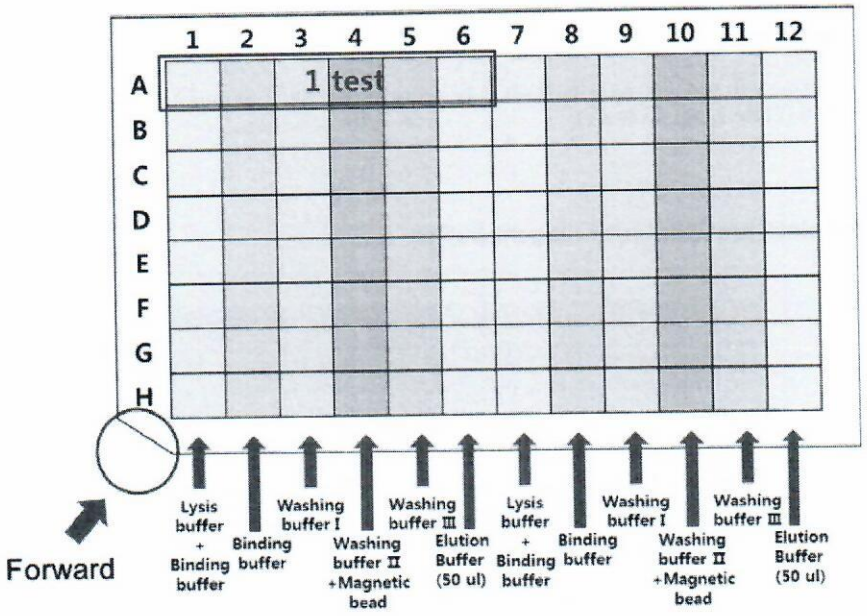
96-well plate pre-filled with reagent buffer

96-well plate pre-filled with reagent buffer is aligned as below :

(The colors provided at figures below are only to distinguish each buffer from one another and help users to understand through the manual. Product itself does not have colors as below.)



Front view of the plate



Upper view of the plate

Align plate as above and dispense biological samples in 1st and 7th column. Each sample requires 6 consequent wells (horizontal) from 1st and 7th column, respectively. Extracted nucleic acid will be collected in 6th and 12th column, respectively depending on where sample are dispensed.

2) Disposable 8-strip

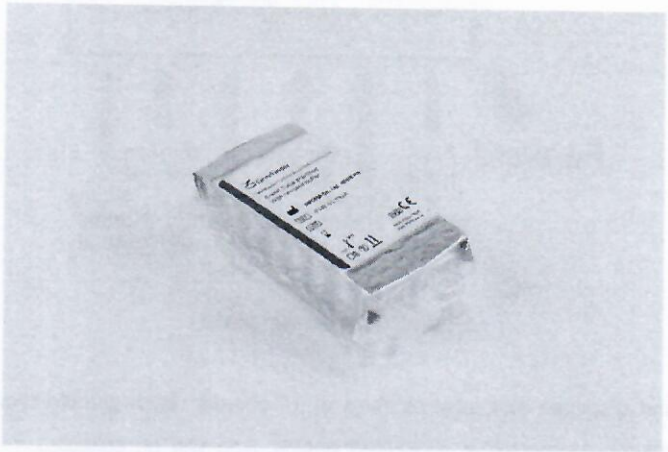


Disposable 8-strip

GeneFinder™ Viral DNA/RNA Extraction kit is capable of simultaneous extraction of 16 samples at once using a 96-well plate pre-filled with reagent buffer and two Disposable 8-strips.

REF OSME-01-T32 (Tube type,32 tests)

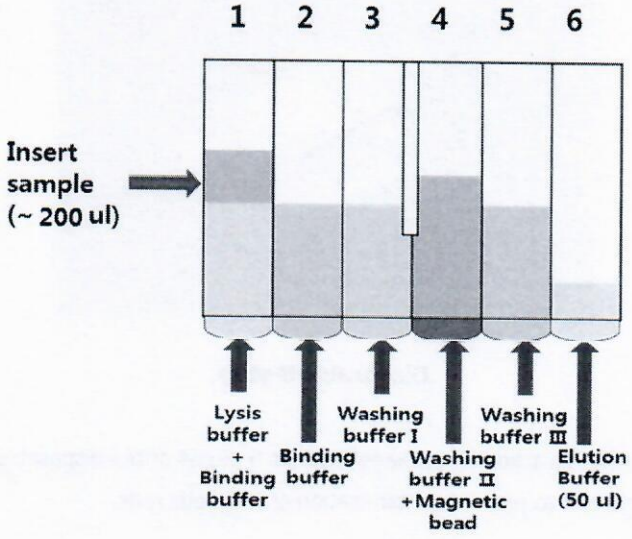
1) 6-well Tube pre-filled with reagent buffer



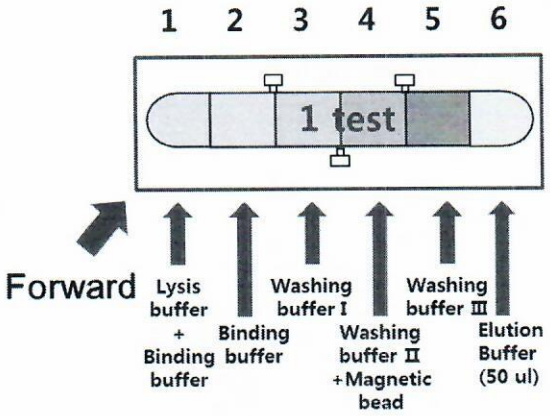
6-well Tube pre-filled with reagent buffer

6-well Tube pre-filled with reagent buffer is aligned as below :

(The colors provided at figures below are only to distinguish each buffer from one another and help users to understand through the manual. Product itself does not have colors as below.)



Front view of the tube



Upper view of the plate

Align plate as above and dispense biological samples in 1st column. Each sample requires 6 consequent wells (horizontal) from 1st column, respectively. Extracted nucleic acid will be collected in 6th column, respectively depending on where sample are dispensed.

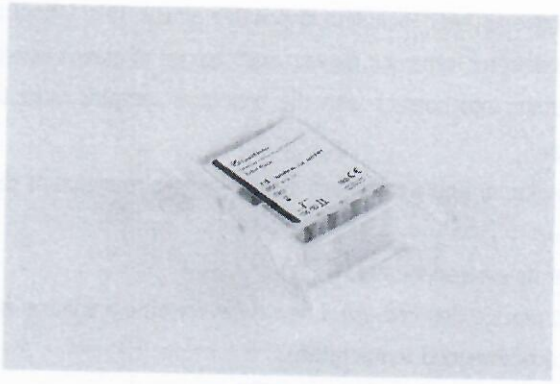
2) Disposable 8-strip



Disposable 8-strip

GeneFinder™ Viral DNA/RNA Extraction kit package includes 6 pieces of the disposable 8-strip. It is the essential component to mix reagents and to prevent contamination of magnetic rods.

3) Tube Rack



Tube Rack

Each Tube Rack can hold up to eight (8) 6-well Tubes that are filled with reagent buffer. EX-MATE32 Plus and EX-MATE 32 can hold up to 2 Tube Racks that it is eligible to process 1~16 samples per run.

5. Storage and Period of use

All components of the GeneFinder™ Viral DNA/RNA Extraction kit shall be stored at **room temperature (15~25°C)** avoiding direct sunlight. The kit is best before the date stated on the outer box, hence shall be used before specified date. Do not use the kit after expiration date.

- The kit is usable for 12 months from manufactured date if intact. The kit shall be used immediately once opened.
- Broken box may damage plates and/or strips. Please do not use if damaged.
  Caution: Direct sunlight may contaminate the kit and give unwanted result.
- Precipitates in lysis buffer may appear depending on the temperature although it is stored in room temperature. Keep the plate at 37°C to dissolute precipitates.

6. Warning and Precaution



General warning and precaution

- Read the instructions in the package carefully before processing samples.
- Clean and disinfect all spills of specimens using 10% bleach or other suitable disinfectant.
- Decontaminate and dispose of all specimens, reagents and other potentially contaminated materials in accordance with local regulations.

- Use universal precautions when performing the assay. Handle samples as if capable of transmitting infection.
- Wear personal protective apparel, including disposable gloves, throughout the assay procedure.
- Thoroughly wash hands after removing gloves, and dispose of gloves as biohazardous wastes.
- The material that comes into contact with the biological samples must be autoclaved for one hour at 120°C before disposal.
- Do not eat, drink, smoke, or apply cosmetics in areas where reagents of samples are handled.
- Do not pipet by mouth.
- Do not use a kit after its expiration date.
- Use aerosol-resistant pipette tips and use a new tip every time a volume is dispensed.
- Store the reagents recommended temperature.
- Do not mix reagent from different batches of the kit
- Store the kit away from any source of contaminating DNA/RNA.
- Use sterile disposable laboratory materials and do not reuse.
- Alterations in the physical appearance of kit components may indicate instability or deterioration.
- Use all pipetting devices and instruments with care and follow the manufacturer's instructions for calibration and quality control
- Do not modify the reagent/sample volume used in the test or use in a wrong way which is not recommended.

Operational warning

- GeneFinder™ Viral DNA/RNA Extraction kit is for research use only and shall not be used for any other purposes.
- GeneFinder™ Viral DNA/RNA Extraction kit shall only be used with GeneFinder™ EX-MATE 32 Plus and EX-MATE 32.
- All components of the kit is disposable hence shall not be reused.
- All components of the kit shall not be mixed with components from other kits with different lot numbers.
- The procedure shall be followed as given in the manual. Users shall not omit or change procedures when using GeneFinder™ Viral DNA/RNA Extraction kit.

7. Procedure

7.1 Preparation of component and specimens.

A. Carrier RNA

Carrier RNA is provided in lyophilized form. Reconstitute the lyophilized Carrier RNA by adding nuclease-free water provided (370ul in case of OSME-01-P48, 270ul in case of OSME-01-T32) before use. Store remaining reagent at -20 ~ 8°C according to the instruction attached on the vial.

B. Specimen

1. Blood (Whole Blood / Serum / Plasma)

① Add 7ul of carrier RNA solution into a 1.5 ml microcentrifuge tube (not provided).

② Transfer up to 200ul of liquid sample into the tube and mix thoroughly.

- We recommend using fresh and unfrozen blood within a week. If hemolysis occurs in the blood sample, dilution with a 1:1 ratio using 1x PBS is recommended.

2. Swab

① Place the swab sample in a 1.5 ml microcentrifuge tube. Clip off the handle with sterile sharp blade or wire cutter. Add 200ul of 1X PBS to the tube.

② Mix thoroughly by vortexing for 1 min and spin down briefly to remove any drops from inside of the lids.

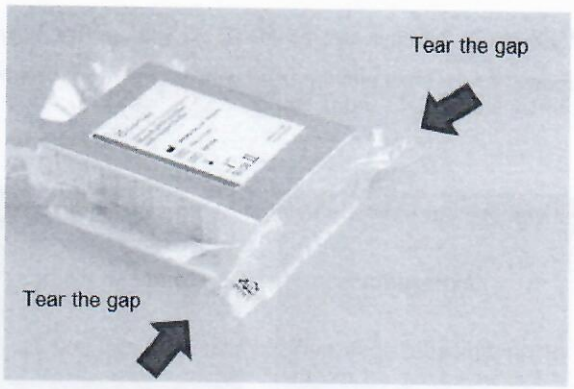
③ Transfer 200ul of liquid sample to a new 1.5 ml microcentrifuge tube.

④ Add 7ul of carrier RNA solution into a 1.5 ml microcentrifuge tube and mix thoroughly

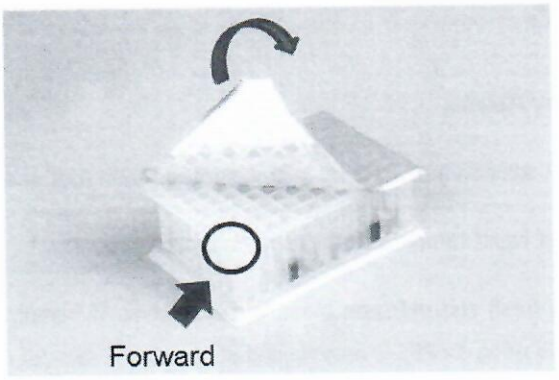
REF OSME-01-P48 (Plate type, 48 tests)

7.2 Specimen dispense on plate

1) Place 96-well plate pre-filled with reagent buffer as below and open the pouch.

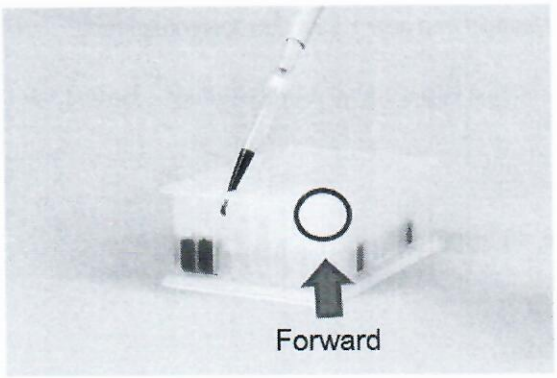


2) Remove sealing film on the plate softly from the spot pointed as below. Be aware that reagent in the plate may spurt or spill if detached too fast or too strong.



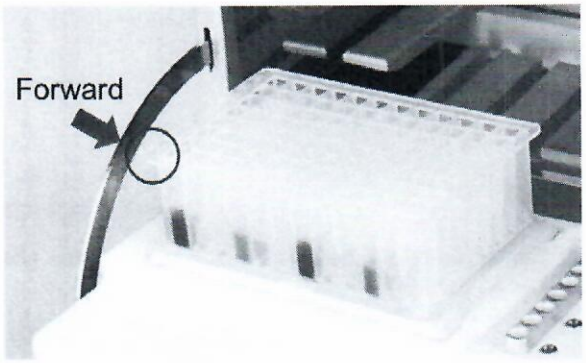
3) Dispense 200 µl of samples to 1st or 7th column using pipette. Be careful not to spill samples in wells of other column. Once dispensed place the plate in GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 immediately and start extraction. If left unextracted, extraction efficiency may decrease and/or DNA/RNA may be damaged.

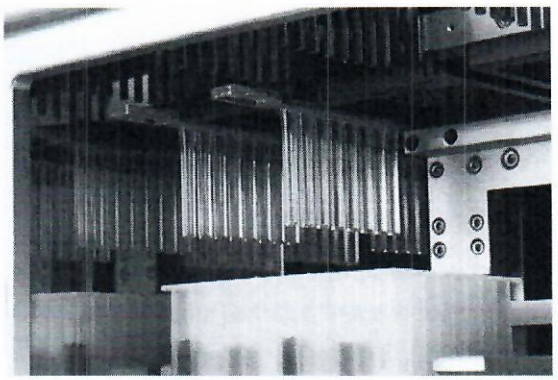
Note. A 96-well plate pre-filled with reagent buffer is optimized for use of 16 samples in single run.



7.3 Load of Plate and strip in device

Please refer to GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 manual for how to load the Plate and strip. GeneFinder™ Viral DNA/RNA Extraction kit shall only be used with GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 system.

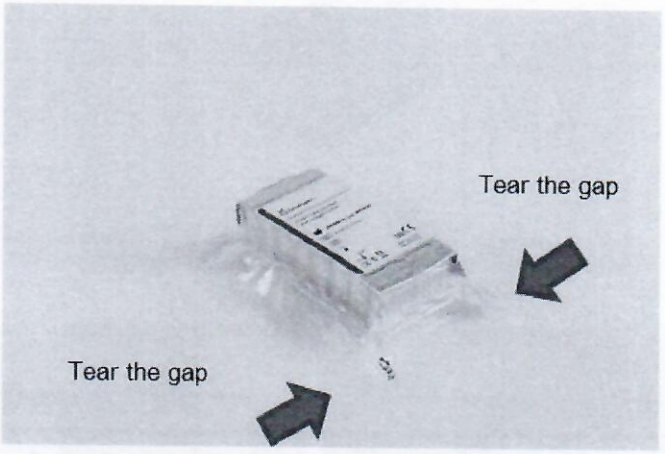




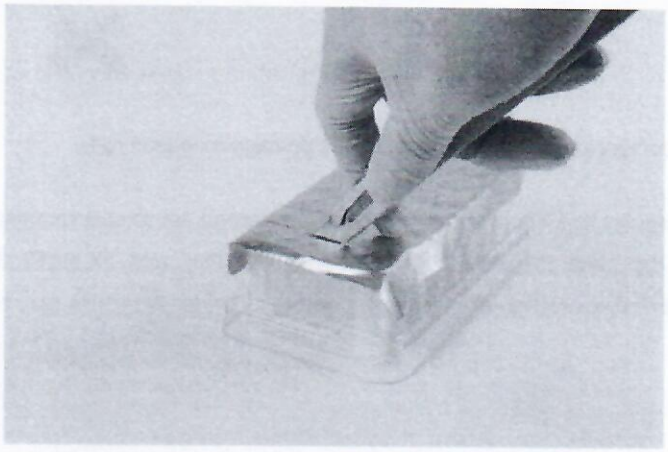
REF OSME-01-T32 (Tube type,32 tests)

7.2 Specimen dispense on tube

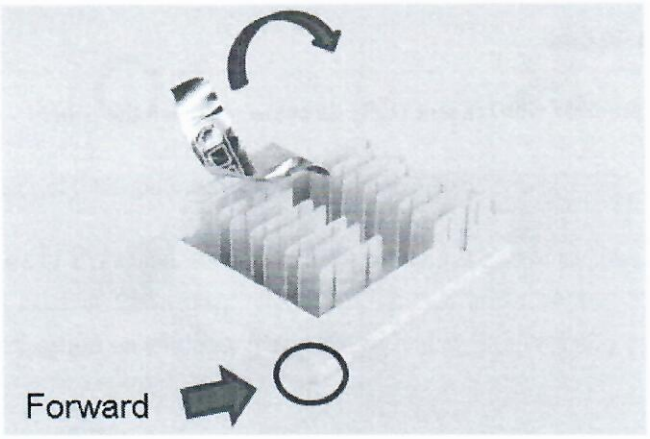
1) Place 6-well Tube pre-filled with reagent buffer as below and open the pouch.

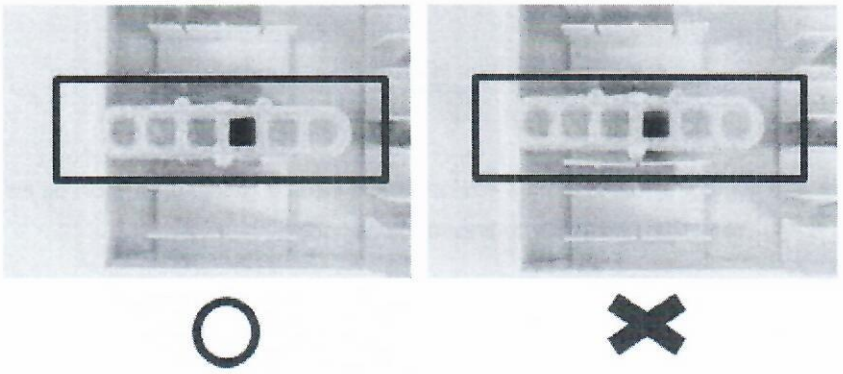


2) Detach desired number of Tubes using a box cutter and insert it to the Tube Rack. Be aware of protruded part on Tubes and cut sealing film gently to prevent damage on it.



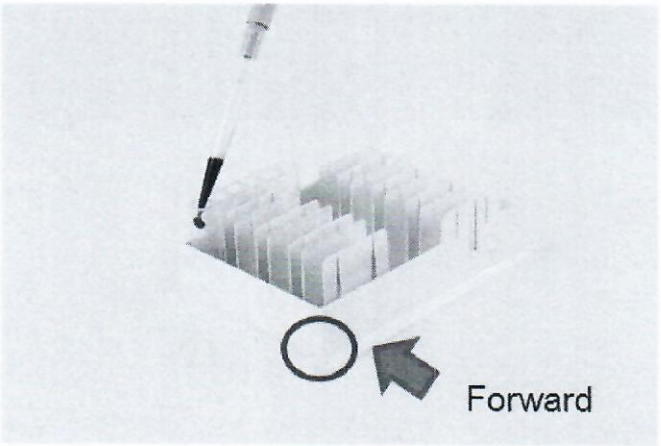
3) Remove sealing film on the plate softly from the spot pointed as below. Be aware that reagent in the plate may spurt or spill if detached too fast or too strong.





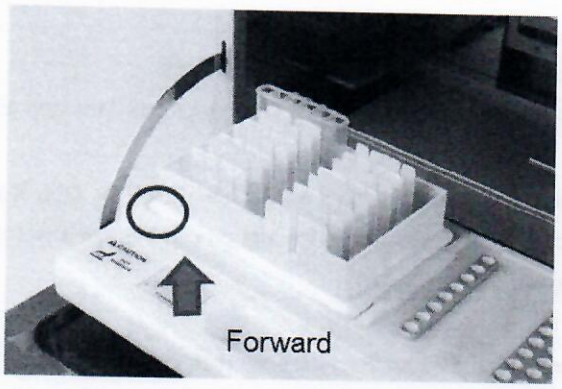
Warning!!: Misplacement of tubes on tube rack may damage magnetic rods.

4) Dispense 200 µl of samples to 1st column using pipette. Be careful not to spill samples in wells of other column. Once dispensed place the plate in GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 immediately and start extraction. If left unextracted, extraction efficiency may decrease and/or DNA/RNA may be damaged.



7.3 Load of Plate and strip in device

Please refer to GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 manual for how to load the rack, tube and strip. GeneFinder™ Viral DNA/RNA Extraction kit shall only be used with GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 system.



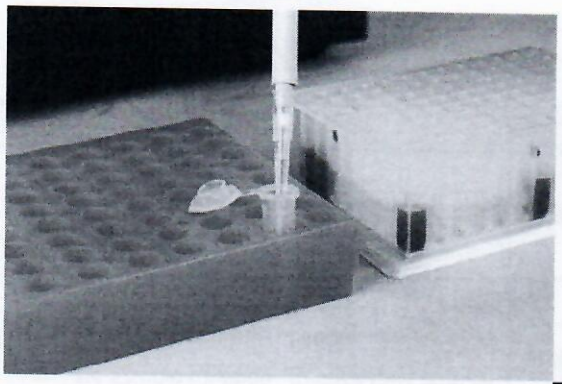


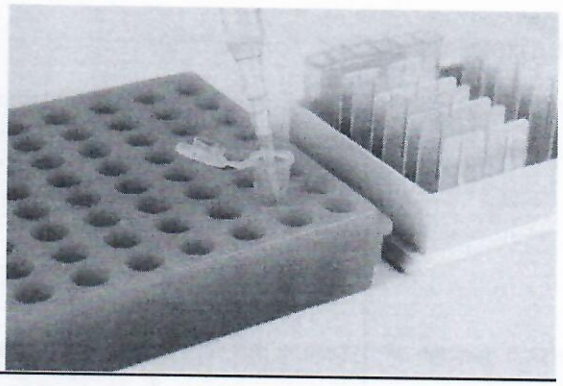
7.4 Device Operation

Please refer to GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 manual for how to operate the device.

① EX-MATE 32 Plus
   A. Click 'Viral DNA' or 'Viral RNA' on the Home screen, and then click 'INIT'
   B. Screen touch for 'START'
② EX-MATE 32
   A. Click 'Viral DNA' or 'Viral RNA' on the Home screen, and then click 'Other type'
   B. Screen touch for 'Start'

7.5 Collection of extracted DNA





Once extraction is completed, take plate out of the device and collect DNA in the eluted buffer from 6th and/or 12th column depending on where samples were dispensed. Amount of eluted buffer will be around 50 µl and it is ready to use. The solution may be transferred into 1.5 ml tube using pipette and refrigerated for continuous use. Keep it in the freezer if the DNA/RNA should be kept for more than one month. It is recommended to aliquot and store extracted DNA/RNA for frequent use to prevent DNA/RNA damage and contamination from repeated freezing and

thawing.

It is strongly recommended to use freshly extracted DNA/RNA for downstream applications such as amplification (PCR, qPCR etc.)

8. Product Limitation

- GeneFinder™ Viral DNA/RNA Extraction kit shall only be used by well-trained individuals.
- GeneFinder™ Viral DNA/RNA Extraction kit is only used with GeneFinder™ EX-MATE 32 Plus and EX-MATE 32.
- Any diagnostic results generated must be interpreted in conjunction with other clinical or laboratory findings. It is the user's responsibility to validate system performance for any procedures used in their laboratory which are not recommended by OsangHealthcare Co., Ltd.
- Do not use contaminated samples.
- Use of Clinical samples stored in long-term may reduce the extraction efficiency than expected.
- Data regarding reduced efficiency by drugs are not provided.
- Do not use any substance that may reduce PCR activity such as heparin.
- Once opened, the plate is never used for extraction procedure anymore. It is optimized for use of 16 samples in single run.

9. Quality control

In accordance with OsangHealthcare's ISO-certified Quality Management System, each lot of GeneFinder™ Viral DNA/RNA Extraction kit is tested against predetermined specifications to ensure consistent product quality.

10. Trouble Shooting

Problems	Possible Causes	Recommendation
Physical damage of the kit	Upside down kit during transportation causing reagent to stick with sealing film	Spin down the plate using centrifuge or by hand
	Sealing film is detached and reagent is spilled to other wells due to improper storage temperature	Spin down the plate or tube & tube rack using centrifuge or by hand and measure reagent volume with eyes. If reagent volumes are insufficient extraction efficiency may decrease. Do not use it and contact customer service immediately.
	Broken plate, strip, tube or tube rack	Broken plate, tube, tube rack or strip may lead to unfavorable result. Do not use it and contact

		customer service immediately.
Inappropriate specimen condition	Specimen condition is not favorable due to inappropriate storage condition. (ex. Coagulation)	Perform vortex and pipetting of specimen. If sample is still coagulated add a bit of PBS or distilled water and vortex again.
	Specimen condition is not favorable due to inappropriate storage condition. (ex. stored in room temperature)	Increase sample volume up to 250 µl if extraction efficiency is low.
Extractor malfunction	Device is not working	Make sure device is plugged. Refer to GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 insert for more details.
	Collision	Improperly attached plate, tube, tube rack or strip may cause collision (between plate & strip, plate & device component/ tube & strip, tube rack & device component and strip & device component). Turn off the device and make sure plate/ tube & tube rack and strip are properly attached. Refer to GeneFinder™ EX-MATE 32 Plus and EX-MATE 32 insert for more details.
Abnormal extraction	Too much bead left in Elution buffer	If DNA density is normal you may proceed with the eluted solution. If DNA/RNA density is low pipette eluted solution to 1.5 ml tube and centrifuge before use.
	Eluted DNA is not transparent or sticky.	Refer to 'Inappropriate specimen condition' part of trouble shooting if specimen condition is unfavorable and perform extraction again. If specimen condition and DNA/RNA density is favorable you may proceed with exacted DNA/RNA. If specimen condition is favorable but DNA density is unfavorable pipette eluted solution to 1.5 ml tube and centrifuge before use. If result is still unfavorable dilute it with elution buffer provided in GeneFinder™ Viral DNA/RNA Extraction kit before use.
	Low DNA density (lower than 10 ng/µl)	Refer to 'Inappropriate specimen condition' part of trouble shooting if specimen condition is unfavorable. Refer to 'Physical damage of the kit' part of trouble shooting for reasons other than specimen condition

	260/280 ratio is lower than 1.6	260/280 ratio may be 1.5~1.6 if DNA/RNA density is around 10~20 ng/μl. Re-extract the DNA using 250 μl of samples. Refer to 'Physical damage of the kit' part of trouble shooting for reasons other than DNA/RNA density.

11. Symbols


Lot or batch number


Catalogue number


In Vitro Diagnostic Medical Device


Consult Instruction For Use


Caution


Temperature limitation


Expiry date


Manufacturer


Do not reuse


Conformité Européenne Mark


Authorized Representatives in European Community


Contains sufficient for <n> tests


This way up

12. Manufacturer

OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Korea

Tel: +82-31-460-0300 / FAX: +82-31-460-9933

http://www.osanghc.com/

Catre: SPITALUL CLINIC JUDETEAN DE URGENTA ARAD

Ofertant : CN UNIFARM SA

Propunere tehnica

Va transmitem mai jos oferta noastra pentru echipamentul ce face obiectul Negocierii fara publicare a unui anunt de participare

Se cere **Extractor automat – 1 bucata**	Se ofera **Extractor automat - TBA EX MATE 32 PLUS – 1 bucata** Specificatiile tehnice sunt conform fiselor tehnice/manual atasate
Reactivi amplificare COVID 19 – 10 bucati	KIT REALAMP COVID-19 PLUS GENEFINDER (100TESTE/KIT) detectie – 10 kituri Specificatiile tehnice sunt conform fiselor tehnice/manual atasate
Reactivi de extractie pentru Covid 19 – 30 bucati	TBA GENEFINDER VIRAL DNA/RNA(32 T) Specificatiile tehnice sunt conform fiselor tehnice/manual atasate – 30 kituri
Termen de livrare10 zile	
Garantie produs 24 luni	Garantie produs 24 luni

Produsele ofertate sunt noi, nu au niciun defect, si corespun de caracteristicilor tehnice din caietul de sarcini.

Compania noastra isi asuma cerintele din caietul de sarcini cu privire la spicificatiile tehice solicitate, garantia produsului, livrare, ambalare, etichetare, transport, instalare, punere in functiune, testare, instruirea perosnalului.

Director General

Adrian IONEL

1.Extractor automat
Sistem automat de extragere care permite extragerea de calitate inalta a acizilor nucleici din probe folosind forta magnetica a EX MATE 32 PLUS.
Permite purificarea acizilor nucleic folosind tehnologia bazata pe bile magnetice in trei pasi: legare, spalare si eluare.
- Sistem integrat pentru pregatire a probelor, destinat pentru a simplifica, standardiza si accelera pregatirea probelor provenite din diferite surse pentru analize moleculara cum ar fi: sange, bacterii, culture celulare proaspete, congelate sau celule in solutie de conservare, ARN, tesuturi, virusuri, etc.
- Sistemul permite extracţie de acizi nucleici din fluide biologice si probe fara celule, aplicatii pentru proteine cum ar fi: imunoprecipitare, purificare proteine de fuziune si imbogatirea fosfopeptidelor.
- Include un pachet software care sa asigure flexibilitatea crearii protocoalor customizate de extractie.
- Sistem de extractie automata si rapida a acizilor nucleici, cu controlul contaminarii (lampa UV inclusa),
System de control prin touch monitor
Greutate 40 kg
Dimensiuni (W x D x H): 365 x 390 x 435mm - Lampa UV: 8W
- Temperatura de lucru: +4°C - +40°C;
- Software-ul: preincarcat.
- Posibilitate de import a protocoalelor, fie prin software-ul intern fie prindispozitiv USB.
- Tastatura / Afişare: START / STOP / patru taste cursor / LCD
- 220–240 V, 50/60 Hz, 2A

2.Reactiv pentru extractie automata a acizilor nucleivi compatibili cu extractorul automat EX MATE 32 PLUS.
Kit de extractie a RNA/ADN compatibili cu extractorul automat EX MATE 32 PLUS necesar in extractia ARN pentru Covid 19
Impachetare 32 teste /kit

3.**Reactivi de amplificare** acizi nucleici
Kit de amplificare REALAMP COVID 19 Plus necesar in identificarea prin RT-PCR a Covid 19.
Impachetare 100 teste/kit

Toate produsele trebuie să fie acoperite de garanţie pentru cel puţin perioada solicitată pentru fiecare produs. Compania noastra are obligatia de a garanta ca toate produsele ofertate **sunt noi**, nu vor avea nici un defect ca urmare a proiectului, materialelor sau manoperei ori oricarei alte actiuni sau omisiuni a producatorului si ca acestea corespundcaracteristicilor mentionate in propunerea tehnica si a cerintelor din prezentul caiet de sarcini.

Perioada de garantie va fi **de 24 luni** de la data achizitiei.

Beneficiarul are dreptul de a notifica, in scris, compania noastreui, orice plangere sau reclamatie ce apare in conformitate cu aceasta garantie, in termen demaxim 5 zile de la data constatarii lor. La primirea unei astfel dc notificari compania noastre are obligatia dc a inlocui produsul necorespunzator in maxim 15 zile, fara costuri suplimentare pentru beneficiar. Produsele carc pe timpul garantiei le inlocuiesc pe cele defecte, beneficiaza de o noua perioada de garantie care curge de la data inlocuirii lor si semnarii procesul verbal de receptie/punere in functiune si vaacoperi perioada de garantic primita initial. Daca compania noastre, dupa ce a

fost instiintat, nu reuseste sa remedieze defectul in perioada convenita, achizitorul are dreptul de a lua masuri de remediere pe riscul si pe cheltuiala compania noastreui si fara a aduce nici un prejudiciu oricaror alte drepturi pe care achizitorul le poate avea fata de compania noastra prin contract.

Garanția trebuie sa acopere toate costurile rezultate din remedierea defectelor în perioada de garanție, inclusiv, dar fără a se limita la:

- demontare, inclusiv închirierea de unelte speciale necesare pe durata intervenției (daca este aplicabil);
- ambalaje, inclusiv furnizarea de material protector pentru transport (carton, cutii, lăzi etc.);
- transport prin intermediul transportatorului, inclusiv de transport internațional (daca este aplicabil);
- diagnoza defectelor, inclusiv costurile de personal;
- repararea tuturor componentelor defecte sau furnizarea unor noi componente;
- înlocuirea părților defecte;
- despachetarea, inclusiv curățarea spațiilor unde se efectuează intervenția;
- instalarea în starea inițială;
- testarea pentru a asigura funcționarea corectă;
- repunerea în funcțiune.

Termenul de livrare este **de maxim 10 de zile** de la data transmiterii comenzii ferme de catre achizitor catre compania noastra. Un produs este considerat livrat dupa intocmirea procesului verbal de **receptie cantitativa.**

Produsele vor fi livrate cantitativ și calitativ catre Autoritatea contractantă la locul indicat de acesta, iar adresa va fi metionata in comanda ferma transmisa de catre achizitor catre compania noastra. Ficcare produs va fi însoțit de toate subansamblele/părțile componente necesare punerii și menținerii în funcțiune.

Compania noastre va ambala și eticheta produsele furnizate astfel încât să prevină orice daună sau deteriorare în timpul transportului acestora către destinația stabilită. Dacă este cazul, ambalajul trebuie prevăzut astfel încât să reziste, fără limitare, manipulării accidentale, expunerii la temperaturi extreme, sării și precipitațiilor din timpul transportului și depozitării în locuri deschise. În stabilirea mărimii și greutății ambalajului compania noastre va lua în considerare, acolo unde este cazul, distanta față de destinația finală a produselor furnizate și eventuala absență a facilităților de manipulare la punctele de tranzitare.

Transportul și toate costurile asociate sunt în sarcina exclusivă a compania noastreui. Produsele vor fi asigurate împotriva pierderii sau deteriorării intervenite pe parcursul transportului și cauzate de orice factor extern.

Destinația de livrare este cea mentionta in comanda ferma pe care achizitorul o va transmite compania noastreui.

Compania noastre este responsabil pentru livrarea în termenul agreat al produselor și se consideră că a avut în vedere toate dificultățile pe care le-ar putea întâmpina în acest sens și nu va invoca nici un motiv de întârziere sau costuri suplimentare.

De la data semnarii procesului verbal de receptie cantativa in termen de **maxim 2 de zile** compania noastre are obligatia de a efectua urmatoarele activitati si de a intocmi:

- instalarea/montareaechipamentului
  - punerea in functiune si verificareatehnicaprivindincadrarea in conditiile de acceptabilitate a echipamentului. Toate acestea se vor realiza cu personal autorizat si vor fi incluse in pretul de achizitie a echipamentului.
  - procesul verbal de instalare si punere in functiune

- procesul verbal de receptiecalitativa
- emitereabuletinul de verificaretehnica.

Cmpania noastre trebuie să instaleze toate produsele în mod corespunzător, asigurând-se în acelaşi timp ca spaţiile unde s-a realizat instalarea rămân curate. După livrarea şi instalarea produselor, compania noastre va elimina toate deşeurile rezultate şi va lua măsurile adecvate pentru a aduna toate ambalajele şi eliminarea acestora de la locul de instalare.
Odată ce produsele sunt asamblate, furnizorul va realiza şi apoi toate configurările/setările necesare pentru a pune produsele în funcţiune. Punerea in funcţiune include, de asemenea, toate ajustările şi setările necesare pentru a asigura instalarea corespunzătoare, în ceea ce priveşte performanţa şi calitatea, cu toate configuraţiile necesare pentru o funcţionare optimă.
După instalare şi punere în funcţiune, *Autoritatea contractanta impreuna cu compania noastre* vor efectua teste funcţionale ale produsului. Testarea produsului va avea în vedere următoarele elemente*si fără a se limita la cele ce urmează:*

- *testare in condiţii de utilizare „reala";*
- *metode de testare; mediul de testare;*
- *funcţionalităţi care trebuie testate;*
- *criterii de succes/eşec ale testelor;*
- *calendar/interval de testare, etc.*

Compania noastre va efectua pe cheltuiala sa şi fără nici un fel de costuri din partea Autorităţii contractante toate testele pentru a asigura funcţionarea produsului la parametri agreaţi. Compania noastre rămâne responsabil pentru protejarea produselor luând toate masurile adecvate pentru a preveni lovituri, zgârieturi şi alte deteriorări, până la acceptare de către Autoritatea/entitatea contractantă.

Compania noastre este responsabil pentru instruirea la faţa locului a personalului desemnat de spital. Scopul instruirii este de a transfera cunoştinţele necesare pentru a opera produsul. Numărul persoanelor care vor instruite este de **aproximativ 6 persoane.**
Instruirea va fi organizata după ce produsul/echipamentul este funcţionalşi trebuie să permită personalului spitalului să:

- înţeleaga componentele produsului/echipamentului;
- înţeleaga funcţionarea si operarea produsului/echipamentului;
- detina informaţii despre mentenanţa de rutină care trebuie să fie efectuată de către utilizator;
- fie instruit in vederea depistarii problemelor şi diagnosticarea lor de baza.

Compania noastre trebuie să propună orice subiect suplimentar care ar putea fi necesar pentru a se asigura că personalul Autorităţii contractante este pe deplin instruit pentru a asigura utilizarea corespunzătoare a produsului.
Durata sesiunii de instruire *va fi pana in momentul in care persoanele instruite vor fi capabile sa utilizeze echipamentele.*

Costurile de instruire vor fi incluse in pretul de achizitie al produsului.Sesiunea de instruire se va desfăşura în limba română.
Compania noastre va asigura pe durata sesiunii de instruire materiale suport în limba română, care includ cel puţin: manuale de operare, fise tehnice, prezentari foto/video.

Mentenanţa preventiva trebuie înţeleasă ca totalitatea operaţiunilor de întreţinere şi reparaţie ale unui echipament/produs care se efectuează pe parcursul ciclului de viaţă al acestuia, la intervale regulate cu scopul de a asigura funcţionarea optima a echipamentului/produsului, pentru a reduce riscurile de defectare şi de deteriorare.

Compania noastre trebuie să efectueze mentenanță preventivă a produsului cel putin o data pe an, in perioada de garanție. Operațiunile care trebuie efectuate de compania noastra pentru fiecare intervenție sunt conform manualului de utilizare recomandate de producator.
Compania noastre este responsabil pentru realizarea operațiunilor de mentenanță preventiva in conformitate cu cerințele stabilite de către producătorul echipamentului.
Înainte de efectuarea operațiunilor de mentenanță preventivă, compania noastre comunică spitalului lista operațiunilor de mentenanță care trebuie efectuate. În funcție de disponibilitatea locației unde este instalat produsului, este posibil ca mentenanța preventivă să trebuiască a fi realizata în afara orelor normale de lucru sau la sfârșit de săptămână sau în sărbători legale.
Operațiunile de mentenanță preventivă care necesită o oprire a produsului se efectuează în afara orelor normale de activitate. Datele exacte vor fi agreate cu spitalul. Mentenanța preventivă trebuie sa acopere toate costurile aferente intervenției, inclusiv forța de muncă, piese de schimb si altele asemenea.
Operațiunile de mentenanța preventiva trebuie efectuate în condiții de securitate, cu protejarea adecvată a personalului care efectuează mentenanță și a altor persoane prezente la locul unde are loc intervenția.
După fiecare intervenție preventivă, compania noastre trebuie să efectueze teste de funcționare ale produsului și să prezinte un raport care să includă activitățile realizate.

Prin prezentul contract compania noastra nu are nici o obligatie cu privire la mentenanța corectiva in perioada post-garanție.

Pe toata durata contractului în perioada de garanție compania noastre va asigura suport tehnic.
Compania noastre va asigura un punct de contact dedicat personalului autorizat al Autorității contractante prin SCJU Arad in calitate de beneficiar, unde se poate semnala orice problemă/defecțiune care necesită mentenanță preventivă sau solicită suport tehnic compania noastreui în gestionarea unui incident, disponibil, pentru a se asigura că orice situație semnalată este tratată cu promptitudine.
Compania noastre va răspunde în timp util la orice incident semnalat de Autoritatea contractantă prin SCJU Arad in calitate de beneficiar, în funcție de nivelul incidentului. Fiecare incident este caracterizat de un nivel de prioritate, care va evidenția impactul acestuia asupra funcționalităților produsului.
Nivelele de prioritate sunt:

- **Urgent** - incidentul are impact major asupra funcționarii produsului. Problema împiedică desfășurarea activității Autorității/entității contractante
- **Critic** - impact semnificativ asupra funcționarii produsului. Problema împiedică desfășurarea în condiții normale a activității Autorității/entității contractante. Nici o soluție alternativa nu este disponibila, însă activitatea Autorității/entității contractante poate totuși continua, însă într-un mod restrictiv.
- **Major** - impact mediu asupra desfășurării activității Autorității/entității contractante. Problema afectează minor funcționalitățile produsului. Impactul reprezintă un inconvenient care necesita soluții alternative pentru refacerea funcționalităților.
- **Minor** - impact minim asupra desfășurării activității Autorității/entității contractante. Problema nu afectează funcționalitățile produsului. Rezultatul este o eroare minora care nu împiedică desfășurarea în bune condiții a activității Autorității/entității contractante.

Compania noastre trebuie sa asigure disponibilitatea serviciilor de suport tehnic. În cazul incidentelor cu prioritate „urgent" intervenția va fi asigurata 24x7, din momentul primirii sesizării și până la remedierea definitiva a problemei și asigurarea funcționalității integrale a produsului.

Contractantul va trebui sa respecte următorii timpi de răspuns, corelați cu nivelul de prioritate a incidentului, astfel:

Nivel prioritate	Timp de răspuns	Timp de implementare soluție provizorie	Timp de rezolvare
Urgent	30 minute	4 ore	24 ore
Critic	2 ore	24 ore	48 ore
Major	4 ore	Următoarea zi lucrătoare	Următoarea zi lucrătoare
Minor	6 ore	A doua zi lucrătoare	A doua zi lucrătoare

Nerespectarea timpilor de mai sus da dreptul Autorităţiicontractante de a solicita penalităţi/daune interese în conformitate cu clauzele contractului de achiziţie publică de produse.

Prin prezentul contract compania noastra nu are nici o obligatie cu privire la asigurarea:

- materialelor consumabile pentru activitățile din programul de mentenanță corectiva după expirarea garanției, acestea vor face obiectul unei noi achizitii publice.

Compania noastre se obliga sa furnizeze produsele in termenele prevazute la cap. 3.2. din prezentul caiet de sarcini.

Compania noastre se obliga sa furnizeze produsele la standardele si/sau performantele prezentate in propunerea tehnica si a caietului de sarcini. Produsele/echipamentele ce urmeaza sa fie livratein cadrul prezentei proceduri vor fi obligatoriu fabricate de catre producatorul mentionatin declaratia de producator depusa in cadrul ofertei.

Compania noastre se obliga sa despagubeasca autoritatea contractanta impotriva oricaror:

- reclamaţii şi acţiuni în justiţie, ce rezultă din încălcarea unor drepturi de proprietate intelectuală (brevete, nume, mărci înregistrate etc.), legate de produsele achiziţionate,
- daune-interese, costuri, taxe şi cheltuieli de orice natură, aferente, cu excepţia situaţiei în care o astfel de încălcare rezultă din solicitarea ofertei întocmite de către entitatea contractanta.

Autoritatea contractanta se obligă să recepţioneze produsele achizitionate.

În cazul in care contractantul nu îşi onorează obligaţiile, atunci va datora entitatii contractantepenalitati de conform contractului însuşit.

În cazul în care autoritateaa contractanta nu îşi onorează obligaţiile de plata, atunci va datora contractantului penalitati conform contractului însuşit.

Nerespectarea obligatiilor asumate de catre una dintre parti, in mod culpabil, da dreptul partii lezate de a considera contractul de drept reziliat si de a pretinde plata de daune-interese, conform cotractului de furnizare.

Documentaţiile pe care Contractantul trebuie să le livreze Spitalului Clinic Judeţean de Urgenţă Arad în cadrul contractului sunt: carti tehnice, cataloage ai alte documentatii similare (prospecte, fise tehnice etc) care sa prezinte caracteristicile si proprietatile produselor, conditii impuse pentru pastrarea lor, intretinerea si indeplinirea rolului lor functional, alte elemente privind manipularea, depozitarea si conservarea precum si orice instructiuni si documentatie de utilizare emisa de producatorul produselor si aferenta acestora pe care compania noastre trebuie sa le respecte pentru a nu aduce prejudicii produselor din necunoasterea lor.

Documentele respective trebuie sa mentioneze concordanta cu paramentrii si caracteristicile mentionate in standardele in vigoare. Toata documentatia va fi prezentata in limba romana.

Recepția produselor se va efectua pe baza de proces verbal semnat de Contractant și Autoritatea contractantă. Recepția produselor se va realiza în mai multe etape, în funcție de progresul contractului, respectiv:

a) recepția cantitativă se va realiza după livrarea produselor în cantitatea solicitată la locația indicată de Autoritatea contractantă;
b) recepția calitativă se va realiza după instalare, punere în funcțiune și testare a produselor și, după caz, când toate defectele au fost remediate.

Procesul verbal de recepție calitativă va include unul din următoarele rezultate:

a) acceptat;
b) acceptat cu observații minore;
c) acceptat cu rezerve;
d) refuzat.

Contractantul va emite factura pentru produsele livrate. Fiecare factura va avea menționat numărul contractului, datele de emitere și de scadența ale facturii respective. Facturile vor fi trimise în original la adresa specificata de Autoritatea contractantă.

Factura va fi emisă după semnarea de către Autoritatea contractantă a procesului verbal de recepție calitativă, acceptat, după livrare, instalare și punere în funcțiune. Procesul verbal de recepție calitativă va însoți factura și reprezintă elementul necesar realizării plății, împreună cu celelalte documente justificative prevăzute mai jos:

a) certificatul de calitate și garanție;
b) declarația de conformitate;
c) avizul de expediție a produsului;
d) procesul verbal de recepție cantitativă;

Plătile în favoarea Contractantului se vor efectua in termen de 15 de zile de la receptia calitativa a produsului

Director General

Adrian IONEL

MINISTERUL SĂNĂTĂŢII
C.N. "UNIFARM" S.A.

Adresa: str. Av.Ştefan Sănătescu nr.48, sector 1, Bucureşti – România
Nr. înreg. Reg. Com.: J40/2908/1999; CUI: RO 11653560; Cont: RO02RNCB0072049687380001-BCR Sect. 1;
Tel: 021.319.28.84; Fax: 021.319.28.89; E-mail: office@unifarm.ro;
Site: www.unifarm.ro

C.N "UNIFARM" S.A.

FORMULAR DE OFERTA

Catre : SPITALUL CLINIC JUDETEAN DE URGENTA ARAD

Domnilor,

1. Examinand documentatia de atribuire, subsemnatii, reprezentanti ai ofertantului C.N. Unifarm S.A , ne oferim ca, in conformitate cu prevederile si cerintele cuprinse in documentatia mai sus mentionata, sa furnizam medicamente pentru suma **de 96,618.90 lei** (nouazecisisasemiisasesuteoptsprezecemiisinoauzecidebani) platibila dupa receptia produselor la care se adauga taxa pe valoarea adaugata in valoare **de 18357.59 lei** (optsprezecemiitreisutecincizecisisapteleisicincizecisinouabani).

2. Ne angajam ca, in cazul in care oferta noastra este stabilita castigatoare, sa furnizam produsele in graficul de timp anexat.

3. Ne angajam sa mentinem aceasta oferta valabila pentru o durata de 60 zile, respectiv pana la data de 31.06.2020 si ea va ramane obligatorie pentru noi si poate fi acceptata oricand inainte de expirarea perioadei de valabilitate.

4. Pana la incheierea si semnarea contractului de achizitie publica aceasta oferta, impreuna cu comunicarea transmisa de dumneavoastra, prin care oferta noastra este stabilita castigatoare, vor constitui un contract angajant intre noi.

5. Precizam ca:

_ |_| depunem oferta alternativa, ale carei detalii sunt prezentate intr-un formular de oferta separat, marcat in mod clar "alternativa";

_ |X| nu depunem oferta alternativa.

6. Am inteles si consimtim ca, in cazul in care oferta noastra este stabilita ca fiind castigatoare, sa constituim garantia de buna executie in conformitate cu prevederile din documentatia de atribuire.

7. Intelegem ca nu sunteti obligati sa acceptati oferta cu cel mai scazut pret sau orice alta oferta pe care o puteti primi.

30.04.2020

Adrian Ionel, in calitate de Director General, legal autorizat sa semnez oferta pentru si in numele C.N. Unifarm S.A.

Intocmit
Beatrice Stroie

MINISTERUL SĂNĂTĂŢII
C.N. "UNIFARM" S.A.

Adresa: str. Av.Ştefan Sănătescu nr.48, sector 1, Bucureşti – România
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Site: www.unifarm.ro

C.N "UNIFARM" S.A.

Nr. Lot	Denumire achizitie	U.M.	Cant.	PU estimat lei fără TVA	Valoare estimata lei fără TVA
LOT 1	Extractor automat	buc	1	41,465.00	41,465.00
	Reactivi amplificare COVID 19	buc	10	3,873.43	38,734.30
	Reactivi de extractie pentru Covid 19	buc	30	547.32	16,419.60
	TOTAL				**96,618.90**

30.04.2020

Director General,
Adrian Ionel

Intocmit
Beatrice Stroie