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

2011~2017

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

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)

2018~2021

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)

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

2022~Present

2024
- Established FemTech Center and acquired CVC authorization
- INCLIX F-9600 Manufacturing Declaration
- Approved by KOREA MFDS
  - SGTi-flex Food Check IgG
  - SGTi-flex Dengue IgM/IgG
  - SGTi-flex Dengue Ns1 Ag
  - INCLIX F Microalbumin

2023
- INCLIX F-100 is listed in CE-IVDR
- S-Blot 3 is listed in CE-IVDR
- Established PIUM Sejong campus
- Surearly SMART FDA listed as Class 1
- S-Blot 2 is listed in CE-IVDR

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

Awards

2023
- Selected as a Global Leading Company 1000+

2022
- Awarded the 'USD 50 Million Export Tower' presented by Korea International Trade Association

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

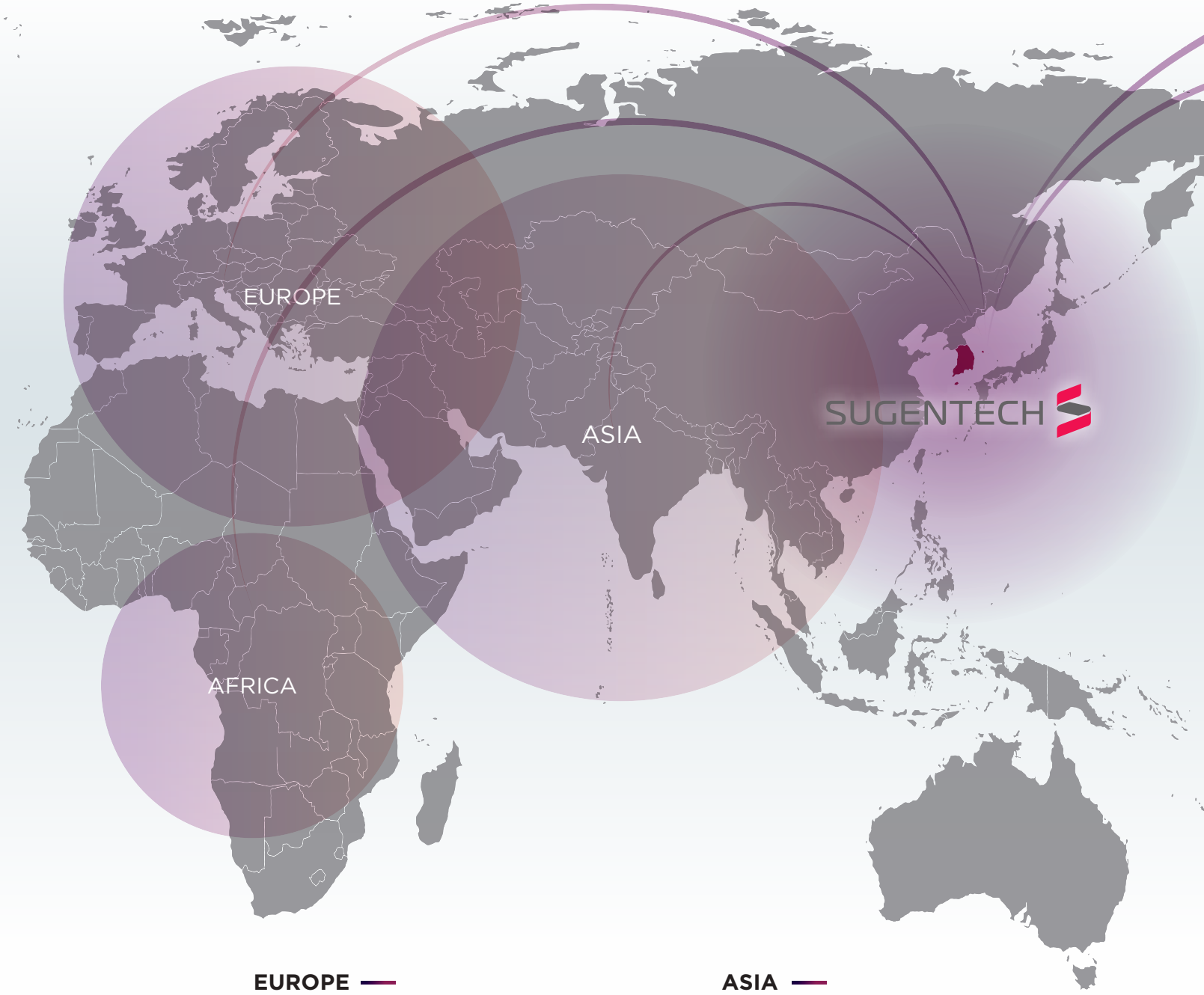
- **Nanoparticle**
- Gold Nanoparticle
- Fluorescent Particle

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

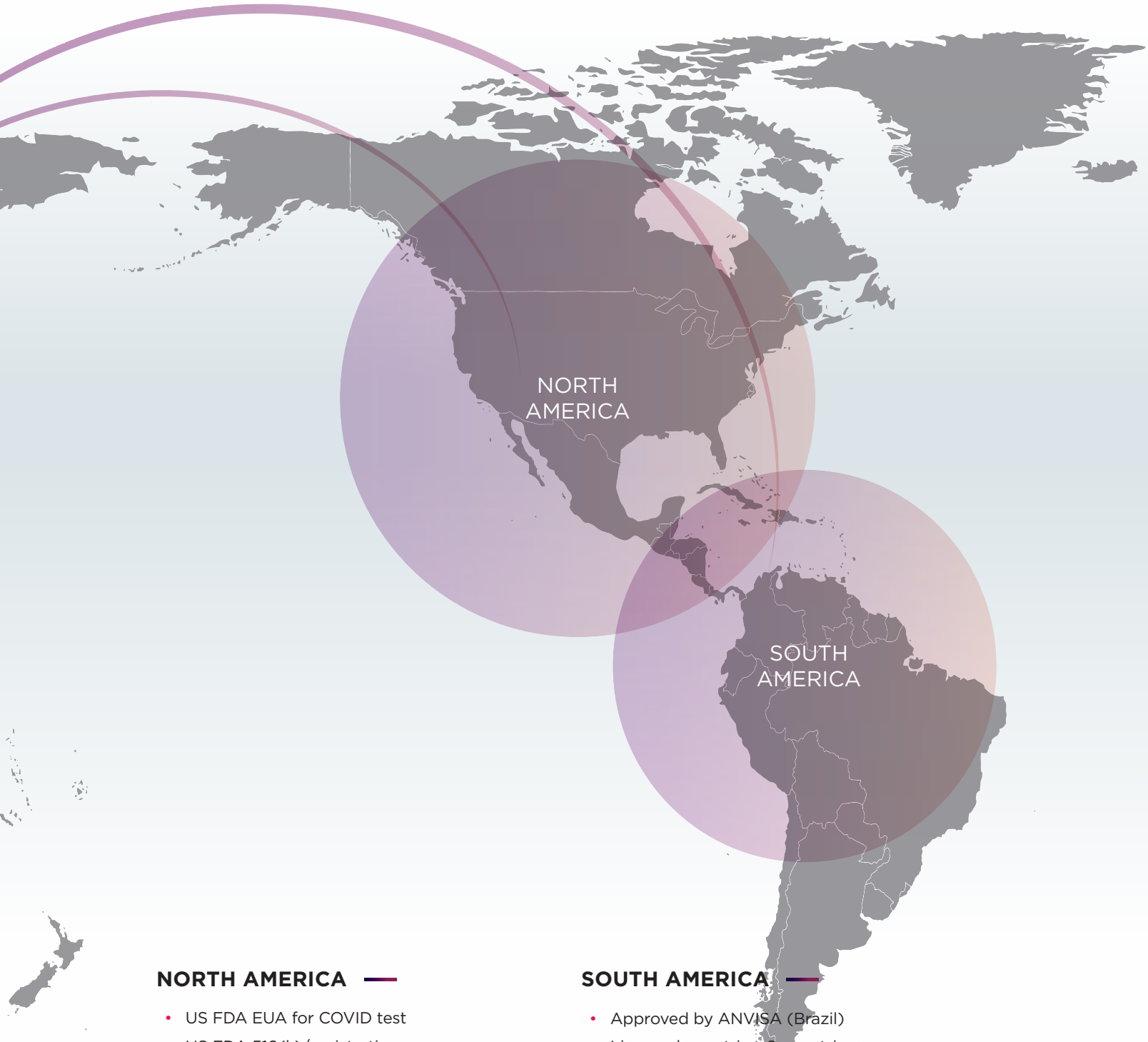
- CE approval for all products
- CE 0123 by TÜV SÜD for OTC products
- Licensed countries: 27 countries including member states of the EU (Germany, Spain, Switzerland, Austria, Belgium, Poland, etc.)

CE

ASIA

- Licensed countries: 18 countries (Korea, Vietnam, Malaysia, Thailand, Singapore, Philippines, India, Indonesia, UAE, Saudi Arabia, Kuwait, Bahrain, Türkiye, 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

POCT TEST

Analyzer	INCLIX F-100		40
Test Item	Cardiovascular Disease	• hsCRP • D-Dimer	
	Inflammation	• CRP • PCT	
	Diabetic, Renal Disease	• HbA1c • Microalbumin	
	Hormone	• TSH • T3 • T4 • ß-hCG	
	Respiratory Disease	• COVID-19 Ag • COVID-19 & Flu A/B Combo • Adeno & RSV Combo	
	Other	• Total IgE • Female Hormones (Progesterone, FSH, LH, and etc.) (coming)	
	COVID-19 & Flu	• COVID-19 Ag • COVID-19 & Flu A/B Ag • COVID-19 IgM/IgG • COVID-19 IgG	50
	ELISA Lab	• Anti-SARS-CoV-2 Total Ab ELISA • SARS-CoV-2 In Vitro Neuralizing Ab Test(IVnAT)	
	Dengue	• Dengue NS1 Ag • Dengue IgM/IgG • Dengue Ab & Ag DUO	

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.

- Total Solution for Allergy Test
  - SGTi-Allergy Screen PLUS / System
  - SGTi-Allergy Screen / System

SGTi-Allergy Screen PLUS

The SGTi-Allergy Screen PLUS is a multi-parameter line immunoblot for allergy diagnosis by detecting 120 types of allergens (food/inhalant) specific IgE at once in human serum or plasma.

▶ Key Feature

- **120 Allergens** - Processing up to 120 types of allergens at once
- **LOT management** - Efficient and systematic LOT-based quality management system through QR code (Patent KR 10-2241251)
- **Various packaging sets** - Custom packagings available such as 12T/24T/60T
- **Stability & Convenience** - Fast and easy strip installation (One touch strip tray) - User-centered reliable testing environment

▶ Product Specification

Product	SGTi-Allergy Screen PLUS+
Test principal	Multiple Allergen Simultaneous Test (Line Immuno-assay)
Panel	120 allergens (1strip)
Sample volume	150 µL
Sample Type	Serum or Plasma
Processing time	~3.5 hours (60 strips)
Storage	2~8°C
Expiration	24 months
Test / Kit	12,24,60 tests / 1 kit
Kit components	· Test Strip · Test ID QR code · 5 kinds of test solution (Sample Diluent, Antibody, Enzyme, Substrate, Washing)
Analytic device	S-Blot 3 PLUS, S-Blot 2 Easy PLUS

Panel Information 120 Types of Allergens

Category	Allergen	Code
Mites	Total IgE	tIgE
	House dust mite (Dp)	D1
	House dust mite (Df)	D2
	Acarus siro	D70
	Storage mite (Tp)	D72
Dust	House dust	H1
Animal Proteins & Epidermal	Cat	E1
	Dog	E5
	Horse	E3
	Guinea pig	E6
	Mouse	E71
	Rat	E73
	Sheep	E81
	Rabbit	E82
	Hamster	E84
Bee venom	Honey bee	I1
	Yellow jacket, wasp	I3
Insect	Cockroach	I6
Latex	Latex	K82
Micro-organisms	Penicillium notatum	M1
	Cladosporium herbarum	M2
	Aspergillus fumigatus	M3
	Candida albicans	M5
	Alternaria alternata	M6
	Rizopus nigricans	M11
Tree	Alder	T2
	Birch	T3
	Hazel	T4
	Oak White	T7
	Elm	T8
	Olive tree	T9
	Sycamore	T11
	Goat willow	T12
	Cottonwood	T14
	Ash tree	T15
	Pine	T16
	Japanese cedar	T17
	Acacia	T19
	Cypress	T222

Category	Allergen	Code
Grass	Sweet vernal grass	G1
	Bermuda grass	G2
	Orchard grass	G3
	Timothy grass	G6
	Common reed	G7
	Redtop, Bent grass	G9
	Rye(Pollen)	G12
Weed	Ragweed, common	W1
	Ragweed, false	W4
	Mugwort	W6
	Oxeye daisy	W7
	Dandelion	W8
	English Plantain	W9
	Goosefoot, Lamb's quarters	W10
	Russian thistle	W11
	Goldenrod	W12
	Cocklebur	W13
	Pigweed	W14
	Japanese hop	W22
Others	CCD	O214
Food others	Yeast, baker	F45
Egg & Poultry & Dairy	Egg Yolk	F75
	Egg White	F1
	Milk	F2
	Cheddar cheese	F81
Crustacean	Crab	F23
	Shrimp	F24
	Lobster	F80
Seefood	Codfish	F3
	Blue mussel	F37
	Tuna	F40
	Salmon	F41
	Mackerel	F206
	Clam	F207
	Squid	F258
	Plaice	F254
	Oyster	F290
	Anchovy	F313
	Scallop	F338

Category	Allergen	Code
Vegetables	Tomato	F25
	Carrot	F31
	Potato	F35
	Garlic	F47
	Onion	F48
	Celery	F85
	Cucumber	F244
	Mushroom	F212
	Eggplant	F262
	Pumpkin	F225
Meat	Pork	F26
	Beef	F27
	Chicken	F83
	Lamb	F88
Fruits	Orange	F33
	Coconut	F36
	Strawberry	F44
	Apple	F49
	Kiwi	F84
	Mango	F91
	Banana	F92
	Cacao	F93
	Peach	F95
Seeds & Nuts & Legumes	Wheat	F4
	Rice	F9
	Maize	F8
	Barley	F6
	Buckwheat	F11
	Sesame	F10
	Peanut	F13
	Soy bean	F14
	White bean	F15
	Hazelnut	F17
	Brazil nut	F18
	Almond	F20
	Cashew nut	F202
	Pistachio	F203
	Pine nut	F253
	Walnut	F256
	Sweet chestnut	F299
	Macadamia nut	F345
	Sunflower seed	K84

S-Blot PLUS System

A new dimension of reliable automation system

S-Blot 3 PLUS

▶ Key Feature

- **High Throughput** - Fully automated analysis system capable of testing up to 60 samples per session (Patent KR 10-2175186)
- **High Efficiency & Stability** - Function to maintain strip temperature ensuring stable test results and high performance liquid handling technology (Patent Application 10-2021-0193129)
- **High Accuracy & Sensitivity** - Securing accuracy and sensitivity through an independent analysis algorithm
- **Fast & Easy** - User-centric software, one-click LIS integration, one-touch easy strip installation

▶ Product Specification

Product	S-Blot 3 PLUS
Throughput	Max. 60 samples
Processing time	~ 3.5 hours (60 strips)
Analysis module	High Resolution Camera (Software dedicated to multi-band analysis)
Incubation	Rocking / Heating (Temperature maintenance)
Drying method	Heater with blower fan
Main features	• Auto hold door adjusted to user height • Optical calibration through reference strip • Auto-cleaning function
Test environment (temperature, humidity)	15 to 40°C, <80%
Power (temperature, humidity)	AC 100-240V, 250V / 4.5A, 400W
Operating System	Window 10 64bit or more, at least 4 GB, at least 250 GB Hard disk
Dimensions (mm)	980(W) x 650(D) x 610(H)
Weight (kg/lbs)	80kg / 176lbs

Ultra-compact automation system

S-Blot 2 Easy PLUS

▶ Key Feature

- **Compact** - A compact all-in-one system the size of one laptop (width 42cm)
- **Affordable Cost & Efficiency** - Optimized testing method for small to medium-sized hospitals (capable of small-volume testing)
- **Convenient** - User-centric designed software
- **Fast & Easy** - Reduced processing time (within 3 hours)
  - Convenient usability

▶ Product Specification

Product	S-Blot 2 Easy PLUS
Throughput	Max. 12 samples
Processing time	~ 3 hours (12 strips)
Analysis module	High Resolution Camera (Software dedicated to multi-band analysis)
Incubation	Rocking / Heating (Temperature maintenance)
Drying method	Heater with blower fan
Main features	• Optical calibration through reference strip • Auto-cleaning function • Convenient user interface
Power (Supply, Main fuses, Consumption)	AC 100-240V, 250V / 4.5A, 300W
Operating System	Window 10 64bit or more, at least 4 GB, at least 250 GB Hard disk
Dimensions (mm)	424(W) x 521(D) x 442(H)
Weight (kg/lbs)	23kg / 50.7lbs

SGTi-Allergy Screen

The SGTi-Allergy Screen is a multi-parameter line immunoblot for allergy diagnosis by detecting allergen (food/inhalant) specific IgE in human serum or plasma.

▶ Key Feature

- **Small sample volume** - 50 µL of serum or plasma
  - Beneficial for pediatric patients
- **More than 100 allergens specific IgE testing** - Inhalant 50 allergens
  - Food 53 allergens
- **Lot calibration by QR code** - Managing the lot variation
- **Enhanced usability** - One touch strip tray & User friendly software

▶ Product Specification

Principal	Multiple Allergen Simultaneous Test (Line Immuno-assay)
Type of Panel	Inhalant / Food
Sample volume	50 µL per Strip
Sample Type	Serum or Plasma (Li-Heparin, Na-Citrate)
Test Time	About 3~ 4 hours (Depends on test amount and device)
Storage	2 ~ 8℃ / 36° ~ 8°F
Period of Validity	24 months
Test / Kit	24 Tests / 1Kit
Control	Positive control (D.p, D.f, Shrimp, Crab)
Kit Components	· Test Strip · 5 kinds of Test Solution (Sample Diluent, Antibody, Enzyme, Substrate, Washing)
Automation	S-Blot 2, S-Blot 2 Easy, S-Blot 3

Panel Information 102 Types of Allergens

INHALANT Panel

Grass	Bermuda grass Orchard grass Sweet vernal grass	Timothy grass Redtop, Bent grass Rye
Tree	Acacia Alder Ash Birch Cottonwood Cypress Goat willow	Hazel Japanese cedar Oak White Olive Pine Sycamore
Weed	Common Ragweed Dandelion English Plantain Goldenrod Japanese hop	Mugwort Oxeye daisy Pigweed Russian thistle

Epidermal & Animal Proteins	Cat Dog Guinea pig Hamster	Horse Mouse Rabbit
Mites & Dust	Dermatophagoides pteronyssinus(D.p) Dermatophagoides farinae(D.f)	Acarus siro Storage mite (T.p) House dust
Mold/ Fungi	Alternaria alternate Aspergillus fumigatus Candida albicans	Cladosporium herbarum Penicillium notatum
Insect	Cockroach Honey bee	Yellow jacket(wasp)
Others	Latex Positive Control	Total IgE

FOOD Panel

Seeds & Nuts & Legumes	Almond Cacao Hazelnut Peanut Sesame	Pine nut Soy bean Sunflower seed Walnut
Grains	Barley Maize Rice	Wheat Buckwheat
Vegetables	Carrot Celery Cucumber Garlic	Onion Potato Tomato
Fruits	Apple Banana Kiwi Mango	Orange Peach Strawberry

Meat	Beef Chicken	Lamb Pork
Seafood	Clam Crab Lobster	Oyster Scallop Shrimp
	Anchovy Blue mussel Codfish Eel Mackerel	Pacific Squid Plaice Salmon Tuna
Dairy	Cheddar cheese	Egg white Milk
ETC	CCD Positive Control	Total IgE Yeast, baker

S-Blot System

Semi-Automated Immunoassay System

S-Blot 2

▶ **Key Feature**

- **Accurate** - Uses an intelligent algorithm for accurate analysis
- **Easy to use** - Semi-automated immunoblot system with user-friendly software and LIS.
- **Reliable** - Over 1,000 units sold domestically and overseas, with proven safety.

Semi-Automated Immunoassay System

S-Blot 2 Easy

▶ **Key Feature**

- **All-inclusive** - Full-featured, the smallest semi-automated system on the market.
- **Affordable** - Reasonable price, making it accessible to a winder range of users.

One-Step Fully-Automated Immunoblot System

S-Blot 3

▶ Key Feature

- **Smart** - Uses improved LLD (Liquid Level Detection) technology for accurate analysis.
- **Simple** - Fully-automated immunoblot system with user-friendly software and LIS for easy operation.
- **Specialized** - Optimized for use in large hospital environments.

▶ Product Specifications

	S-Blot 2	S-Blot 2 Easy	S-Blot 3
System Description	Semi-automated process	Semi-automated process	Fully-automated process
Throughput	48	12	48
Incubation	Tray Rocking / 7.5°+ / -0.5 / 20RPM		
Drying Method	Heater with Blower fan		
Power (Supply, Main fuses, Consumption)	AC 100-240V 50 / 60Hz, 300VA	AC 100-240V 50 / 60Hz, 300VA	AC 100-240V 50 / 60Hz, 300VA
Test Time	~3 Hours	~3 Hours	4 Hours
Operating System	Window 10 64bit or more, at least 4GB, at least 250GB Hard disk		
Dimensions (L x W x H mm)	886 x 540 x 560	450 x 400 x 400	870 x 540 x 565
Weight (kg)	70	22	80

DEGITAL HEALTH & HOME TEST

Diagnosis for All, Anytime and Anywhere

- Surearly SMART with App
- Surearly SMART Pro with App
- Surearly Digital
- Surearly Midstream(Early Sign)
- Surearly Strip

Surearly SMART

Surearly SMART Track and Monitor 5-female hormones level changes by charts through App for Pregnancy(hCG), Ovulation(LH,P3G),Menopause (FSH) and others(Estrogen, Progesterone).

▶ Key Features

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

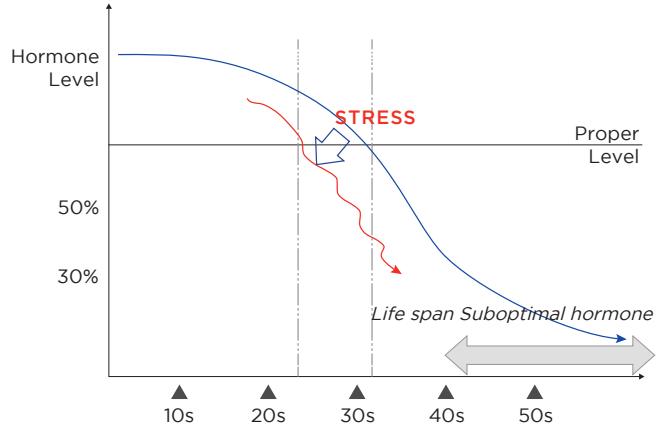
▶ Product Specification

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 With App

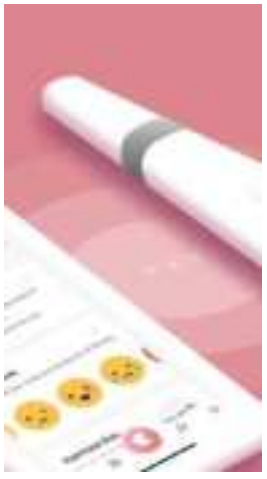
Why Testing Hormone?

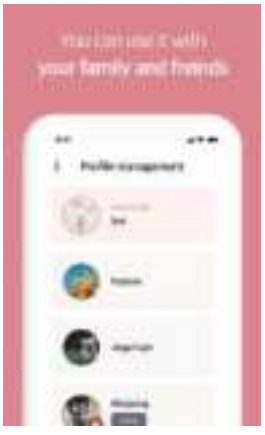
Hormones are essential for life and your health. However, aging and stress can cause hormone imbalance and many different symptoms can result from it. The key is to understand your hormones, know how they change throughout the months, and SUREARLY SMART makes testing your hormones easy with at-home test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

Scan QR code for video instructions





Surearly SMART Pregnancy (hCG)

Surearly SMART Pregnancy is in vitro diagnostic medical device for the rapid detection of human chorionic gonadotropin (hCG) 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 to aid in the determination of ectopic pregnancy. The Test line is hCG 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 hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

Performance Clinical Data

The sensitivity of the Surearly SMART Pregnancy is 25mIU/mL for hCG. Surearly SMART Pregnancy 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),
Sensitivity	25mIU/mL (hCG)
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	10 Tests	SCGD010E

Surearly SMART Ovulation (LH&P3G)

Surearly SMART Ovulation is in vitro diagnostic medical device for the rapid detection of Luteinizing hormone (LH) and 5β-Pregnane-3α,20α-diol glucuronide (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 is 10mIU/mL for LH (Test line 1) and 5ug/mL for P3G (Test line 2). Surearly SMART Ovulation 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 (Luteinizing 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	10 Tests	SLHD010E

Surearly SMART Menopause (FSH)

Surearly SMART Menopause is in vitro diagnostic medical device for the rapid detection of Follicle Stimulating Hormone (FSH) in urine. The Test line is FSH 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 hormone detection in urine
- Accurate semi-quantitative results
- Hormone pattern analysis

Performance Clinical Data

The sensitivity of the Surearly SMART Menopause is 25mIU/mL for FSH. Surearly SMART Menopause 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)
Sensitivity	25mIU/mL (FSH)
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	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 glucuronide (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 With App

Scan QR code for video instructions

Surearly SMART Pro is optimized for home-use mobile healthcare for managing various kinds of diseases such as infection, diabetes, kidney function, cardiovascular risk, hormones, etc. The product is well integrated into the mobile App, which offers structured monitoring, personalized health advice, professional guidance, and data-driven analysis.

▶ Key Features

- **Efficient homecare solution or chronic disease management**
- **Personalized, Smart healthcare service linked with App**
- **Compact, hand-held & low-power device**
- **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 Cassette
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 ACR (Albumin Creatinine Ratio)**
- **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 minutes
- 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 (Luteinizing 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 Midstream (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

POCT TEST

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

Analyzer

- INCLIX F-100

Test Items

- Cardiovascular Disease
- Inflammation
- Diabetic, Renal Disease
- Hormone
- Respiratory Disease
- Other
- COVID-19 & Flu
- ELISA Lab
- Dengue

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 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 µlU/mL
Reference range	0.4 – 4.0 µlU/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

RESPIRATORY DISEASE

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

OTHER

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

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

▸ LAUNCHING SOON

- Female Hormones
  (Testosterone, Progesterone, Estradiol, FSH, LH, AMH, Prolactin, and etc.)

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)

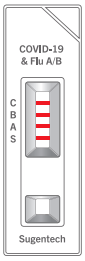
Clinical Data

	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



C Control Line
B Influenza B
A Influenza A
S SARS-Cov-2

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

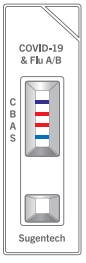
▶ Clinical Data

	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



C Control Line
B Influenza B
A Influenza A
S SARS-Cov-2

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 pipette 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: 9035 minutes Washing: 20-30 seconds x 5 Substrate solution: 3031 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: 1531 minutes Washing: 20-30 seconds x 5 Substrate solution: 1531 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

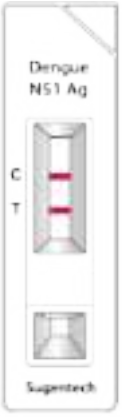
	Sensitivity	Specificity
IVnAT	95.90%	100.00%

▶ Order Information

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

SGTi-flex Dengue NS1 Ag

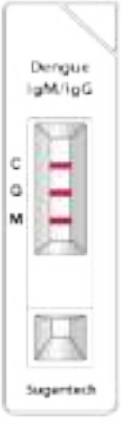
SGTi-flex Dengue NS1 Ag is an immunoassay for qualitative detection of NS1 protein antigen from Dengue virus (I, II, III, IV) in the whole blood, plasma or serum. The test is used as an aid in the rapid diagnosis of Dengue virus infections.



C Control Line
T Test Line

SGTi-flex Dengue IgM/IgG

SGTi-flex Dengue IgM/IgG is an immunoassay for the qualitative detection of IgM and IgG antibodies to Dengue in human blood, serum, or plasma. The test is useful as a screening test for Dengue.

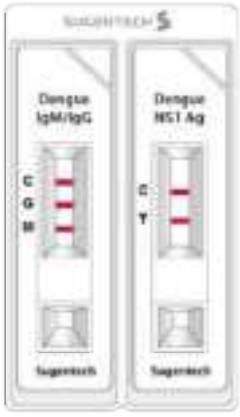


C Control Line
G IgG
M IgM

SGTi-flex Dengue Ab & Ag Duo

SGTi-flex Dengue Ab & Ag Duo is an immunoassay for the simultaneous qualitative detection of NS1 antigen of Dengue virus and IgM or IgG antibodies against all types of Dengue virus (I,II,III,IV) in human whole blood, serum or plasma.

C Control Line
G IgG
M IgM
T Test Line



Product Specification

	SGTi-flex Dengue NS1 Ag	SGTi-flex Dengue IgM/IgG	SGTi-flex Dengue Ab & Ag Duo
Test type	Professional use		
Sample type	Whole blood, plasma or serum		
Sample volume	50 µL	10 µL	10 µL for IgM/IgG, 50 µLfor NS1 Ag
Testing time	15 minutes	15 minutes	15 minutes
Pack Size	25 Tests	25 Tests	25 Tests
Storage temperature	2~30°C (36~86°F)	2~30°C (36~86°F)	2~30°C (36~86°F)
Shelf life	24 months	24 months	24 months
Quality control material	Positive or negative control for Dengue NS1 antigen	Positive or negative control for IgG antibodies or IgM antibodies	Positive or negative control for NS1 antigen, IgG antibodies or IgM antibodies

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TO A GLOBAL HEALTHCARE GROUP TO HELP PEOPLE
DETECT DISEASES FASTER AND FIND TREATMENTS.

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