SUGENTECH HAS IMPLEMENTED PERSONALIZED DIAGNOSIS AND MOBILE HEALTHCARE SYSTEM BY USING THE COMPLEMENTARY AND COMMERCIALIZED PLATFORM BASED ON BIO, NANO, AND IT CONVERGENCE TECHNOLOGY.

WE DREAM OF A LEAP FROM A LEADER IN IN-VITRO DIAGNOSTICS TO A GLOBAL HEALTHCARE GROUP THAT ACTUALIZES TIMELY AND ACCURATE DIAGNOSIS FOR PEOPLE.
WE WILL PROVIDE A HEALTHIER LIFE TO MANKIND THROUGH OUR RELIABLE DIAGNOSIS TOTAL PLATFORM.

GLOBAL IN VITRO DIAGNOSTIC TOTAL PLATFORM LEADER

GLOBAL IN VITRO DIAGNOSTIC
TOTAL PLATFORM LEADER

SUGENTECH DREAMS OF A LEAP FROM A LEADER IN
IN VITRO DIAGNOSTICS TO A GLOBAL HEALTHCARE GROUP
SO THAT PEOPLE CAN DETECT DISEASES FASTER
AND FIND THE RIGHT TREATMENT FOR THEM.

WE WILL PROVIDE A HEALTHIER LIFE TO MANKIND
THROUGH A DIGITAL HEALTHCARE DIAGNOSIS PLATFORM.

Company Introduction & History

2011~2015

2015
- Received CE mark for Pregnancy & Ovulation tests (digital, midstream, strip)

2014
- Received the Korea Biochip Society Technology Award
- Obtained GMP certification
- Digital Ovulation Test US FDA registered

2013
- Obtained ISO 13485:2016 certification by TÜV SÜD
- Obtained a medical device manufacturing license in Korea

2011
- Registered as 28th INNOPOLIS Research Institute Spin-off by Ministry of Science & ICT, Korea
- Established Sugentech, Inc., Technology transfer from ETRI (Korea public research institute)

2016~2020

2020
- Listed in CE
  - SGTi-flex COVID-19 IgM/IgG
  - SGTi-flex COVID-19 IgG
  - SGTi-flex COVID-19 Ag
  - SGTi-Allergy Screen(Inhalant, Food, Combined)
  - SGT Anti-SARS-COV-2 Total Ab ELISA
- Approved by the FDA (EUA)
  - SGTi-flex COVID-19 IgG

2019
- Listed on KOSDAQ (Korea Stock Market)

2018
- Designated as "Export Promising Small and Medium Business" by the Ministry of SMEs and Startups
- Designated as a lead company from "Bio industry core technology development project" by Ministry of Trade and Industry

2017
- Designated as "K-Brain Power" by Ministry of Trade and Industry
- Acquisition of K-MAC BIO CENTER Corp.

2016
- Listed on KONEX(Korea New Exchange)
- Received CE mark for INCLIX POCT analyzer and the tests
- Pregnancy Test(digital, strip) US FDA 510(k) cleared
- Contract with Dong-A Pharmaceutical for pregnancy test

2020~Present

2022
- Obtained MDSAP certification
- Listed in CE
  - Surearly™ SMART Pregnancy DUO
  - Surearly™ SMART Ovulation DUO
  - Surearly™ SMART Menopause DUO
  - SGTi-flexM COVID-19 & Flu A/B Ag
  - INCLIX™ TRF Troponin I(AMI IVD)
- Approved by Korea MFDS
  - Type 1 diabetes diagnostic kit
- Approved by ANVISA (Brazil)
  - SGTi-flex COVID-19 Ag (Self test)
- Approved by Health Canada
  - SGTi-flex COVID-19 Ag

2021
- Received CE mark for self-testing
  - SGTi-flex COVID-19 IgM/IgG
  - SGTi-flex COVID-19 IgG
  - SGTi-flex COVID-19 Ag
- Listed in CE
  - SGTi-flex COVID-19 & Flu A/B Ag DUO
  - SGT SARS-CoV-2 In Vitro Neutralizing Antibody Test (IVnAT)
  - S-Blot(Immunoblot automation system for Allergy test)

Awards

2018
- Received the "Minister of Trade, Industry and Energy Award" at the Korea Technology Awards

2017
- Awarded the Chairman's Commendation by the National Assembly Health and Welfare Committee
- Received the grand prize of the 2017 Korea First Brand Award

2015
- Awarded the Minister of Science and Technology Information and Communication

2014
- Received the Korea Biochip Society Technology Award

2012
- Received Frost & Sullivan Technology Innovation Award for Ampli&Array technology
- Established Sugentech, Inc., Technology transfer from ETRI (Korea public research institute)

BIO·NANO TECHNOLOGY

We have biotechnology and experience in developing various types of high-level antibodies, such as structure-specific antibodies, antibodies that distinguish microstructural differences, and neutralizing antibodies used for biopharmaceutical analysis.

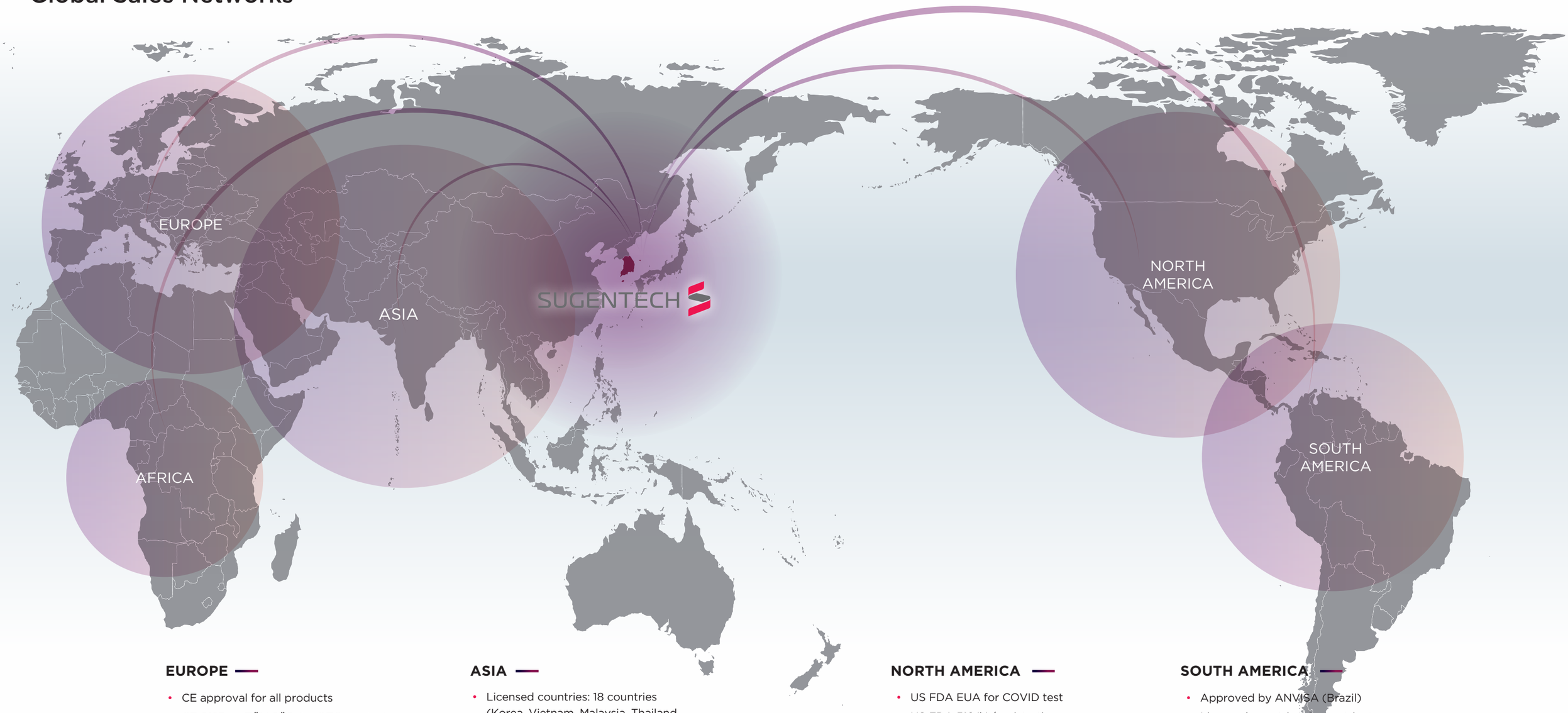
- **Antibody**
  - Antibody Development Technology
  - Antibody Production Using Serum-free Suspension Culture
- **Immunoassay Rapid Diagnosis Technology**
  - Fluorescence Quantitative Analysis and High-sensitivity Time-resolved Fluorescence Analysis Technology
  - Multiplexed Immunoblot
  - Enzyme immunoassay technology
- **Nanoparticle**
  - Gold Nanoparticle
  - Fluorescent Particle

PLATFORM TECHNOLOGY

We have developed and commercialized the multi-immunoblot automation system used in general hospitals and medical examination centers, the on-site diagnosis system used in small and medium-sized hospitals, and the mobile diagnosis system used by individuals at home.

- **Micro & Low Power Analysis System**
- **Time-resolved Fluorescence (TRF)**
- **Liquid Level Detection (LLD)**
- **Automation System**

Global Sales Networks



EUROPE

- CE approval for all products
- CE 0123 by TÜV SÜD for OTC products
- Licensed countries: 27 countries including member states of the EU (Germany, Spain, Switzerland, Austria, Belgium, Poland, etc.)

CE

ASIA

- Licensed countries: 18 countries (Korea, Vietnam, Malaysia, Thailand, Singapore, Philippines, India, Indonesia, UAE, Saudi Arabia, Kuwait, Bahrain, Turkey, Russia, etc.)

Ministry of Food and Drug Safety

NORTH AMERICA

- US FDA EUA for COVID test
- US FDA 510(k)/registration for digital fertility tests
- Health Canada Approval for COVID test
- Licensed countries: 4 countries (USA, Canada, Dominican Republic, Mexico)

SOUTH AMERICA

- Approved by ANVISA (Brazil)
- Licensed countries: 8 countries (Brazil, Bolivia, Argentina, Ecuador, Chile, Colombia, Peru, Brazil)

Agência Nacional de Vigilância Sanitária

AFRICA

- Licensed countries: 2 countries (Nigeria, South Africa)

Table of Contents

COVID-19
DIAGNOSTICS

Rapid and Accurate POCT & OTC for COVID-19 Diagnostics that allows for detection of acute to convalescent phase.

Antigen & Antibody Rapid Test

- SGTi-flex COVID-19 Ag
- SGTi-flex COVID-19 & Flu A/B Ag
- SGTi-flex COVID-19 IgM/IgG
- SGTi-flex COVID-19 IgG

ELISA Lab Test

- SGT Anti-SARS-CoV-2 Total Ab ELISA
- SGT SARS-CoV-2 In Vitro Neutralizing Ab Test (IVnAT)

SGTi-flex COVID-19 Ag

SGTi-flex COVID-19 Ag is an immunoassay for qualitative detection of Nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal and nasal swab specimen. The SGTi-flex COVID-19 Ag can detect the SARS-CoV-2 variants such as Alpha, Beta, Gamma, Kappa, Delta, Epsilon and Omicron.

Product Specification

Test type	Professional use
Sample type	Nasopharyngeal swab, Nasal swab
Sample volume	3 drops
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control swab and negative control swab
Certificate	CE

Clinical Data

	Sensitivity	Specificity
Ag	95.07%	99.38%
LOD (Limit of Detection)	3.5×10^2 $TCID_{50}$/mL	

Order Information

Product	Pack Size	Cat. No.
SGTi-flex COVID-19 Ag	25 Tests	CAGT025E0

SGTi-flex COVID-19 Ag(Self-testing)

SGTi-flex COVID-19 Ag(Self-testing) is an immunoassay for qualitative detection of SARS-CoV-2 antigens from nasal swab specimens.

Product Specification

Test type	Self-testing use
Sample type	Nasal swab
Sample volume	3 drops
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control swab and negative control swab
Certificate	CE0123 (Certified by TÜV SÜD)

Clinical Data

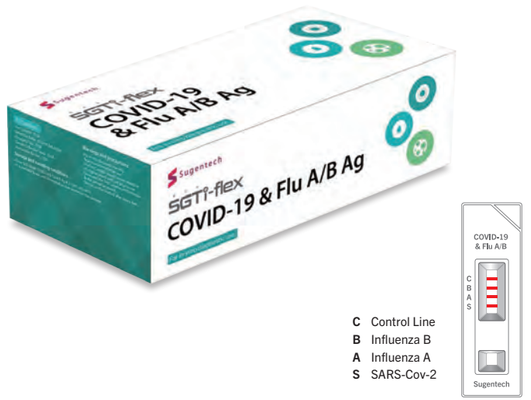
	Sensitivity	Specificity
Ag	95.06%	99.29%
LOD (Limit of Detection)	3.5×10^2 $TCID_{50}$/mL	

Order Information

Product	Pack Size	Cat. No.
SGTi-flex COVID-19 Ag (Self-testing)	1 Test	CAGT001E0
	2 Tests	CAGT002E0
	5 Tests	CAGT005E0

SGTi-flex COVID-19 & Flu A/B Ag

SGTi-flex COVID-19 & Flu A/B Ag is an immunoassay for simultaneous qualitative detection of SARS-CoV-2, Influenza virus A and/or influenza B in nasopharyngeal swab specimen. Intended for use by trained laboratory personnel or healthcare professionals.



Product Specification

Test type	Professional use
Sample type	Nasopharyngeal swab
Sample volume	3 drops
Testing time	15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive or negative control swabs for influenza A, influenza B or SARS-CoV
Certificate	CE

Clinical Data

	Sensitivity	Specificity
COVID-19	91.00%	100.00%
Influenza A	92.50%	100.00%
Influenza B	91.25%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGTi-flex COVID-19 & Flu A/B Ag	25 Tests	CFGC025E

SGTi-flexM COVID-19 & Flu A/B Ag

SGTi-flex COVID-19 & Flu A/B Ag is an immunoassay for simultaneous qualitative detection of SARS-CoV-2, Influenza virus A and/or influenza B in nasopharyngeal swab specimen. Intended for use by trained laboratory personnel or healthcare professionals.

Product Specification

Test type	Professional use
Sample type	Nasopharyngeal swab
Sample volume	3 drops
Testing time	15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive or negative control swabs for influenza A, influenza B or SARS-CoV
Certificate	CE

Clinical Data

	Sensitivity	Specificity
COVID-19	91.00%	100.00%
Influenza A	92.50%	100.00%
Influenza B	91.25%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGTi-flexM COVID-19 & Flu A/B Ag	25 Tests	CFNC025E

SGTi-flex COVID-19 IgM/IgG

SGTi-flex COVID-19 IgM/IgG Test is an immunoassay for qualitative detection of IgM or IgG antibodies to COVID-19 in human whole blood, serum or plasma.

Product Specification

Test type	Professional use
Sample type	Whole blood (finger, venous), Serum, Plasma
Sample volume	10 µL
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control and negative control
Certificate	CE

Clinical Data

	Sensitivity	Specificity
IgM/IgG	94.48%	98.33%
IgM	90.80%	98.33%
IgG	90.18%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGTi-flex COVID-19 IgM/IgG	25 Tests	COVT025E
SGTi-flex COVID-19 IgM/IgG (lancet, alcohol swab, blood pippette included)	5 Tests	COVT005E

SGTi-Self COVID-19 IgM/IgG (Self-testing)

SGTi-flex COVID-19 IgM/IgG Test is an immunoassay for qualitative detection of IgM or IgG antibodies to COVID-19 in human fingerstick whole blood.

Product Specification

Test type	Self-testing use
Sample type	Fingerstick whole blood
Sample volume	10 µL
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control and negative control
Certificate	CE0123 (Certified by TÜV SÜD)

Clinical Data

	Sensitivity	Specificity
IgM/IgG	94.48%	98.33%
IgM	90.80%	98.33%
IgG	90.18%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGTi-Self COVID-19 IgM/IgG (lancet, alcohol swab, blood pipette included)	5 Tests	COST005E

SGTi-flex COVID-19 IgG

The SGTi-flex COVID-19 IgG is a lateral flow immunoassay intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, venous whole blood, plasma, and fingerstick whole blood.

Product Specification

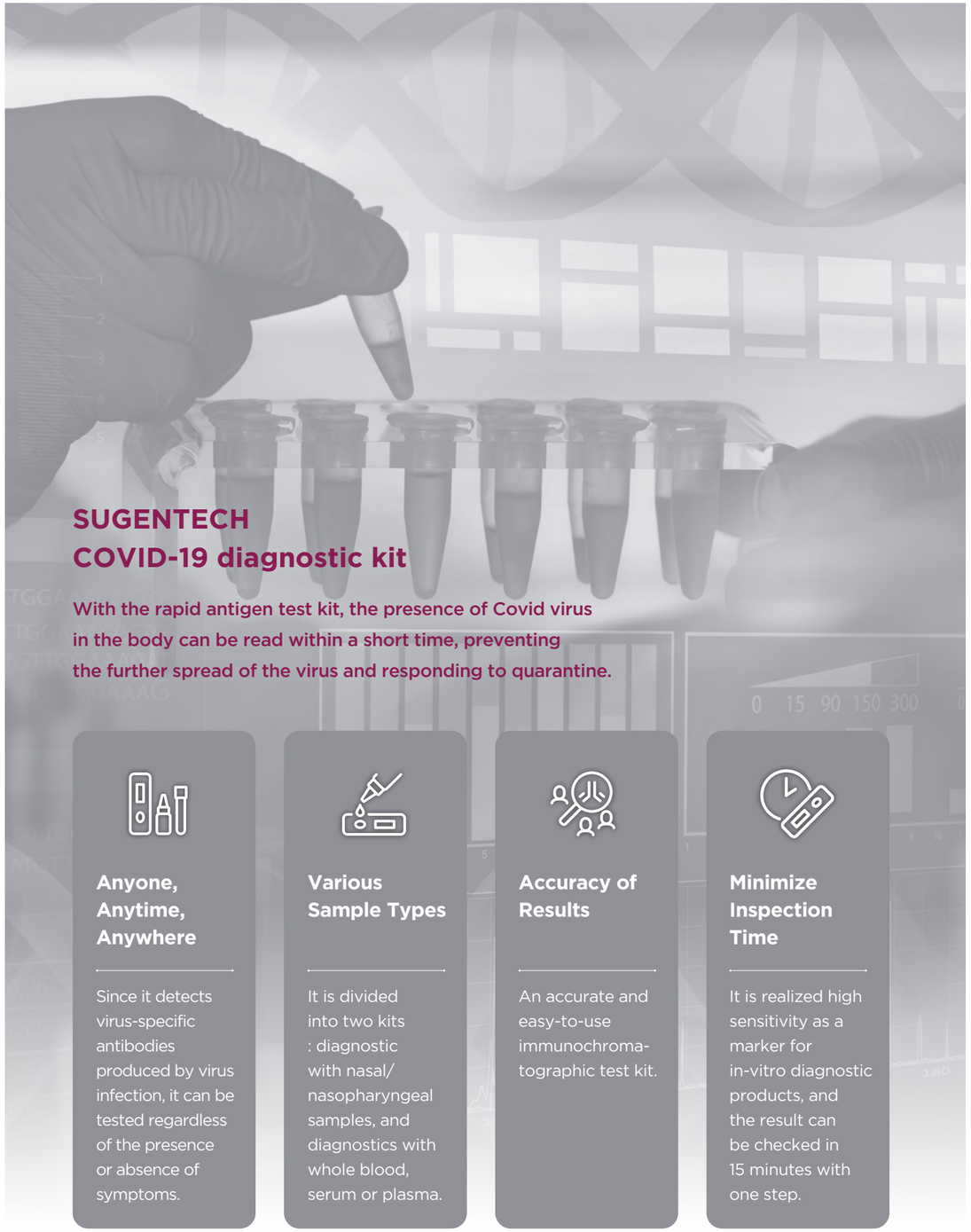
Test type	Professional use
Sample type	Whole blood (finger, venous), Serum, Plasma
Sample volume	10 µL
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control and negative control
Certificate	US FDA Emergency Use Authorized, CE

Clinical Data

	Sensitivity	Specificity
IgG	92.43%	99.15%

Order Information

Product	Pack Size	Cat. No.
SGTi-flex COVID-19 IgG	25 Tests	COGT025E
SGTi-flex COVID-19 IgG (lancet, alcohol swab, blood pipette included)	5 Tests	COGT005E



SUGENTECH
COVID-19 diagnostic kit

With the rapid antigen test kit, the presence of Covid virus in the body can be read within a short time, preventing the further spread of the virus and responding to quarantine.

Anyone, Anytime, Anywhere

Since it detects virus-specific antibodies produced by virus infection, it can be tested regardless of the presence or absence of symptoms.

Various Sample Types

It is divided into two kits : diagnostic with nasal/ nasopharyngeal samples, and diagnostics with whole blood, serum or plasma.

Accuracy of Results

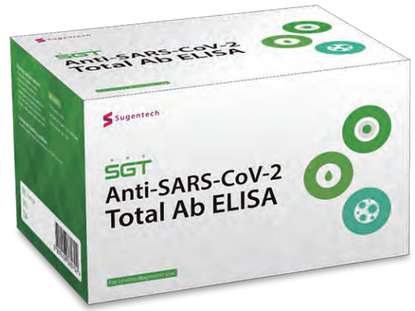
An accurate and easy-to-use immunochroma-tographic test kit.

Minimize Inspection Time

It is realized high sensitivity as a marker for in-vitro diagnostic products, and the result can be checked in 15 minutes with one step.

SGT Anti-SARS-CoV-2 Total Ab ELISA

SGT Anti-SARS-CoV-2 Total Ab ELISA is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for the qualitative detection of total antibodies (IgM/IgA/IgG) to SARS-CoV-2 in human serum and plasma.



Product Specification

Test type	Professional use
Sample type	Serum, Plasma
Sample volume	10 µL
Operating hours	Incubation: 90±5 minutes Washing: 20-30 seconds x 5 Substrate solution: 30±1 minutes Measurement: within 1 hour
Storage temperature	2-8°C
Shelf life	Before opening : 6 Months After opening : 4 weeks
Quality control material	positive control and negative control
Certificate	CE

Clinical Data

	Sensitivity	Specificity
Total Ab	100.00%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGT Anti-SARS-CoV-2 Total Ab ELISA	1kit of 96 well	COVE001E

SGT SARS-CoV-2 In Vitro Neutralizing Ab (IVnAT)

The SGT SARS-CoV-2 In Vitro Neutralizing Antibody Test (IVnAT) is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for qualitative detection of neutralizing antibodies to SARS-CoV-2 in human serum and plasma.

Product Specification

Test type	Professional use
Sample type	Serum, Plasma
Sample volume	60 µL
Operating hours	Incubation: 30 minutes Incubation after adding pre-reacted mixture: 15±1 minutes Washing: 20-30 seconds x 5 Substrate solution: 15±1 minutes Measurement: within 1 hour
Storage temperature	2-8°C
Shelf life	Before opening : 6 Months After opening : 4 weeks
Quality control material	positive control and negative control
Certificate	CE

Clinical Data

	Sensitivity	Specificity
IVnAT	95.90%	100.00%

Order Information

Product	Pack Size	Cat. No.
SGT SARS-CoV-2 In Vitro Neutralizing Antibody Test (IVnAT)	1kit of 96 well	CONE001E

LAB TEST

Full and Semi Automation systems for Multiplex Immunoblot Assays

Sugentech provides the optimized automation solutions including sample barcode identification,
LIS connectivity, reagent dispensing, incubation, washing, drying and analysis for diagnostic laboratories.

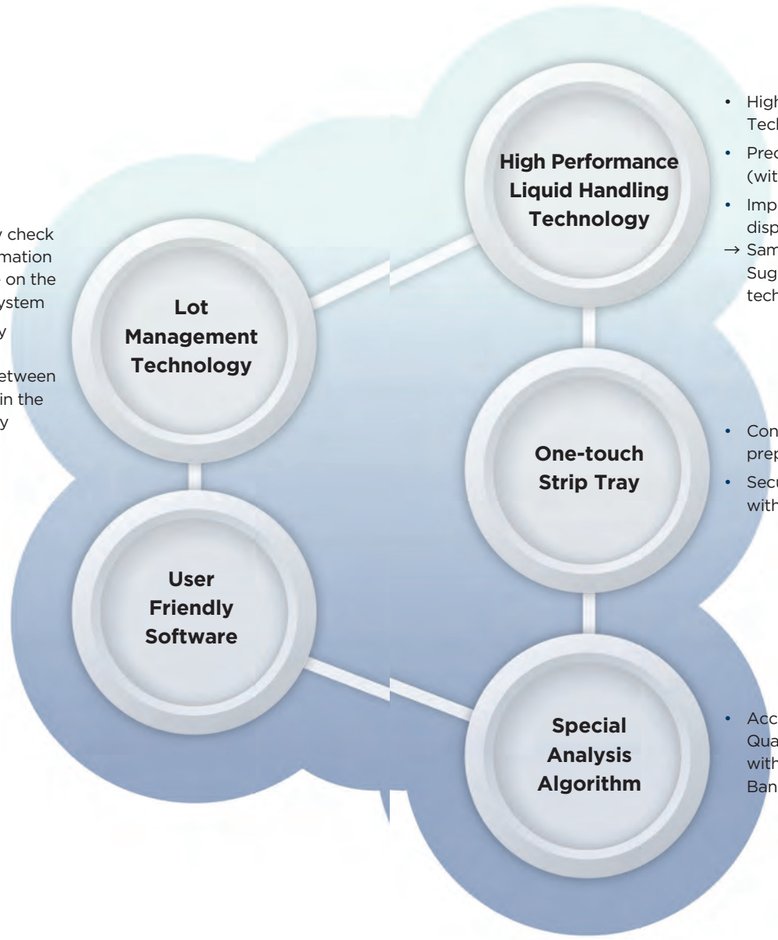
- Clinical automation solutions
  S-Blot Series
- Total Solution for Allergy Blood Test
  SGTi-Allergy Screen

S-Blot Series

S-Blot 3
(Full Automation)

Manual to Full automation
Depends on market situations

- **Unique and Special analysis algorithm**
  - Accuracy and Quantitation with Multiplex Band Analysis
- **Liquid level detection**
  - Essential technology of a fully automated analysis system High sensitivity sample detection(cLLD&pLLD)
- **Automation technology**
  - Over 13 years of R&D for automation technology
- **User Friendly Software**



- Automatically check product information with QR code on the automation system
- Systematically management of variation between Lot to maintain the highest quality at all times

- High Sensitivity Detection Technology (cLLD, pLLD)
- Precise dispensing (within 5% CV)
- Improving sample dispensing accuracy
  → Sample holder as applied Sugentech's patented technology (patent 10-1999604)

- Convenient sample preparation
- Securing stability with hook type strip

- Accuracy and Quantitation with Multiplex Band Analysis

▸ Technical Specifications

Analysis	**Camera**	High resolution Camera
	Capacity	Sample 48ea / Test Strip 48ea
	No. of Reagent	Incubation, Washing, Enzyme, Substrate, STOP Sol., DI Water
Sample	**Sample Tube**	Tube Diameter 13mm ~ 16mm
	LLD & Detection	Error Rate 1% ↓, retry rate 3% ↓, Clot & Bubble Detection
	Barcode Reader	Code 39, Code 128, Codebar, Interleaved 2 of 5 / Error (1% ↓, Sequence /1 retry)
Dimensions	**Width x Depth x Height**	870mm X 540mm X 565mm
	Weight	Approx. 80kg

S-Blot 2
(Semi Automation)

- **Unique and Special analysis algorithm**
  - Accuracy and Quantitation with Multiplex Band Analysis
- **Minimal maintenance and maximal conveniences**
- **Optimized system for customers**
- **User Friendly Software**

▸ Technical Specifications

Analysis	**Camera Resolution**	1600 X 1200pixel (2mega pixel)
	Capacity	Test Strip 48ea
	No. of Reagent	Incubation, Washing, Enzyme, Substrate, STOP Sol., DI Water
System	**Dispensing Accuracy(pump)**	Within 500μL < ±10%
	Incubation Method	Tray Rocking
	Drying Method	Heater with Blower fan
Dimensions	**Width x Depth x Height**	900mm X 490mm X 580mm
	Weight	75kg

SGTi-Allergy Screen

SGTi-Allergy Screen is an immunoblotting method in vitro diagnostic medical device for semi-quantitative determination of allergen-specific immunoglobulin E (IgE) for inhalation and food in human serum or plasma (Li-Heparin, Na-Citrate).

CE

Ministry of Food and Drug Safety

Small Sample Volume, More Allergens, Easier to Use

- **Small sample volume (50ul)** - Advantages of pediatric patients
- **High coverage of 102 common allergens**
  - Inhalant panel 50 types, Food panel 52 types
- **QR Code management** - Managing the lot variation
- **Easier to use** - One touch strip tray & Fully automated process

▸ Product Specification

Test name	Allergy Test (Human)
Principal	Multiple Allergen Simultaneous Test (Line Immuno-assay)
Type of panel	Food, Inhalant panel
Sample type	Serum or plasma
Test time	~ 4 hours / 48 tests at a time in full automation process
Storage	2 ~ 8°C
Period of validity	18 months
Packaging	24 Tests/Kit
Compositions	· Test Strip · Test Solutions(Sample Diluent, Antibody, Enzyme, Substrate, Washing) · Test ID QR code
Device	Manual, S-Blot 2, S-Blot 3

COMBINED Panel

INHALANT Panel

Total IgE	Aspergillus fumigatus5
House dust mite(D.p)	Candida albicans
House dust mite(D.f)	Alternaria alternata
Acarus siro	Alder
Storage mite (T.p)	Birch
Cat	Hazel
Horse	Oak White
Dog	Olive tree
Guinea pig	Sycamore
Mouse	Goat willow
Rabbit	Cottonwood
Hamster	Ash tree
Sweet vernal grass	Pine
Bermuda grass	Japanese cedar
Orchard grass	Acacia
Timothy grass	Cypress
Redtop, Bent grass	Ragweed, common
Rye	Mugwort
House dust	Oxeye daisy
Honey bee	Dandelion
Yellow jacket, wasp	English Plantain
Cockroach	Russian thistle
Latex	Goldenrod
Penicillium notatum	Pigweed
Cladosporium herbarum	Japanese hop

FOOD Panel

Egg White	Hazelnut
Milk	Yeast, baker
Cheddar cheese	Peach
Soy bean	Apple
Carrot	Strawberry
Tomato	Orange
Garlic	Mango
Onion	Kiwi
Wheat	Banana
Rice	Shrimp
Maize	Lobster
Potato	Scallop
Barley	Codfish
Cucumber	Crab
Buckwheat	Salmon
Sesame	Tuna
Celery	Squid
CCD	Blue mussel
Pork	Oyster
Beef	Clam
Chicken	Mackerel
Lamb	Anchovy
Cacao	Pine nut
Peanut	Sunflower seed
Almond	Eel
Walnut	Plaice

POCT TEST

Intelligent, Reliable, Compact
TRF(fluorescence) Immunoassay
for Point-of-Care Testing

Analyzer

- INCLIX F-100
  INCLIX F-9600 (coming)

Test Items

- Cardiovascular Disease
- Inflammation
- Diabetic, Renal Disease
- Hormone
- Respiratory Disease
- Other

INCLIX F-100

INCLIX F-100 is a Time-Resolved Fluorescence immunoassay analyzer both for quantitative and qualitative measurement of various biomarkers, such as cardiovascular disease, infectious disease, cancer, diabetes, allergy, etc. with high accuracy and sensitivity. It provides Point-Of-Care Testing (POCT) at patient care settings or clinical laboratories with high accuracy and sensitivity.

Key Features

- High performance by TRF
- Easy-to-use, user-friendly interface
- Quantitative Analysis (Standard & Quick Dual Mode)
- Convenient Internal Quality Control
- Portable & compact Portable
- Automatic Power Saving
- Rechargeable Built-in Battery
- LIS/HIS compatible

Product Specification

Test method	Fluorescent immunoassay (FIA) / TRF(Time-Resolved Fluorescence)
Analysis	Quantitative / Qualitative tests
Data management	10,000 Patients
Test mode	Standard / Quick
Power	AC/DC Adapter, 12Vdc, 3.3A, 40W
Inner battery	Rechargeable Lithium-ion battery 5,200mAh
Display	5” Color LCD touch screen
I/O Interface	2 USB2.0
Printer	Built-in
Connectivity / Data export	LIS / Excel, SAM, PDF files
Accessories	Mouse/Keyboard, USB to Ethernet module or WiFi dongle
Dimensions	117 x 250 x 118 mm (4.60 x 9.84 x 4.65 in.)
Weight	1.0 kg (35.3oz)

INCLIX F hsCRP

INCLIX F hsCRP is for quantitative determination of high-sensitivity C-reactive protein (hsCRP) in serum, plasma and whole blood. The test is used as an aid to monitor risk of cardiovascular disease.

Product Specification

Sample type	Whole blood (finger, venous), Serum, Plasma
Sample volume	5 µL
Testing time	3 minutes
Measuring range	0.1 – 10 mg/L
Reference range	< 1 mg/L
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F) Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX F hsCRP	25 Tests	HCRF025E

INCLIX F D-dimer

INCLIX F D-dimer is for quantitative determination of D-dimer in plasma and whole blood to help eliminate the possibility of thrombosis or diagnose acute diseases associated with thrombosis.

Product Specification

Sample type	Whole blood, Plasma
Sample volume	50 µL
Testing time	12 minutes
Measuring range	50 – 10,000 ng/mL
Reference range	500 ng/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F) Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX F D-dimer	25 Tests	DIMF025E

INCLIX TRF Troponin I

INCLIX TRF Troponin I is for quantitative determination of Troponin I (TnI) in serum and plasma. The test is used as an aid to diagnose acute myocardial infarction (AMI).

Product Specification

Sample type	Serum, Plasma
Sample volume	80 µL
Testing time	15 minutes
Measuring range	0.05 – 20 ng/mL
Reference range	0.3 ng/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	No detection buffer
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF Troponin I	25 Tests	TPIF025E

INCLIX TRF CK-MB

INCLIX TRF CK-MB is for quantitative determination of Creatine Kinase MB (CK-MB) isoenzyme in serum, plasma, and whole blood. The test is used as an aid to diagnose Acute Myocardial infarction (AMI) and Acute Coronary Syndrome (ACS)

Product Specification

Sample type	Whole blood, Serum, Plasma
Sample volume	40 µL
Testing time	12 minutes
Measuring range	2.5 – 100 ng/mL
Reference range	5 ng/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF CK-MB	25 Tests	CKMF025E

INCLIX TRF Myoglobin

INCLIX TRF Myoglobin is for quantitative determination of Myoglobin in serum, plasma, and whole blood. The test is used as an aid to diagnose Acute Myocardial infarction (AMI).

Product Specification

Sample type	Whole blood, Serum, Plasma
Sample volume	10 µL
Testing time	12 minutes
Measuring range	5 – 500 ng/mL
Reference range	58 ng/mL (50 - 70 ng/mL)
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF Myoglobin	25 Tests	MYOF025E

INCLIX F CRP

INCLIX F CRP is for quantitative determination of C-reactive protein (CRP) in serum, plasma and whole blood. The test is used as an aid to detect bacterial or viral infection and to monitor a progression for inflammation.

Product Specification

Sample type	Whole blood (finger, venous), Serum, Plasma
Sample volume	5 µL
Testing time	5 minutes
Measuring range	0.5 – 200 mg/L
Reference range	<5 mg/L
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF CK-MB	25 Tests	CRPF025E

INCLIX TRF PCT

INCLIX TRF PCT is for quantitative determination of Procalcitonin (PCT) in serum and plasma. The test is useful in the diagnosis of bacterial infection and sepsis.

Product Specification

Sample type	Serum, Plasma
Sample volume	80 µL
Testing time	10 minutes
Measuring range	0.1 – 100 ng/mL
Reference range	0.5 ng/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	No Detection Buffer
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF PCT	25 Tests	PCTF025E

INCLIX F HbA1c

INCLIX F HbA1c is for quantitative determination of glycated hemoglobin (HbA1c) in whole blood. The test is used as an aid to diagnose diabetes and for monitoring long-term glycemic control in patients with diabetes.

Product Specification

Sample type	Whole blood (finger, venous)
Sample volume	5 µL
Testing time	12 minutes
Measuring range	4.0 – 14.0 %
Reference range	4.0 - 6.5%
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE, NGSP

Order Information

Product	Pack Size	Cat. No.
INCLIX F HbA1c	25 Tests	HBAF025E

INCLIX F Microalbumin

INCLIX F Microalbumin is for quantitative determination of Microalbumin in human urine. The test is used as an aid to monitor early signs of kidney damage in people who are at risk of developing kidney disease.

Product Specification

Sample type	Urine
Sample volume	5 µL
Testing time	10 minutes
Measuring range	2-300 mg/L
Reference range	<20 mg/L
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX F Microalbumin	25 Tests	ACRF025E

INCLIX TRF TSH

INCLIX TRF TSH is for quantitative determination of Thyroid Stimulating Hormone (TSH) in serum and plasma.
The test is used as an aid to assessment and monitoring of thyroid function.

Product Specification

Sample type	Serum, Plasma
Sample volume	40 µL
Testing time	15 minutes
Measuring range	0.1 – 100 µIU/mL
Reference range	0.4 – 4.0 µIU/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF TSH	25 Tests	TSHF025E

INCLIX F T3

INCLIX F T3 is for quantitative determination of T3 in serum or plasma. The test is used an aid to monitor risk of thyroid disease.

Product Specification

Sample type	Serum, Plasma
Sample volume	100 µL
Testing time	10 minutes
Measuring range	0.5 - 5.0 ng/mL
Reference range	0.8 – 2.0 ng/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX F T3	25 Tests	TRIF025E

INCLIX F T4

INCLIX F T4 is for quantitative determination of T4 in serum or plasma. The test is used an aid to monitor risk of thyroid disease.

Product Specification

Sample type	Serum, Plasma
Sample volume	75 µL
Testing time	10 minutes
Measuring range	0.5-20 µg/dL
Reference range	4.5 – 12.0 µg/dL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX F T4	25 Tests	TETF025E

INCLIX TRF ß-hCG

INCLIX TRF ß-hCG is for quantitative determination of ß-human chorionic gonadotropin (ß-hCG) in serum, plasma and whole blood. The test is used as an aid to diagnose early pregnancy.

Product Specification

Sample type	Whole blood, Serum, Plasma
Sample volume	40 µL
Testing time	15 minutes
Measuring range	10 – 20,000 mIU/mL (Serum, Plasma) 10 – 10,000 mIU/mL (Whole Blood)
Reference range	10 mIU/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF ß-hCG	25 Tests	BCGF025E

INCLIX TRF COVID-19 Ag

INCLIX TRF COVID-19 Ag is a lateral flow immunoassay for qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal and nasal swab specimen. The test is used as an aid in the rapid diagnosis of SARS- CoV-2 viral infections. The INCLIX TRF COVID-19 Ag is intended for use by trained laboratory personnel or healthcare professionals.

Product Specification

Sample type	Nasopharyngeal swab, Nasal swab
Sample volume	3 drops
Testing time	15 minutes
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Extraction Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Clinical Data

	Sensitivity	Specificity
Nasopharyngeal	91.00%	100%
Nasal	88.57%	100%

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF COVID-19 Ag	25 Tests	CAFF025E

INCLIX TRF COVID-19 & Flu A/B Ag

INCLIX TRF COVID-19 & Flu A/B Ag is an immunoassay for the qualitative detection of SARS-CoV-2, Influenza A and/or influenza B directly from nasopharyngeal swab specimens. Intended for use by trained laboratory personnel or healthcare professionals.

Product Specification

Sample type	Nasopharyngeal swab
Sample volume	3 drops
Testing time	15 minutes
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Extraction Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Clinical Data

Clinical Data	Sensitivity	Specificity
SARS CoV-2	91.00%	100%
Flu A	93.75%	100%
Flu B	92.50%	100%

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF COVID-19 & Flu A/B Ag	25 Tests	CFFF025E

INCLIX TRF Adeno & Flu A/B Ag

INCLIX TRF Adeno & Flu A/B Ag is an immunoassay for qualitative detection of adenovirus, Influenza A and/or influenza B directly from nasopharyngeal swab specimens. Intended for use by trained laboratory personnel or healthcare professionals.

Product Specification

Sample type	Nasopharyngeal Swab
Sample volume	3 drops
Testing time	15 minutes
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Extraction Buffer : 2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

Clinical Data

Clinical Data	Sensitivity	Specificity
SARS CoV-2	91.00%	100%
Flu A	93.75%	100%
Flu B	92.50%	100%

Order Information

Product	Pack Size	Cat. No.
INCLIX TRF Adeno & Flu A/B Ag	25 Tests	ADFF025E

INCLIX F Total IgE

INCLIX F Total IgE is for quantitative determination of total immunoglobulin E (IgE) in serum, plasma, and whole blood. The test is used as an aid in the diagnosis of IgE mediated allergic disorders.

Product Specification

Sample type	Whole blood, Serum, Plasma
Sample volume	25 µL
Testing time	12 minutes
Measuring range	5 – 2,000 IU/mL
Reference range	<100 IU/mL
CV	< 10%
Storage temperature	Test Cassette : 2-30°C (36-86°F)
	Detection Buffer : 2-8°C (36-46°F)
Shelf life	18 months
Quality control material	Internal quality control reagent
Certificate	CE

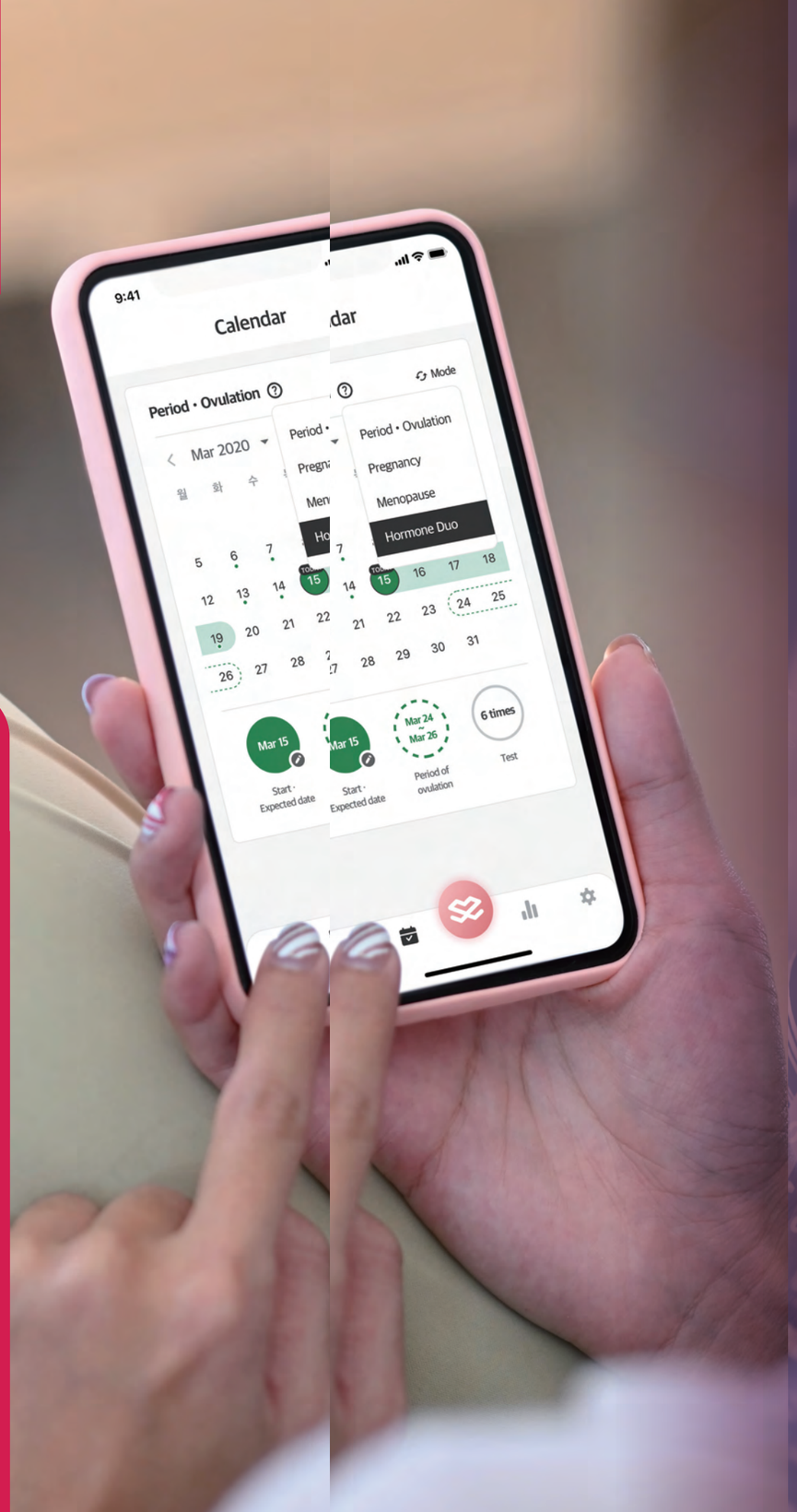
Order Information

Product	Pack Size	Cat. No.
INCLIX F Total IgE	25 Tests	IGEF025E

INCLIX F-100 Parameters

Categoty	Catalog No.	Item	Sample Type	Sample Volume	Measuring Time	Measuring Range
Cardiovascular	HCRF025E	hsCRP	WB(finger), Serum, Plasma	5 µL	3 min	0.1-10 mg/L
	DIMF025E	D-Dimer	WB, Plasma	50 µL	12 min	50-10,000 ng/mL
	TPIF025E	Troponin I	Serum, Plasma	80 µL	15 min	0.05-20 ng/mL
	CKMF025E	CK-MB	WB, Serum, Plasma	40 µL	12 min	2.5-100 ng/mL
	MYOF025E	Myoglobin	WB, Serum, Plasma	10 µL	12 min	5-500 ng/mL
Infection, Inflammation	CRPF025E	CRP	WB(finger), Serum, Plasma	5 µL	5 min	0.5-200 mg/L
	PCTF025E	PCT	Serum, Plasma	80 µL	10 min	0.1-100 ng/mL
Diabetes, Renal	HBAF025E	HbA1c	WB(finger)	5 µL	12 min	4-14%
	ACRF025E	µAlbumin	Urine	5 µL	10 min	2-300 mg/L
Hormones	TSHF025E	TSH	Serum, Plasma	40 µL	15 min	0.1-100 µIU/mL
	TRIF025E	T3	Serum, Plasma	100 µL	10 min	0.5-5.0 ng/mL
	TETF025E	T4	Serum, Plasma	75 µL	10 min	0.5-20 ug/dL
	BCGF025E	β-hCG	WB, Serum, Plasma	40 µL	15 min	S/P : 10-20,000 mIU/mL WB: 10-10,000 mIU/mL
Respiratory	CAFF025E	COVID-19 Ag	NP swab, Nasal swab		15 min	sensitivity 91.00%, specificity 100.00%
	CFFF025E	COVID & Flu A/B Combo	NP swab		15 min	COV : 91.00% / 100% FluA : 93.75% / 100% FluB : 92.50% / 100%
	ADFF025E	Adeno & Flu A/B Combo	NP swab		15 min	ADN : 91.00% / 100% FluA : 93.75% / 100% FluB : 92.50% / 100%
Others	IGEF025E	Total IgE	WB, Serum, Plasma	25 µL	12 min	5-2,000 IU/mL

DIGITAL HEALTH & HOME TEST



Diagnosis for All, Anytime and Anywhere

- Surearly SMART with mobile App
- Surearly SMART Pro (coming)
- Surearly Digital
- Surearly Midstream
- Surearly Strip

Surearly SMART

Surearly SMART and SUREARLY SMART App is an in vitro diagnostic medical device for the rapid detection of hormone levels such as pregnancy, ovulation and menopause in a semi-quantitative.

Key Features

- **Bluetooth connection** : The Smartphone Application will provide calendar, result recording, hormone pattern analysis and related advice, etc.
- S**emi-quantitative analysis**
  - Pregnancy test (hCG, P3G) : pregnancy, risk of pregnancy
  - Ovulation test(LH, P3G): ovulation with “high fertile” and “Peak”, ovulation disorder, PMS
  - Menopause test(FSH, P3G): menopause, early menopauses Estrogen test
  - Hormone test(E1G, P3G) : Estrogen, Progesteron
- Reusable device : The battery is replaceable.
- Test Stick refill : More cost-efficient, Users can buy a refill stick for each test.

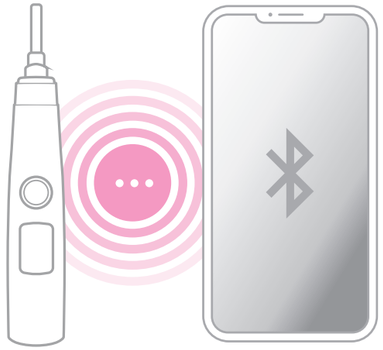
▸ Product Specification

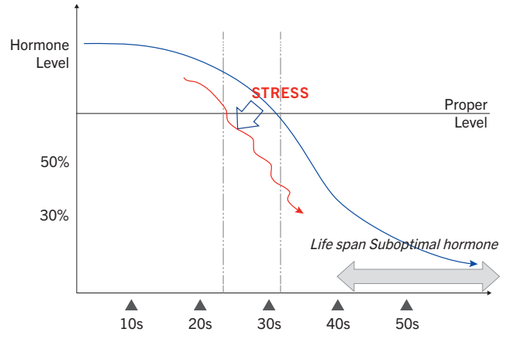
Power	Single 3.0V lithium coin battery
Rated Current	20 mA
Temperature	2-30°C (36-86°F)
Relative humidity	10 – 90%
Atmospheric pressure	80 – 101 kPa
IP Classification	IPX1
Environmental Conditions	Indoor use
	Altitude : <2,000m
	Overvoltage Category : OVC I (battery operated)
RF Specification	Bluetooth Low Energy (BLE)
Certificate	CE0123 (certified by TÜV SÜD)

Surearly SMART Mobile App

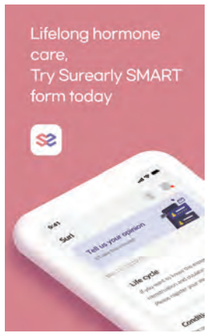
Why Testing Hormone?

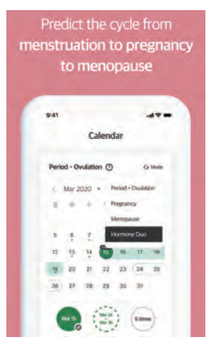
Hormones are essential for life and your health. However, aging and stress can cause hormone imbalance and many different symptoms can result from it. The key is to understand your hormones, know how they change throughout the months, and SUREARLY SMART makes testing your hormones easy with at-home test kits. Plus, you can monitor your results on the SUREARLY SMART App.

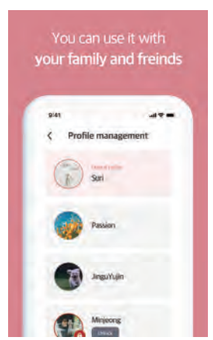


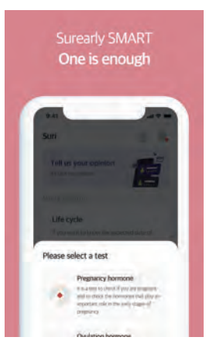


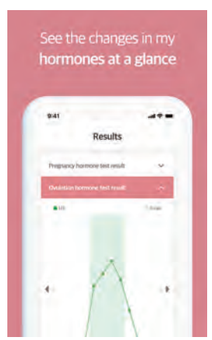
- Monitors personal hormone balance
- Manages personal symptom and condition
- Structurally manages life pattern and interest











Surearly SMART
Pregnancy DUO(hCG&P3G)

Surearly SMART Pregnancy Duo is in vitro diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) and 5β-Pregnane-3α,20α-diol glucuronid (P3G) in urine. The test is for the semi-quantitative detection of hCG to aid in the early determination of pregnancy and analysis of the levels of hCG and P3G to aid in the determination of ectopic pregnancy. The Test line 1 is hCG and Test line 2 is P3G on the test stick. It is intended for nonprofessional, over-the-counter (OTC) use only.

Key Features

- Easy hormone care using mobile App
- Checks for Pregnancy & Risk of Pregnancy
- hCG and P3G(progesterone) dual hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

▸ Performance Clinical Data

The sensitivity of the Surearly SMART Pregnancy DUO is 25mIU/mL for hCG (Test line 1) and 5ug/mL for P3G (Test line 2). Surearly SMART Pregnancy DUO has no cross-reactivity with the biologically similar hormones such as LH (up to 500mIU/mL), FSH (up to 1000mIU/mL), TSH (up to 1mIU/mL), E3G (up to 200 ng/mL) which may exist in urine.

▸ Product Specification

Detection Hormone	hCG (human chorionic gonadotropin), P3G (Pregnanediol-3-glucuronide)
Sensitivity	25mIU/mL (hCG)
	5ug/mL (P3G)
Test Method (Required Time)	urine in a container(10-15 Sec.)
Testing Time	5-7 min
Shelf life	24 months
Certificate	CE0123 (certified by TÜV SÜD)

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Pregnancy DUO	10 Tests	SCGD010E

Surearly SMART
Ovulation DUO(LH&P3G)

Surearly SMART Ovulation Duo is in vitro diagnostic medical device for the rapid detection of Luteinizing hormone (LH) and 5β-Pregnane-3α,20α-diol glucuronid (P3G) in urine. Since normal LH surges vary between women, semi-quantitative detection of LH to aid to determination the ovulation and analysis of the levels of LH and P3G to aid to confirm the ovulation. The Test line 1 is LH and Test line 2 is P3G on the test stick. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Easy hormone care using mobile App
- Checks for the Ovulation (high & peak)
- LH and P3G(progesterone) dual hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

▸ Performance Clinical Data

The sensitivity of the Surearly SMART Ovulation DUO is 10mIU/mL for LH (Test line 1) and 5ug/mL for P3G (Test line 2). Surearly SMART Ovulation DUO has no cross-reactivity with the biologically similar hormones such, FSH (up to 1000mIU/mL), TSH (up to 8μIU/mL), E3G (up to 200 ng/mL) which may exist in urine.

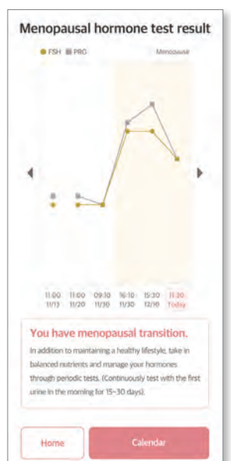
▸ Product Specification

Detection Hormone	LH (Luteinuizing Hormone), P3G (Pregnanediol-3-glucuronide)
Sensitivity	10mIU/mL (LH)
	5ug/mL (P3G)
Test Method (Required Time)	urine in a container(10-15 Sec.)
Testing Time	5-7 min
Shelf life	24 months
Certificate	CE0123 (certified by TÜV SÜD)

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Ovulation DUO	10 Tests	SLHD010E

Surearly SMART
Menopause DUO(FSH&P3G)



Surearly SMART Menopause Duo is in vitro diagnostic medical device for the rapid detection of Follicle Stimulating Hormone (FSH) and second hormone is 5β-Pregnane-3α,20α-diol glucuronid (P3G) in urine. The Test line 1 is FSH and Test line 2 is P3G on the test stick. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Easy hormone care using mobile App
- Checks for Menopause and Menopausal Transition
- FSH and P3G(progesterone) dual hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

▸ Performance Clinical Data

The sensitivity of the Surearly SMART Menopause DUO is 25mIU/mL for FSH (Test line 1) and 5ug/mL for P3G (Test line 2). Surearly SMART Menopause DUO has no cross-reactivity with the biologically similar hormones such, LH (up to 500mIU/mL), TSH (up to 8μIU/mL), hCG (up to 100 IU/mL) and E3G (up to 200 ng/mL) which may exist in urine.

▸ Product Specification

Detection Hormone	FSH (Follicle-stimulating hormone), P3G (Pregnanediol-3-glucuronide)
Sensitivity	25mIU/mL (FSH)
	5ug/mL (P3G)
Test Method (Required Time)	urine in a container(10-15 Sec.)
Testing Time	5-7 min
Shelf life	24 months
Certificate	CE0123 (certified by TÜV SÜD)

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Menopause DUO	10 Tests	SFHD010E

Surearly SMART
Hormone DUO(E1G&P3G)

Surearly SMART Hormone DUO is in vitro diagnostic medical device for the rapid detection of Estrone-3-Glucuronide (E1G) and second hormone is 5β-Pregnane-3α,20α-diol glucuronid (P3G) in urine. The Test line 1 is E1G and Test line 2 is P3G on the test stick. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Easy hormone care using mobile App
- E1G(Estrogen) and P3G(progesterone) dual hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

▸ Product Specification

Detection Hormone	E1G (Estrone-3-Glucuronide), P3G (Pregnanediol-3-glucuronide)
Measuring range	E1G : 5-50 ng/ml
	P3G : 2-30 ug/ml
Reference range (Ovulation)	E1G : >30 ng/ml
	P3G : >5 ug/ml
Test Method (Required Time)	urine in a container(10-15 Sec.)
Testing Time	5-7 min
Shelf life	24 months
Certificate	In progress

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Hormone DUO	10 Tests	SEPD010E

Surearly SMART Pro

Introduction video

Surearly SMART Pro is the mobile App integrated infectious disease care system, the first application of which is COVID-19. It consists of Multiplex Biosensor (not only for COVID-19 test), Micro/Low power Analysis System, Bluetooth and a unique Mobile App.
The product is well integrated into the mobile App service, which offers a structured monitoring system, personalized warning and care system and professional guide and analysis.

Key Features

- Compatibility with App
- Portable and User-friendly
- Personalized Guide
- Integrated into medical professional care

▸ Product Specification

Parameter	Value	Remark
Communication	Bluetooth	App Connection & Data Transfer
Alarm	User can check it via App	
Display	LED Indicator	Power, Charge, BLE, Check the status of Casette
Power	Li Polymer	Internal Battery Charge
External port	USB Type-C(Charge Port)	Rechargeable
Size dimensions	45 x 140 x 23 mm	
Weight	80 g	

Both for semi to full quantitative analysis

Surealry SMART Pro App provides visual guide, diagnosis results, symptom checker (digital diary), and map tracker. Effective data management provides interactive report/dashboard, fresh update of key guideline, and personalized guide. Knowledge network is possible with integrated into medical professional care, R&D network for key and recent findings, and support of various decision making process. In addition, the app is compatible with all iPhone devices (iOS 10.0 and up) and Android devices (Android 5.0 and up).

Surearly SMART Pro Microalbumin

Surearly SMART Pro Microalbumin along with Surearly SMART Pro Test reader is an immunoassay for quantitative determination of Microalbumin in human urine. The test is used as an aid to monitor early signs of kidney damage in people who are at risk of developing kidney disease.

▸ Product Specification

Sample type	Urine
Sample volume	100 µL
Testing time	5-7 minutes
Measuring range	10-300 mg/L
Reference range	<20 mg/L
Storage Temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	Control reagents are available from commercial sources
Certificate	CE

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Pro Microalbumin	25 Tests	ACRM025E

Surearly SMART Pro CRP

Surearly SMART Pro CRP along with Surearly SMART Pro test reader is an immunoassay for quantitative determination of C-Reactive Protein (CRP) in serum, plasma and whole blood. The test is used as an aid to detect bacterial or viral infection and to monitor a progression of inflammation.

▸ Product Specification

Sample type	Whole Blood, Serum, Plasma
Sample volume	100 µL
Testing time	5~7 minutes
Measuring range	5-200 mg/L
Reference range	<5 mg/L
Storage Temperature	2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Control reagents are available from commercial sources
Certificate	CE

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Pro CRP	25 Tests	CRPM025E

Surearly SMART Pro hsCRP

Surearly SMART Pro hsCRP along with Surearly SMART Pro Test reader is an immunoassay for quantitative determination of high sensitivity C-Reactive Protein (hsCRP) in serum, plasma and whole blood. The test is used as an aid to monitor risk of cardiovascular disease.

▸ Product Specification

Sample type	Whole Blood, Serum, Plasma
Sample volume	100 µL
Testing time	5-7 minutes
Measuring range	0.5-10 mg/L
Reference range	<1 mg/L
Storage Temperature	2-30°C (36-86°F)
Shelf life	18 months
Quality control material	Control reagents are available from commercial sources
Certificate	CE

▸ Order Information

Product	Pack Size	Cat. No.
Surearly SMART Pro hsCRP	25 Tests	HCRM025E

Surearly SMART Pro COVID-19 Ag Self

Surearly SMART Pro COVID-19 Ag self is an immunoassay for qualitative detection of SARS-CoV-2 antigens from nasal swab specimens.

▸ Product Specification

Test type	Self-testing use
Sample type	Nasal swab
Sample volume	3 drops
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control swab and negative control swab

▸ Clinical Data

	Sensitivity	Specificity
Ag	95.06%	99.29%
LOD (Limit of Detection)	3.5×10^2 $TCID_{50}$/mL	

Surearly SMART Pro COVID-19 IgM/IgG Self

Surearly SMART Pro COVID-19 IgM/IgG Self Test is an immunoassay for qualitative detection of IgM or IgG antibodies to COVID-19 in human fingerstick whole blood.

▸ Product Specification

Test type	Self-testing use
Sample type	Fingerstick whole blood
Sample volume	10 µℓ
Testing time	10-15 minutes
Storage temperature	2-30°C (36-86°F)
Shelf life	24 months
Quality control material	positive control and negative control

▸ Clinical Data

	Sensitivity	Specificity
IgM/IgG	94.48%	98.33%
IgM	90.80%	98.33%
IgG	90.18%	100.00%

Coming Soon

- Surearly SMART Pro HbA1c
- Surearly SMART Pro Creatinine
- Etc.

Surearly Digital Multi-Use Pregnancy Test

How to use

Surearly Digital Pregnancy Test is a rapid self-testing immunoassay for the qualitative determination of hCG in urine to aid in the early detection of pregnancy. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Rapid, Easy-to-Read Digital results in 3 min
- Over 99% accurate
- User's procedural error detection
- hCG hormone detection in urine

▸ Performance Clinical Data

Surearly Digital Multi-Use Pregnancy Test detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Fifth International Standard. The addition of Luteinizing Hormone (LH, 500 mIU/mL), Follicle Stimulating Hormone (FSH, 1000 mIU/mL), and Thyroid Stimulating Hormone (TSH, 1 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 and 50mIU/mL hCG) specimens showed no cross-reactivity.

▸ Product Specification

Detection Hormone	hCG(human Chorionic Gonadotropin)
Sensitivity	25mIU/mL
Test Method (Required Time)	Mid-stream in urine (3 Sec.) urine in a container(10 Sec.)
Testing Time	Within 3 min
Sensitivity	24 months
Certificate	CE0123 (certified by TÜV SÜD)

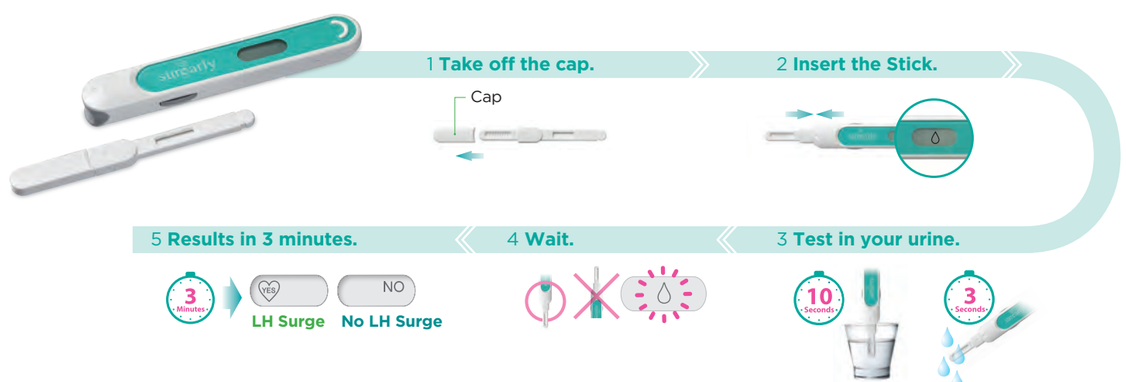
▸ Order Information

Product	Pack Size	Cat. No.
Surearly Digital Multi-Use Pregnancy Test	3 Tests	HCGM003E
	5 Tests	HCGM005E

Surearly Digital Ovulation Test

How to use

Surearly Digital Ovulation Test is an in-vitro diagnostic medical device for the rapid determination of Luteinizing Hormone (LH) in urine. The test is for the qualitative detection of LH to predict a woman's most fertile period. It is intended for non-professional, over-the-counter (OTC) use only.



Key Features

- Rapid, Easy-to-Read Digital results in 3 minutes
- Over 99% accurate
- User's procedural error detection
- LH hormone detection in urine

▸ Performance Clinical Data

Surearly Digital Ovulation Test detects LH at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of Follicle Stimulating Hormone (FSH, 200 mIU/mL), and Thyroid Stimulating Hormone (TSH, 1mIU/mL) to negative (0 mIU/mL LH) and positive (25 and 150 mIU/mL LH) specimens showed no cross-reactivity.

▸ Product Specification

Detection Hormone	LH(Luteinuizing Hormone)
Sensitivity	25mIU/mL
Test Method (Required Time)	Mid-stream in urine (3 Sec.) urine in a container(10 Sec.)
Testing Time	Within 3 min
Ovulation date prediction	2 most fertile days
Sensitivity	24 months
Certificate	CE0123 (certified by TÜV SÜD), FDA Registered

▸ Order Information

Product	Pack Size	Cat. No.
Surearly Digital Ovulation Test	7 Tests	HLHM007E
	20 Tests	HLHM020E

Surearly Early Sign Pregnancy Test

Surearly Early Sign Pregnancy Test is an in-vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the early determination of pregnancy. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Extra-sensitive : Sensitivity level of 10mIU/mL
- Early detection of pregnancy
- Easy-to-use midstream type
- Rapid results in 3-5 minutes
- hCG hormone detection in urine

▸ Performance Clinical Data

Surearly Early Sign Pregnancy Test detects hCG at a concentration of 10 mIU/mL or greater. The test has been standardized to the W.H.O. Fifth International Standard. The addition of Luteinizing Hormone (LH, 500 mIU/mL), Follicle Stimulating Hormone (FSH,1000 mIU/mL), and Thyroid Stimulating Hormone (TSH, 1 mIU/mL) to negative (0 mIU/mL hCG) and positive (10 mIU/mL hCG) specimens showed no cross-reactivity.

▸ Product Specification

Sample type	Urine
Testing time	3-5 min.
Sensitivity	10 mIU/mL
Storage Temperature	2~30°C (36~86°F)
Shelf life	30 months
Certificate	CE0123 (certified by TÜV SÜD)

▸ Order Information

Product	Pack Size	Cat. No.
Surearly Early Sign Pregnancy Test	1 Test	HCGF001E

Surearly Pregnancy Test Strip

Surearly Pregnancy Test Strip is an in vitro diagnostic medical device for the rapid determination of human chorionic gonadotropin (hCG) in urine. The test is for the qualitative detection of hCG to aid in the determination of pregnancy. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Cost-effective
- Over 99% accurate
- Rapid results in 5 minutes
- hCG hormone detection in urine

▸ Performance Clinical Data

Surearly Pregnancy Test Strip detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Fifth International Standard. The addition of Luteinizing Hormone (LH, 500 mIU/mL), Follicle Stimulating Hormone (FSH, 1000 mIU/mL), and Thyroid Stimulating Hormone (TSH, 1 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

▸ Product Specification

Testing time	3-5 min
Sensitivity	25 mIU/mL
Temperature	2-30°C (36-86°F)
Shelf life	24 months
Certificate	CE0123 (certified by TÜV SÜD), FDA 510(k) cleared

▸ Order Information

Product	Pack Size	Cat. No.
Surearly Pregnancy Test Strip	3 Tests	HCGS003E
	5 Tests	HCGS005E

Surearly Ovulation Test Strip

Surearly Ovulation Test Strip is an in vitro diagnostic medical device for the rapid determination of Luteinizing Hormone (LH) in urine. The test is for the qualitative detection of LH to predict a woman's most fertile period. It is intended for non-professional, over-the-counter (OTC) use only.

Key Features

- Cost-effective
- Over 99% accurate
- Rapid results in 5 minutes
- LH hormone detection in urine

▸ Performance Clinical Data

Surearly Ovulation Test Strip detects LH at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Fifth International Standard. The addition of human Chorionic Gonadotropin (hCG, 1000mIU/mL), Follicle Stimulating Hormone (FSH, 1000 mIU/mL), and Thyroid Stimulating Hormone (TSH, 1mIU/mL) to negative (0 mIU/mL LH) and positive (25 mIU/mL LH) specimens showed no cross-reactivity.

▸ Product Specification

Testing time	3-5 min
Sensitivity	25 mIU/mL
Temperature	2-30°C (36-86°F)
Shelf life	24 months
Certificate	CE0123 (certified by TÜV SÜD), FDA Registered

▸ Order Information

Product	Pack Size	Cat. No.
Surearly Ovulation Test Strip	10 Tests	HLHS010E
	20 Tests	HLHS020E
	30 Tests	HLHS030E

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