

Molecular Diagnostic System

SMART Solution for Better Life
COVID-19

OHC
OSANG HEALTHCARE

COVID-19 Plus RealAmp Kit

On January 11, 2020, Chinese health authorities preliminarily identified more than 40 human infections with a novel coronavirus in an outbreak of pneumonia under investigation in Wuhan City, Hubei Province, China. The Chinese authorities identified a new type of coronavirus (novel coronavirus, named as COVID-19), which was isolated on 7 January 2020.

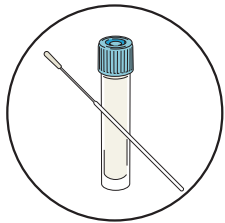
GeneFinder™ COVID-19 Plus RealAmp Kit is the One-Step Reverse Transcription Real-Time PCR Kit designed to detect Novel Corona virus (COVID-19) qualitatively through Reverse Transcription reaction and Real-Time Polymerase Chain Reaction.



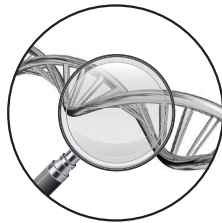
CE IVD

- About 120 minutes detection for COVID-19
- Reverse Transcription reaction and Real-Time Polymerase Chain Reaction
- Easy-to-use(One-Tube) and interpretation
- Reliable result by Internal/Positive/Negative Control

Process



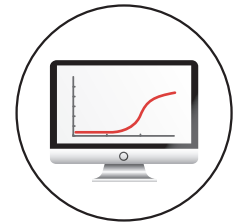
Specimen Collection



Viral RNA Extraction



cDNA synthesis & Amplification



Data Analysis

Content

COVID-19 Plus Reaction Mixture

COVID-19 Plus Positive Control

COVID-19 Plus Probe Mixture

COVID-19 Plus Negative Control

Target

RdRp Gene

N Gene

E Gene

Internal Control

Specimen

Respiratory Specimen
(Sputum, Nasopharyngeal swab,
Oropharyngeal swab)

Compatible Instrument

Applied Biosystems
7500/7500FAST(Thermo fisher)
CFX96(Bio-Rad)

Product

GeneFinder™ COVID-19 Plus RealAmp Kit

Cat. No.

IFMR-45


Size

100 Tests/Kit

GeneFinder™ COVID-19 Plus RealAmp Kit

REF IFMR-45

Σ 100 tests/Kit

 Store at -20 °C or below.
Shelf life is 12 months after manufacturing.

CE-IVD
For ABI7500/7500Fast & CFX96

INTENDED USE

GeneFinder™ COVID-19 Plus RealAmp 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.

KIT COMPONENT

COVID-19 Plus RealAmp Kit	100 tests/Kit
COVID-19 Plus Reaction Mixture ¹⁾	1,050 µL
COVID-19 Plus Probe Mixture ²⁾	550 µL
COVID-19 Plus Positive Control ³⁾	50 µL
COVID-19 Plus Negative Control ⁴⁾	50 µL

- 1) COVID-19 Plus Reaction Mixture: Containing Tris-HCl, MgCl₂ and dNTPs
- 2) COVID-19 Plus Probe Mixture: Primer pairs and probes for amplification and detection of each target
- 3) COVID-19 Plus Positive Control; Positive control for targets
- 4) COVID-19 Plus Negative Control; Ultrapure quality water, PCR-grade

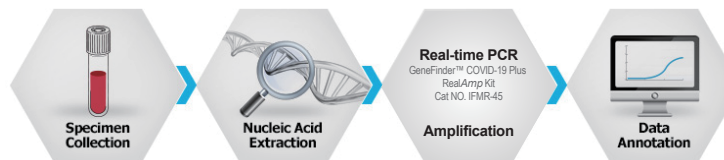
PREREQUISITE

- Applied Biosystems 7500/7500Fast and CFX96 Real-time PCR Instrument system
- Pipettes and Pipettes tips with aerosol barrier
- Vortex mixer
- Centrifuge with rotor for microtiter plates
- Disposable powder-free gloves.

WARNING AND PRECAUTION

- This product is designed for *In vitro diagnostics* (IVD).
- The test has to be performed by well-trained and qualified personnel.
- Dispose of unused reagents and waste in accordance with country, federal, state and local regulations.
- Unnecessary repeated freezing and thawing will be occurred inaccurate results.
- Do not mix reagent from different batches of the kit.
- Do not modify the reagent/sample volume used in the test or use in a wrong way which is not recommended.

WORK FLOW



PROTOCOL

A. Specimen

This product is must be used with viral RNA samples extracted from human respiratory specimens such as alveolar lavage fluid, nasopharyngeal swabs (NPS), sputum etc.

PROTOCOL

B. RNA Extraction

It is recommended to use commercialized extraction kit such as QIAamp Viral RNA mini kit (Qiagen).

C. Reagent Preparation

Before setting up PCR, all components need to be thawed, gently mixed and centrifuged briefly to collect solution at the bottom.

1. Mix 10 µL of COVID-19 Plus Reaction Mixture and 5 µL of COVID-19 Plus Probe Mixture to prepare master mixture per each reaction (refer to the below). Prepare enough volume of master mixture for all the reactions plus extra to prevent pipetting error.
2. After mixing well, place 15 µL of master mixture into 96-well plate or PCR tube.
3. Add 5 µL of extracted RNA sample into 96-well plate or tube, then mix all components by pipetting. Proceed in the same way with other RNA samples, Positive Control and Negative Control.
4. Accurately close the tube with the cap or seal the 96-well plate.
5. Transfer the tubes or 96-well plate for test into the Real-time PCR and start for the amplification.

Component	Per reaction (µL)
COVID-19 Plus Reaction Mixture	10
COVID-19 Plus Probe Mixture	5
Sample or PC ¹ or NC ²	5
Total volume	20

¹, PC, Positive Control; ², NC, Negative Control

D. Setting of Real-time PCR

This product is validated on ABI7500/7500Fast and CFX96 Real-time PCR instrument system.

- Referring to the instrument manual, set on the dedicated software for the parameters of thermal cycle.
- Set up the PCR program and fluorescence as following, and then click the start "Run" button.

PCR program			
	Cycle	Temp.	Time
Segment 1	1 cycle	50 °C	20 min
	1 cycle	95 °C	5 min
Segment 2	45 cycles	95 °C	15 sec
		58 °C*	60 sec

* Select "Collect Data"

Fluorescence Setting	
Target	Fluorophore
RdRp gene	FAM
N gene	JOE (ABI) / VIC (CFX96)
E gene	Texas Red
IC	Cy5
NO QUENCHER, Reference dye None	

E. Analysis Setting

The values of fluorescence emitted by the specific probes and by the specific internal control probe in amplification reactions should be analyzed by the instrument software.

- Click Analysis mode after completion and choose analysis setting from Amplification Plot.
- Click "Edit Default Settings" to set threshold values as shown below.

Target	Threshold		Baseline	
	ABI	CFX96	Begin	End
RdRp gene	30,000	300	3	15
N gene	30,000	300	3	15
E gene	30,000	300	3	15
IC	10,000	100	3	15

F. Result Interpretation

#	RdRp	N	E	IC	Assay Result
1	≤43	≤43	≤43	≤35	COVID-19 Positive
2	≤43	≤43	U,D*	≤35	COVID-19 Positive
3	≤43	U,D	≤43	≤35	COVID-19 Positive
4	≤43	U,D	U,D	≤35	Repeat the test (COVID-19 Positive if RdRp≤43)
5	U,D	≤43	≤43	≤35	Repeat the test (COVID-19 Positive if E and N≤43)
6	U,D	≤43	U,D	≤35	Repeat the test (COVID-19 Positive if N≤43)
7	U,D	U,D	≤43	≤35	Beta coronavirus
8	U,D	U,D	U,D	≤35	Negative
9	U,D	U,D	U,D	U,D	Invalid (re-test)

* U.D: Undetermined (or Not applicable (N/A))

Quality Control

- Positive Control and Negative Ct range should be as below:

#	FAM	JOE/VIC	Texas Red	Cy5
PC	≤35	≤35	≤35	≤35
NC	U,D	U,D	U,D	U,D

PERFORMANCE

Criteria	Result
Analytical Specificity	14 DNA/RNA samples were tested on the GeneFinder™ COVID-19 Plus RealAmp Kit in order to evaluate the possibility of cross-reactivity. 14 DNA/RNA samples which have no concern with the detection target of the kit were negative. * Cross reactivity : 100% Specificity
Analytical Sensitivity	Serial dilutions (1,000, 100, 10, 1 copies/test) of COVID-19 RNA (3 batches, 24 times of repeat test each) were tested. * Analytical Sensitivity : 1) RdRp gene: 10 copies/test 2) N gene: 10 copies/test 3) E gene: 10 copies/test

Repeatability	Repeatability was confirmed with identical standard substances at different conditions; different LOT, place, time and testers by 3 batch testing. Criteria of repeatability was CV < 5% of Ct Value.
Freeze/Thaw Safety	Freeze/Thaw safety of GeneFinder™ COVID-19 Plus RealAmp Kit was confirmed by 12 times of Freeze/Thaw repeat test. Criteria of safety was CV < 5% of Ct Value.

TROUBLE SHOOTING

Problem	Possible Cause	Recommendation
No signal in all samples including positive control	Error in Master mixture preparation	Check the dispensing volume during preparation of master mixture
	Inhibitors added	Repeat the extraction step with new sample
	Probe degradation	Use a new probe reagent
	Positive Control degradation	Use a new positive control
	Omitted components	Verify each component, repeat the RT-PCR mixture preparation
Instrument setting error		Check the position setting for the positive control on the instruments. Check the Thermal cycle settings on sample instrument
		Make sure that the equal volume of reactants is added in each tube or plate
Diverse intensity of fluorescent signals	Pipetting error	
	Contamination in the outer surface of PCR tubes or Plate	Wear gloves during the experiment
Weak or no fluorescent signal in samples only	Poor RNA quality	Use recommended kit for RNA extraction and store extracted RNA at -70 °C
	Insufficient volume of RNA	Repeat PCR reaction with correct volume of RNA



OSANG Healthcare

Company Introduction

GROUP OSANG

OSANG Healthcare

Group Chairman's Message

"Through differentiating technology and state-of-the-art materials, OSANG will leap forward to become a global group that creates value for customers."

Group OSANG Chairman **DONG-HYUN, LEE**



OSANG Vision

Technology and materials to create customer value

In the spirit of the Confucius' five virtues (benevolence, righteousness, propriety, wisdom and sincerity) Group OSANG will create value in the lives of customers. Toward this ideal, Group OSANG is promoting its divisions under "IT's a TEAM"



Business Divisions



IT & Advanced Materials



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



- Thermal Plasma Application – Urban mining

Fruit Packaging



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

Biotechnology & Agriculture



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



- Agricultural Biotech



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

Environmental Engineering



- Environmental Engineering
- Natural River Method
- Greenscaping
- Plasma Heat Recycling

New Growth Engines

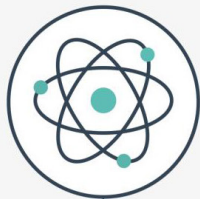
Jaielite™ - New Solution Material

Customized for Medical / Cosmetic Use
Safe for Human Use / Non irritating / Fast Acting / Non Tolerance Building



**Chemically neutral
in structure**

No effect on
PH level Neutral,
gamma structure PH 6,5



**Chemically resistant,
Non-reactive
(strong acid/base)**

Fluoric/Hydrochloric/
Nitric/Sulfuric Acids



**High capacity of
particles
for oil absorption**

Superior oil absorption
capacity
For medical and
cosmetic applications



Bacteria Trapping

Trapping by
electrophoretic effect,
Anti-histaminic effect, etc.



Non-toxic material

Eco-friendly method
Using only high-purity raw
materials and DI water

Cosmetic Products



OSANG HEALTHCARE

OSANG Healthcare

PROFILE AND HISTORY

OSANG Healthcare

OSANG Healthcare

OSANG Healthcare (formerly known as “Infopia”) has been a leader in the Korean IVD (In-Vitro Diagnosis) industry since its founding in 1996, ever expanding a wide array of medical devices for Biochemical, Immunoassay and Molecular Diagnostics.

Giving the first priority to our customers and partners, we will further develop powerful synergies with other affiliates in the group, each an industry leader.



1996
Establishment of Infopia

2001
Selected as an “INNO-BIZ” company

2002
OEM Supply Agreement with B.Braun

2003
Acquired Korea’s first US FDA approval for BGM

2007
Listed on KOSDAQ

2011
Selected as one of the “World Class 300 Companies”

2012
Selected as a “2012 Global Hidden Champion”

2013
Acquisition of Molecular Diagnostics Division

2015
OEM Supply Agreement with HemoCue

2017
Renamed as OSANG Healthcare

2018
Developing CGMS

PRODUCTS DEVELOPMENT

OSANG Healthcare



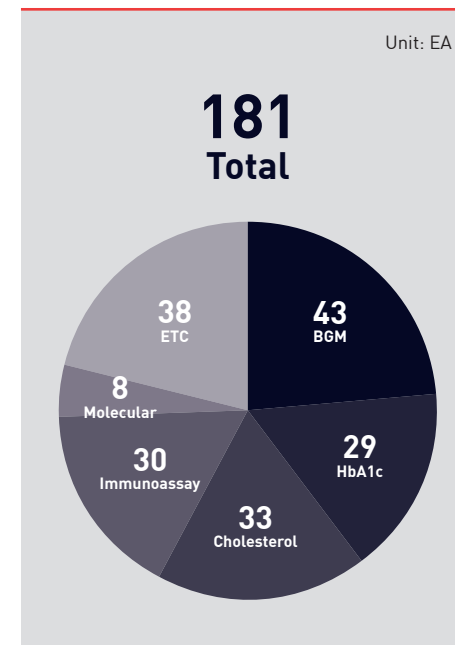
Overview of OSANG Healthcare

- Established
 - 1996
- Address
 - 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
- Homepage
 - www.osanghc.com
- Employees
 - 315 (52 R&D employees; 27 PhD and Masters' degree holders)
- Sales
 - Approx. US\$ 50 million (2018)
- R&D investment
 - 5.4%
- Patents and regulatory approvals held
 - 181
 - ISO 9001, ISO 13485; 35 US FDA certificates; 89 CE certificates; 25 CFDA certificates; 170 MFDS certificates; 2 TGA certificates; ANVISA and MDSAP certificates
 - First Korean company to receive approval from US FDA.

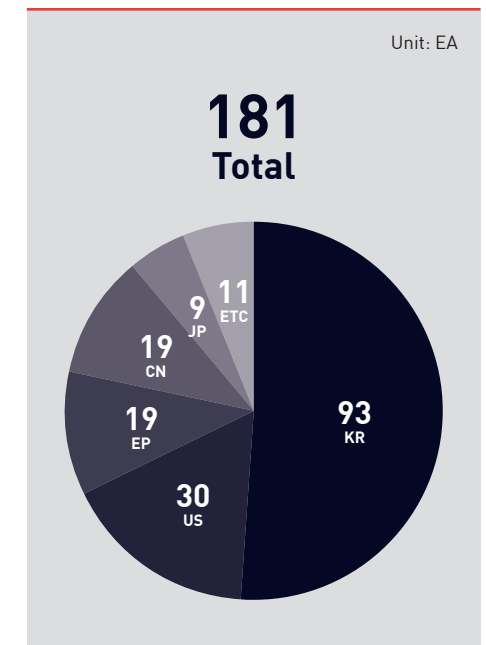
Core Technologies

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

Patents by Technology



Patents by Country



CURRENT PRODUCTS - OVERVIEW

OSANG Healthcare

BGM

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



Oh'Care



Oh'Care Lite



GluNEO



GluNEO Smart



GluNEO Lite



GluNEO Plus

HbA1c

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



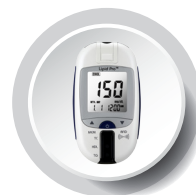
Clover A1c



Clover A1c Plus

Cholesterol

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



LipidPro



Element Multi



Landmark

Immunoassay

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



SelexOn



SelexOn-V

Molecular Diagnostics

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



PCR Kits



Nucleic Acid Extractor

CURRENT PRODUCTS

OSANG Healthcare

BGM

Product Overview

- Self monitoring of blood glucose with only a small amount of capillary blood
- The medical device essential to diabetics for blood sugar management

Competitiveness

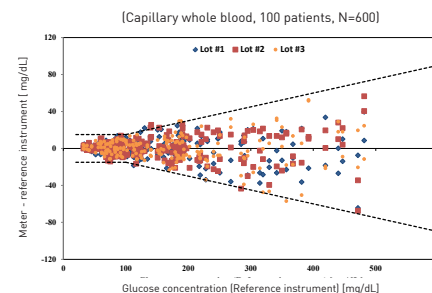
Improved performance	GDH-FAD strips in accordance with ISO 15197:2013 standard Clinically Confirmed by IDT
Technology	Patents for sales in diverse markets, including US, EU and China markets
Economic	Price competitiveness



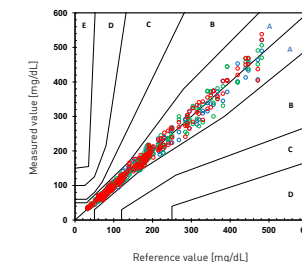
Accuracy

< 100 mg/dL	Strip Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
	Lot 1	34/62 (54.8%)	58/62 (93.5%)	62/62 (100%)
	Lot 2	35/62 (56.5%)	57/62 (91.9%)	62/62 (100%)
	Lot 3	34/62 (54.8%)	59/62 (95.2%)	62/62 (100%)
	Combined	103/186 (55.4%)	174/186 (93.5%)	186/186 (100%)
≥ 100 mg/dL	Strip Lot	Within ± 5 %	Within ± 10 %	Within ± 15 %
	Lot 1	68/138 (49.3%)	121/138 (87.7%)	136/138 (98.6%)
	Lot 2	70/138 (50.7%)	123/138 (89.1%)	135/138 (97.8%)
	Lot 3	75/138 (54.3%)	119/138 (86.2%)	135/138 (97.8%)
	Combined	213/414 (51.4%)	363/414 (87.7%)	406/414 (98.1%)
Total combined		316/600 (52.7%)	537/600 (89.5%)	592/600 (98.7%)

Absolute differences between Meter and Reference Instrument



Error grid (3 Lots combined)



CURRENT PRODUCTS

OSANG Healthcare

HbA1c Measuring System

Product Overview

- HbA1c means glycated hemoglobin
- The most useful indicator of diabetes control
- Average level of blood sugar over the past 3 months
- Reliable data—not affected by diet, medication and exercise

Competitiveness

Proven accuracy	Correlates closely to reference measurement
Easy to use	One step system: 4µl blood sample insertion → measurement → reading 5min Room temperature storage for cartridges
Reliability	IFCC and NGSP certified (w/in bias 6%) Clinically confirmed by ISALA Lab

Specifications

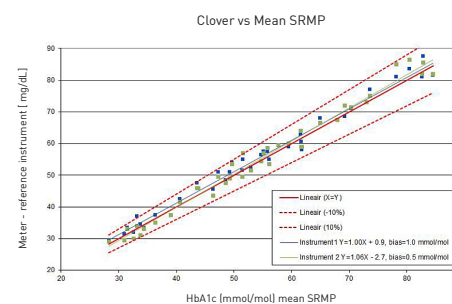
Sample type	Capillary whole blood obtained from fingertip. Venous blood with anticoagulant
Test range	20~130 mmol / mol(IFCC), 4.0~14.0% (NGSP)
Sample size / Test time	4µl / 5min.
Storage temperature	Meter: 10~35°C (36~95°F), Test Cartridge : 2~32°C (36~90°F)
Operating temperature	17~32°C (63~90°F)

Precision

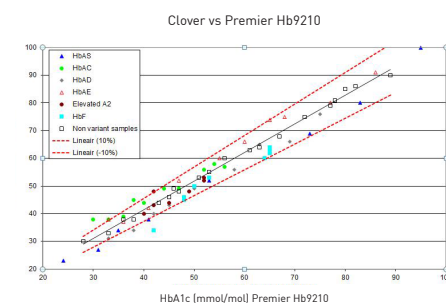
		CV (%) SI units	CV (%) DCCT units
EP-5	HbA1c 47.0 mmol/mol (6.46% DCCT)	2.9	2.0
	HbA1c 73.2 mmol/mol (8.85% DCCT)	2.2	1.6
EP-9 (duplicates)	Instrument 1	2.4	1.8
	Instrument 2	2.9	2.0

Table: Imprecision results of the Clover A1c based on the EP-5 protocol and on the duplicates in the EP-9 protocol.

Accuracy



Hb variant analysis



CLOVER A1c



HemoCue



Cartridge

Cholesterol Measuring System

Product Overview

- The essential medical device to manage metabolic syndrome
 - a risk factor for heart disease, stroke and cancer
- Preventing complications caused by metabolic syndrome through regular TG, HDL check-ups

Competitiveness

Efficiency	Measuring not only TC, TG, HDL, and LDL, but also glucose on the same meter
Easy to use	Automatic code recognition by RFID-tag Fast measurement (2 minutes) with 5µl blood sample
Portability	Handheld design suitable for POCT Anytime, anywhere testing

Lipidpro and Landmark



Cholesterol measurement

Sample Type	Capillary whole blood
Test Range	TC 100-400mg/dL (2.59-10.36mmol/L) TG 50-600mg/dL (0.57-6.78mmol/L) HDL 25-80mg/dL (0.65-2.07mmol/L) (LDL: calculated)
Sample Size	5µl
Test Time	about 2 minutes

Glucose measurement

Sample Type	Capillary whole blood
Test Range	10-600 mg/dL (0.6-33.3 mmol/L)
Sample Size	0.3µl
Test Time	3 sec

Immunoassay

Product Overview

- The essential POCT to manage various diseases
- Various biological markers

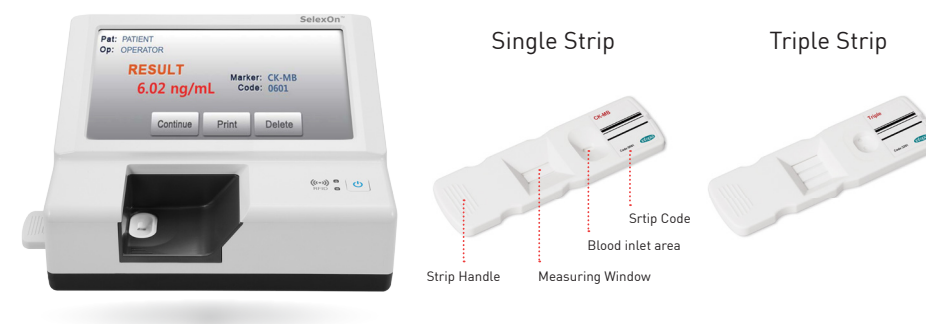
Competitiveness

Accuracy	Identification of a quantitative result within 10 minutes Clinically confirmed by Seoul Samsung Hospital in 2013
Easy to use	Automatic code recognition by RFID-tag Easy to carry and use with wide color touch screen Room temperature storage for strips
All-in-one	Measure various and multiple biomarkers on the same meter Qualitative and quantitative system

Specifications

Test Mode	Patient Test mode: 10 minutes/test, Quick Test mode: Up to 100 tests/hour
Operational Temperature	18 ~ 32°C (64 ~ 90°F)
Storage Temperature	Meter: 10-35°C (50-95°F)
Dimensions & Weight	Meter: 16.8x19x9.5cm, 0.8kg

SelexOn



Markers

• Cardiac	Myoglobin, CK-MB, Troponin I, BNP, hs-CRP, D-dimer, Triple(Myo, CK-MB, Tnl) Cardio-3(BNP, CK-MB, Tnl)
• Cancer	AFP, CEA, PSA, freePSA
• Thyroid	TSH
• Hepatitis	HBsAg, HBeAg, Anti-HBs, HCV, Hepa-Tri(HBsAg, HBeAg, HCV)
• Pregnancy	hCG
• Infection	CRP
• Influenza	Influenza A&B
• Diabetes	C-peptide, Insulin

Molecular Diagnostics

Product Overview

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

Competitiveness

S . M . A . R . T . Solution	Simple and Convenient Multiplex Assay Automation Reliable Result Time-saving & Cost-effective
Turn-key Set-up	DNA Extractor + Diagnostic Kits + Real-time PCR Machine



GeneFinder Kits



HLA-B*27 & B*51 RealAmp Kit



STD Multiplex Real-time PCR Kit



HLA-ABCD1DQ RealAmp Kit



HPV Liquid Bead MicroArray Kit (LBMA)



TB&NTM Multiplex Real-time PCR Kit

EX-MATE 32 Plus DNA Extractor



Specifications

Type	Stand-alone desktop
Number of Samples	1 ~ 32 samples
Processing Time	Within 30 minutes
Dimensions (W x D x H)	365 x 390 x 435 mm
Power Requirements	220 ~ 240v / 2A

NEW PRODUCTS

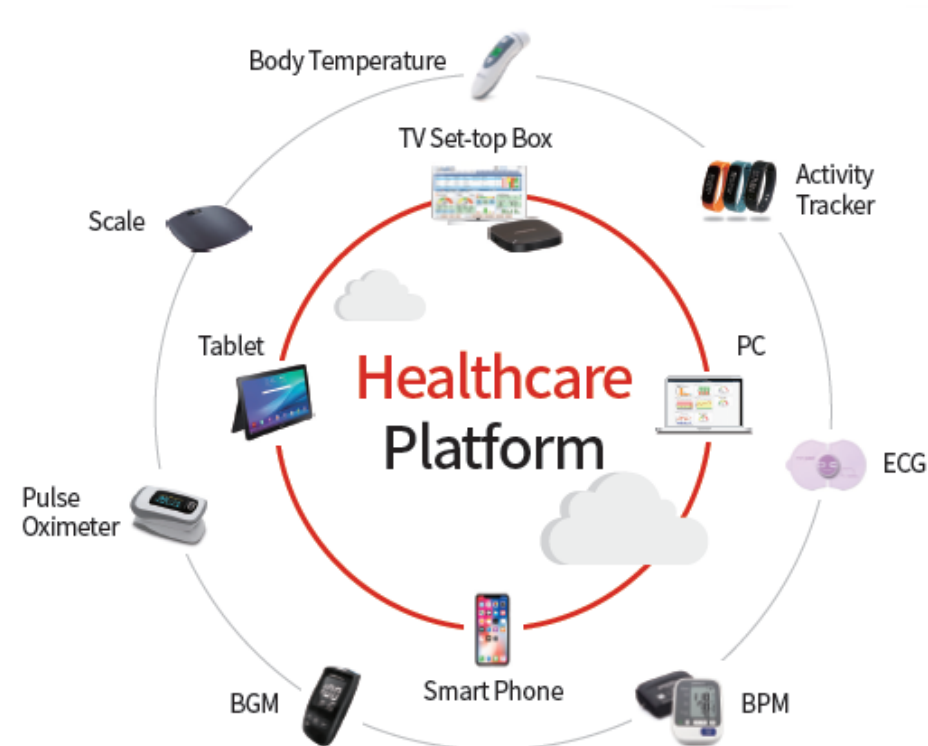
OSANG Healthcare

BGM: OTC / Home Use

- High Quality (ISO 15197:2013)
- Improved Accuracy ($\pm 15\%$ in 97%)
- Improved Hematocrit Range (20~60%)
- Reduced Interference from Oxygen and Others
- User-friendly and Aesthetically Impressive Design



Digital Healthcare Platform: Smart Healthcare



Next HbA1c Measuring System: CloverA1c Plus

Features

- Dual LED wavelength
- Increased temperature range (10 ~ 40°C)
- More data can be stored
- Error proof alert with G-sensor
- Compatible with USB memory stick
- Virtual keyboard
- Color display

Regulatory Approvals

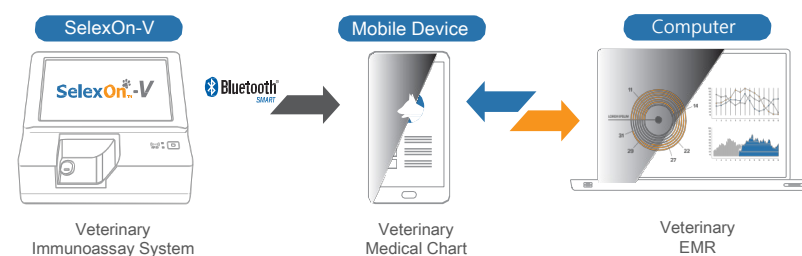
- CE Approved
- Special 510(k) and CLIA-Waiver in progress



Veterinary Immunoassay System: SelexOn-V

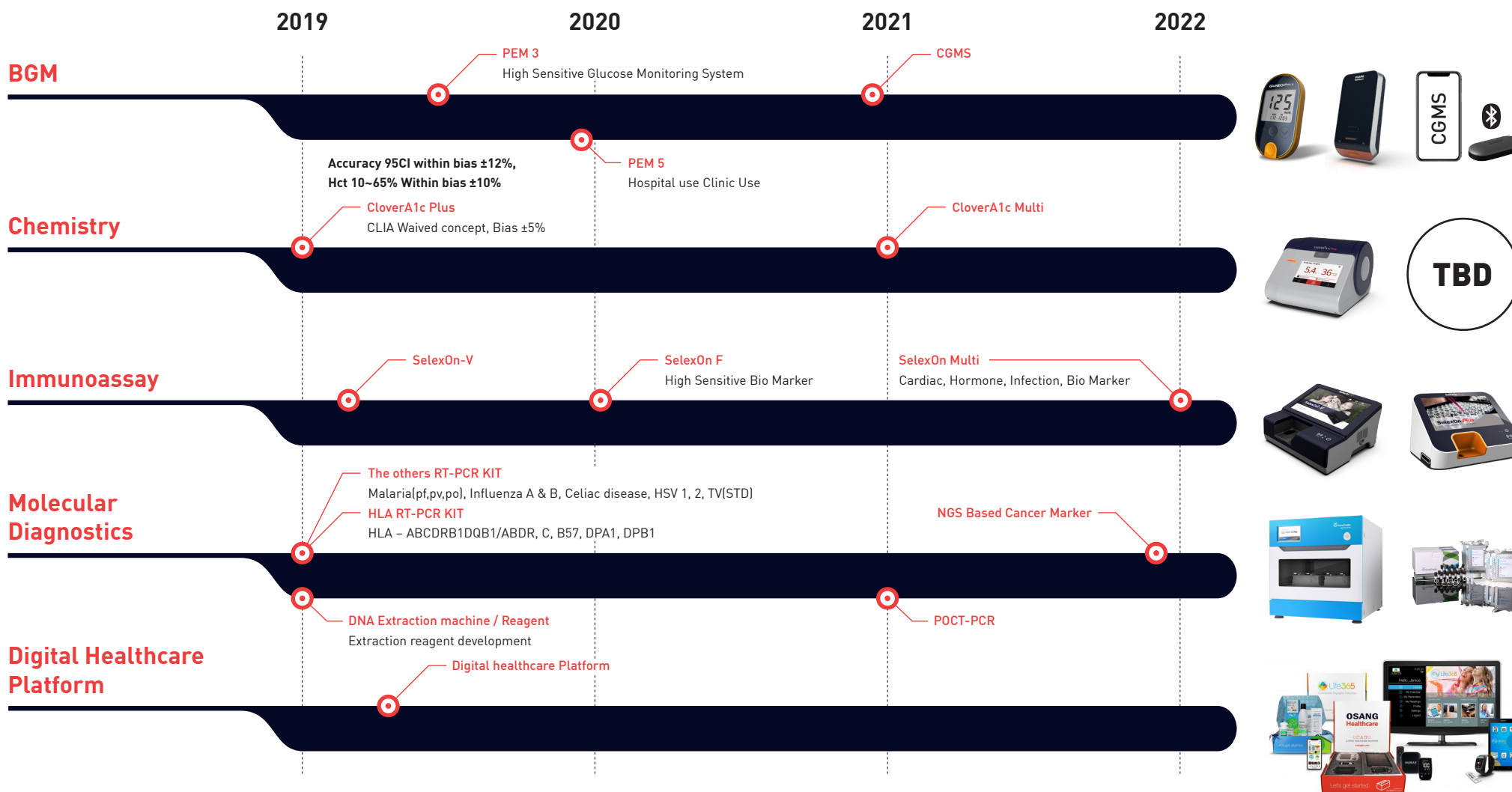
Features

- Streamlined Operation with RFID
- Accuracy and Reliability
- Quick Results
- Room Temperature for Strip Storage



PRODUCT & TECHNOLOGY ROADMAP

OSANG Healthcare

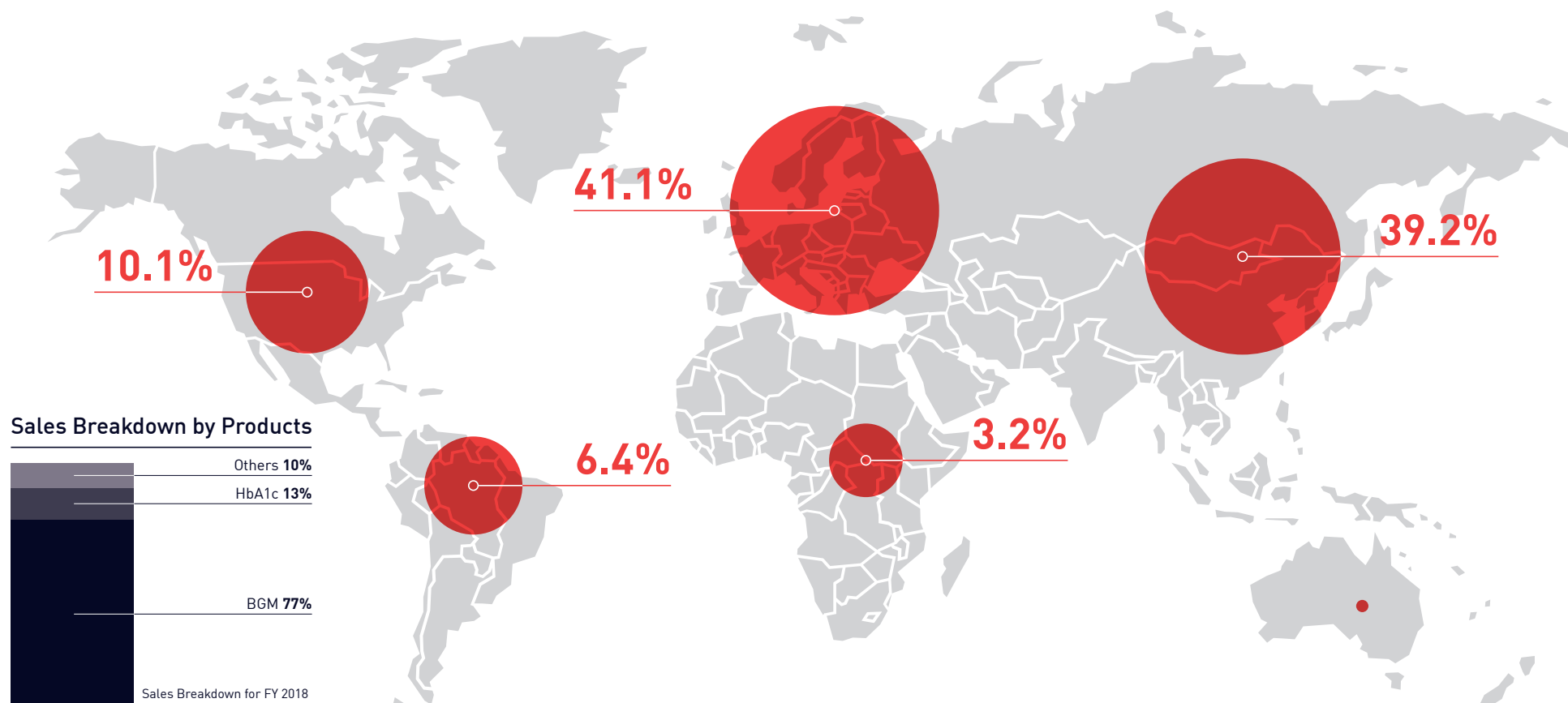


TBD

GLOBAL SALES NETWORK

OSANG Healthcare

We export our products to more than **100** countries.
Exports represent about **88%** of the total sales.



GLOBAL PARTNERS

OSANG Healthcare

Domestic



Overseas



Thank You

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

www.osanghc.com

Ref. OSCO-OSAEN01 Rev. 2019-01-02


OSANG Healthcare