SD BIOSENSOR
PRODUCT CATALOG

POC *in-vitro* Total Platform Company

Global leader and a Korean pioneer to provide full-line solution
from initial screening to confirmatory tests.

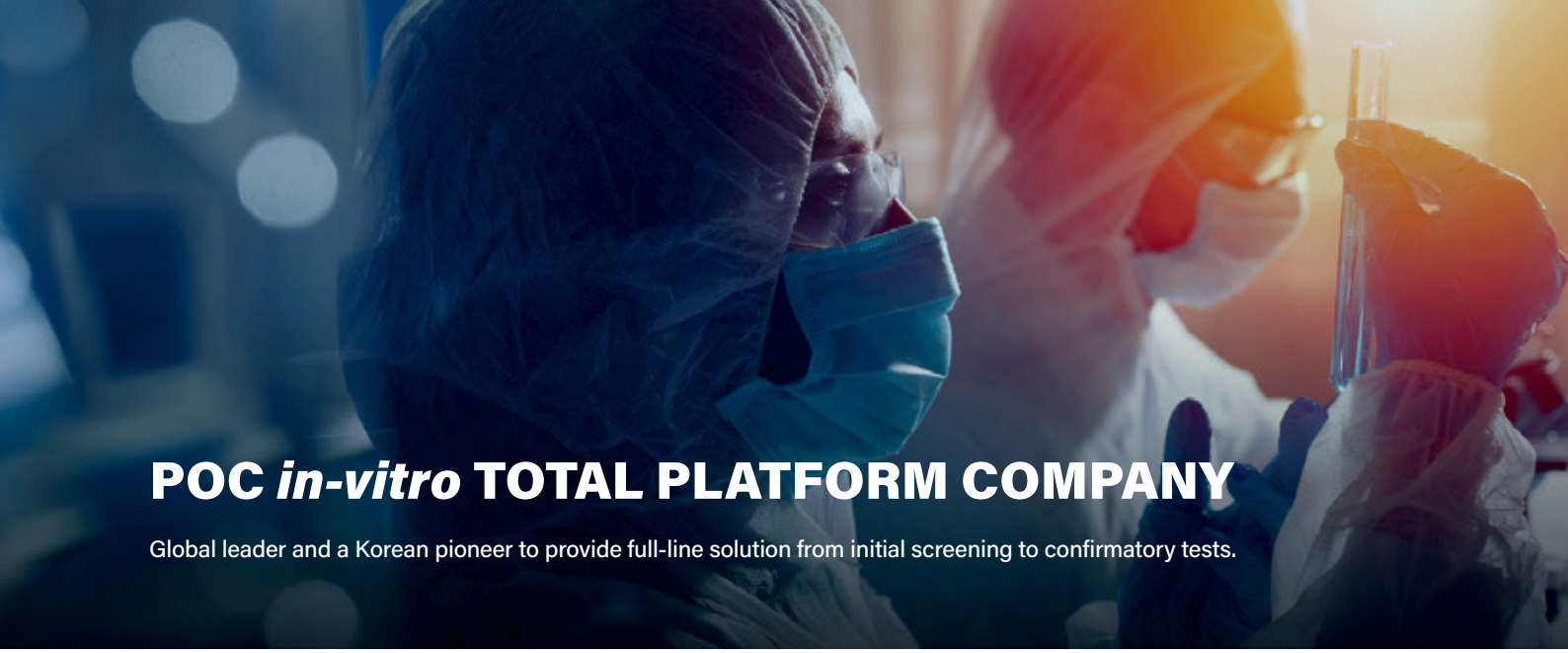
SD BIOSENSOR

Beginning of all things that protect lives

SD Biosensor, Inc., with its slogan 'Beginning of all things that protect lives,' is a global *in-vitro* diagnostics company that contributes to improving everyone's quality of life by diagnosing diseases quickly and accurately. SD Biosensor is a Total Solution Provider in the IVD industry that develops and researches innovative diagnostic platforms.

Continuous technological innovations for a global biotech company

Based on R&D know-how, Mass Production Capacity, and Global Sales Network, SD Biosensor, Inc. will continue to grow as a global biotech company by creating new value through accumulating data using AI as well as in the areas of diagnosis, products, and services.



POC *in-vitro* TOTAL PLATFORM COMPANY

Global leader and a Korean pioneer to provide full-line solution from initial screening to confirmatory tests.

Screening Test

01

- **General Users**

Self test, qualitative test that can be tested by patient like a COVID-19 home test kit (for screening purpose)

- BGMS
- STANDARD Q

02

- **Primary Care Providers**

Tests that can be examined by a medical staff Qualitative/Quantitative test

- BGMS
- STANDARD Q

Confirmatory Test

03

Secondary Healthcare

Test to diagnose the presence or absence of disease through medical staff

- BGMS
- STANDARD Q
- STANDARD F
- STANDARD M

04

Tertiary Healthcare

Test to diagnose the presence

- BGMS
- STANDARD Q
- STANDARD F
- STANDARD M
- STANDARD E

2010 ~ 2011

- Established SD BIOSENSOR, Inc.
- Obtained 510(k) cleared for SD CodeFree
- Obtained Health Canada and 510(k) cleared for SD CHECK GOLD
- Obtained Health Canada Approval for SD CodeFree
- Launched and obtained CE for STANDARD LipidoCare
- Launched and obtained CE for STANDARD Link 0.3

2012

- Established a branch office in India
- Launched and obtained CE for STANDARD Mentor
- Awarded “2012 The Customer Quality Satisfaction Awards”
- Established a branch office in the U.S.
- Launched STANDARD A1cCare / GlucoNavii GDH / GlucoNavii NFC

2013

- Awarded “The Best Brand Award” chosen by consumers from Forbes Korea
- Obtained CE for STANDARD GlucoNavii GDH / GlucoNavii NFC
- Obtained CE for STANDARD A1cCare
- Achieved ISO15197 (2013) standards for SD CodeFree cleared
- Established the 2nd production factory in O-song, Korea

2014 ~ 2015

- Obtained U.S. 510(k) cleared for STANDARD Mentor
- Achieved ISO15197 (2013) standards for STANDARD Mentor & STANDARD GlucoNavii NFC/GDH
- Launched and obtained MFDS Approval for STANDARD Mentor BT
- Developed Ebola *Zaire* Ag rapid diagnosis kit & MERS-CoV Ag rapid diagnosis kit
- Established a branch office in China
- Established built a local factory in India

2016

- Awarded “Promising Enterprise in Gyeonggi-do”
- Launched STANDARD MultiCare
- Launched STANDARD Q(Rapid Diagnostic Test)
- Launched STANDARD F(Fluorescent Immunoassay)
- Launched STANDARD E(Enzyme Immunoassay)

2017

- Changed CI for our dynamic future with expanding IVD portfolio
- Listed on UNICEF Supply Chain Catalog for SD Q Line Ebola *Zaire* Ag
- Signed a long-term contracts with UNICEF for Zika RDT kits
- Developed G6PD Test
- Developed TB-Feron ELISA

SD BIOSENSOR
HISTORY OF INNOVATION

Since 2010, SD BIOSENSOR has grown and evolved to make the world healthier through our innovative IVD products. Our goal is to be the global leading *in-vitro* diagnostics company. From starting with BGMS products, we have expanded our business to STANDARD Q(RDT), STANDARD F(FIA), STANDARD E(ELISA) and STANDARD M(POC Molecular Diagnostic Platform). We are never complacent where we are but strive to become the No.1 global *in-vitro* diagnostics company through continuous technological innovations.

2019

- Listed on Global Fund/UNITAID Catalog with ERPD authorization
  - STANDARD G6PD
  - STANDARD Q HIV/Syphilis Combo
- Obtained CE for STANDARD Q HCV Ab

2020

- Obtained WHO PQ Approval for 6 STANDARD Q products
  - STANDARD Q Malaria P.f Ag
  - STANDARD Q Malaria P.f/P.v Ag
  - STANDARD Q Malaria P.f/Pan Ag
  - STANDARD Q HIV/Syphilis Combo
  - STANDARD Q HIV 1/2 Ab 3-Line
  - STANDARD Q HCV Ab
- Obtained WHO EUL Approval for STANDARD Q COVID-19 Ag Test **World 1st**
- Obtained MFDS Approval for STANDARD™ M10
- Obtained Emergency Use Authorized for STANDARD™ M nCoV Real-Time Detection kit
- Reached KRW 1.68 trillion in sales

2021

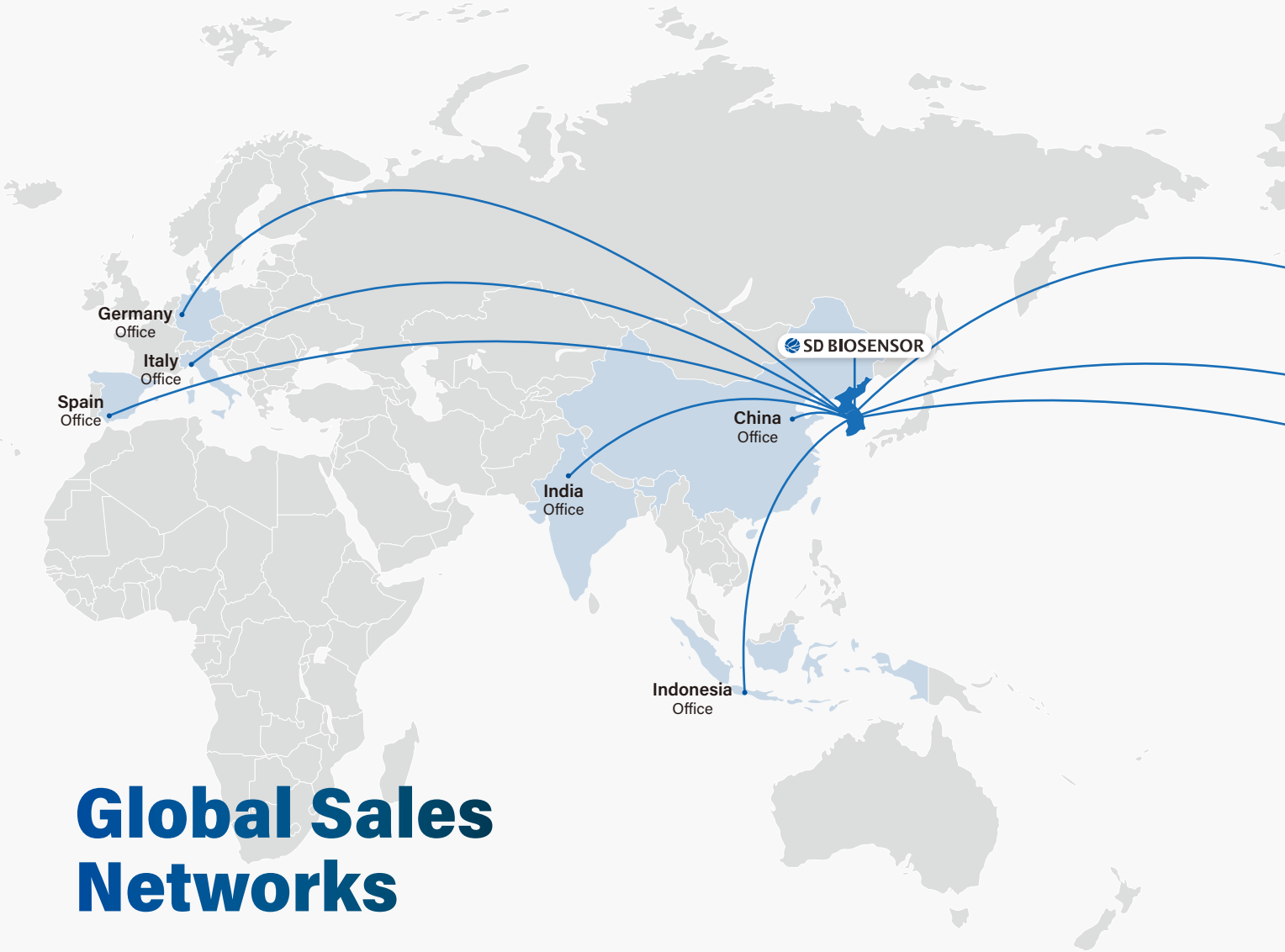
- Obtained CE for STANDARD™ M10 and STANDARD™ M10 SARS-CoV-2
- Obtained Emergency Use Authorized for COVID-19 At-Home Test
- Invested in “UXN”, a CGMS specialized company
- Acquired “ECO Diagnostica”, a Brazil IVD company
- Reached KRW 2.93 trillion in sales
- Achieved the Korean No.1 Bio/Pharmaceutical industry based on annual sales

2022

- Awarded “2022 Korea Best Brand Awards” from Forbes Korea
- Acquired “Bestbion dx”, a Germany IVD Products distributor
- Acquired “Relab S.r.l.”, an Italy IVD Products distributor
- Acquired “Meridian Bioscience”, the U.S. IVD company
- Awarded “2022 First Trusted Premium Brands” from Forbes Korea
- Established STANDARD™ M10 cartridge automation factory in Jeugpyeong, Korea
- Established SD Biosensor Spain, S.L. subsidiary
- Awarded “2022 Technology Innovation Management Awards”
- Awarded “2 Billion Dollars Export Tower” from the Korea International Trade Association
- Reached KRW 2.93 trillion in sales

2023 ~ to date

- Acquired “Mirero Corp.”, a Panama IVD Products distributor
- Awarded “2023 Korea Best Brand Awards” from Forbes Korea
- Obtained MFDS Approval for STANDARD M10 Flu/RSV/SARS-CoV-2 cartridge
- Obtained Emergency Use Authorized for STANDARD Q COVID-19 Ag Test 2.0
- Awarded “STANDARD Q Brand Tower” from the Korea International Trade Association



Global Sales Networks

SD BIOSENSOR has grown and evolved in chronic care and *in-vitro* diagnostics(IVD) industries over the last few years. Our IVD portfolio has expanded from immuno-based IVD to POC Molecular Diagnostics through the continuous technological innovations. As our product line has expanded in accordance with the global needs for IVD, our customers have increased world-wide.

SD BIOSENSOR, INC. Headquarter

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Tel	+82-80-970-9700
E-mail	ts@sdbiosensor.com
Website	www.sdbiosensor.com

- **Giheung** (Office 2)
  A-28F ~ 29F, Giheung ICT Valley 58-1, Giheung-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea
- **Seoul** (Office 3)
  6F ~ 7F, 509, Dosan-daero, Gangnam-gu, Seoul, Republic of Korea
- **Osong** (Factory 1)
  74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea
- **Osong** (Factory 2)
  765, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea
- **Pyeongtaek** (Factory 3)
  4-18, Dongbu-daero, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of Korea
- **Jeungpyeong** (Factory 4)
  14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, Republic of Korea

Direct sales
in **9** countries

COVID-19
2.4 Bn Tests sold
(As of Dec. 2023)

In **199** countries
848 dealers
(As of Dec. 2023)

We are based in South Korea and have 9 global offices in USA, Brazil, Panama, India, Indonesia, China, Germany, Italy and Spain. We also have more than 800 distribution partners in more than 190 countries, and the number is still growing.

Subsidiaries

America

USA Office
2 Corporate Park Ste 202 Irvine, CA 92606

Brazil Office
R. Ministro Orozimbo Nonato, 215. 11 andar
Vila da Serra. CEP: 34006-053 Nova Lima. MG

Panama Office
Juan Diaz, Urb. San fernando, edificio samgwang.
primer piso, oficina 1, Ciudad de Panama

Asia

India Office
Unit #202 A-D, 2nd Floor, Tower-A,
Unitech Signature Towers, South City-I,
Gurugram Haryana India Pin code 122001

Indonesia Office
KP.Nagrog, RT004 RW002, Kel. Kertamukti,
Kec Campaka, Kab. Purwakarta, Jawa barat
41181 Indonesia

China Office
Room 520, 5th Floor, Building 20,
3998 Hongxin Road, Minhang District,
Shanghai, China Zip code201103

Europe

Italy Office
C.so Perrone 25r 16152 Genova

Spain Office
Avd. Diagonal 210,(Modulo A) 2nd Floor,
Barcelona, Spain

Germany Office
Horbeller Strasse 33, 50858 Cologne,
Germany District Court of Cologne, HRB 73687

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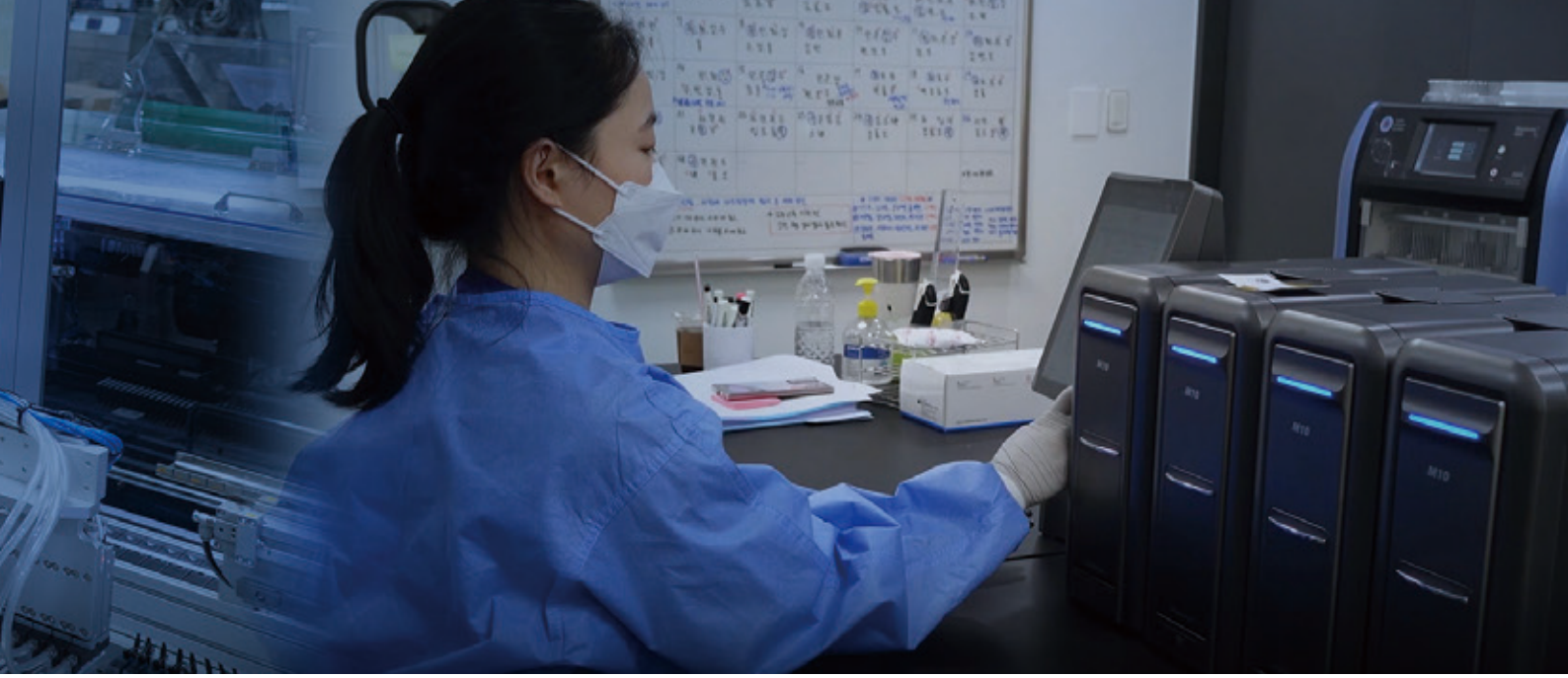



01.

STANDARD M

Molecular Diagnostics

STANDARD™ M is a molecular diagnostic brand including STANDARD M10, a point-of-care molecular diagnostic system, PCR reagents and other related products. STANDARD™ M10 is a versatile POC system designed for more accurate, simpler and faster clinical decision making near-the-patient using real-time PCR or real-time LAMP. STANDARD™ M10 is an automated system that integrates extraction and amplification of nucleic acids from various specimens and detection of target sequences. STANDARD™ M10 consists of STANDARD™ M10 Module and STANDARD™ M10 Console. The entire testing process is carried out inside STANDARD™ M10 Module, and STANDARD™ M10 Console controls the process, analyzes the result and manages the database using the software. The patented all-in-one STANDARD™ M10 cartridges hold the nucleic acid extraction reagents and real-time PCR/LAMP reagents. STANDARD™ M10 portfolio covers infectious disease diagnosis, drug resistance confirmation, and genetic testing.

STANDARD M10

Versatile Point-of-Care Molecular Diagnostic Platform

POC Molecular Diagnostic Platform designed for more accurate, simpler and faster clinical decision making near-the-patient.

Respiratory Infections
- SARS-CoV-2
- Flu/RSV/SARS-CoV-2
- Flu/RSV/SARS-CoV-2 Fast*
- Strep A*
- Respiratory Panel*

Tuberculosis
- MDR-TB
- MTB/NTM
- MTB-RIF/INH*
- pre XDR-TB*

Vector Borne Disease
- Arbovirus Panel
- DENV 1-4

Gastrointestinal Infections
- *C. difficile* (tcdB)
- *C. difficile* BT*
- GI Panel*

Sexual Health
- HPV
- STI Panel*
- CT/NG*

Healthcare-Associated Infections
- MRSA/SA*
- vanA/vanB*

Virology
- HIV-1 VL*

Others
- MPX/OPX RUO
- MPXV (Monkeypox)

It includes upcoming products.
*Marked products are scheduled to be released.

Versatile POC MDx System

STANDARD M10 is a novel Point-of-Care molecular diagnostic (MDx) system that enables simple, fast and accurate diagnosis of infectious disease, drug resistance, and genetic testing. Its scalable modular configuration is suitable for any healthcare settings from near-patient to a large laboratory. STANDARD M10 all-in-one cartridge enables 'Sample-in-Result-out' process with minimum hands-on time which minimizes human error and contamination.

COMPACT SIZE

M10 Console : 17 x 23 x 39 cm / M10 Module (1 pcs) : 14 x 33 x 32 cm

STANDARD *M10*

Versatile Point-of-Care Molecular Diagnostic Platform

FEATURES

- User friendly GUI with animated guide
- Seamless connectivity with HIS/LIS
- Memory up to 5,000 with Ct values & amplification curves
- 10.1” touch screen
- Customized configuration up to 8 modules
- Minimized maintenance requirements
- Intuitive status indicator
- Small footprint

INNOVATIVE DEVELOPMENT FOR ALL MOLECULAR DIAGNOSTIC EQUIPMENT

STANDARD M10 can be used anywhere diagnostics are needed, from clinics to large laboratories.


University hospital laboratory


Emergency room

Testing site


Clinics

ORDERING INFORMATION

Category	Products	Tests / Kit	Cat. no.
Respiratory Disease	STANDARD™ M10 Flu/RSV/SARS-CoV-2	10T	11FLU10A
	STANDARD™ M10 SARS-CoV-2	10T	11COV10A
	STANDARD™ M10 SARS-CoV-2 Turbo	10T	11COV20A
Tuberculosis	STANDARD™ M10 MDR-TB	10T	11MTB10A
	STANDARD™ M10 MTB/NTM	10T	11MTB20A
Vector Borne Disease	STANDARD™ M10 Arbovirus Panel	10T	11ARB10A
	STANDARD™ M10 DENV 1-4	10T	11DEN10A
Gastrointestinal Infections	STANDARD™ M10 *C. difficile*	10T	11CDC10A
Sexual Health	STANDARD™ M10 STI Panel	10T	11STI10A
	STANDARD™ M10 HPV	10T	11HPV10A
Others	STANDARD™ M10 MPXV	10T	11MPX20A
	STANDARD™ M10 MPX/OPX[RUO]	10T	11MPX10A

STANDARD M10 Flu/RSV/SARS-CoV-2

CE MFDS

STANDARD M10 Flu/RSV/SARS-CoV-2 is a multiplex real-time RT-PCR test intended for use with STANDARD M10 system for the qualitative detection of Influenza A, Influenza B, RSV and SARS-CoV-2 nucleic acids in human nasopharyngeal swab.

Test type Professional Use Only
Specimen type Nasopharyngeal swab
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection and differentiation of Flu A, Flu B, RSV and SARS-CoV-2
- Result in 60 minutes (Early call: 30 mins)
- One minute hands-on preparation
- Room temperature storage

Test Performance

The single-center, single-blind, randomizing, and retrospective confirmatory clinical trial for the clinical performance evaluation of STANDARD M10 Flu/RSV/SARS-CoV-2 for detection of Influenza virus A/B, Respiratory Syncytial Virus, SARS-CoV-2 in a nasopharyngeal specimen of suspected respiratory diseases. This clinical trial was conducted with residual nasopharyngeal swab specimens stored to be discarded after confirmation of positive or negative influenza A/B, RSV, or SARS-CoV-2 by Allplex™ Respiratory Panel 1 (Seegene Inc. *in vitro* PL 18-436).

Reference	Clinical Sensitivity	Clinical Specificity
Influenza A	98.18% (108/110) [95% CI: 93.59% - 99.78%]	100.00% (535/535) [95% CI: 99.31% - 100.00%]
Influenza B	98.91% (91/92) [95% CI: 94.09% - 99.97%]	99.82% (552/553) [95% CI: 99.00% - 100.00%]
RSV	98.78% (81/82) [95% CI: 93.39% - 99.97%]	100.00% (563/563) [95% CI: 99.35% - 100.00%]
SARS-CoV-2	96.49% (165/171) [95% CI: 96.69% - 99.98%]	98.73% (468/474) [95% CI: 97.72% - 99.53%]

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Flu/RSV/SARS-CoV-2	10 tests	11FLU10A
STANDARD Fixed volume dropper (300µl)	10 EA	90DR20

STANDARD M10 SARS-CoV-2

CE MFDS

Multiplex real-time RT-PCR test intended for use with STANDARD™ M10 system for the qualitative detection of nucleic acid from the SARS-CoV-2 ORF1ab(RdRp) gene and E gene in upper respiratory specimens(such as nasopharyngeal) collected from individuals suspected of COVID-19.

Test type Professional Use Only
Specimen type Nasopharyngeal swab
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of ORF1ab gene and E gene
- Result in 60 minutes (Early call: 30 mins)
- One minute hands-on preparation
- 100% of Sensitivity and Specificity

Test Performance

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	100% (109/109, 95% CI: 96.67% -100%)	100% (120/120, 95% CI: 96.67% -100%)	- ORF1ab (RdRp) gene- $6.63x10^{-4}$ $TCID_{50}$/ml - E gene- $6.63x10^{-4}$ $TCID_{50}$/ml

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 SARS-CoV-2	10 Tests	11COV10A
STANDARD Fixed volume dropper (600µl)	10 EA	90DR10

STANDARD *M10*
SARS-CoV-2 *Turbo* (LAMP)

CE

STANDARD M10 SARS-CoV-2 *Turbo* is a real-time RT-LAMP test intended for use with STANDARD M10 system for the qualitative detection of SARS-CoV-2 nucleic acids in human nasopharyngeal swab.

Test type Professional Use Only

Specimen type Nasopharyngeal swab

Storage condition 2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Result in 30 minutes
- One minute hands-on preparation
- Multi-target: ORF1ab and N gene
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 SARS-CoV-2 *Turbo*	10 Tests	11COV20A
STANDARD Fixed volume dropper (300µl)	10 EA	90DR20

STANDARD *M10*
C. difficile

CE

STANDARD M10 *C. difficile* is a Real-Time PCR test intended for use with STANDARD M10 system for the qualitative detection of *Clostridioides difficile* nucleic acids in unformed(watery or soft) stool sample.

Test type Professional Use Only

Specimen type Unformed stool

Storage condition 2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Detection of toxin B gene (*tcd B*)
- Result in 47 minutes
- Simple stool pretreatment process
- Room temperature storage

Test Performance

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	98.52% (133/135) [95% CI: 94.75% - 99.82%]	100.00% (535/535) [95% CI: 99.31% - 100.00%]	0.55 CFU/ml

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 *C. difficile*	10 Tests	11CDC10A
STANDARD M10 Stool Pretreatment Kit	10 Tests	11PRT20A

STANDARD *M10* MDR-TB

CE

STANDARD M10 MDR-TB is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of *Mycobacterium tuberculosis* nucleic acids and drug-resistance against rifampicin(RIF) and isoniazid (INH) in human normal sputum or sputum sediment sample.

Test type Professional Use Only
Specimen type Pretreated normal sputum, sputum sediment sample
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of *M. tuberculosis* and drug-resistance against rifampicin (RIF) and isoniazid (INH)
- Result in 80 minutes
- Simple sputum pretreatment process
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MDR-TB	10 Tests	11MTB10A
STANDARD M10 Sputum Pretreatment Kit	10 Tests	11PRT10A

STANDARD *M10* MTB/NTM

CE

STANDARD M10 MTB/NTM is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of *Mycobacterium tuberculosis* complex and non-tuberculous mycobacteria (NTM) nucleic acids in human normal sputum or sputum sediment sample.

Test type Professional Use Only
Specimen type Pretreated normal sputum, sputum sediment sample
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of *M. tuberculosis* complex and NTM
- Result in 72 minutes
- Simple sputum pretreatment process
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MTB/NTM	10 Tests	11MTB20A
STANDARD M10 Sputum Pretreatment Kit	10 Tests	11PRT10A

STANDARD *M10*
STI Panel

STANDARD M10 STI Panel is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of STI pathogens *Chlamydia trachomatis, Neisseria gonorrhoeae*, Human herpesvirus 1, Human herpesvirus 2, *Mycoplasma genitalium, Mycoplasma hominis, Trichomonas vaginalis*, and *Ureaplasma urealyticum* in human urine sample.

Test type Professional Use Only
Specimen type Urine
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (Bacterial DNA extraction + qPCR)
- Syndromic Testing of Sexually Transmitted Infections (STIs)
  Chlamydia trachomatis , Neisseria gonorrhoeae, Mycoplasma genitalium, Trichomonas vaginalis, Ureaplasma urealyticum Mycoplasma hominis, Human herpesvirus 1 (HSV1), Human herpesvirus 2 (HSV2)
- Result in about 1 hour with a simple test procedure

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 STI Panel	10 Tests	11STI10A

STANDARD *M10*
HPV

CE

STANDARD M10 HPV is a real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of Human papillomavirus(HPV) nucleic acids in human cervical swab sample.

Test type Professional Use Only
Specimen type Cervical swab
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Separate detection of HPV high risk types
- HPV 16, HPV 18, HPV HR (31,33,35,39,45,51,52,56,58,59,66,68)
- Result in 64 minutes
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 HPV	10 Tests	11HPV10A
STANDARD M10 STI Sample Pretreatment Kit	10 Tests	11PRT30A

STANDARD *M10*
Arbovirus Panel

CE

STANDARD M10 Arbovirus Panel is a multiplex real-time RT-PCR test intended for use with STANDARD M10 system for the qualitative detection of Arbovirus; Dengue virus 1-4 (DENV 1-4), Zika virus(ZIKV), Chikungunya virus(CHIKV), Yellow Fever virus(YFV) and West Nile virus(WNV) nucleic acids in human serum or plasma sample.

Test type Professional Use Only
Specimen type Serum, Plasma
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of DENV 1-4, ZIKV, CHIKV, YFV and WNV
- Identification of DENV 1-4 serotypes
- Result in 60 minutes
- Serum / plasma sample
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Arbovirus Panel	10 Tests	11ARB10A
STANDARD Fixed volume dropper (600µl)	10 EA	90DR10

STANDARD *M10*
DENV 1-4

STANDARD M10 DENV 1-4 is a multiplex real-time RT-PCR test intended for use with STANDARD M10 system for the qualitative detection of Dengue virus (DENV1,2,3,4) nucleic acids in human serum or plasma sample.

Test type Professional Use Only
Specimen type Serum, Plasma
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Detection and identification of DENV 1-4 serotypes
- Result in 60 minutes
- Serum / plasma sample
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 DENV 1-4	10 tests	11DEN10A
STANDARD Fixed volume dropper (300µl)	10 EA	90DR20

STANDARD M10 MPXV

STANDARD™ M10 MPXV is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of MPXV nucleic acids in serum, plasma, whole blood, nasopharyngeal swab or oropharynegeal swab specimen.

Test type Professional Use Only

Specimen type Serum, plasma, whole blood, nasopharyngeal swab, oropharynegeal swab

Storage condition 2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of MPXV E9L and G2R gene
- Application of target genes for Clade I (CB) and Clade II (WA) respectively.
- Result in 60 minutes
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MPXV	10 tests	11MPX20A

STANDARD M10 MPX/OPX

RUO

STANDARD M10 MPX/OPX is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of MPX and OPX nucleic acids in human skin lesion, serum, plasma, whole blood, nasopharyngeal swab or oropharynegeal swab specimen.

Test type Research Use Only

Specimen type skin lesion material, serum, plasma, whole blood, nasopharyngeal swab, oropharynegeal swab

Storage condition 2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection and identification of MPX and OPX
- Application of target genes for monkeypox virus Clade I (CB) and Clade II (WA) respectively
- Result in 60 minutes
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MPX/OPX	10 Tests	11MPX10A

STANDARD M
SARS-CoV-2 Real-Time Detection Kit

CE MFDS

STANDARD M SARS-CoV-2 Real-Time Detection kit is a real-time RT-PCR assay intended for the *in vitro* qualitative detection of severe acute respiratory syndrome coronavirus 2(SARS-CoV-2) RNA in human nasopharyngeal swab and oropharyngeal swab specimens.

Test type Professional Use Only
Specimen type Nasopharyngeal swab, Oropharyngeal swab
Storage condition -25 ~ -15 °C

Test Performance

Concentration (copies/ml)	ORF1ab gene	N gene	Limit of Detection (LoD)
4.0 × 10^3 copies/ml	120/120 (100%)	120/120 (100%)	- ORF1ab gene: 1 copies/µl - N gene: 0.5 copies/ µl
2.0 × 10^3 copies/ml	120/120 (100%)	120/120 (100%)	
1.0 × 10^3 copies/ml	**119/120 (99%)**	120/120 (100%)	
5.0 × 10^2 copies/ml	108/120 (90%)	**115/120 (95%)**	
2.5 × 10^2 copies/ml	78/120 (65%)	101/120 (84%)	

Ordering Information

Products	Tests / Kit	Cat. No.
M SARS-CoV-2 Real-Time Detection Kit	100 Tests	11NCO30

STANDARD M
SARS-CoV-2/Variant I Real-Time Detection Kit

STANDARD M SARS-CoV-2/Variant I Real-Time Detection Kit is a real-time RT-PCR assay intended for the *in vitro* qualitative detection and differentiation of SARS-CoV-2 RNA and the Omicron variant in human nasopharyngeal swab specimens.

Test type Professional Use Only
Specimen type Nasopharyngeal swab
Storage condition -25 ~ -15 °C

Test Performance

Concentration (copies/ml)	ORF1ab gene	N gene	S gene_ins214EPE	S gene_E484A	Limit of Detection (LoD)
4.0 × 10^3 copies/ml	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)	- SARS-CoV-2 Wild Type: 1 copies/ µl - Omicron Variant: 2 copies/ µl
2.0 × 10^3 copies/ml	144/144 (100%)	144/144 (100%)	**141/144 (97.9%)**	**144/144 (100%)**	
1.0 × 10^3 copies/ml	**144/144 (100%)**	**143/144 (99.3%)**	124/144 (86.1%)	134/144 (93.1%)	
5.0 × 10^2 copies/ml	135/144 (93.8%)	134/144 (93.1%)	88/144 (61.1%)	125/144 (86.8%)	
2.5 × 10^2 copies/ml	104/144 (72.2%)	120/144 (83.3%)	51/144 (35.4%)	95/144 (66.0%)	

Ordering Information

Products	Tests / Kit	Cat. No.
M SARS-CoV-2/Variant I Real-Time Detection Kit	100 Tests	11NCO50


02.

STANDARD F

Fluorescence immunoassay

STANDARD F is a fluorescence immunodiagnostic system capable of performing a variety of qualitative and quantitative diagnosis items, providing accurate diagnosis result.

STANDARD F

Experience highly accurate FIA test with STANDARD F Analyzers

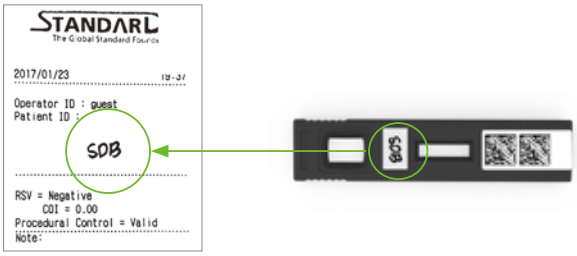
STANDARD F Analyzer is a next-generation fluorescent immunoassay system. It is a multi-parametric and random accessible immunoassay system providing accurate diagnostic results to your laboratory.

RANDOM ACCESS

All the parameters can be randomly accessible to the STANDARD F Analyzer without any pre-procedure. The analyzer recognizes each parameter once the test device is inserted, and displays graphical test procedure for the sample preparation.

PATIENT ID PRINTING SYSTEM

A hand-written patient ID on the test device is printed with the test result for user's convenience.



ASSAY PRINCIPLE

Fluorescent Immunoassay (FIA)

Specific Antigen or Antibody

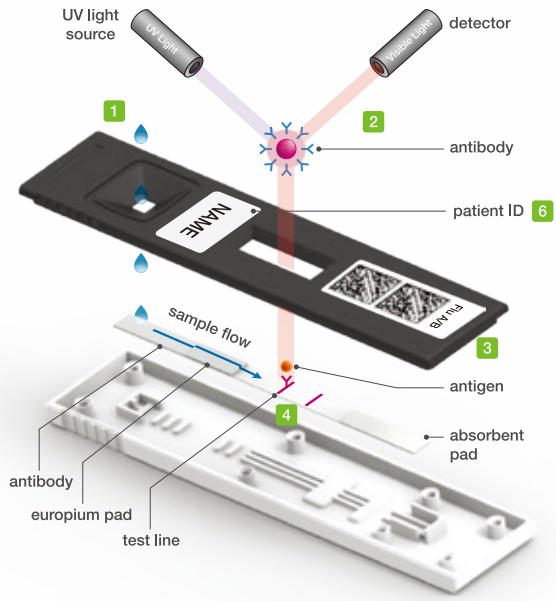
- High sensitivity and specificity
- Fast assay time
- Cost effective

Europium bead

- Strong signals
- Excellent stability
- Minimized interference

Parameter information

2D barcode contains all the information required for the test



CONNECTIVITY

LIS/HIS connectivity

Connect to the majority of existing information systems.

Data share

Via the cloud server

Direct cable

STANDARD F Analyzers connect with computer via the direct cable

STANDARD
F2400

CE MFDS

The best way to reduce turn-around time and improve service quality of your laboratory.

Technical Specification

Model	STANDARD™ F2400 Analyzer
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative Tests
Test capacity	70 Tests per hour
Test mode	STANDARD TEST
Power	AC/DC Adapter
Display	10.1” Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01)
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	510 x 566 x 297 mm
Weight	20.0 kg

STANDARD
F200

CE MFDS

- Convenient and powerful immunoassay analyzer.
- F200 is a user friendly designed FIA analyzer. Its compact design and convenience features will make your lab-work easier and smoother.

Technical Specification

Model	STANDARD™ F200 Analyzer
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative Tests
Test capacity	50 Tests per hour
Test mode	STANDARD TEST, READ ONLY
Power	AC/DC Adapter
Display	7" Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01)
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	214.9 x 261 x 203 mm
Weight	2.5 kg

STANDARD

d-BLOCK Incubator

CE

STANDARD d-BLOCK Incubator is an auxiliary device providing a constant temperature during the test. This product is designed for IVD products required thermal incubation.

Technical Specification

Model	STANDARD™ d-BLOCK Incubator
Dimension	220*184*73 mm
Initial time	15 minutes
Set temperature range	35 ~ 40°C (95 ~ 104°F)
Accuracy of temperature	+/- 1°C
Environment condition	Temperature: 10°C ~ 30°C (50°F to 86°F) Humidity: 20% ~ 80% Non condensing
Storage condition	Temperature: 0°C ~ 70°C (32°F to 125°F) Humidity: 10 ~ 90%
Equipment Control	4 buttons
Equipment Measurement unit	°C, °F
Equipment Display type	LCD (Customized)
Weight	1.9 Kg
Equipment Ratings	12 V(DC), 5A

STANDARD F

SARS-CoV-2 Variant nAb FIA

CE

STANDARD F SARS-CoV-2 Variant nAb FIA is the fluorescent immunoassay for qualitative measurement of circulating neutralizing antibodies against SARS-CoV-2 Omicron variant in human serum and plasma.

Test type	Professional Use Only
Specimen type	Neutralizing antibody against Omicron variant
Storage condition	Serum, Plasma
Specimen volume	100 µl
Testing time	35 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F SARS-CoV-2 Variant nAb FIA	20 Tests	10COV110B
F SARS-CoV-2 nAb Control	Pos x 10 / Neg x 10	10COVC40

STANDARD F

SARS-CoV-2 Total nAb FIA

CE

STANDARD F SARS-CoV-2 Total nAb FIA is the fluorescent immunoassay for qualitative measurement of circulating neutralizing antibodies against SARS-CoV-2 except for Omicron variant in human serum and plasma.

Test type	Professional Use Only
Specimen type	Neutralizing antibody against Wild type, Alpha, Beta, Gamma and Delta variants
Storage condition	Serum, Plasma
Specimen volume	100 µl
Testing time	35 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F SARS-CoV-2 Total nAb FIA	20 Tests	10COV120B
F SARS-CoV-2 nAb Control	Pos x 10 / Neg x 10	10COVC40

STANDARD F

COVID-19 Ag FIA

CE MFDS

STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay for the qualitative detection of specific nucleoprotein antigens to SARS-CoV-2 present in human nasopharynx.

Test type	Professional Use Only
Specimen type	Nasal swab, Nasopharyngeal swab / Transport media
Storage condition	Serum, Plasma
Specimen volume	4 drops
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
PCR	94.23%	100%

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F COVID-19 Ag FIA	25 Tests	10COV30D
F COVID-19 Ag FIA (Nasal)	25 Tests	10COV31D
COVID-19 Ag Control swab	Pos x 10 / Neg x 10	10COVC11

STANDARD F

COVID/Flu Ag Combo FIA

CE

STANDARD F COVID/Flu Ag Combo FIA is the fluorescent immunoassay for the qualitative detection of specific antigens to SARS-CoV-2, Influenza A and Influenza B present in human nasopharyngeal swab specimens.

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab / Transport media
Specimen volume	4 drops
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F COVID/Flu Ag Combo FIA	25 Tests	10COV71D
F COVID/Flu Ag Control swab	C Pos x10/ F Pos x10 / Neg x 10	10COVC50

STANDARD F

Covi-FERON FIA

CE

STANDARD F Covi-FERON (IFN-gamma) is a fluorescence immunoassay for detecting cell-mediated immune responses to SARS-CoV-2 specific proteins in heparinized whole blood. Plasma from the stimulated samples in Covi-FERON tubes can be used for detection of IFN-gamma(IFN-γ) using Covi-FERON FIA(IFN-gamma).

Test type Professional Use Only
Specimen type Plasma
Specimen volume 1 mL for each tube
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Infection history	95.96% (95/99)	96% (96/100)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Covi-FERON FIA	40 Tests	13COVF20G
Covi-FERON tubes 500	Nil tube x 100, Original SP Antigen tube x 100, Variant SP Antigen tube x 100, NP Antigen tube x 100, Mitogen tube x 100	13CVFT50
Covi-FERON tubes 300	Nil tube X 100, Total SP Antigen tube X 100, Mitogen tube X 100	13CVFT300
Covi-FERON tubes 100	NP Antigen tube x 100	13CVFT100

STANDARD F

Influenza A/B FIA

CE MFDS

STANDARD F Influenza A/B FIA (Analyzer+Test device) is a commercially available rapid diagnostics test system. It can perform the test accurately and rapidly within 1.5-10 minutes with the STANDARD F analyzer.

Test type Professional Use Only
Specimen type Nasal swab / Nasopharyngeal swab / Nasopharyngeal wash / Nasopharyngeal aspirate / Transport media
Specimen volume 4 drops
Testing time 10 mins (Early detection available)
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	A : 97.0% (93.0-99.0%) / B : 94.3% (88.0-97.9%)	A : 97.6% (93.1-99.5%) / B : 97.6% (93.1-99.5%)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Influenza A/B FIA	25 Tests	10INF20D
F Influenza A/B Control swab	Pos x 10 / Neg x 10	10INFC20

STANDARD F

RSV Ag FIA

CE MFDS

STANDARD F RSV Ag FIA is the fluorescence immunoassay to detect RSV antigen present in nasopharyngeal swab or nasopharyngeal aspirate/wash specimens from patients with symptoms of a viral respiratory infection.

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab / Nasopharyngeal aspirate / Naso-pharyngeal wash / Transport media
Specimen volume	4 drops
Testing time	15 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
PCR	98.11% (52/53)	100% (128/128)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F RSV Ag FIA	25 Tests	10RSV10D
RSV Ag Control	Pos x 10 / Neg x 10	10RSVC10

STANDARD F

Strep A Ag FIA

CE

STANDARD F Strep A Ag FIA is the fluorescence immunoassay to detect group A streptococcal (Strep A) antigen present in throat specimens from patients with clinical symptoms. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of group A streptococcal infection. It provides only an initial screening test result.

Test type	Professional Use Only
Specimen type	Throat swab
Specimen volume	3 drops
Testing time	5 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Bacterial culture	95.0%	95.2%

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Strep A Ag FIA	25 Tests	10STR10D
Strep A Ag Control	Pos x 10 / Neg x 10	10STRC10

STANDARD F

Legionella Ag FIA

CE MFDS

STANDARD F *Legionella* Ag FIA test system (Analyzer + Test device) detects *Legionella pneumophila serogroup* 1, 3, 5, 6 and 8 antigens via urine sample. Without any further sample processing, STANDARD F *Legionella* Ag FIA performs highly sensitively, and the test is less affected by Rheumatoid factor than other Products.

Test type Professional Use Only
Specimen type Urine
Specimen volume 100 µl
Testing time 15~30 mins (Early detection available)
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Fluorescent immunoassay	97.5%	98.5%

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F *Legionella* Ag FIA	25 Tests	10LEG10D
Legionella Ag Control	Pos x 10 / Neg x 10	10LEGC10

STANDARD F

S. pneumoniae Ag FIA

CE MFDS

STANDARD F *S. pneumoniae* Ag FIA test system (Analyzer + Test Device) finds *S. pneumoniae* antigen in urine if patients have pneumonia, and in cerebral spinal fluid sample if patients have meningitis.

Test type Professional Use Only
Specimen type Urine, CSF
Specimen volume 100 µl
Testing time 10 mins (Early detection available)
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Blood culture	100% (52/52)	99.26% (135/136)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F *S. pneumoniae* Ag FIA	25 Tests	10SPN10D
S. pneumoniae Ag Control	Pos x 10 / Neg x 10	10SPNC10

STANDARD F

Adeno Respi Ag FIA

CE

STANDARD F Adeno Respi FIA is the fluorescence immunoassay to detect adenovirus infection in human nasal swab and nasopharyngeal swab, identifying existence of adenovirus.

Test type	Professional Use Only
Specimen type	Nasal swab, Nasopharyngeal swab
Specimen volume	4 drops
Testing time	15 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F Adeno Respi Ag FIA	25 Tests	10ADE10D
Adeno Ag Control	M Pos x 10 / G Pos x 10 / Neg x 10	10ADEC10

STANDARD F

TB-Feron FIA (IFN-gamma)

CE

STANDARD F TB-Feron FIA (IFN-gamma) aids to diagnosis of Tuberculosis infection. TB Antigens coated in TB-Feron Tube stimulate T cells in heparinized whole blood from patients with symptoms of Tuberculosis (TB), and T cells secrete interferon-γ (IFN-γ). The concentration of IFN-γ is measured by fluorescent immunoassay (FIA) to identify *in vitro* responses to those recombinant TB Antigens that are associated with *M.tuberculosis* infection.

Test type	Professional Use Only
Specimen type	Plasma (collected from sensitized whole blood in TB-Feron Tubes)
Specimen volume	100 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F TB-Feron FIA (IFN-gamma)	30 Devices/Kit	10TBF10E
TB-Feron Tube SPP	30 Pcs/Kit (Nil tube x 10, TB Antigen tube x 10, Mitogen tube x 10)	07TBFA40
F TB-Feron Control	Lv1 x 10 / Lv2 x 10 / Lv3 x 10	10TBFC10
TB-Feron Tubes 100	Mitogen tube x 100	07TBFA10
TB-Feron Tubes 200	TB Antigen tube x 100 / Nil tube x 100	07TBFA20
TB-Feron Tubes 300	Mitogen tube x 100 / TB Antigen tube x 100 / Nil tube x 100	07TBFA30

STANDARD F

TB LAM Ag FIA

CE

STANDARD F TB LAM Ag FIA is a fluorescent immunoassay for the qualitative detection of specific antigen from mycobacterial lipoarabinomannan (LAM) in urine specimen. STANDARD F TB LAM Ag FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of tuberculosis infection.

Test type	Professional Use Only
Specimen type	Urine
Specimen volume	100 µl
Testing time	30 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD F TB LAM Ag FIA	20 Tests	10TBL10B

STANDARD F

Dengue NS1 Ag FIA

CE

STANDARD F Dengue NS1 Ag FIA is a fluorescent immunoassay for the detection of Dengue virus NS1 antigen in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	5 ~ 15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	100% (130/130)	100% (280/280)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Dengue NS1 Ag FIA	25 Tests	10DEN10D
Dengue NS1 Ag Control	Pos x 10 / Neg x 10	10DENC10

STANDARD F

Dengue IgM/IgG FIA

CE

STANDARD F Dengue IgM/IgG FIA is a fluorescent immunoassay for the detection of Dengue virus–specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
ELISA	97.7% (42/43)	99.5% (183/184)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Dengue IgM/IgG FIA	25 Tests	10DEN20D
Dengue IgM/IgG Control	Pos x 10 / Neg x 10	10DENC20

STANDARD F

Zika IgM FIA

CE

STANDARD F Zika IgM FIA is a fluorescent immunoassay for the detection of Zika virus-specific IgM antibody in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
ELISA	94.7% (36/38)	100% (174/174)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Zika IgM FIA	25 Tests	10ZK30D

STANDARD F

Chikungunya IgM/IgG FIA

CE

STANDARD F Chikungunya IgM/IgG FIA is a fluorescent immunoassay for the detection of Chikungunya virus-specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
ELISA	97.2% (35/36)	98.9% (178/180)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Chikungunya IgM/IgG FIA	25 Tests	10CHI10D

STANDARD F

Tsutsugamushi IgM/IgG FIA

Scrub typhus is a disease caused by Orientia tsutsugamushi that is spread through chiggers (larval mites). STANDARD F Tsutsugamushi IgM/IgG FIA is a fluorescent immunoassay for the detection of *O. tsutsugamushi* bacteria specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
ELISA	IgM 100% (35/35) IgG 100% (63/63)	100% (180/180)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Tsutsugamushi IgM/IgG FIA	25 Tests	10TSU10D

STANDARD F

Lyme IgM/IgG FIA

Lyme disease is caused by bacteria, Borrelia burgdorferi that are transmitted through black-legged or deer tick. STANDARD F Lyme IgM/IgG FIA is a fluorescent immunoassay for the detection of *B. burgdorferi* specific IgM and IgG antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
ELISA	IgM 100% (29/29) IgG 100% (30/30)	100% (212/212)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Lyme IgM/IgG FIA	25 Tests	10LYM10D

STANDARD F

Norovirus Ag Plus FIA

CE

STANDARD F Norovirus Ag Plus FIA is a rapid, qualitative fluorescent immunoassay to detect norovirus GI and GII genotype in the human fecal specimen. The test is for *in vitro* diagnostic use and is intended as an aid to early diagnosis of norovirus infection. This is intended for professional use, only for an initial screening test.

Test type Professional Use Only
Specimen type Feces
Specimen volume 40-70mg
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
PCR&ELISA	96.88% (93/96)	98.75% (158/160)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Norovirus Ag Plus FIA	25 Tests	10NOR20D
F Norovirus Ag Control	Pos x 10 / Neg x 10	10NORC10

STANDARD F

Rota/Adeno Ag FIA

CE

STANDARD F Rota/Adeno Ag FIA is a fluorescent immunoassay for the qualitative detection of the presence of Rotavirus and/or Adenovirus antigens in fecal specimens. STANDARD F Rota/Adeno Ag FIA should be used with STANDARD F Analyzers manufactured by SD BIOSENSOR.

Test type Professional Use Only
Specimen type Feces
Specimen volume 50 ~ 75 mg
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F Rota/Adeno Ag FIA	25 Tests	10ROT10D
F Rota/Adeno Ag Control	Pos x 10 / Neg x 10	10ROTC20

STANDARD F

H. pylori Ag FIA

CE

STANDARD F *H. pylori* Ag FIA is a fluorescent immunoassay for the detection of *H. pylori* antigen in human fecal samples.

Test type Professional Use Only
Specimen type Feces
Specimen volume 40 ~ 70 mg
Testing time 10 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Biopsy	95.56% (129/135)	94% (188/200)

Reference : Samsung Medical Center

Ordering Information

Products	Tests / Kit	Cat. No.
F *H. pylori* Ag FIA	25 Tests	10HPY10D
H. pylori Ag Control	Pos x 10 / Neg x 10	10HPYC10

STANDARD F

C. difficile GDH FIA

CE

STANDARD F *C. difficile* GDH FIA is the fluorescence immunoassay for the qualitative detection of *C. difficile* GDH from fecal specimens.

Test type Professional Use Only
Specimen type Feces
Specimen volume 40~ 70 mg
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Internal Study	95.24% (80/84)	100% (77/77)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F *C. difficile* GDH FIA	25 Tests	10CDG10D
C. difficile GDH Control	Pos x 10 / Neg x 10	10CDGC10

STANDARD F

C. difficile Toxin A/B FIA

CE

STANDARD F *C. difficile* Toxin A/B FIA is an *in vitro* diagnostic use to qualitative measure the *C. difficile* Toxin A/B.

Test type	Professional Use Only
Specimen type	Feces
Specimen volume	40 ~ 70 mg
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Internal Study	95% (64/67)	100% (70/70)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F *C. difficile* Toxin A/B FIA	25 Tests	10CDT10D
C. difficile Toxin A/B Control	Pos x 10 / Neg x 10	10CDTC10

STANDARD F

Anti-HBs FIA

STANDARD F Anti-HBs FIA is a fluorescent immunoassay for the qualitative detection of antibodies directed against Hepatitis B surface antigen(HBsAg) present in patients' whole blood, serum, and plasma.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F Anti-HBs FIA	25 Tests	10AHB10D

STANDARD F

HBsAg FIA

STANDARD F HBsAg FIA is a fluorescent immunoassay for the qualitative detection of Hepatitis B surface antigen(HBsAg) present in whole blood, serum and plasma.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	20 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Immunoassay	99.0% (99/100)	100% (1,174/1,174)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F HBsAg FIA	25 Tests	10HBS10D
HBsAg Control	Pos x 10 / Neg x 10	10HBSC10

STANDARD F

HCV Ab FIA

According to WHO, about 130-150 million people globally have chronic HCV infection, with more than 350,000 people dying from Hepatitis C-related liver diseases each year. STANDARD F HCV Ab FIA is the fluorescent immunoassay for the detection of Hepatitis C virus (HCV) antibodies in human whole blood, serum, and plasma samples.

Test type Professional Use Only
Specimen type Whole blood, Serum, Plasma
Specimen volume 10 µl
Testing time 15 mins (5 mins early detection for strong positive sample)
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
CLIA	99.77% (439/440)	100% (1,210/1,210)

Reference : Clinical evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F HCV Ab FIA	25 Tests	10HCV10D
HCV Ab Control	Pos x 10 / Neg x 10	10HCVC10

STANDARD F

HAV IgM FIA

Hepatitis A infection is caused worldwide and typically transmitted by the fecal-oral route either via direct contact with an infectious person or consumption of contaminated food or water. STANDARD F HAV IgM FIA is the fluorescent immunoassay for the detection of Hepatitis A virus IgM antibody in human whole blood, serum, and plasma samples.

Test type Professional Use Only
Specimen type Whole blood, Serum, Plasma
Specimen volume 10 µl
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Immunoassay	99.0% (99/100)	100% (1,174/1,174)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F HAV IgM FIA	10 Tests	10HAV10A

STANDARD F

HIV Ag/Ab FIA

Fourth-generation HIV test detects both HIV antibodies and p24 antigens, which provides a faster diagnosis of HIV than 2nd or 3rd generation Tests. STANDARD F HIV Ag/Ab FIA is a fluorescent immunoassay for the simultaneous detection of p24 antigen and HIV antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Immunoassay	99.0% (99/100)	100% (1,174/1,174)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F HIV Ag/Ab FIA	25 Tests	10HIV20D
F HIV Ag/Ab Control	Ag Pos x 10 / HIV-1 Pos x 10 / HIV-2 Pos x 10 / Neg x 10	10HIVC10

STANDARD F

Syphilis Ab FIA

CE

Syphilis is a sexually transmitted infection(STI) caused by Treponema pallidum(TP). It is transmissible by sexual contact with infectious lesions, from mother to fetus in utero and via blood products transfusion. STANDARD F Syphilis Ab FIA is a fluorescent immunoassay for the detection of TP antibodies in human whole blood, serum, and plasma samples.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20 µl Serum/Plasma: 10 µl
Testing time	15 mins (5 mins early detection for strong positive sample)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
CLIA	100% (56/56)	100% (531/531)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Syphilis Ab FIA	25 Tests	10SYP10D
Syphilis Ab Control	Pos x 10 / Neg x 10	10SYPC10

STANDARD F

HbA1c

CE NGSP IFCC MFDS

STANDARD F HbA1c is a test for quantitative measurement of glycated hemoglobin (HbA1c) in human capillary or venous whole blood. This test is to monitor glycemic control in people with diabetes.

Test type	Professional Use Only
Specimen type	Capillary or Venous Whole Blood
Specimen volume	5 µl
Measuring range	4 ~ 15 % [NGSP], 20 ~ 140 mm/mol [IFCC]
Reference range	≤ 5.6% (Normal) | 5.7 ~ 6.4% (Prediabetes) | ≥ 6.5% (Diabetes) 7% (ADA target for diabetes patients)
Testing time	3 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F HbA1c	
Correlation with HPLC	**Differ(%)**
y = 0.9932x + 0.0423, R^2=0.9908, n=210	within 6% (NGSP criteria)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F HbA1c	20 Tests	10A1C10B
SDB HbA1c Control	Lv1 x 10 / Lv2 x 10	03ACS10

STANDARD F

U-Albumin FIA

CE MFDS

STANDARD F U-Albumin FIA is a test for the quantitative measurement of microalbumin in human urine. This test is to aid to the prediction of diabetic nephropathy and cardiovascular diseases(CVD).

Test type	Professional Use Only
Specimen type	Random urine
Specimen volume	3 µl
Measuring range	5 ~ 250 mg/L
Reference range	< 20 mg/L (Normal) | 20 ~ 200 mg/L (Microalbuminuria) | > 200 mg/L (Macroalbuminuria or proteinuria)
Testing time	5 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F HbA1c	
Correlation with ECLIA Method	**Differ(%)**
y=0.9969x + 0.0181, R^2=0.9983, n=210	within 25%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F U-Albumin FIA	20 Tests	10UAL10B
F U-Albumin Control	Lv1 x 10 / Lv2 x 10	10UALC10

STANDARD F
PCT FIA

CE MFDS

STANDARD F PCT FIA is the fluorescent immunoassay for the quantitative measurement of procalcitonin level in human serum, plasma, and whole blood. Procalcitonin helps assess the severity and prognosis of bacterial infections, and support early diagnosis of sepsis.

Test type	Professional Use Only
Specimen type	Venous whole blood, Serum, Plasma
Specimen volume	100 µl
Measuring range	0.05 ~ 50 ng/ml
Reference range	< 0.5 ng/mL (SEPSIS) | < 0.25 ng/mL (LRTI)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F PCT FIA	
Correlation vs ECLIA Method	**Differ(%)**
Plasma: y = 1.011x - 0.0831, R^2=0.9951, n=210 Whole blood: y = 1.0188x - 0.0297, R^2=0.9927, n=210 Serum: y = 0.9974x + 0.0404, R^2=0.9933, n=210	within 20% (serum) / within 25% (whole blood)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F PCT FIA	20 Tests	10PCT20B
F PCT-02 Control	Lv1 x 10 / Lv2 x 10	10PCTC20

STANDARD F
CRP

CE MFDS

STANDARD F CRP is an immunoassay for the quantitative measurement of C-reactive protein level in human serum, plasma and whole blood. The measurement of CRP provides information for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Test type	Professional Use Only
Specimen type	Capillary or Venous Whole blood, Serum, Plasma
Specimen volume	5 µl
Measuring range	1 ~ 150 mg/L (Whole blood) | 1 ~ 130 mg/L (Serum, Plasma)
Reference range	< 10.0 mg/L
Testing time	3 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CRP	
Correlation vs ECLIA Method	**Differ(%)**
Plasma: y = 0.983x - 0.323, R^2=0.976, n=180 Whole blood: y = 0.989x - 0.449, R^2=0.981, n=180 Serum: y = 0.998x + 0.519, R^2=0.974, n=180	within 20%

Ordering Information

Products	Tests / Kit	Cat. No.
F CRP	20 Tests	10CRP10B
SDB CRP Control	Lv1 x 10 / Lv2 x 10	03CCS10

STANDARD F

TnI Pro FIA

CE

STANDARD F TnI Pro FIA is a fluorescence immunoassay for the quantitative determination of cardiac Troponin I (cTnI) levels in human serum and whole blood using STANDARD F Analyzers, manufactured by SD BIOSENSOR. This test is an *in vitro* diagnostic use and intended for use as an aid in the screening and monitoring of acute myocardiac infarction (MI).

Test type	Professional Use Only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	10 ~ 20,000 ng/L
Reference range	< 70.0 ng/L (99th Percentile URL)
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F PCT FIA	
Correlation vs ECLIA Method	**Differ(%)**
Serum: y = 0.9704x + 47.971, R^2 =0.9910, n=210 Whole blood: y = 1.0022x + 7.425, R^2 =0.9890, n=210	within 25%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F TnI Pro FIA	20 Tests	10HST20B
F TnI Control	Lv1 x 10 / Lv2 x 10	10TNIC10

STANDARD F

TnI/CK-MB Combo FIA

CE

STANDARD F TnI/CK-MB Combo FIA is a fluorescent immunoassay for the quantitative determination of cardiac troponin I and total creatine kinase isoenzyme-MB(CK-MB) levels in human serum and whole blood using STANDARD F analyzers manufactured by SD BIOSENSOR. This test is an *in vitro* professional diagnostic use and intended for use as an aid in the screening and monitoring of myocardiac infarction (MI).

Test type	Professional Use Only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	Troponin I : 10 ~ 20,000 ng/L (0.01 ~ 20 ng/mL), CK-MB : 1-200 ng/mL
Reference range	Troponin I: < 70.0 ng/L (99th Percentile URL), CK-MB: < 5.0 ng/mL
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F TnI/CK-MB Combo FIA		
Correlation vs ECLIA Method (Serum)	**Correlation vs ECLIA Method (Whole Blood)**	**Differ(%)**
Troponin I: y = 0.9558x + 105.9, R^2=0.9909, n=210 CK-MB: y = 1.0016x - 0.0267, R^2=0.9931, n=210	Troponin I: y = 1.0039x + 0.3879, R^2=0.9922, n=210 CK-MB: y = 0.9914x + 0.2689, R^2=0.9939, n=210	Within 25%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F TnI/CK-MB Combo FIA	20 Tests	10TNI20B
F TnI Control	Lv1 x 10 / Lv2 x 10	10TNIC10
F CK-MB Control	Lv1 x 10 / Lv2 x 10	10CKBC10

STANDARD F

TnI FIA

CE

STANDARD F TnI FIA is a fluorescent immunoassay for the quantitative measurement of Troponin I level in human serum and whole blood. This test is to screen and monitor the Acute Myocardial Infarction (AMI).

Test type	Professional Use Only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	0.05 ~ 20 ng/mL
Reference range	< 0.05 ng/mL
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TnI FIA	
Correlation vs ECLIA Method	**Differ(%)**
Serum: y = 0.9704x + 47.971, R^2=0.9910, n=210 Whole blood: y = 0.9918x + 0.0034, R^2=0.9833, n=210	Within 20% (Serum) / Within 25% (Whole blood)

Ordering Information

Products	Tests / Kit	Cat. No.
F TnI FIA	20 Tests	10TNI10B
F TnI Control	Lv1 x 10 / Lv2 x 10	10TNIC10

STANDARD F

CK-MB FIA

CE

STANDARD F CK-MB FIA is a fluorescent immunoassay for the quantitative measurement of Creatine Kinase Isoenzyme-MB level in human serum and whole blood. This test is to screen and monitor the Acute Myocardial Infarction (AMI).

Test type	Professional Use Only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	1 ~ 200 ng/mL
Reference range	< 5.0 ng/mL
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CK-MB FIA	
Correlation vs ECLIA Method	**Differ(%)**
Serum: y = 0.9937x - 0.047, R^2=0.9946, n=210 Whole blood: y = 1.0127x - 0.1945, R^2 =0.9919, n=210	within 20% (serum) / within 25% (whole blood)

Ordering Information

Products	Tests / Kit	Cat. No.
F CK-MB FIA	20 Tests	10CKM10B
F CK-MB Control	Lv1 x 10 / Lv2 x 10	10CKBC10

STANDARD F

D-dimer FIA

CE MFDS

STANDARD F D-dimer FIA is a fluorescent immunoassay for the quantitative measurement of D-dimer level in human plasma and whole blood. This test is performed to help rule out Deep Vein Thrombosis(DVT), Pulmonary embolism(PE), and stroke.

Test type	Professional Use Only
Specimen type	Whole blood (Sodium citrate), Plasma (Sodium citrate)
Specimen volume	10 µl
Measuring range	25 ~ 5,000 ng/mL FEU
Reference range	≤ 500 ng/mL FEU
Testing time	7 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F D-dimer FIA	
Correlation vs ECLIA Method	**Differ(%)**
Whole blood: y = 0.9927x + 8.5607, R^2=0.9983, n=120 Plasma: y = 0.9905x + 10.4267, R^2=0.9976, n=120	within 1.96SD

Ordering Information

Products	Tests / Kit	Cat. No.
F D-dimer FIA	20 Tests	10DDI10B
F D-dimer Control	Lv1 x 10 / Lv2 x 10	10DDIC10

STANDARD F

hs-CRP

CE MFDS

STANDARD F hs-CRP is an immunoassay for the quantitative measurement of C-reactive protein level in human serum, plasma, and whole blood. This test is performed to help predict a healthy person's risk of cardiovascular disease as part of a cardiovascular risk profile.

Test type	Professional Use Only
Specimen type	Capillary or Venous Whole blood, Serum, Plasma
Specimen volume	5 µl
Measuring range	0.1 ~ 15 mg/L
Reference range	< 1.0 mg/L (Normal), 1.0 mg/L ~ 3.0 mg/L (Average risk), > 3.0 mg/L (High risk)
Testing time	3 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F hs-CRP	
Correlation vs ECLIA Method (Serum)	**Differ(%)**
y = 1.0057x + 0.0257, R^2=0.9784, n=180	within 20%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F hs-CRP	20 Tests	10HSC10B
F hs-CRP Control	Lv1 x 10 / Lv2 x 10	10HSCC10

STANDARD F

NT-proBNP FIA

CE

STANDARD F NT-proBNP FIA is a fluorescent immunoassay for the quantitative measurement of N-terminal B-type Natriuretic Peptide (NT-proBNP) level in human serum and whole blood (EDTA). This test is to help diagnose congestive heart failure.

Test type	Professional Use Only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	50 ~ 25,000 pg/mL
Reference range	• Acute HF Rule-out : <300 pg/mL • Symptomatic chronic HF Rule-out : <125 pg/mL
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F NT-proBNP FIA	
Correlation vs ECLIA Method	**Differ(%)**
Serum: y = 0.9949x + 56.487, R^2=0.9797, n=180 Whole blood: y = 1.0056x - 55.5455, R^2=0.9772, n=180	within 25%

Ordering Information

Products	Tests / Kit	Cat. No.
F NT-proBNP FIA	20 Tests	10NTP10B
F NT-proBNP Control	Lv1 x 10 / Lv2 x 10	10NTPC10

STANDARD F

Vitamin D FIA

CE

STANDARD F Vitamin D FIA is the *in vitro* diagnostic for the quantitative measurement of total 25-hydroxy Vitamin D (25-OH Vitamin D) in human serum and plasma.

Test type	Professional Use Only
Specimen type	Serum, Plasma
Specimen volume	35 µl
Testing time	45 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F Vitamin D FIA	
Correlation vs ECLIA Method	**Differ(%)**
Y = 0.937x +1.347, R = 0.960, n=100	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F Vitamin D FIA	20 Tests	10VIT10B
F Vitamin D Control	Lv1 x 10 / Lv2 x 10	10VITC10

STANDARD F

β-hCG FIA

CE MFDS

STANDARD F β-hCG FIA is a fluorescent immunoassay for the quantitative measurement of β-hCG level in human serum and whole blood. This test is performed to help diagnose pregnancy if a women is to undergo a medical treatment, be placed on certain drugs, or have other testing, such as x-rays, that might harm the developing baby.

Test type	Professional Use Only
Specimen type	Whole blood, Serum
Specimen volume	50 µl
Measuring range	5 ~ 1,500 mIU/mL
Reference range	≥ 5.0 mIU/mL
Testing time	15 mins (Whole blood) | 10 mins (Serum)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F β-hCG FIA	
Correlation vs ECLIA Method	**Differ(%)**
Serum: y=1.0161x - 6.6452, R=0.9973, n=180 Whole blood: y=0.9889x + 2.2289, R=0.9979, n=180	within 15%

Ordering Information

Products	Tests / Kit	Cat. No.
F β-hCG FIA	20 Tests	10BHC10B
F β-hCG Control	Lv1 x 10 / Lv2 x 10	10BHCC10

STANDARD F

LH FIA

CE MFDS

STANDARD F LH FIA is a fluorescent immunoassay for the quantitative measurement of LH level in human serum, plasma and whole blood. This test is performed to help evaluate fertility issues, function of reproductive organs (ovaries or testicles), or to detect the ovulation.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	20 µl
Measuring range	1 ~ 100 mIU/mL
Reference range	14.0 ~ 95.6 mIU/mL (during ovulation phase)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F LH FIA	
Correlation vs ECLIA Method	**Differ(%)**
y=0.9916x - 0.0866, R=0.9921, n=210	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F LH FIA	20 Tests	10LH10B
F LH Control	Lv1 x 10 / Lv2 x 10	10LHC10

STANDARD F

TSH-II FIA

CE MFDS

STANDARD F TSH-II FIA is the fluorescent immunoassay for the quantitative measurement of Thyroid Stimulating Hormone level in human serum and whole blood. This test is to help diagnose thyroid disorder to monitor treatment of hypothyroidism and hyperthyroidism.

Test type	Professional Use Only
Specimen type	Whole blood, Serum
Specimen volume	35 µl
Measuring range	0.1 ~ 100 mIU/mL
Reference range	0.45 ~ 4.5 mIU/L
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F TSH-II FIA		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=0.9874 + 0.1170, R=0.9971, n=180	QCL=11.6% / QCM=12.0% / QCH=11.0%	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F TSH-II FIA	20 Tests	10TSH20B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F

TSH FIA

CE MFDS

STANDARD F TSH FIA is the fluorescent immunoassay for the quantitative measurement of Thyroid Stimulating Hormone level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

Test type	Professional Use Only
Specimen type	Serum
Specimen volume	100 µl
Measuring range	0.1 ~ 100 mIU/mL
Reference range	0.45 ~ 4.5 mIU/L
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F TSH FIA		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=1.1097x ~ 0.5, R=0.9943, n=110	QCL=7.4% / QCM=6.5% / QCH=4.9%	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F TSH FIA	20 Tests	10TSH10B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F
fT4

CE MFDS

STANDARD F fT4 is an immunoassay for the quantitative measurement of free thyroxin(fT4) level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

Test type	Professional Use Only
Specimen type	Serum
Specimen volume	50 µl
Measuring range	1 ~ 100 pmol/L
Reference range	12 ~ 22 pmol/L (0.93 ~ 1.7 ng/dL)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F fT4		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=1.002x - 0.1452, R= 0.9943, n=120	QCL=7.5% / QCM=8.0% / QCH=8.0%	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F fT4	20 Tests	10FT410B
F fT4 Control	Lv1 x 10 / Lv2 x 10	10FT4C10

STANDARD F
T4

CE MFDS

STANDARD F T4 is an immunoassay for the quantitative measurement of thyroxin(T4) level in human serum. This test is to help diagnose thyroid disorder; to monitor treatment of hypothyroidism and hyperthyroidism.

Test type	Professional Use Only
Specimen type	Serum
Specimen volume	50 µl
Measuring range	20 ~ 300 nmol/L
Reference range	66 ~ 181 nmol/L (0.93 ~ 1.7 ng/dL)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F fT4		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=1.0113x - 0.6502, R= 0.9943, n=120	QCL=7.7% / QCM=7.7% / QCH=8.0%	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F T4	20 Tests	10T410B
F T4 Control	Lv1 x 10 / Lv2 x 10	10T4C10

STANDARD F
T3

CE MFDS

STANDARD F T3 is an immunoassay for the quantitative measurement of T3 level in human serum. The test is for *in vitro* diagnostic use and is intended as an diagnose thyroid disorder; hypothyroidism and hyperthyroidism.

Test type	Professional Use Only
Specimen type	Serum
Specimen volume	100 µl
Measuring range	0.3 ~ 10 nmol/L
Reference range	1.3 ~ 3.1 nmol/L (0.8 ~ 2.0 ng/mL)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F T3		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=0.9961x-0.0246, R=0.9744, n=180	QCL = 5% / QCM = 11% / QCH = 4%	within 15%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F T3	20 Tests	10T310B
F T3 Control	Lv1 x 10 / Lv2 x 10	10T3C10

STANDARD F

PSA FIA

STANDARD F PSA FIA is a fluorescent immunoassay for the quantitative measurement of Prostate Specific Antigen level in human serum, plasma and whole blood. This test is performed to help screen men for prostate cancer, and to help determine the necessity for a biopsy of the prostate.

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl (Serum, Plasma) / 20µl (Whole blood)
Measuring range	0.1 ~ 100 ng/ml (Serum/Plasma) | 2 ~ 100 ng/ml (Whole blood)
Reference range	≤ 4.0 ng/ml
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference method vs STANDARD F PSA FIA	
Correlation vs ECLIA Method	**Differ(%)**
Plasma: y = 0.9950x - 0.0340, R^2=0.9971, n=180 Whole blood: y = 0.9913x + 0.2821, R^2=0.9961, n=180 Serum: y = 0.9972x -0.1555, R^2=0.9993, n=180	within 1.96SD

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
F PSA FIA	20 Tests	10PSA10B
F PSA Control	Lv1 x 10 / Lv2 x 10	10PSAC10

STANDARD F

iFOB FIA

CE MFDS

STANDARD F iFOB FIA is the fluorescent immunoassay for the quantitative measurement of hemoglobin in fecal sample. This test is offered as a screening test for the early detection of bowel cancer in patients without symptoms.

Test type	Professional Use Only
Specimen type	Feces
Specimen volume	3 drops
Measuring range	25 ~ 1,000 ng/mL (5 ~ 200 µg Hb/g feces)
Reference range	< 100 ng/mL (20 µg Hb/g feces)
Testing time	5 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
F iFOB FIA	50 Tests	10IFO10C
F iFOB Control	Lv1 x 10 / Lv2 x 10	10IFOC10


03.

STANDARD Q

Rapid diagnostic test

STANDARD Q provides rapid diagnostic products with high sensitivity and specificity through quality control from raw material development to production. STANDARD Q rapid diagnostic products have been globally recognized with 6 WHO-PQ-approved diagnostic products for Malaria, HIV, HCV and HIV/Syphilis, and 2 WHO approved diagnostic products for COVID-19(EUL) and Ebola (EUAL). With fast development lead time, STANDARD Q COVID-19 Ag Test was the first COVID-19 rapid antigen test to be approved for WHO EUL in September, 2020. STANDARD Q COVID-19 Ag Test 2.0 and STANDARD COVID-19 Ag Control swab was authorized for emergence use in September, 2023.

STANDARD Q
COVID-19 Ag 2.0

CE

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasopharyngeal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	99.00% (99/100)	99.75%(401/402)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test 2.0	25 Tests	09COV172D

STANDARD Q
COVID-19 Ag 2.0

CE

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	96.00% (96/100)	100% (402/402)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
COVID-19 Ag Test 2.0	25 Tests	09COV173D

STANDARD Q
COVID-19 Ag 2.0

EUA

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasal swab
Specimen volume 4 drops
Testing time 20 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	93.2% (95% CI: 81.8 to 97.7%)	100% (95% CI: 96.7–100%)

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test 2.0	25 Tests	09COV174D
COVID-19 Ag Control swab	Pos x 5, Neg x 5	10COVC14J

STANDARD Q
COVID-19 Ag

WHO EUL CE 0123 TGA Health Canada MFDS

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasopharyngeal swab
Specimen volume 3 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	95.92% ~ 100% (CT≤25)	98.94% (1490/1506)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test	25 Tests	09COV30D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q
COVID-19 Ag

WHO EUL CE TGA MFDS

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	82.7%	99.1%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test	25 Tests	09COV31D

STANDARD Q
COVID-19 Ag Nasal

CE Health Canada

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	82.7% (95% CI: 75.6 - 88.4%)	99.1% (95% CI: 97.9 – 99.7%)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Nasal Test	25 Tests	09COV36D
Q COVID-19 Ag Nasal Test	2 Tests	09COV37H

STANDARD Q
COVID-19 Ag Saliva

CE

Test type Professional Use Only
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Saliva with mucus
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	94.74% (18/19)	100% (73/73)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Saliva Test	25 Tests	09COV90D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q
COVID/Flu Ag Combo

CE MFDS

Test type Professional Use Only
Intended Use Detection of specific antigens to SARS-CoV-2 and Influenza A and Influenza B
Specimen type Nasopharyngeal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
SARS-CoV-2	92.73% (95%CI: 82.41% ~ 97.98%)	99.49% (95%CI: 97.18% ~ 99.99%)
Influenza A	92.22% (95%CI: 84.63% ~ 96.82%)	100.00% (95%CI: 98.13% ~ 100.00%)
Influenza B	91.18% (95%CI: 81.78% ~ 96.69%)	99.49% (95%CI: 97.18% ~ 99.99%)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID/Flu Ag Combo Test	25 Tests	09COV102D
COVID/Flu Ag Control swab	COVID Pos x 10, Flu Pos x 10, Neg x 10	09COVC30

STANDARD Q
COVID-19 Ag Home Test

MFDS

Test type Self-diagnostic test
Intended Use Detection of nucleocapsid antigens to SARS-CoV-2 virus
Specimen type Nasal swab
Specimen volume 4 drops
Testing time 15 ~ 30 mins
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	94.94% (75/79)	100% (217/217)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Home Test	1 Test	09COV130
	2 Test	09COV130H
	5 Test	09COV130J
	25 Test	09COV130D

STANDARD i-Q

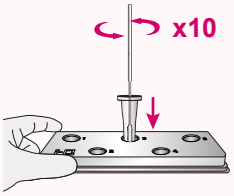
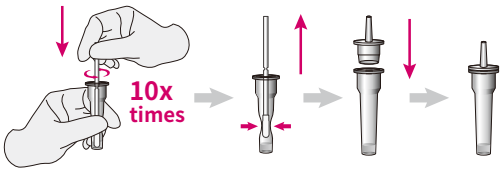
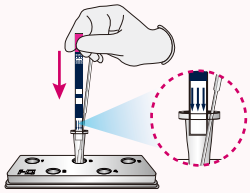
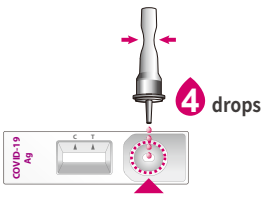
STANDARD i-Q is a new brand of SD BIOSENSOR that **pursues convenience and safety** while improving its performance as well.

From the **general casette types** of STANDARD Q Productss, STANDARD i-Q Productss are developed in **dipstick types**.

Advantage

- Improved testing procedures for better usability
- Minimized human error with **lesser procedural steps**
- Compact packaging for better portability and logistics

COVID-19 Swab Test Procedure Comparison : i-Q vs Q

	i-Q Test Procedure (2 Steps)	Q Test Procedure (4 Steps)
Point 1 Nozzle Cap		
	Don't need to put nozzle cap	**Take out swab and put nozzle cap**
Point 2 Swab and Drops		
	Just leave the swab and Insert test strip	**Need to put 4 drops**

STANDARD i-Q COVID-19 Ag Home Test

Health Canada MFDS

Test type	Self-diagnostic test
Intended use	Detection of SARS-CoV-2 nucleocapsid antigen present in human nasal samples.
Specimen type	Nasal swab
Testing time	15 ~ 30 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	94.94% (75/79)	100% (217/217)

Reference : Internal evaluation

STANDARD i-Q COVID/Flu Ag Combo Test

CE

Test type	Professional Use Only
Intended use	Detection of specific antigens to SARS-CoV-2 and Influenza A and Influenza B present in human nasopharyngeal specimens.
Specimen type	Nasophayngeal swab
Testing time	15 ~ 30 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

Test Performance

	Reference	Sensitivity	Specificity
SARS-CoV-2	PCR	94.55% (52/55)	100% (195/195)
Flu A/B	PCR	93.33%(A, 84/90) 91.18% (B, 62/68)	100% (195/195)

Reference : Internal evaluation

STANDARD i-Q COVID-19 Ag Test 2.0

CE

Test type	Professional Use Only
Intended use	Detection of specific antigens to SARS-CoV-2 and Influenza A and Influenza B present in human nasal, nasophryngeal, and oral specimens.
Specimen type	Nasal / Nasopharyngeal
Testing time	15 ~ 30 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

STANDARD Q MERS-CoV Ag

CE

Test type	Professional Use Only
Intended use	Detection of MERS-CoV antigens
Specimen type	Sputum/ BAL (Bronchoalveolar Lavage) or pleural fluid/ Tracheal aspirate/ Nasopharyngeal aspirate/ Oropharyngeal aspirate
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 ~ 40°C / 36 ~ 104°F

STANDARD i-Q SARS-CoV-2 Spike IgG Test

CE

Test type	Professional Use Only
Intended use	Detection of IgG antibodies specific to SARS-CoV-2 spike protein present in human serum, plasma or whole blood.
Specimen type	Whole blood, Plasma, Serum
Specimen volume	Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time	10 ~ 15 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

Ordering Information

Products	Tests / Kit	Cat. No.
i-Q COVID-19 Ag Home Test	2 Tests	09COV120H
	5 Tests	09COV120J
	25 Tests	09COV120D
	25 Tests	09COV120DM
i-Q COVID-19 Ag Test 2.0 (NP)	25 Tests	09COV270D
i-Q COVID-19 Ag Test 2.0 (NS)	25 Tests	09COV272D
i-Q COVID/Flu Ag Combo Test	25 Tests	09COV280D
i-Q SARS-CoV-2 Spike IgG Test	25 Tests	09COV290D
Q MERS-CoV Ag	25 Tests	05MC10
COVID/Flu Ag Control swab	COVID Pos x 10, Flu Pos x 10, Neg x 10	10COVC30

STANDARD Q

Influenza A/B

CE MFDS

Test type Professional Use Only
Intended use Detection of influenza A/B antigens
Specimen type Nasopharyngeal swab
Specimen volume 4 drops
Testing time 8 ~ 12 mins (Do not read after 20 mins)
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	A: 97.44% (95% CI: 86.52~99.94%), B: 90.63% (95% CI: 74.98~98.02%)	A: 100% (95% CI: 99.12~100.00%), B: 98.82% (95% CI: 97.26~99.61%)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Influenza A/B Test	25 Test	09INF40D
Influenza A/B Control	Pos x 10, Neg x 10	10INFC10

STANDARD Q

RSV Ag

CE MFDS

Test type Professional Use Only
Intended use Detection of Respiratory Syncytial Virus (RSV) antigens
Specimen type Nasopharyngeal swab
Specimen volume 4 drops
Testing time 15 mins (Do not read after 30 mins)
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
PCR	92.45% (49/53)	98.44% (126/128)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q RSV Ag	25 Tests	09RSV40D
RSV Ag Control	Pos x 10, Neg x 10	10RSVC10

STANDARD Q

Strep A Ag

CE

Test type Professional Use Only
Intended use Detection of Group A streptococcal antigens
Specimen type Throat swab
Testing time 5 mins (Do not read after 15 mins)
Storage condition 2 ~ 30°C / 36 ~ 86°F

Test Performance

Reference	Sensitivity	Specificity
FIA	98.2% (56/57)	99.26% (135/136)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Strep A Ag	25 Tests	09STR40D
Strep A Ag Control	Pos x 10, Neg x 10	10STRC10

STANDARD Q

Adeno Respi Ag

CE

Test type	Professional Use Only
Intended use	Detection of adenovirus antigens in respiratory specimens
Specimen type	Nasopharyngeal swab
Specimen volume	4 drops
Testing time	15 mins (Test can be read up to 20 minutes.)
Storage condition	2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q Adeno Respi Ag	25 Tests	09ADE10D
Adeno Ag Control	Pos x 10 / Neg x 10	10ADEC10

STANDARD Q

TB MPT64 Ag

CE

Test type	Professional Use Only
Intended use	Detection of Mycobacterium tuberculosis MPT64 antigen
Specimen type	Liquid culture, Solid culture
Testing time	10 mins (Do not read after 15 mins)
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
PCR	100%	100%

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q TB MPT64 Ag	25 Tests	09MPT10D

STANDARD Q

Dengue Duo

CE TGA

Test type Professional Use Only
Intended use Detection of Dengue NS1 antigen & IgM/IgG antibodies
Specimen type Whole blood, Serum, Plasma
Specimen volume NS1: 100 µl, IgM/IgG: 10 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
NS1	RT-PCR	92.4 % (183/198)	98.7% (222/225)
IgM	ELISA	97.5% (77/79)	96.6% (346/358)
IgG	ELISA	97.2% (140/144)	96.2% (282/293)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Dengue Duo Test	10 Tests	09DEN30A

STANDARD Q

Dengue NS1 Ag

CE TGA

Test type Professional Use Only
Intended use Detection of Dengue NS1 antigen
Specimen type Whole blood, Serum, Plasma
Specimen volume 100 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
RT-PCR	92.4 % (183/198)	98.7% (222/225)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Dengue NS1 Ag Test	25 Tests	09DEN10D

STANDARD Q

Dengue IgM/IgG

CE TGA

Test type Professional Use Only
Intended use Detection of Dengue IgM and IgG antibodies
Specimen type Whole blood, Serum, Plasma
Specimen volume 10 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
IgM	ELISA	97.5% (77/79)	96.6% (346/358)
IgG	ELISA	97.2% (140/144)	96.2% (282/293)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Dengue IgM/IgG Test	25 Tests	09DEN20D

STANDARD Q
Zika IgM

Test type	Professional Use Only
Intended use	Detection of Zika IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
MAC- ELISA / PCR	98.0% (49/50)	100% (70/70)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Zika IgM Test	25 Tests	09ZK40D

STANDARD Q
Chikungunya IgM/IgG

Test type	Professional Use Only
Intended use	Detection of Chikungunya IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
IgM	ELISA	100% (22/22)	97.7% (253/259)
IgG	ELISA	100% (22/22)	99.6% (258/259)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Chikungunya IgM/IgG Test	25 Tests	09CHI20D

STANDARD Q
Yellow Fever IgM

Test type	Professional Use Only
Intended use	Detection of Yellow Fever IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
ELISA	Lot 1: 80% (24/30) / Lot 2: 86.7% (26/30)	Lot 1: 100% (49/49) / Lot 2: 98% (48/49)

Reference : WHO evaluation data

Ordering Information

Products	Tests / Kit	Cat. No.
Q Yellow Fever IgM Test	25 Tests	09YEL20D

STANDARD Q

Arbo Panel I (Z/D/C/Y)

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika, Dengue, Chikungunya, or Yellow fever
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100 µl, IgM : 10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

STANDARD Q

ZIKV/DENV/CHIKV Fast Quad

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika, Dengue, or Chikungunya
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100 µl, IgM : 10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

STANDARD Q

Dengue/Chikungunya Trio

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM/IgG specific to Dengue or Chikungunya
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100 µl, IgM/IgG : 10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

STANDARD Q

Zika/Dengue Fast Trio

CE

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen and IgM specific to Zika or Dengue
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100 µl, IgM : 10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q Arbo Panel I (Z/D/C/Y) Test	10 Tests	09ZK110U
Q ZIKV/DENV/CHIKV Fast Quad Test	10 Tests	09ZK100A
Q Dengue/Chikungunya Trio Test	10 Tests	09DEN40A
Q Zika/Dengue Fast Trio Test	10 Tests	09ZK61A

STANDARD Q

Malaria P.f Ag

WHO PQ CE

Test type Professional Use Only
Intended use Detection of Malaria *Plasmodium falciparum* specific Histidine Rich Protein 2 (HRP-2)
Specimen type Whole blood
Specimen volume 5 µl
Testing time 15 ~ 30 mins (Do not read after 30 mins)
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
Venous whole blood	Microscopy	99.59% (487/489)	100% (1104/1104)
Capillary whole blood	Microscopy	99.38% (322/324)	100% (256/256)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Malaria P.f Ag Test	25 Tests	09MAL10D

STANDARD Q

Malaria P.f/P.v Ag

WHO PQ CE

Test type Professional Use Only
Intended use Detection of Malaria *P. falciparum* specific HRP-2 and *Plasmodium vivax* specific Plasmodium lactate dehydrogenase (pLDH)
Specimen type Whole blood
Specimen volume 5 µl
Testing time 15 ~ 30 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference		Sensitivity	Specificity
Venous whole blood	Microscopy	P.f	99.59% (487/489)	100% (1006/1006)
		P.v	100% (123/123)	
Capillary whole blood	Microscopy	P.f	99.38% (322/324)	100% (256/256)
		P.v	100% (25/25)	

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Malaria P.f/P.v Ag Test	25 Tests	09MAL20D

STANDARD Q

Malaria P.f/Pan Ag

WHO PQ CE TGA

Test type Professional Use Only
Intended use Detection of Malaria *P. falciparum* specific HRP-2 and Plasmodium species (*P. falciparum, vivax, ovale* and *malariae*) specific pLDH
Specimen type Whole blood
Specimen volume 5 µl
Testing time 15 ~ 30 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference		Sensitivity	Specificity
Venous whole blood	Microscopy	P.f	99.58% (476/478)	100% (1000/1000)
		P.v, P.m. and P.o. confirmed specimen on Pan	100% (129/129)	
Capillary whole blood	Microscopy	P.f	99.68% (312/313)	100% (250/250)
		P.v, P.m. and P.o. confirmed specimen on Pan	100% (31/31)	

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Malaria P.f/Pan Ag Test	25 Tests	09MAL30D

STANDARD Q
Malaria/CRP Duo

CE

Test type Professional Use Only
Intended use Detection of Malaria *P. falciparum* specific HRP-2 and Plasmodium species (*P. falciparum*, *vivax, ovale* and *malariae*) specific pLDH & C-Reactive Protein (CRP)
Specimen type Whole blood
Specimen volume Mal: 5 µl / CRP: 10 µl
Testing time Mal: 15 ~ 30 mins / CRP: 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
P.f	Microscopy	100% (17/17)	pf: 99% (199/201) pan: 100% (201/201)
P.v, P.m. and P.o. confirmed specimen on Pan	Microscopy	100% (24/24)	
CRP	Immunoturbidimetric	87.5% (21/24)	100% (50/50)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Malaria/CRP Duo Test	25 Tests	09MAL50D

STANDARD Q
Leptospira IgM/IgG

CE

Test type Professional Use Only
Intended use Detection of Leptospira interrogans IgM and IgG antibodies
Specimen type Whole blood, Serum, Plasma
Specimen volume 10 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q Leptospira IgM/IgG Test	25 Tests	09LEP10D

STANDARD Q
Tsutsugamushi IgM/IgG

CE

Test type Professional Use Only
Intended use Detection of Orientia tsutsugamushi IgM and IgG antibodies
Specimen type Whole blood, Serum, Plasma
Specimen volume 10 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

	Reference	Sensitivity	Specificity
IgM	ELISA	97.52% (117/120)	96.90% (126/130)
IgG	ELISA	49.15% (59/120)	98.48% (128/130)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Tsutsugamushi IgM/IgG Test	25 Tests	09TSU10D

STANDARD Q
HIV/Syphilis Combo

WHO PQ

Test type Professional Use Only
Intended use Detection of specific antibodies to all isotypes of HIV-1/2 and Treponema pallidum
Specimen type Whole blood, Serum, Plasma
Specimen volume Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time 15 mins (Do not read after 20 mins)
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

in accordance with CTS

Detection of HIV Ab			
Sensitivity		**Specificity**	
Total	**100.0%** [99.4~100.0%](637/637)	Total	**99.9%** [99.6~100.0%](1,898/1,900)
HIV-1 positive	100.0% (497/497)	EDTA plasma	100.0% (1,000/1,000)
HIV-1 positive(non-B subtypes*)	100.0% (40/40)	Whole blood	99.8% (499/500)
HIV-2 positive	100.0% (100/100)	Hospitalized patients	99.5% (199/200)
		Pregnant women	100.0% (200/200)

* non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

Detection of Treponema pallidum Ab			
Sensitivity [95% CI]		**Specificity** [95% CI]	
Total	**98.8%** [97.1~99.5%](395/400)	Total	**100.0%** [99.8~100.0%](1,900/1,900)
Tp & HIV positive	98.4% (246/250)	EDTA plasma	100.0% (1,000/1,000)
Tp positive	99.3% (149/150)	Whole blood	100.0% (500/500)
		Hospitalized patients	100.0% (200/200)
		Pregnant women	100.0% (200/200)

Ordering Information

Products	Tests / Kit	Cat. No.
Q HIV/Syphilis Combo Test	25 Tests	09HIV20D

STANDARD Q
Syphilis Ab

ERPD CE

Test type Professional Use Only
Intended use Detection of specific antibodies to Treponema pallidum
Specimen type Whole blood, Serum, Plasma
Specimen volume Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time 5 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
TPHA	100% (56/56)	99.1% (443/447)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Syphilis Ab Test	25 Tests	09SYP10D
Q Syphilis Ab Test	100 Tests	09SYP10FM
Syphilis Ab Control Pos	Pos x 10 / Neg x 10	10SYPC10

STANDARD Q
HIV 1/2 Ab 3-Line

WHO PQ MFDS

Test type Professional Use Only
Intended use Detection of specific antibodies to all isotypes of HIV-1/2
Specimen type Whole blood, Serum, Plasma
Specimen volume Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time 10 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

in accordance with CTS

Test Performance

STANDARD Q HIV 1/2 Ab 3-Line Test			
Sensitivity[95% CI]		**Specificity[95% CI]**	
Total	**99.8% [98.9~100.0%](500/501)**	Total	**100.0% [99.8~100.0%] (1,900/1,900)**
HIV-1 positive	99.7% (360*/361)	EDTA plasma	100.0% (1,000/1,000)
HIV-1 positive(non-B subtypes*)	100.0% (40/40)	Whole blood	100.0% (500/500)
HIV-2 positive	100.0% (100/100)	Hospitalized patients	100.0% (200/200)
		Pregnant women	100.0% (200/200)

* The missed sample was collected from a patient receiving HAART very soon after seroconversion phase.
* non-B subtypes: A, A1, CRF01_AE, CRF02_AG, CRF06_cpx, CRF36_cpx, D, F1, F2, G, H, J, K, Group O

Ordering Information

Products	Contents	Tests / Kit	Cat. No.
Q HIV 1/2 Ab 3-Line Test	Device/Assay diluent/Capillary Tube/Lancet/Alcohol swab	25 Tests	09HIV30D
	Device/Assay diluent	25 Tests	09HIV30DM
	Multi-Device/Assay diluent (MFDS only)	100 Tests	09HIV30F

STANDARD Q
Ebola *Zaire* Ag

WHO EUAL CE

Test type Professional Use Only
Intended use Detection of *Zaire* ebolavirus antigens
Specimen type Whole blood, Serum, Plasma
Testing time 20 mins (Do not read after 30 mins)
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q Ebola *Zaire* Ag	25 Tests	05EZ10

STANDARD Q
HAV IgM

CE

Test type	Professional Use Only
Intended use	Detection of Hepatitis A virus IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10 µl
Testing time	15 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
CLIA	100% (26/26)	98.04% (450/459)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q HAV IgM Test	25 Tests	09HAV10D

STANDARD Q
HCV Ab

WHO PQ CE 0123 MFDS

Test type	Professional Use Only
Intended use	Detection of Hepatitis C virus antibody
Specimen type	Whole Blood (PQ), Serum, Plasma
Specimen volume	Whole blood: 20 µl, Serum / Plasma: 10 µl
Testing time	5 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

in accordance with CTS

Detection of HCV Ab			
Sensitivity[95% CI]		**Specificity[95% CI]**	
Total	**100.0% [99.1~100.0%](413/413)**	Total	**97.67% [96.77~98.32%](1465/1500)**
HCV positive	100.0% (311/311)	EDTA plasma	97.2% (972/1000)
HCV positive(genotypes*)	100.0% (102/102)	Whole blood	98.6% (493/500)

*HCV genotypes: 1, 1a, 1b, 2a, 2c, 2b, 3, 3a, 3b, 3k, 4a, 4c, 4d, 4e, 4h, 5, 5a, 6, 6a

Ordering Information

Products	Contents	Tests / Kit	Cat. No.
Q HCV Ab Test	Device/Assay diluent/Capillary Tube	25 Tests	09HCV10D
	Device/Assay diluent	25 Tests	09HCV20D
	Multi-Device/Assay diluent	100 Tests	09HCV20F

STANDARD Q
Anti-HBs

MFDS

Test type	Professional Use Only
Intended use	Detection of antibody against HBV surface antigen
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	15 ~ 30 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
CLIA	98.5% (197/200)	98.0% (294/300)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Anti-HBs Test	25 Tests	09AHB10D
Q Anti-HBs Test	100 Tests	09AHB10F

STANDARD Q
HBsAg

MFDS

Test type	Professional Use Only
Intended use	Detection of Hepatitis B virus surface antigen (HBsAg)
Specimen type	Venous whole blood, Serum, Plasma
Specimen volume	100 µl
Testing time	20 ~ 30 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
CLIA	100% (43/43)	100% (162/162)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q HBsAg Test	25 Tests	09HBS10D
Q HBsAg Test	100 Tests	09HBS10FM

STANDARD Q
H. pylori Ab

CE

Test type	Professional Use Only
Intended use	Detection of Helicobacter pylori antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time	10 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q *H. pylori* Ab Test	25 Tests	09HPY10D

STANDARD Q
H. pylori Ag

CE

Test type	Professional Use Only
Intended use	Detection of Helicobacter pylori antigen
Specimen type	Feces
Specimen volume	40 ~ 70 mg
Testing time	10 ~ 15 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
ELISA	98.5% (64/65)	100% (35/35)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q *H. pylori* Ag Test	25 Tests	09HPY20D

STANDARD Q
Filariasis Ag

CE

Test type	Professional Use Only
Intended use	Detection of *Wuchereria bancrofti* antigens
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20 µl, Serum/Plasma: 10 µl
Testing time	10 ~ 20 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Test Performance

Reference	Sensitivity	Specificity
Microscopy / ELISA / CFA (ICT/FTS)	100% (99/99)	-
Microscopy / PCR / Stool	-	95.3% (181/190)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q Filariasis Ag Test	25 Tests	09FIL10D


04.
Ref ETBA010
Patient ID
Add 1 ml of blood and shake 10 times
STERILE EO IVD
SD BIOSENSOR

STANDARD E

Enzyme-Linked Immunosorbent assay

STANDARD E is an enzyme immunoassay that shows high sensitivity and specificity as an evaluation test method for large-volume tests.

STANDARD E
TB-Feron ELISA

Test type	Professional use only
Intended use	Detection of specific to human IFN-γ antibody
Specimen type	Plasma (collected from sensitized whole blood in TB-Feron Tubes)
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	18 months
Positive agreement rate with Q ELISA	98.4%
Negative agreement rate with Q ELISA	95.9%

Ordering Information

Products	Specimen	Tests / Kit	Cat. No.
E TB-Feron ELISA (2 plates)	Plasma	192 wells/Kit	07TBF10C
TB-Feron Tubes 100	WB	Mitogen tube x 100	07TBFA10
TB-Feron Tubes 200	WB	TB Antigen tube x 100 / Nil tube x 100	07TBFA20
TB-Feron Tubes 300	WB	Mitogen tube x 100 / TB Antigen tube x 100 / Nil tube x 100	07TBFA30
TB-Feron SPP	WB	Mitogen Tube x 10 / TB Antigen Tube x 10 / Nil Tube x 10	07TBFA40
E TB-Feron Control	-	Lv1 x 15 / Lv2 x 15 / Lv3 x 15	07TBFC10

STANDARD E
Covi-FERON ELISA

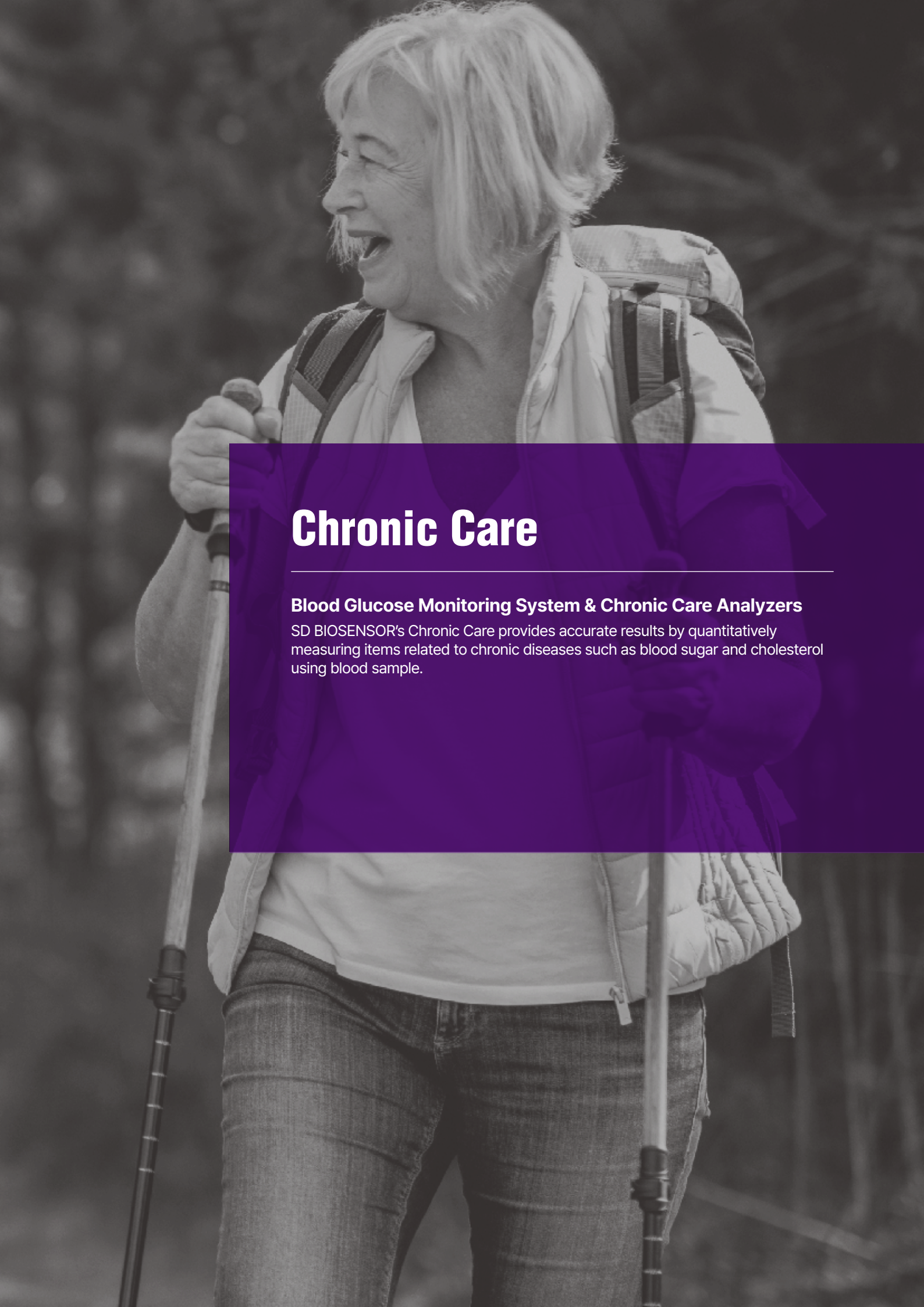
Covi-FERON ELISA is an enzyme linked immunosorbent assay for detecting cellmediated immune responses to SARS-CoV-2 specific proteins in heparinized whole blood. Plasma from the stimulated samples in Covi-FERON tubes can be used for detection of IFN-gamma(IFN-γ) using Covi-FERON ELISA.

Test type	Professional use only
Specimen type	Heparinized whole blood
Specimen volume	1 mL for each tube
Shelf life	18 months
Storage condition	2 ~ 8°C / 36 ~ 46°F

Ordering Information

Products	Tests / Kit	Cat. No.
E Covi-FERON ELISA	192 wells/Kit	13COVF10C
Covi-FERON tubes 500	Nil tube x 100, Original SP Antigen tube x 100, Variant SP Antigen tube x 100, NP Antigen tube x 100, Mitogen tube x 100	13CVFT50
Covi-FERON tubes 300	Nil tube X 100, Total SP Antigen tube X 100, Mitogen tube X 100	13CVFT300
Covi-FERON tubes 100	NP Antigen tube x 100	13CVFT100


05.



Chronic Care

Blood Glucose Monitoring System & Chronic Care Analyzers

SD BIOSENSOR's Chronic Care provides accurate results by quantitatively measuring items related to chronic diseases such as blood sugar and cholesterol using blood sample.

CHRONIC CARE

The vision of SD BIOSENSOR Diabetes Care is to help people with diabetes manage their diabetes more easily and conveniently. For over 23 years, SD BIOSENSOR has been dedicated to ***enabling patients to live healthier lives, as well as empowering healthcare professionals to care their patients more conveniently.*** With our various BGMS portfolio, SD BIOSENSOR will offer better care for patients and we will continuously innovate our products.

Satisfying Customers with the Best Quality

EN ISO 15197 : 2015 Compliance by TUV

Mass Production Capacity

Blood glucose strips: 1.9B Tests / Yr

Full Automation Manufacturing Facility

Full automation manufacturing facility of 18,115 m² area KMGP, EN ISO 13485 : 2016, MDSAP certification

For Patients

SD **CodeFree**

SD CHECK **GOLD 2**

STANDARD **Mentor**

STANDARD **GlucoNavii GDH**

STANDARD CHECK **GOLD PLUS**

GlucoNavii® PRO

For Healthcare Professionals

STANDARD GlucoNavii Elite

Small in Size,
Big in Performance

Lipid&Glucose Meter

STANDARD LipidoCare

Blood Glucose (GOD)
Monitoring System for Hospitals

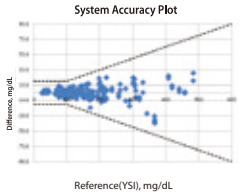
TECHNOLOGY

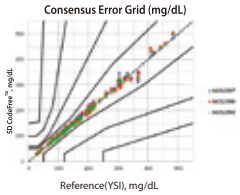
SD BIOSENSOR Diabetes Care constantly innovates the products and technologies to improve the efficiency and effectiveness of patient care.

Blood Glucose Monitoring Meter

Clinically Proven Accuracy

Comply with the system accuracy requirements of EN ISO 15197:2015 standard





ODM Available

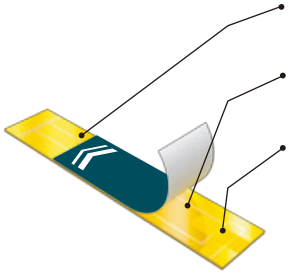
- Various customized ODM models
- Distribute your own brand model

Diabetes Management Software & Android App

- Transferring data from the meter to PC or Smartphone via cable, NFC or Bluetooth. (model- specific)
- Managing the glucose results with PC software and Mobile app.

Blood Glucose Monitoring Strip

Gold is the best stable material for electrical resistance, so it helps to get the best accuracy rather than other material like carbon.

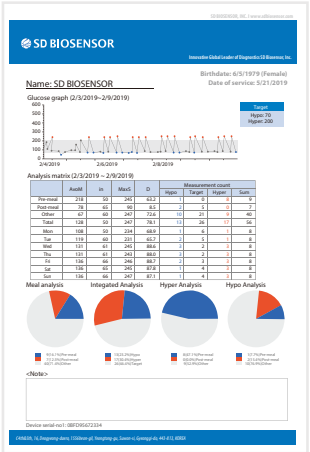


Wide Gold Electrode
Makes best accurate results

Laser Patterning
Makes test fast and easy

99.9% Pure Gold Electrode
Ensures an excellent precision

STANDARD™ DMS (Diabetes Management Software)



Trend Graph
Able to monitor change in glucose level during designated period through dotted line of the graph.

Analysis Table

- Analysis of glucose value during designated time and weekdays.
- Able to filter average, minimum and maximum glucose value.

Logbook

- Analysis of pre and post meal glucose value based on target range.
- Prevention through analysis of hypo and hyperglycemia.

Free DMS Download

www.sdbiosensor.com → Support Center → Download
→ **Download "STANDARD™ DMS (Diabetes Management System)"**

STANDARD GlucoNavii® Elite

Blood Glucose (GDH-FAD) Monitoring System for Hospitals

CE MFDS

Cable & Wi-Fi Communication
Transfer test results through cable or wi-fi to Electronic Medical Records (EMR) and to LIS/HIS

Touch Screen and Color LCD
Similar operating method to a mobile phone

Strip Ejector
Prevents secondary infection removing the test strip through an ejector

Handy and Portable
Comes in a handy size at 170g for easy portability

2D & 3D Barcode Scan
Read the barcode data used for patients, nurses, materials, etc.

STANDARD GlucoNavii Elite Blood Glucose Meter

Size	80 x 150 x 16.2mm
Weight	170g
Measurement Result Range	10-600 mg/dL
Correction Method	Plasma correction
Sample Type	Capillary and venous whole blood
Sample Volume	Minimum 0.5 µl
Hematocrit Range	0% ~ 70%
Measurement Time	5 seconds
Measurement Method	Glucose Dehydrogenase Biosensor
Measurement Units	mg/dL or mmol/L
Memory	8GB (actual storing capacity 4GB)
BT Version	Bluetooth 5.0 (LE)
Storage Conditions	-20°C ~ 50°C
Operating Conditions	8 ~ 45°C / 10% ~ 93% RH
Power Consumption	- 5 Vd.c., 1.0 A (for C-type cable charging) - 3.7 Vd.c., 1700 mAh (for Lithium Polymer battery pack)

STANDARD GlucoNavii Elite Cradle

Size	142.8 x 100.8 x 101mm
Weight	200g
Power Supply	C-Type USB or Charging Adapter
External Ports	Adapter charging port, LAN port (data transfer)

Ordering Information

Category	Products	Contents	Cat. No.
STANDARD GlucoNavii Elite	GlucoNavii Elite Blood Glucose Meter	1 EA	01GM100
	STANDARD GlucoNavii Elite Cradle	1 EA	01CRD100
	GlucoNavii Elite Blood Glucose Test Strip	50T x 2	01GS100D

GlucoNavii® PRO

Blood Glucose (GDH-FAD) Monitoring System

CE 0123

Management for Target Glucose Level
High & Low Limit set-up

Glucose Status with Color LED and Signal
Intuitive status alert

Strip Ejection Function
Reduce the risk of cross-infection

Various Sample type
- Capillary Blood
- Venous, Arterial, Neonatal Blood (Professional Use Only)

Bluetooth Low Energy (Optional model)

Ordering Information

Category	Products	Contents	Cat. No.
GlucoNavii PRO	GlucoNavii PRO Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC60
	GlucoNavii PRO Blood Glucose Monitoring System	1 Unit	01GC62
	GlucoNavii PRO BT Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC610
	GlucoNavii PRO BT Blood Glucose Monitoring System	1 Unit	01GC612
	GlucoNavii PRO Blood Glucose Test Strip	25T x 2	01GS60

STANDARD GlucoNavii® GDH

Blood Glucose (GDH-FAD) Monitoring System

CE 0123 MFDS

Clinically Proven Accuracy
Compliance with EN ISO15197:2015 standard

GDH-FAD
Minimizing risk of interference

Broad HCT Range
0-70%

Pre & Post Meal Mark
Easy analyze glucose results before or after meal

Ordering Information

Category	Products	Contents	Cat. No.
STANDARD GlucoNavii GDH	STANDARD GlucoNavii GDH Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC30
	STANDARD GlucoNavii GDH Blood Glucose Monitoring System	1 Unit	01GC32
	STANDARD GlucoNavii GDH Blood Glucose Test Strip	25T x 2	01GS30

STANDARD Mentor

The smallest blood volume

510(k) cleared CE 0123 MFDS

Clinically Proven Accuracy
Compliance with EN ISO15197:2015 standard

0.3μl Smallest Blood Volume
Less blood, less pain

Pre & Post Meal Mark
Easy analyze glucose results before or after meal

No Coding
Easy and accurate

Bluetooth Low Energy (Optional model)

Ordering Information

Category	Products	Contents	Cat. No.
STANDARD Mentor	STANDARD Mentor Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC210
	STANDARD Mentor Blood Glucose Monitoring System	1 Unit	01GC212
	STANDARD Mentor Blood Glucose Test Strip	25T x 2	01GS21

SD CHECK® GOLD 2

Convenient to use

MFDS

No Coding
Improved previous model

Wide Gold Electrode
Conductive and stable for electrode reaction

Glucose Specific Detection
Minimizing risk of interference

Adhere to Basic Function for blood glucose test

Ordering Information

Category	Products	Contents	Cat. No.
SD CHECK GOLD 2	SD CHECK GOLD 2 Blood Glucose Monitoring System	1 Unit	01GC22
	SD CHECK GOLD 2 Blood Glucose Test Strip	50T x 1	01GS20C

STANDARD CodeFree® Plus

Simply accurate

CE 0123 MFDS

Color Customization
OEM service is available

No Coding
Easy and accurate

Hypo Warning
Helpful to warm hypoglycemia symptom

Ordering Information

Category	Products	Contents	Cat. No.
STANDARD CodeFree Plus	STANDARD CodeFree Plus Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC50
	STANDARD CodeFree Plus Blood Glucose Test Strip	25T x 2	01GS50

SD CodeFree

The best seller

510(k) cleared CE 0123 MFDS

Clinically Proven Accuracy
Compliance with EN ISO15197:2015 standard

No Coding
Easy and accurate

Wide Gold Electrode
Conductive and stable for electrode reaction

Pre & Post Meal Mark
Easy analyze glucose results before or after meal

Hypo Warning
Helpful to warn hypoglycemia

Post-Meal Alarm
Helpful reminder to test 2 hours after meal

Ordering Information

Category	Products	Contents	Cat. No.
SD CodeFree	SD CodeFree Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC110
	SD CodeFree Blood Glucose Monitoring System	1 Unit	01GC112
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11

STANDARD LipidoCare

Small in size, Big in performance

510(k) cleared CE 0123 TGA MFDS

Method	Lipid: Photometric Glucose: Electrochemical
Specimen type	Lipid: Fresh capillary whole blood or venous whole blood, serum or plasma Glucose: Fresh capillary whole blood
Sample volume	TC: 10 µl / Lipid Profile: 35 µl / Glucose: 0.9 µl
Measuring range	TC: 100 ~ 450 mg/dL , HDL: 25 ~ 95 mg/dL, TG: 45 ~ 650 mg/dL Calculated LDL, LDL/HDL, non-HDL, Glucose: 10 ~ 600 mg/dL
Measuring time	3 mins (Lipid), 5 sec. (Glucose)
Data transfer	Mini USB cable, Bluetooth(optional)
Storage temperature	2 ~ 32°C / 36 ~ 90°F
Shelf life	Lipid: 18 months Glucose: 24 months

*Different from 510k cleared specification.

Ordering Information

Category	Products	Contents	Cat. No.
Analyzer	STANDARD LipidoCare Analyzer	1 Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1 Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip - Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20
Control Solution	STANDARD LipidoCare Control	TC•TG Level 1 x 1 / TC•TG Level 2 x 1 HDL Level 1 x 1 / HDL Level 2 x 1	02LCS20

STANDARD G6PD

Quantitative G6PD enzyme activity analyzer

CE TGA ERPD MFDS

Method	Colorimetric
Specimen type	Whole blood
Sample volume	10µl
Measuring range	Total hemoglobin: 4 ~ 25 g/dL, G6PD: 0 ~ 20 U/g Hb
Measuring time	2 mins
Storage temperature	2 ~ 30°C / 36 ~ 86°F
Shelf life	STANDARD G6PD Test : 18 months STANDARD G6PD Control : 12 months

Ordering Information

Category	Products	Contents	Cat. No.
Analyzer	STANDARD G6PD Analyzer	1 Unit	02GA10
Test device	STANDARD G6PD Test	25T	02G6S10
Test device	STANDARD G6PD Test	10T	02G6S10A
Control	STANDARD G6PD Control	Level 1x10/ Level 2x10	02G6C10


CGMS
Continuous Glucose Monitoring System
COMING SOON!

Chronic Care Systems

BGMS (Blood Glucose Monitoring System)

Category	Products	Contents	Cat. No.
GlucoNavii® PRO	GlucoNavii PRO Blood Glucose Monitoring System (Test Strips x 10)	1 Unit	01GC60
	GlucoNavii PRO Blood Glucose Test Strip	25T X 2	01GS60
GlucoNavii® PRO BT	GlucoNavii PRO BT Blood Glucose Monitoring System (Test Strips x 10)	1 Unit	01GC610
STANDARD GlucoNavii GDH	STANDARD GlucoNavii GDH Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC30
	STANDARD GlucoNavii GDH Blood Glucose Monitoring System	1 Unit	01GC32
	STANDARD GlucoNavii GDH Blood Glucose Test Strip	25T x 2	01GS30
STANDARD Mentor	STANDARD Mentor Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC210
	STANDARD Mentor Blood Glucose Monitoring System	1 Unit	01GC212
	STANDARD Mentor Blood Glucose Test Strip	25T x 2	01GS21
STANDARD CodeFree Plus	STANDARD CodeFree Plus Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC50
	STANDARD CodeFree Plus Blood Glucose Test Strip	25T x 2	01GS50
SD CodeFree	SD CodeFree Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC110
	SD CodeFree Blood Glucose Monitoring System	1 Unit	01GC112
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11
SD CHECK GOLD 2	SD CHECK GOLD 2 Blood Glucose Monitoring System	1 Unit	01GC22
	SD CHECK GOLD 2 Blood Glucose Test Strip	50T x 1	01GS20C
Control Solution	STANDARD Glucose Control Solution	Lv M x 1 / Lv H x 1	01GCS10
	STANDARD GlucoNavii Control Solution	Lv 2 x 1 / Lv 3 x 1	01GCS20

STANDARD LipidoCare

Category	Products	Contents	Cat. No.
Analyzer	STANDARD LipidoCare Analyzer	1 Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1 Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip - Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20
Control Solution	STANDARD LipidoCare Control	HDL Level 1 x 1 / HDL Level 2 x 1 TC·TG Level 1 x 1 / TC·TG Level 2 x 1	02LCS20

STANDARD G6PD

Category	Products	Contents	Cat. No.
Analyzer	STANDARD G6PD Analyzer	1 Unit	02GA10
Test device	STANDARD G6PD Test	25T	02G6S10
Test device	STANDARD G6PD Test	10T	02G6S10A
Control	STANDARD G6PD Control	Lv 1 x 10 / Lv 2 x 10	02G6C10

STANDARD M

STANDARD M10 Analyzer

Products	Contents	Dimension (W/L/H)	Weight	Cat. No.
STANDARD M10 Console	1 M10 Console	18x23x41cm	2 kg	11M1011
STANDARD M10 Module	1 M10 Module	14x33x32cm	7 kg	11M1012

STANDARD M10 Assay Menu

Category	Products	Specimen	Specimen volume	Testing time	Pack size	Cat. No.
Respiratory Infections	STANDARD M10 Flu/RSV/SARS-CoV-2	NP** swab	300 µl	30 ~ 60 min	10T	11FLU10A
	STANDARD M10 SARS-CoV-2	NP** swab	600 µl	30 ~ 60 min	10T	11COV10A
	STANDARD M10 SARS-CoV-2 *Turbo*	NP** swab	300 µl	30 min	10T	11COV20A
Tuberculosis	STANDARD M10 MDR-TB	Sputum/sputum sediment sample	1 ml	80 min	10T	11MTB10A
	STANDARD M10 MTB/NTM	Sputum/sputum sediment sample	1 ml	72 min	10T	11MTB20A
Sexual Health	STANDARD M10 HPV	Cervical swab	1 ml	64 min	10T	11HPV10A
	STANDARD M10 STI Panel	Urine	1 ml	64 min	10T	11STI10A
Vector Borne Disease	STANDARD M10 Arbovirus Panel	Serum / Plasma	600 µl	60 min	10T	11ARB10A
	STANDARD M10 DENV 1-4	Serum / Plasma	300 µl	60 min	10T	11DEN10A
Gastrointestinal Infections	STANDARD M10 *C. difficile*	Unformed stool	1 ml	47 min	10T	11CDC10A
Others	STANDARD M10 MPXV	WB/S/P*, NP** swab, Oro** swab	300 µl	60 min	10T	11MPX20A
	STANDARD M10 MPX/OPX[RUO]	skin lesion, WB/S/P*, NP** swab, Oro** swab	300 µl	60 min	10T	11MPX10A

WB/S/P* : Whole Blood / S : Serum / P : Plasma , Oro** : Oropharyngeal swab, NP** : Nasopharyngeal swab

qPCR Reagent

Category	Products	Specimen	Specimen volume	Testing time	Pack size	Cat. No.
Respiratory Infections	STANDARD M SARS-CoV-2 Real-Time Detection Kit	NP** swab, Oro** swab	10 µl (Extracted RNA)	43 min	100T	11NCO30
	STANDARD M SARS-CoV-2/Variant I Real-Time Detection Kit	NP** swab	10 µl (Extracted RNA)	60 min	100T	11NCO50

Oro** : Oropharyngeal swab, NP** : Nasopharyngeal swab

Etc

Products	Contents	Tests / Kit	Cat. No.
STANDARD M10 Calibration Kit	Calibration Cartridge	2T	11CAL10H
STANDARD M10 SARS-CoV-2 Quality Control Kit	Positive 5 vials / Negativie 5 vials	5T	11COVC10J
STANDARD M10 Flu/RSV/SARS-CoV-2 Quality Control Kit	Positive 3 vials / Negativie 3 vials	9T	11COV20N
STANDARD M10 Printer	M10 Printer, Thermal paper	1EA	MD80I
STANDARD M10 Side Bracket Set	M10 Side Bracket, Long communication cable	1 SET	11M1013
STANDARD M10 Puncher	M10 Cartridge Puncher	1EA	X9001

STANDARD F

Analyzer

Products	Contents	Dimension (W/L/H)	Weight	Cat. No.
F2400 Analyzer	Unit	510 x 566 x 297mm	20.0Kg	10FA24
F200 Analyzer	Unit	214.9 x 261 x 203mm	2.5Kg	10FA20
d-BLOCK Incubator	Unit	220 x 184 x 73mm	1.9 kg	12INC10

Parameters

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. No.
Qualitative assays						
Respiratory Disease	COVID-19 Ag FIA	NP**swab	-	15 mins	25T	10COV30D
		Nasal swab	-	15 mins	25T	10COV31D
	SARS-CoV-2 Variant nAb FIA	S/P*	100 µl	35 mins	20T	10COV120B
	SARS-CoV-2 Total nAb FIA	S/P*	100 µl	35 mins	20T	10COV120B
	COVID/Flu Ag Combo FIA	NP**swab	-	15 mins	25T	10COV71D
	Influenza A/B FIA	NP** swab /wash /aspirate	-	1.5-10 mins	25T	10INF20D
	RSV Ag FIA	NP** swab /wash /aspirate	-	5-15 mins	25T	10RSV10D
	Strep A Ag FIA	Throat swab	-	5 mins	25T	10STR10D
	Legionella Ag FIA	Urine	100 µl	5-15 mins	25T	10LEG10D
	S. *pneumoniae* Ag FIA	Urine, CSF	100 µl	5-10 mins	25T	10SPN10D
	Adeno Respi Ag FIA	NP**swab, Nasal swab	-	15 mins	25T	10ADE10D
	TB-Feron FIA (IFN-gamma)	Plasma	100 µl	15 mins	30 Devices	10TBF10E
Vector Borne Disease	Dengue NS1 Ag FIA	WB/S/P*	100 µl	5-15 mins	25T	10DEN10D
	Dengue IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10DEN20D
	Zika IgM FIA	WB/S/P*	10 µl	15 mins	25T	10ZK30D
	Chikungunya IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10CHI10D
	Tsutsugamushi IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10TSU10D
	Lyme IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10LYM10D
Gastrointestinal Disease	Norovirus Ag Plus FIA	Feces	50-75 mg	15 mins	25T	10NOR20D
	Rota/Adeno Ag FIA	Feces	50-75 mg	20 mins	25T	10ROT10D
	H. pylori Ag FIA	Feces	40-70 mg	10 mins	25T	10HPY10D
	C. difficile GDH FIA	Feces	40-70 mg	15 mins	25T	10CDG10D
	C. difficile Toxin A/B FIA	Feces	40-70 mg	15 mins	25T	10CDT10D
Hepatitis	Anti-HBs FIA	WB/S/P*	100 µl	15 mins	25T	10AHB10D
	HBsAg FIA	WB/S/P*	100 µl	20 mins	25T	10HBS10D
	HCV Ab FIA	WB/S/P*	10 µl	15 mins	25T	10HCV10D
	HAV IgM FIA	WB/S/P*	10 µl	15 mins	10T	10HAV10A
Blood Borne Disease	HIV Ag/Ab FIA	WB/S/P*	100 µl	15 mins	25T	10HIV20D
STI	Syphilis Ab FIA	WB/S/P*	WB: 20 µl, S/P: 10 µl	15 mins	25T	10SYP10D
Quantitative assays						
Chronic Disease	HbA1c	Whole blood	5 µl	3 mins	20T	10A1C10B
	U-Albumin FIA	Urine	3 µl	5 mins	20T	10UAL10B
Inflammation	PCT FIA	WB/S/P*	100 µl	15 mins	20T	10PCT20B
	CRP	WB/S/P*	5 µl	3 mins	20T	10CRP10B
Cardiovascular Disease	TnI Pro FIA	WB/S*	100 µl	10 mins	20T	10HST20B
	TnI/CK-MB Combo FIA	WB/S*	100 µl	10 mins	20T	10TNI20B
	TnI FIA	WB/S*	100 µl	10 mins	20T	10TNI10B
	CK-MB FIA	WB/S*	100 µl	10 mins	20T	10CKM10B
	D-dimer FIA	WB/P*	10 µl	7 mins	20T	10DDI10B
	hs-CRP	WB/S/P*	5 µl	3 mins	20T	10HSC10B
	NT-proBNP FIA	WB/S*	100 µl	15 mins	20T	10NTP10B
Hormone	Vitamin D FIA	S/P*	35 µl	45 mins	20T	10VIT10B
	β-hCG FIA	WB/S*	50 µl	15 mins	20T	10BHC10B
	LH FIA	WB/S/P*	20 µl	15 mins	20T	10LH10B
Thyroid function	TSH-II FIA	WB/S*	35 µl	15 mins	20T	10TSH20B
	TSH FIA	Serum	100 µl	15 mins	20T	10TSH10B
	fT4	Serum	50 µl	15 mins	20T	10FT410B
	T4	Serum	50 µl	15 mins	20T	10T410B
	T3	Serum	100ul	25 mins	20T	10T310B
Tumor Marker	PSA FIA	WB/S/P*	WB: 20 µl, S/P: 100 µl	10 mins	20T	10PSA10B
	iFOB FIA	Feces	3 drops	5 mins	50T	10IFO10C

*WB/S/P : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

STANDARD Q

Parameters

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. No.
Respiratory Disease	COVID-19 Ag 2.0 (CE)	NP**swab	4 drops	15 ~ 30 mins	25T	09COV172D
	COVID-19 Ag 2.0	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV173D
	COVID-19 Ag 2.0 (EUA)	Nasal swab	4 drops	20 ~ 30 mins	25T	09COV174D
	COVID-19 Ag	NP**swab	3 drops	15 ~ 30 mins	25T	09COV30D
	COVID-19 Ag	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV31D
	COVID-19 Ag Nasal Test	Nasal swab	4 drops	15 ~ 30 mins	2T	09COV37H
	COVID-19 Ag Nasal Test	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV36D
	COVID-19 Ag Saliva	Saliva with mucus	-	15 ~ 30 mins	25T	09COV90D
	COVID/Flu Ag Combo	NP** swab	4 drops	15 ~ 30 mins	25T	09COV102D
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	1T	09COV130
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	2T	09COV130H
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	5T	09COV130J
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV130D
	i-Q COVID-19 Ag Test 2.0	NP** swab	-	15 ~ 30 mins	25T	09COV270D
	i-Q COVID-19 Ag Test 2.0	Nasal swab	-	15 ~ 30 mins	25T	09COV272D
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	2T	09COV120H
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	5T	09COV120J
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	25T	09COV120D
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	25T	09COV120DM
	i-Q SARS-CoV-2 Spike IgG Test	WB/S/P*	-	10 ~ 15 mins	25T	09COV290D
	i-Q COVID/Flu Ag Combo	NP** swab	-	15 ~ 30 mins	25T	09COV280D
	Influenza A/B	NP** swab	-	8 ~ 12 mins	25T	09INF40D
	RSV Ag	NP** swab	-	15 ~ 30 mins	25T	09RSV40D
	Strep A Ag	Throat swab	-	5 ~ 15 mins	25T	09STR40D
	Adeno Respi Ag	NP**swab	4 drops	15 ~ 20 mins	25T	09ADE10D
	MERS-CoV Ag (strip)	NP** swab /wash /aspirate	-	15 ~ 30 mins	25T	05MC10
	TB MPT64 Ag	Liquid culture, Solid culture	-	10 ~ 15 mins	25T	09MPT10D
Vector Borne Disease	Dengue Duo	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15 ~ 20 mins	10T	09DEN30A
	Dengue NS1 Ag	WB/S/P*	100 µl	15 ~ 20 mins	25T	09DEN10D
	Dengue IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09DEN20D
	Zika IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09ZK40D
	Chikungunya IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09CHI20D
	Yellow Fever IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09YEL20D
	Arbo Panel I (Z/D/C/Y)	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK110U
	ZIKV/DENV/CHIKV Fast Quad	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK100A
	Dengue/Chikungunya Trio	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15 ~ 20 mins	10T	09DEN40A
	Zika/Dengue Fast Trio	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK61A
	Malaria P.f Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL10D
	Malaria P.f/P.v Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL20D
	Malaria P.f/Pan Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL30D
	Malaria/CRP Duo	WB	Mal: 5 µl / CRP: 10 µl	Mal: 15 ~ 30 mins CRP: 15 ~ 20 mins	25T	09MAL50D
	Leptospira IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09LEP10D
	Tsutsugamushi IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09TSU10D
Blood Borne Disease	HIV/Syphilis Combo	WB/S/P*	WB: 20 µl, S/P: 10 µl	15 ~ 20 mins	25T	09HIV20D
	Syphilis Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	25T	09SYP10D
	Syphilis Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5 ~ 20 mins	100T	09SYP10FM
	HIV 1/2 Ab 3-Line	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09HIV30D
	HIV 1/2 Ab 3-Line (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	100T	09HIV30F
	Ebola *Zaire* Ag	WB/S/P*	100 µl	20 ~ 30 mins	25T	05EZ10
Hepatitis	HAV IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09HAV10D
	HCV Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5 ~ 20 mins	25T	09HCV10D
	HCV Ab	S/P*	10 µl	5 ~ 20 mins	25T	09HCV20D
	HCV Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5 ~ 20 mins	100T	09HCV20F
	HBsAg	WB/S/P*	100 µl	20 ~ 30 mins	25T	09HBS10D
	HBsAg	WB/S/P*	100 µl	20 ~ 30 mins	100T	09HBS10FM
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	25T	09AHB10D
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	100T	09AHB10F
Gastrointestinal Disease	H. pylori Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09HPY10D
	H. pylori Ag	Feces	40-70 mg	10 ~ 15 mins	25T	09HPY20D
Parasitic Disease	Filariasis Ag	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09FIL10D

*WB : Whole Blood / S : Serum / P : Plasma, **NP : Nasopharyngeal

STANDARD Q & F Control Solution

Category	Products	Tests / Kit	Shelf life	Storage	Cat. No.
STANDARD Q & F	COVID-19 Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10COVC10
	COVID-19 Ag Control Swab	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10COVC11
	COVID/Flu Ag Control swab	COVID Pos x 10, Flu Pos x 10, Neg x 10	18M	2 ~ 30°C / 36 ~ 86 °F	09COVC30
	COVID-19 IgM/IgG Control	M Pos x10 / G Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10COVC20
	H. pylori Ag Control	Pos x10 / Neg x10	36M	2 ~ 30°C / 36 ~ 86 °F	10HPYC10
	HBsAg Control	Pos x10 / Neg x10	24M	2 ~ 30°C / 36 ~ 86 °F	10HBSC10
	Dengue NS1 Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10DENC10
	Dengue IgM/IgG Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10DENC20
	HIV 1/2 Ab Control	HIV-1 Pos x 10/ HIV-2 Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10HIVC20
	HCV Ab Control	Pos x10 / Neg x10	36M	2 ~ 30°C / 36 ~ 86 °F	10HCVC10
	Influenza A/B Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10INFC10
	RSV Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10RSVC10
	Strep A Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10STRC10
	Adeno Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10ADEC10
	Syphilis Ab Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10SYPC10
STANDARD F	F Influenza A/B Control swab	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10INFC20
	F COVID/Flu Ag Control swab	COVID Pos x10 / Flu Pos x10 / Neg x 10	18M	2 ~ 30°C / 36 ~ 86 °F	10COVC50
	Vitamin D Control	Lv1 x10 / Lv2 x10	36M	2 ~ 30°C / 36 ~ 86 °F	10VITC10
	PCT-02 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10PCTC20
	CRP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	03CCS10
	HbA1c Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	03ACS10
	U-Albumin Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10UALC10
	CK-MB Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10CKBC10
	TnI Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10TNIC10
	NT-proBNP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10NTPC10
	D-dimer Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10DDIC10
	hs-CRP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10HSCC10
	β-hCG Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10BHCC10
	LH Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10LHC10
	TSH Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10TSHC10
	fT4 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10FT4C10
	T4 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10T4C10
	T3 Control	Lv1 x 10 / Lv2 x 10	24M	2 ~ 30°C / 36 ~ 86 °F	10T3C10
	PSA Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10PSAC10
	iFOB Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10IFOC10
	TB-Feron Control	Lv1 x10 / Lv2 x10 / Lv3 x 10	18M	2 ~ 30°C / 36 ~ 86 °F	10TBFC10
	Norovirus Ag Control	Pos x 10 / Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10NORC10
	Rota/Adeno Ag Control	Pos x 10 / Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10ROTC20
	SARS-CoV-2 nAb Control	Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10COVC40
	C. difficile Control	Pos x10 / Neg x10	36M	2 ~ 30°C / 36 ~ 86 °F	10CDGC10
	C. difficile Toxin A/B Control	Pos x10 / Neg x10	36M	2 ~ 30°C / 36 ~ 86 °F	10CDTC10
	Legionella Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10LEGC10
	S.pneumoniae Ag Control	Pos x10 / Neg x10	18M	2 ~ 30°C / 36 ~ 86 °F	10SPNC10
	Rota/Adeno Ag Control	Pos x 10 / Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10ROTC20
	HIV Ag/Ab Control	HIV Ag Pos x 10 / HIV-1 Pos x 10 / HIV-2 Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10HIVC10
	M. pneumoniae Ag Control	Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10MPNC10
	M. pneumoniae IgM/IgG Control	Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10MPNC20

STANDARD E

Parameters

Category	Products	Specimen	Specimen volume	Cat. no.
Respiratory Disease	TB-Feron ELISA	P*	192wells	07TBF10C
	TB-Feron Tubes 100	WB*	100T (Mitogen Tube)	07TBFA10
	TB-Feron Tubes 200	WB*	100T (TB Antigen Tube) , 100T (Nil Tube)	07TBFA20
	TB-Feron Tubes 300	WB*	100T (Mitogen tube), 100T (TB Antigen Tube) , 100T (Nil Tube)	07TBFA30
	TB-Feron SPP	WB*	10T (Mitogen Tube), 10T (TB Antigen Tube), 10T (Nil Tube)	07TBFA40
	Covi-Feron ELISA	P*	192 wells	13COVF10C
	Covi-FERON tubes 500	WB*	100T (Nil tube), 100T (Original SP tube), 100T (Variant SP tube), 100T (NP Antigen tube), 100T (Mitogen tube)	13CVFT50
	Covi-FERON tubes 300	WB*	100T (Nil tube), 100T (Total SP tube), 100T (Mitogen tube)	13CVFT300
	Covi-FERON tubes 100	WB*	100T (NP Antigen tube)	13CVFT100

STANDARD E Control Solution

Products	Tests / Kit	Shelf life	Storage	Cat. No.
E TB-Feron Control	Lv1 x15 / Lv2 x15 / Lv3 x 15	18M	2 ~ 30°C / 36 ~ 86 °F	07TBFC10

Beginning of all things that protect lives

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