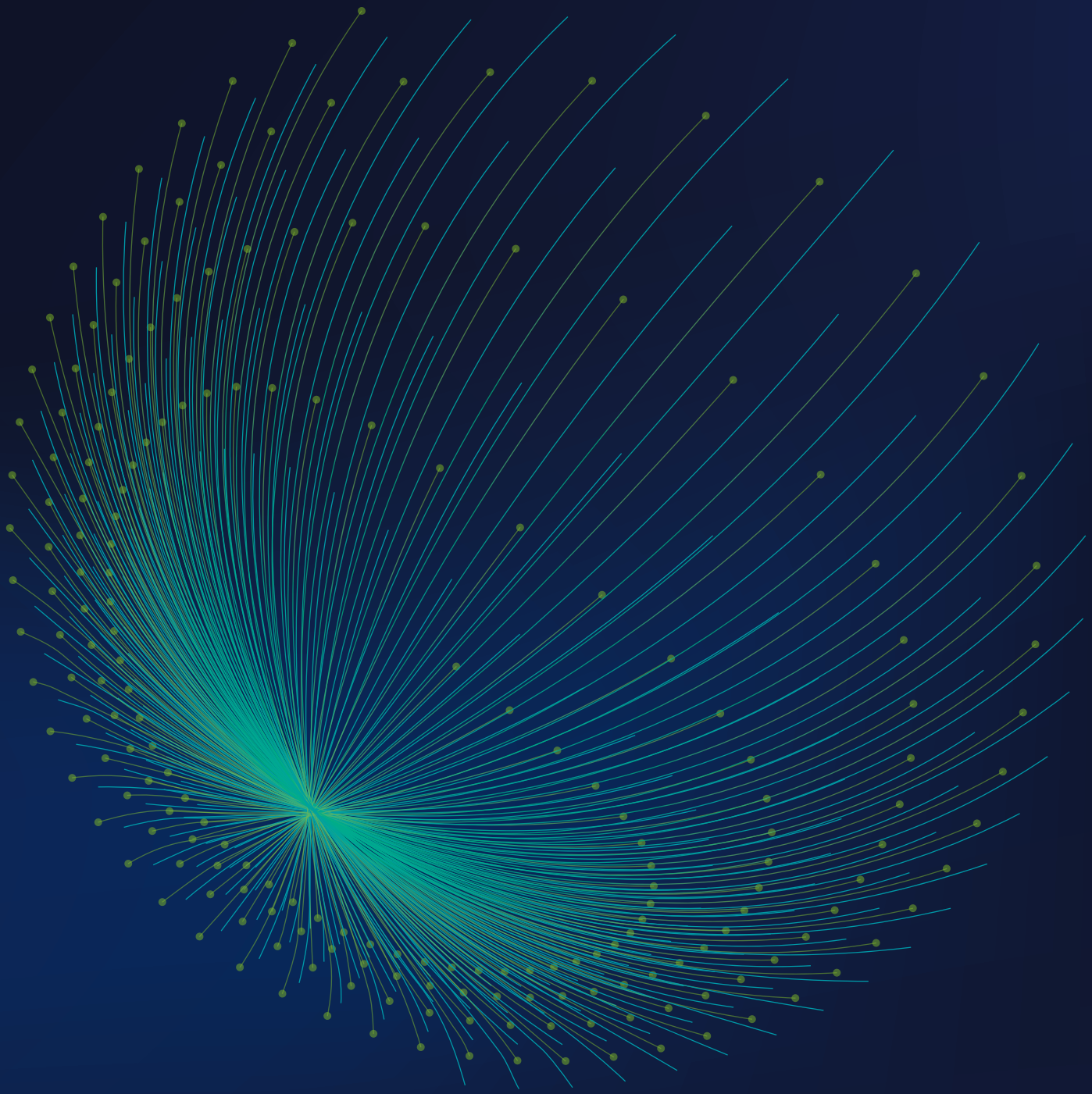
POC *in-vitro* Total Platform Company

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

PRODUCT CATALOG 2025



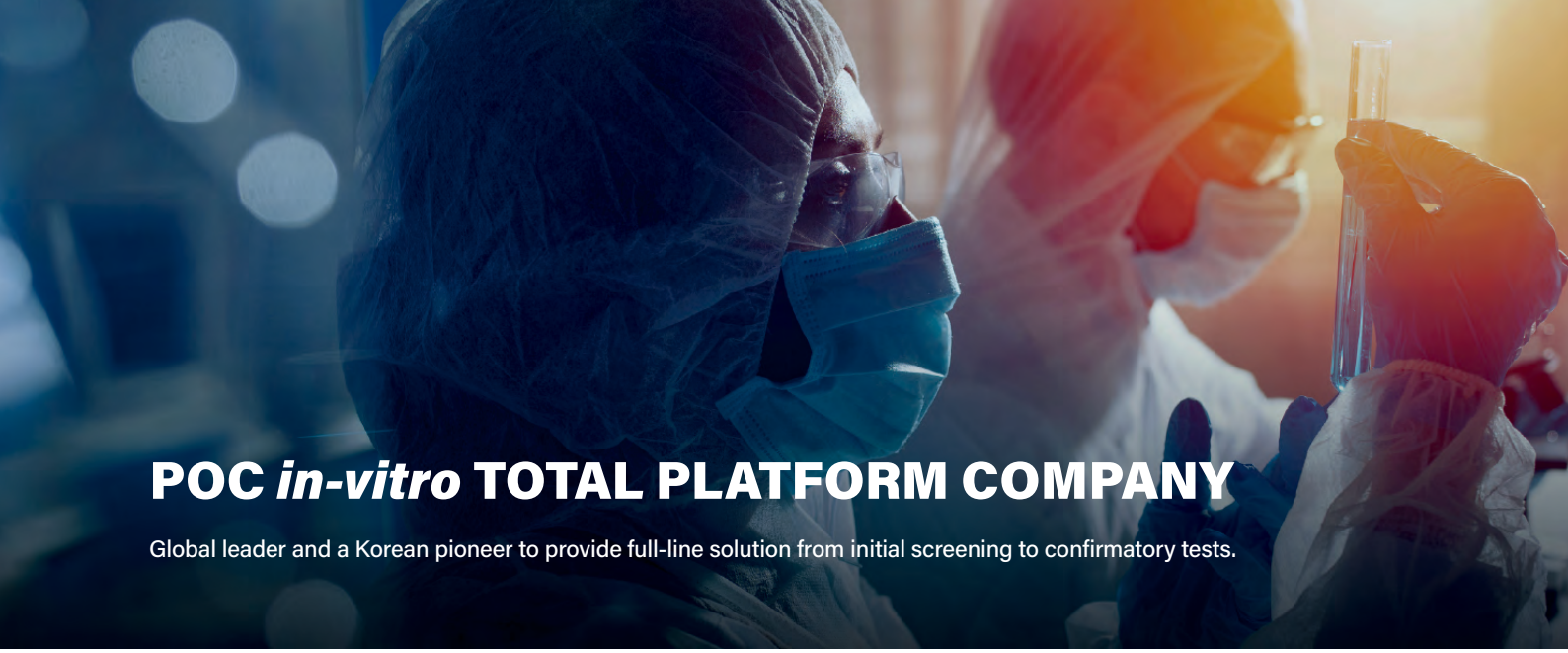
www.sdbiosensor.com

SD BIOSENSOR

SD BIOSENSOR

SD BIOSENSOR is an *in-vitro* diagnostics company that contributes to improving the quality of life by quickly and accurately diagnosing diseases under the slogan 'Beginning of all things that protect lives'. We have provided various diagnostic platforms to the IVD industry through the constant technological innovation. Our IVD diagnostic portfolio has expanded from immune-based IVD to POC Molecular Diagnostics, including over 190 diagnostic products. We are currently planning to launch a CGMS(Continuous Glucose Monitoring System), and we will continue to release innovative diagnostic platforms through the enthusiastic research and development.

The headquarters of SD BIOSENSOR is located in Korea, and the subsidiaries are placed in the USA, Brazil, Panama, India, Indonesia, China, Germany, Italy and Spain. SD BIOSENSOR's strong point to be able to become a global top IVD company throughout the world is having around 199 distribution sales networks globally along with subsidiaries' sales channels. SD BIOSENSOR will continuously create new values by accumulating and analyzing data using AI technology as well as by offering accurate, innovative and effective diagnostics products and services to pursue our goal of contributing to human health.



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 or absence of disease through medical staff

- 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 Osong, 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

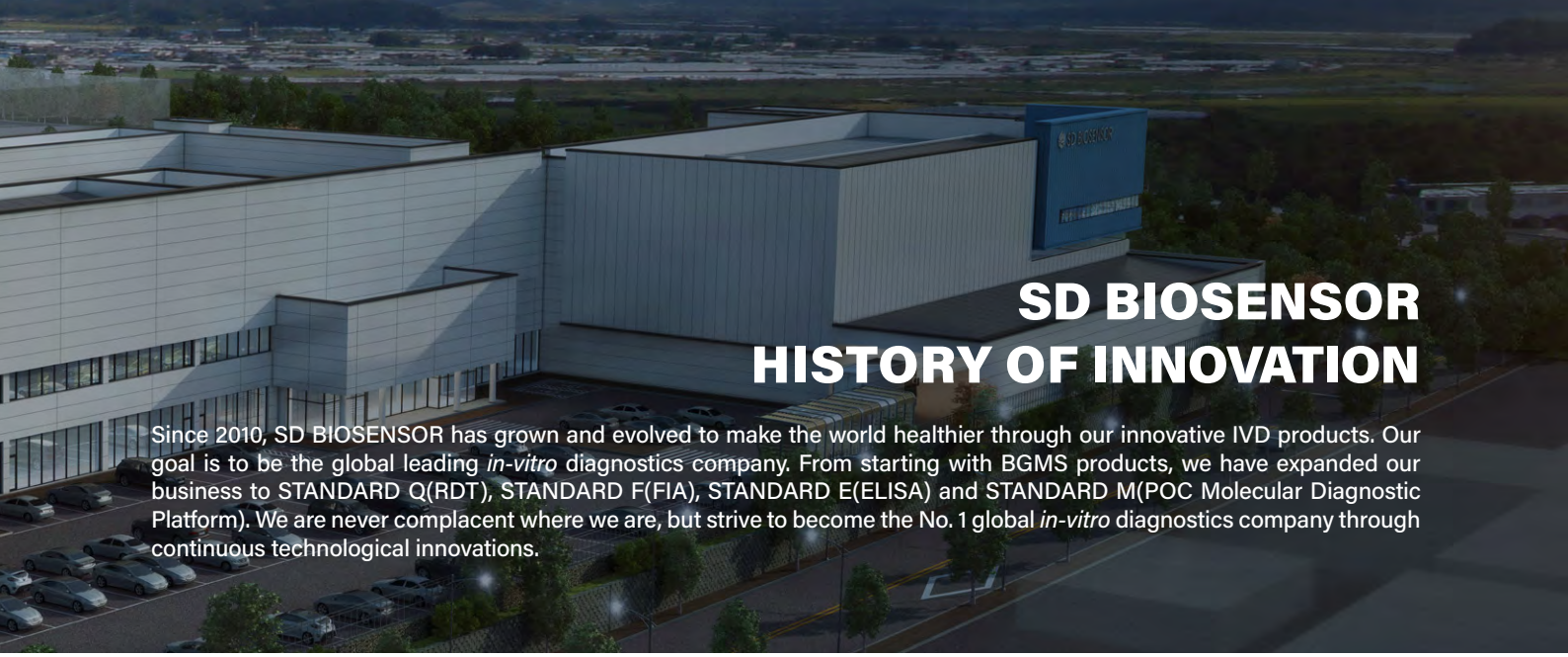
- Awarded “Promising Enterprise in Gyeonggi-do”
- Launched STANDARD™ MultiCare
- Launched STANDARD™ Q(Rapid Diagnostic Test)
- Launched STANDARD™ F(Fluorescent Immunoassay)
- Launched STANDARD™ E(Enzyme Immunoassay)

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 contract with UNICEF for Zika RDT kits
- Developed G6PD Test
- Developed TB-Feron ELISA

2019

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



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.

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 **World 1st**
- Obtained MFDS Approval for STANDARD™ M10
- Obtained Emergency Use Authorization 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 Authorization 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 in Bio/Pharmaceutical industry based on annual sales

2022

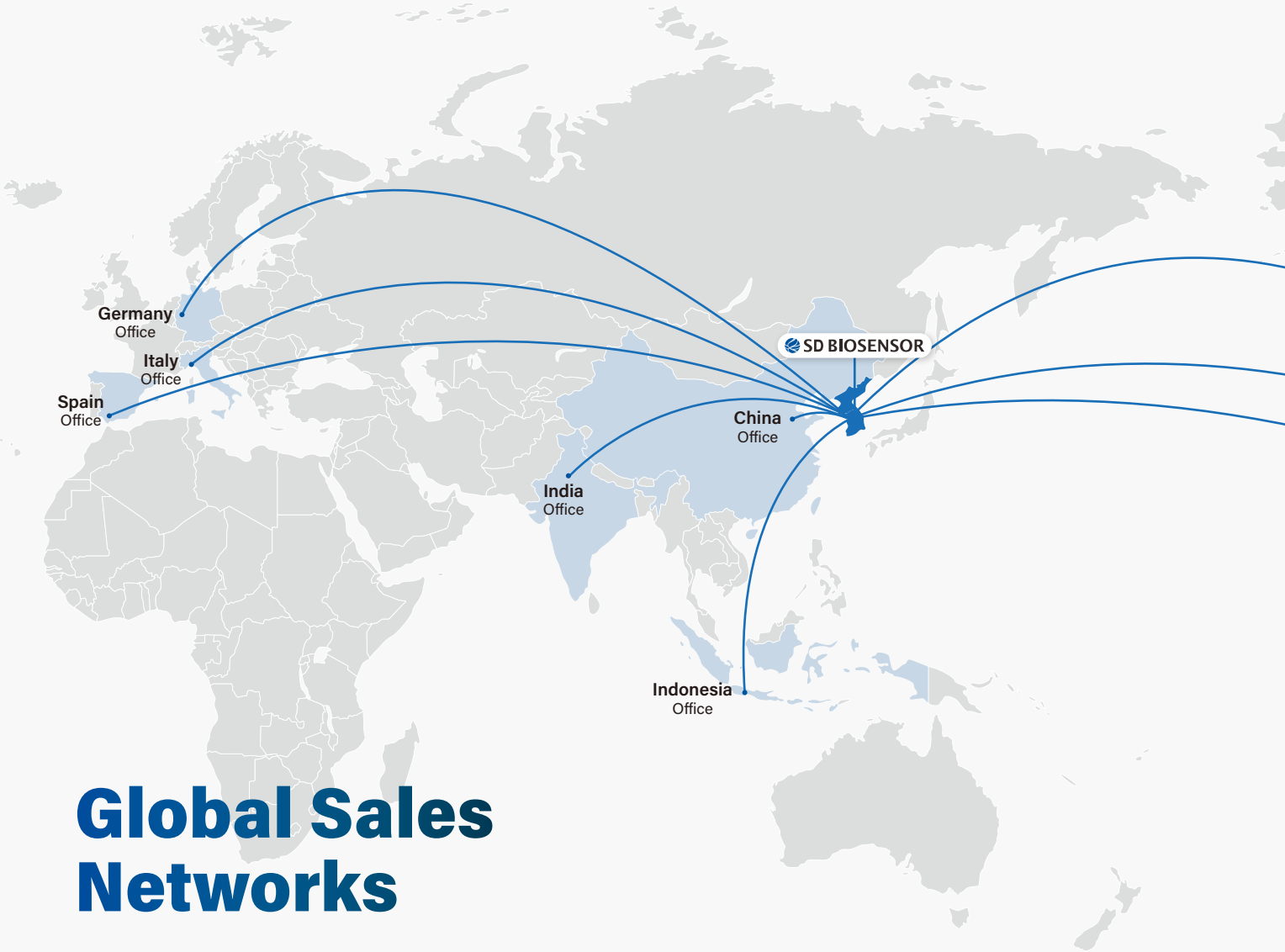
- Awarded “2022 Korea Best Brand Awards” from Forbes Korea
- Acquired “Bestbion dx”, a Germany IVD Products distributor
- Acquired “Relab S.r.l.”, an Italy IVD Products distributor
- Acquired “Meridian Bioscience”, a U.S. IVD company
- Awarded “2022 First Trusted Premium Brands” from Forbes Korea
- Established STANDARD™ M10 cartridge automation factory in Jeungpyeong, 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

- 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

2024 ~ to date

- Obtained WHO PQ Approval for STANDARD™ G6PD
- Obtained STANDARD™ M10 *C. difficile* approval in Korea
- Obtained IVDR CE for STANDARD™ F10 Analyzer and STANDARD™ M10 v2.0
- Established a New Production Plant in India



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	+82-31-300-0400
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 ~ 8F, 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
- **Jeungpyeong** (Factory 4)
  14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, Republic of Korea

Direct sales
in **9** countries

COVID-19
2.5 Bn Tests sold
(As of Dec. 2024)

In **199** countries
856 dealers
(As of Dec. 2024)

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
3471 River Hills Drive, Cincinnati, OH 45244, USA

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

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

Asia

India Office
Plot No. 63, Udyog Vihar, Phase IV, Gurgaon, Haryana, 122015, India

Indonesia Office
KP. Nagrog, RT 004 RW 002, Kel. Kertamukti, Kec Campaka. Kab. Purwakarta, Jawa Barat, 41181, Indonesia

China Office
Room 520, 5th Floor, Building 20, 3998 Hongxin Road, Minhang District, Shanghai, 201103, China

Europe

Italy Office
Corso Perrone 25r, 16152, Genoa, Italy

Spain Office
Avinguda Diagonal, 210, 08018, Barcelona, Spain

Germany Office
An der Hasenkaule 10 / Halle 9, 50354, Hürth, Germany

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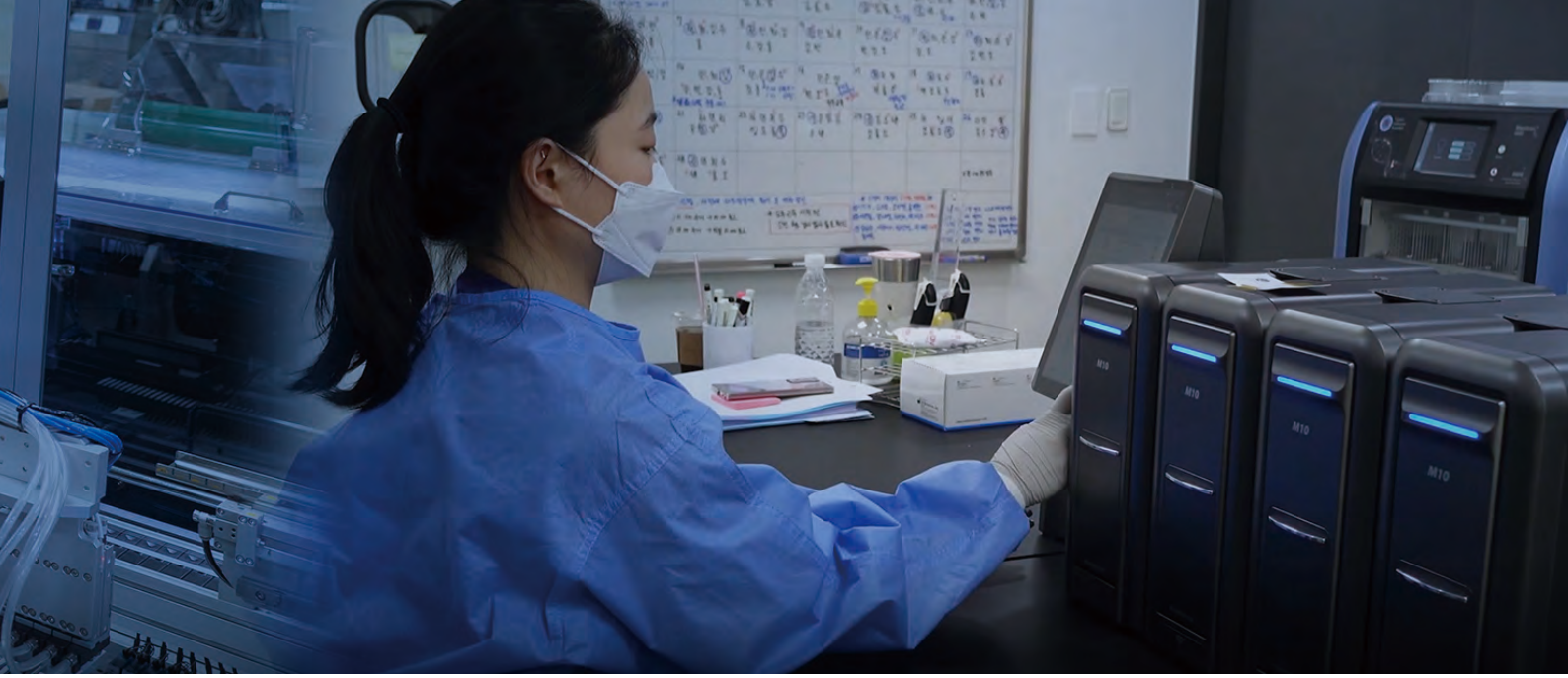

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STANDARD M

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. 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 reagents. STANDARD™ M10 portfolio covers infectious disease diagnosis, drug resistance confirmation, and genetic testing.

CE MFDS ARTG

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*
- MTB/NTM v2.0*

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
- CT/NG/NG-AMR
- Hr-HPV

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

Virology
- HIV-1 VL*

Others
- MPX/OPX

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 Infections	STANDARD™ M10 Flu/RSV/SARS-CoV-2 Fast	10T	11FLU30A
	STANDARD™ M10 Flu/RSV/SARS-CoV-2	10T	11FLU10A
	STANDARD™ M10 SARS-CoV-2	10T	11COV10A
Tuberculosis	STANDARD™ M10 MTB-RIF/INH	10T	11MTB30A
	STANDARD™ M10 MDR-TB	10T	11MTB10A
	STANDARD™ M10 MTB/NTM	10T	11MTB20A
Sexual Health	STANDARD™ M10 STI Panel	10T	11STI10A
	STANDARD™ M10 CT/NG	10T	11CTN10A
	STANDARD™ M10 HPV	10T	11HPV10A
	STANDARD™ M10 Hr-HPV	10T	11HPV20A
Vector Borne Disease	STANDARD™ M10 Arbovirus Panel	10T	11ARB10A
	STANDARD™ M10 DENV 1-4	10T	11DEN10A
Gastrointestinal Infections	STANDARD™ M10 *C. difficile*	10T	11CDC10A
Others	STANDARD™ M10 MPX/OPX	10T	11MPX20A

STANDARD *M10*
Flu/RSV/SARS-CoV-2 Fast

STANDARD M10 Flu/RSV/SARS-CoV-2 Fast 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 36 minutes (Early call: 25 mins)
- One minute hands-on preparation
- Including fixed volume dropper

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Flu/RSV/SARS-CoV-2 Fast	10 Tests	11FLU30A

STANDARD *M10*
Flu/RSV/SARS-CoV-2

CE MFDS ARTG

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 : 94.09% - 99.97%]	100.00% (563/563) [95% CI: 99.35% - 100.00%]
SARS-CoV-2	99.42% (170/171) [95%CI : 96.78% - 99.99%]	98.73% (468/474) [95%CI : 99.00% - 100.00%]

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*
MTB-RIF/INH

STANDARD M10 MTB-RIF/INH is a multiplex real-time PCR and melting curve analysis assay intended for use with STANDARD M10 system. It enables the qualitative detection of *Mycobacterium tuberculosis* complex nucleic acids and drug-resistance against rifampicin (RIF) and isoniazid (INH) in human sputum or sputum sediment samples.

Test type Professional Use Only
Specimen type Sputum, sputum sediment
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of MTB Complex and drug-resistance against RIF and INH
- Result in 99 minutes
- Including sputum prtreatment solution
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MTB-RIF/INH	10 Tests	11MTB30A

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* complex 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 sputum, sputum sediment
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of MTB Complex and drug-resistance against rifampicin (RIF) and isoniazid (INH)
- Result in 86 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 sputum or sputum sediment.

Test type	Professional Use Only
Specimen type	Pretreated 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/viral 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*
CT/NG

STANDARD M10 CT/NG is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of STI pathogens *Chlamydia trachomatis* and *Neisseria gonorrhoeae* 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)
- Simultaneous detection of major STI pathogenes
  - *Chlamydia trachomatis*
  - *Neisseria gonorrhoeae*
- Result in about 1 hour with a simple test procedure

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 CT/NG	10 Tests	11CTN10A

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

Ordering Information

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

STANDARD M10
Hr-HPV

STANDARD M10 Hr-HPV is a multiplex real-time PCR test intended for use with STANDARD M10 system for the qualitative detection of high-risk HPV DNA in LBC specimen.

Test type Professional Use Only
Specimen type LBC
Storage condition 2 ~ 28°C
Advantage
- All-in-one cartridge (NA extraction + amplification)
- Detects more than 99% of HPV types that cause cervical cancer
- Genotyping of high-risk genotypes 16, 18, and 12 others (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
- Result in 64 minutes

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Hr-HPV	10 Tests	11HPV20A

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

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

UK CA

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

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
C. difficile

CE MFDS

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 specimen.

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 (*tcdB*)
- 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% to 99.82%]	98.49% (196/199) [95% CI: 95.66% to 99.69%]	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
MPX/OPX

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 skin lesion swab, serum, plasma, whole blood, nasopharyngeal swab or oropharynegeal swab specimen.

Test type Professional Use Only
Specimen type skin lesion swab, 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
- Result in 60 minutes
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 MPX/OPX	10 Tests	11MPX20A
STANDARD Fixed volume dropper (300µl)	10 EA	90DR20

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
Flu/RSV/SARS-CoV-2 Real-Time Detection Kit

MFDS

STANDARD M Flu/RSV/SARS-CoV-2 Real-Time Detection Kit is a real-time RT-PCR assay intended for the *in vitro* qualitative detection of iInfluenza A, Influenza B, RSV and SARS-CoV-2 (ORF1ab gene, N gene) RNA in human nasopharyngeal swab.

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

Ordering Information

Products	Tests / Kit	Cat. No.
M Flu/RSV/SARS-CoV-2 Real-Time Detection Kit	50 Tests	11NCO60

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

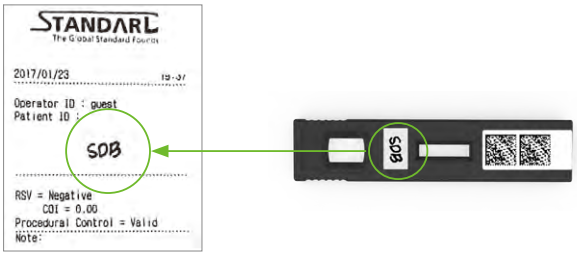
STANDARD F Analyzer is a next-generation fluorescent immunoassay system. It is a multi-parametric and random accessible immunoassay system providing accurate diagnostic results to your laboratory.

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

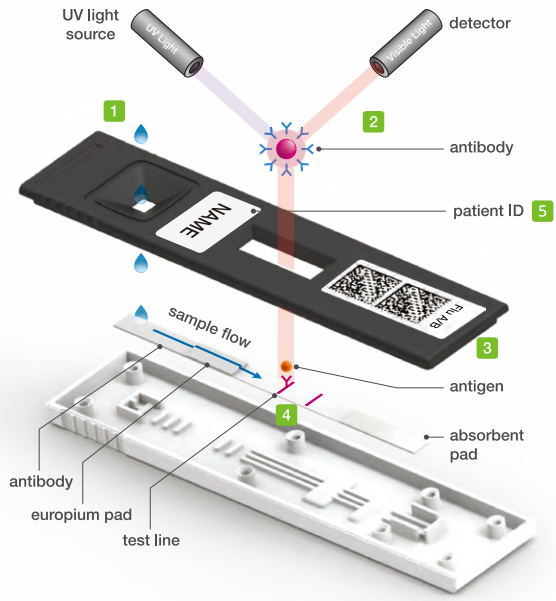
- High sensitivity and specificity
- Fast assay time
- Cost effective

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 Analyzer

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 Analyzer

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	215 x 261 x 202.8 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

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
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 : 100% (97.1-100.0%) / 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 / Nasopharyngeal 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 is a fluorescence immunoassay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen present in urine specimen from patients with symptoms of pneumonia.

Test type	Professional Use Only
Specimen type	Urine
Specimen volume	100 µl
Testing time	15 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	96.2%	100%

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 Ag 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	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 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 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

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
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

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.

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 MFDS

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	97.5% (80/82)	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

MFDS

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	Clinical sensitivity	Clinical specificity
CLIA	100% (440/440)	99.92% (1,209/1,210)

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 ~ 8°C / 36 ~ 46°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
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

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

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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)
Testing time	3 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	7 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	3 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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

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	Venous whole blood, Serum
Specimen volume	50 µl
Measuring range	5 ~ 1,500 mIU/mL
Testing time	15 mins (Whole blood) | 10 mins (Serum)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

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
Testing time 15 mins
Storage condition 2 ~ 30 °C / 36 ~ 86 °F

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
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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)
Testing time	10 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

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)
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

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 Emergency Use in September, 2023.

STANDARD Q
COVID-19 Ag

WHO EUL CE ARTG 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% (1,490/1,506)

Reference : Internal evaluation

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test	25 Tests	09COV30D
Q COVID-19 Ag Test	25 Tests (1 Pos and 1 Neg control swab included)	09COV32D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q
COVID-19 Ag

WHO EUL CE ARTG 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
Q COVID-19 Ag Test	25 Tests (1 Pos and 1 Neg control swab included)	09COV33D

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

CE 0123 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 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 ~ 30°C / 36 ~ 86°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 ARTG

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 ARTG

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 ARTG

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

CE

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

CE

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

WHO Recommended CE

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

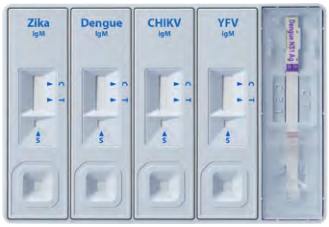
Ordering Information

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

STANDARD Q

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

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



Ordering Information

Products	Tests / Kit	Cat. No.
Q Arbo Panel I (Z/D/C/Y) Test	10 Tests	09ZK110U

STANDARD Q

Dengue/Chikungunya Trio

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

Ordering Information

Products	Tests / Kit	Cat. No.
Q Dengue/Chikungunya Trio Test	10 Tests	09DEN40A

STANDARD Q

Zika/Dengue Fast Trio

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 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% (1,104/1,104)
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
Malaria Ag Control	Pos x 10, Neg x 10	10MALC10

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% (1,006/1,006)
		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 ARTG

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% (1,000/1,000)
		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
hs-Malaria P.f Ag Test

Test type	Professional Use Only
Intended use	Detection of *Plasmodium falciparum* (P.f) antigen for malaria diagnosis
Specimen type	Whole blood
Specimen volume	5 µl
Testing time	15 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q hs-Malaria P.f Ag Test	25 Tests	09MAL60D

STANDARD Q
hs-Malaria P.f/P.v Ag Test

Test type	Professional Use Only
Intended use	Detection of *Plasmodium falciparum* (P.f) and *Plasmodium vivax* (P.v) antigens for malaria diagnosis
Specimen type	Whole blood
Specimen volume	5 µl
Testing time	15 mins
Storage condition	2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q hs-Malaria P.f/P.v Ag Test	25 Tests	09MAL70D

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

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

Filariasis Ag

WHO ERPD 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

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

in accordance with CTS

Test Performance

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 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	**99.76% [99.30~99.95%] (1,249/1,252)**	Total	**99.97% [99.83~100.0%] (3,203/3,204)**
HIV-1 positive	99.7% (1,029/1,032)	Plasma specimens	100.0% (1,177/1,177)
HIV-1 positive(non-B subtypes*)	100.0% (50/50)	Serum specimens	99.92% (1,276/1,277)
HIV-2 positive	100.0% (170/170)	Venous whole blood specimens	100.0% (750/750)

* 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/Buffer bottle/Capillary Tube/Lancet/Alcohol swab	25 Tests	09HIV30D
	Device/Buffer bottle	25 Tests	09HIV30DM
	Multi-Device/Buffer bottle (MFDS only)	100 Tests	09HIV30F

STANDARD Q
HIV/Syp/HBsAg Triple Test

Test type Professional Use Only
Intended use Detection of HIV-1/2 antibodies, *Treponema pallidum* (Syphilis) antibodies, and Hepatitis B surface antigen (HBsAg)
Specimen type Whole blood, Serum, Plasma
Specimen volume 60 µl
Testing time 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q HIV/Syp/HBsAg Triple Test	25 Tests	09HIV300D

STANDARD Q

HIV Self Test

Test type Self-diagnostic test
Intended use Detection of HIV-1/2 antibodies
Specimen type Whole blood (fingerstick)
Specimen volume 20 µl
Testing time 10 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q HIV Self Test	1 Test	09HIV100
Q HIV Self Test	25 Tests	09HIV100D
Q HIV Self Test	50 Tests	09HIV100C

STANDARD Q

HIV Oral Self Test

Test type Self-diagnostic test
Intended use Detection of HIV-1/2 antibodies
Specimen type Oral fluid
Specimen volume Wipe the upper and lower gums 3 to 4 times using the sterile swab
Testing time 15 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q HIV Oral Self Test	1 Test	09HIV201

STANDARD Q

HIV/Syphilis Self Test

Test type Self-diagnostic test
Intended use Detection of HIV-1/2 antibodies and *Treponema pallidum* (Syphilis) antibodies
Specimen type Whole blood
Specimen volume 20 µl
Testing time 15 ~ 20 mins
Storage condition 2 ~ 40°C / 36 ~ 104°F

Ordering Information

Products	Tests / Kit	Cat. No.
Q HIV/Syphilis Self Test	1 Tests	09HIV211

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%](1,465/1,500)**
HCV positive	100.0% (311/311)	EDTA plasma	97.2% (972/1,000)
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/Buffer bottle/Capillary Tube	25 Tests	09HCV10D
	Device/Buffer bottle	25 Tests	09HCV20D
	Multi-Device/Buffer bottle	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

ERPD 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 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

CE MFDS

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

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

CE

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

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

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™ **CodeFree® Plus**

GlucoNavii® PRO

Lipid&Glucose Meter

STANDARD™ LipidoCare

Revolutionary mobile analyzer for cholesterol and blood sugar monitoring

Glucose-6-Phosphate Dehydrogenase

STANDARD™ G6PD

First point-of-care test for G6PD deficiency receives WHO Prequalification

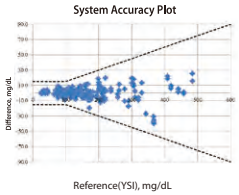
TECHNOLOGY

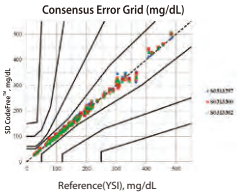
SD BIOSENSOR Diabetes Care constantly innovates the products and technologies to improve the efficiency and effectiveness of patient care.

Blood Glucose Monitoring Meter

Clinically Proven Accuracy

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





ODM Available

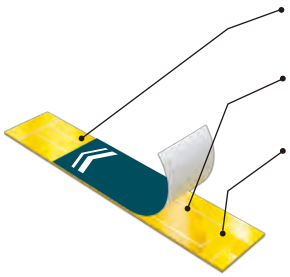
- Various customized ODM models
- Distribute your own brand model

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.

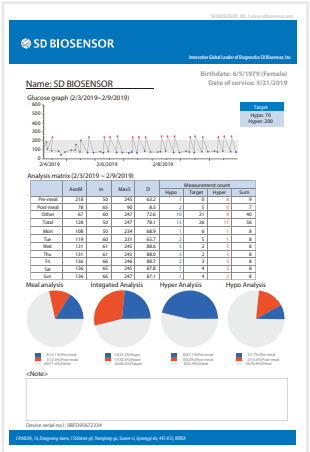


Wide Gold Electrode
Makes best accurate results

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)"**

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 Connection (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

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 Connection (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
	STANDARD Mentor BT Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC270
	STANDARD Mentor BT Blood Glucose Monitoring System	1 Unit	01GC272

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 warn 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

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 Monitoring System	1 Unit	01GC152
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11

STANDARD LipidoCare

Small in size, Big in performance

CE 0123 ARTG 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	Strip: 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	02LS10B
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20B
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

WHO PQ CE ARTG ERPD

Method	Colorimetric
Specimen type	Whole blood
Sample volume	10µl
Measuring range	G6PD: 0 ~ 20 U/g HB (in case of T-Hb value: 7 ~ 25 g/dL)
Measuring time	2 mins
Storage temperature	Strip: 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
	STANDARD G6PD Analyzer (WHO PQ)	1 Unit	02GA11
Test device	STANDARD G6PD Test	25T	02G6S10
	STANDARD G6PD Test	10T	02G6S10A
	STANDARD G6PD Test (WHO PQ)	25T	02G6S11
	STANDARD G6PD Test (WHO PQ)	10T	02G6S11A
Control Solution	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 Monitoring System	1 Unit	01GC62
	GlucoNavii PRO BT Blood Glucose Monitoring System	1 Unit	01GC612
	GlucoNavii PRO BT Blood Glucose Monitoring System (Test Strips x 10)	1 Unit	01GC610
	GlucoNavii PRO Blood Glucose Test Strip	25T X 2	01GS60
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 Mentor BT Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC270
	STANDARD Mentor BT Blood Glucose Monitoring System	1 Unit	01GC272
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	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 Monitoring System	1 Unit	01GC152
	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11
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	02LS10B
	STANDARD LipidoCare Lipid Test Strip - TC	25T	02LS20B
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

Category	Products	Contents	Cat. No.
Analyzer	STANDARD G6PD Analyzer	1 Unit	02GA10
	STANDARD G6PD Analyzer (WHO PQ)	1 Unit	02GA11
Test device	STANDARD G6PD Test	25T	02G6S10
	STANDARD G6PD Test	10T	02G6S10A
	STANDARD G6PD Test (WHO PQ)	25T	02G6S11
	STANDARD G6PD Test (WHO PQ)	10T	02G6S11A
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	17 x 23 x 39cm	2 kg	11M1011
STANDARD M10 Module	1 M10 Module	14 x 33 x 32cm	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 Fast	NP** swab	300 µl	25 ~ 36 mins	10T	11FLU30A
	STANDARD M10 Flu/RSV/SARS-CoV-2	NP** swab	300 µl	30 ~ 60 mins	10T	11FLU10A
	STANDARD M10 SARS-CoV-2	NP** swab	600 µl	30 ~ 60 mins	10T	11COV10A
Tuberculosis	STANDARD M10 MTB-RIF/INH	Sputum/sputum sediment	1 ml	99 mins	10T	11MTB30A
	STANDARD M10 MDR-TB	Sputum/sputum sediment	1 ml	86 mins	10T	11MTB10A
	STANDARD M10 MTB/NTM	Sputum/sputum sediment	1 ml	72 mins	10T	11MTB20A
Sexual Health	STANDARD M10 STI Panel	Urine	1 ml	64 mins	10T	11STI10A
	STANDARD M10 CT/NG	Urine	1 ml	64 mins	10T	11CTN10A
	STANDARD M10 HPV	Cervical swab	1 ml	64 mins	10T	11HPV10A
	STANDARD M10 Hr-HPV	LBC	1 ml	64 mins	10T	11HPV20A
Vector Borne Disease	STANDARD M10 Arbovirus Panel	Serum / Plasma	600 µl	60 mins	10T	11ARB10A
	STANDARD M10 DENV 1-4	Serum / Plasma	300 µl	60 mins	10T	11DEN10A
Gastrointestinal Infections	STANDARD M10 *C. difficile*	Unformed stool	0.1 g	47 mins	10T	11CDC10A
Others	STANDARD M10 MPX/OPX	skin lesion, WB/S/P*, NP** swab, Oro** swab	300 µl	60 mins	10T	11MPX20A

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 mins	100T	11NCO30
	STANDARD M Flu/RSV/SARS-CoV-2 Real-Time Detection Kit	NP** swab	10 µl (Extracted RNA)	43 mins	50T	11NCO60

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 Printer Cable	Cable for the M10 Printer	1EA	P0071903
STANDARD M10 Side Bracket Set	M10 Side Bracket L, R, Long communication cable	1 SET	11M1013
STANDARD M10 Puncher	M10 Cartridge Puncher	1EA	X9001
STANDARD M10 Sputum Pretreatment Kit	Components for spumum sample pretreatment	10T	11PRT10A
STANDARD M10 Stool Pretreatment Kit	Components for stool sample pretreatment	10T	11PRT20A
STANDARD M10 STI Sample Pretreatment Kit	Components for STI sample pretreatment	10T	11PRT30A

STANDARD F

Analyzer

Products	Contents	Dimension (W/L/H)	Weight	Cat. No.
F2400 Analyzer	Unit	510 x 566 x 297mm	20.0 kg	10FA24
F200 Analyzer	Unit	215 x 261 x 202.8mm	2.5 kg	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
	COVID/Flu Ag Combo FIA	NP**swab	-	15 mins	25T	10COV71D
	Covi-FERON FIA	Plasma	-	15 mins	40T	13COVF20G
	Influenza A/B FIA	NP** swab /wash /aspirate	-	10 mins	25T	10INF20D
	RSV Ag FIA	NP** swab /wash /aspirate	-	15 mins	25T	10RSV10D
	Strep A Ag FIA	Throat swab	-	5 mins	25T	10STR10D
	Legionella Ag FIA	Urine	100 µl	15 mins	25T	10LEG10D
	S. *pneumoniae* Ag FIA	Urine, CSF	100 µl	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
	TB LAM Ag FIA	Urine	100 µl	30mins	20T	10TBL10B
Vector Borne Disease	Dengue NS1 Ag FIA	WB/S/P*	100 µl	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	15 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	WB: 15 mins, S: 10 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	100 µl	15 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	NP**swab	3 drops	15 ~ 30 mins	25T	09COV30D
	COVID-19 Ag	NP**swab with 1 each Pos/Neg control	3 drops	15 ~ 30 mins	25T	09COV32D
	COVID-19 Ag	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV31D
	COVID-19 Ag	Nasal swab with 1 each Pos/Neg control	4 drops	15 ~ 30 mins	25T	09COV33D
	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	4 drops	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
	Influenza A/B	NP** swab	4 drops	8 ~ 12 mins	25T	09INF40D
	RSV Ag	NP** swab	4 drops	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
	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
	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
	hs-Malaria P.f Ag	WB	5 µl	15 mins	25T	09MAL60D
	hs-Malaria P.f/P.v Ag	WB	5 µl	15 mins	25T	09MAL70D
	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
	Ebola *Zaire* Ag	WB/S/P*	100 µl	20 ~ 30 mins	25T	05EZ10
	Filariasis Ag	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09FIL10D
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
	HIV/Syp/HBsAg Triple	WB/S/P*	60 µl	20 mins	25T	09HIV300D
	HIV Self	WB	20 µl	10 ~ 20 mins	1T	09HIV100
	HIV Self	WB	20 µl	10 ~ 20 mins	25T	09HIV100D
	HIV Self	WB	20 µl	10 ~ 20 mins	50T	009HIV100C
	HIV Oral Self	Oral fluid	-	15 mins	1T	09HIV201
	HIV/Syphilis Self	WB/S/P*	20 µl	15 ~ 20 mins	1T	09HIV211
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
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	25T	09AHB10D
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	100T	09AHB10F
	HBsAg	WB/S/P*	100 µl	20 ~ 30 mins	25T	09HBS10D
	HBsAg	WB/S/P*	100 µl	20 ~ 30 mins	100T	09HBS10FM
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

*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
	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
	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

SD BIOSENSOR

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