SD BIOSENSOR

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 2022

STANDARD F
Fluorescence immunoassay

STANDARD Q
Rapid diagnostic test

STANDARD M
Molecular diagnostics

STANDARD E
Enzyme-Linked Immunosorbent assay

Chronic Care
Blood Glucose Monitoring System
& Chronic Care Analyzers

www.sdbiosensor.com

SD BIOSENSOR

PRODUCT CATALOG 2022

Pursuing to be the global leading IVD company

At SD BIOSENSOR, we strive to make the world healthier through our innovative IVD products. Our goal is to be the global leading *In-vitro* diagnostics company. We pursue to grow harmoniously with our clients through infinite trust and responsibility.

We are never complacent where we are.

From starting with BGMS products, we have expanded our business to STANDARD Q(RDT), STANDARD F(FIA), STANDARD E(ELISA) and STANDARD M(POC MDx). SD BIOSENSOR's broad range portfolio of IVD products will bring success to your business.

www.sdbiosensor.com

SD BIOSENSOR

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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 → **Confirmatory Test**

General Users

Self test, qualitative test that can be tested by patient like a pregnancy test (for screening purpose)

- BGMS
- STANDARD Q (Rapid Diagnostic Test)

Primary Care Providers

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

- BGMS
- STANDARD Q (Rapid Diagnostic Test)
- STANDARD F (Fluorescent Immunoassay)

Secondary Healthcare

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

- BGMS
- STANDARD Q (Rapid Diagnostic Test)
- STANDARD F (Fluorescent Immunoassay)
- STANDARD M (Molecular Diagnostics)

Tertiary Healthcare

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

- BGMS
- STANDARD Q (Rapid Diagnostic Test)
- STANDARD F (Fluorescent Immunoassay)
- STANDARD M (Molecular Diagnostics)
- STANDARD E (Enzyme Immunoassay)

SD BIOSENSOR
History of Innovation

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

2010 ~ 2011
- Established SD BIOSENSOR, Inc
- Obtained FDA Approval for SD CodeFree
- Obtained Health Canada and FDA Approval for SD CHECK GOLD
- Obtained Health Canada Approval for SD CodeFree
- Obtained CE for and launched STANDARD LipidoCare
- Obtained CE for and launched STANDARD Link 0.3

2012
- Established a branch office in India
- Obtained CE for and launched STANDARD Mentor
- Awarded for “2012 The Customer Quality Satisfaction Awards”
- New construction of 2nd Productsion factory in O-song, Korea
- Established a branch office in the U.S.
- Launched STANDARD A1cCare / GlucoNavii GDH / GlucoNavii NFC

2013
- Won “The Best Brand Award” chosen by consumers from Forbes Korea
- Obtained STANDARD GlucoNavii GDH / GlucoNavii NFC CE Marking
- Obtained STANDARD A1cCare CE Marking
- Met ISO15197 (2013) standards for SD CodeFree cleared
- Completed construction of 2nd Factory in O-song Bio Techno Valley in Sejong-si, Korea

2014 ~ 2015
- Obtained approval for STANDARD Mentor by U.S. FDA
- Met ISO15197 (2013) standards for STANDARD Mentor & STANDARD GlucoNavii NFC/ GDH
- Obtained MFDS approval for and launched STANDARD Mentor BT
- Developed Ebola Zaire Ag rapid diagnosis kit & MERS-CoV Ag rapid diagnosis kit
- Established a branch office in China
- Newly built a local factory in India

2016
- Awarded “Promising Enterprise in Gyenggi-Do”
- Launched STANDARD MultiCare
- Launched STANDARD Q (Immunochromatographic assay)
- Launched STANDARD F (Fluorescent Immunoassay)
- Launched STANDARD E (ELISA)

2017
- Newly changed CI for our dynamic future with expanding IVD portfolio
- Listed on UNICEF Supply Chain Catalog for Q Line Ebola Zaire Ag Kit
- Long-term Contracts 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

2020
- WHO PQ Approval for 6 STANDARD Q Productss
  - STANDARD Q Malaria P.f Ag
  - STANDARD Q Malaria P.f/P.v Ag
  - STANDARD Q Malaria P.f/Pan Ag
  - STANDARD Q HIV/Syphilis Combo
  - STANDARD Q HIV 1/2 Ab 3-Line
  - STANDARD Q HCV Ab
- Obtained WHO EUL Approval for STANDARD Q COVID-19 Ag Test **World 1st**
- Obtained Korea MFDS Approval for STANDARD™ M10
- Obtained FDA EUA Approval for STANDARD™ M10 nCoV Real-Time Detection kit
- Sales reached USD 1.2 billion

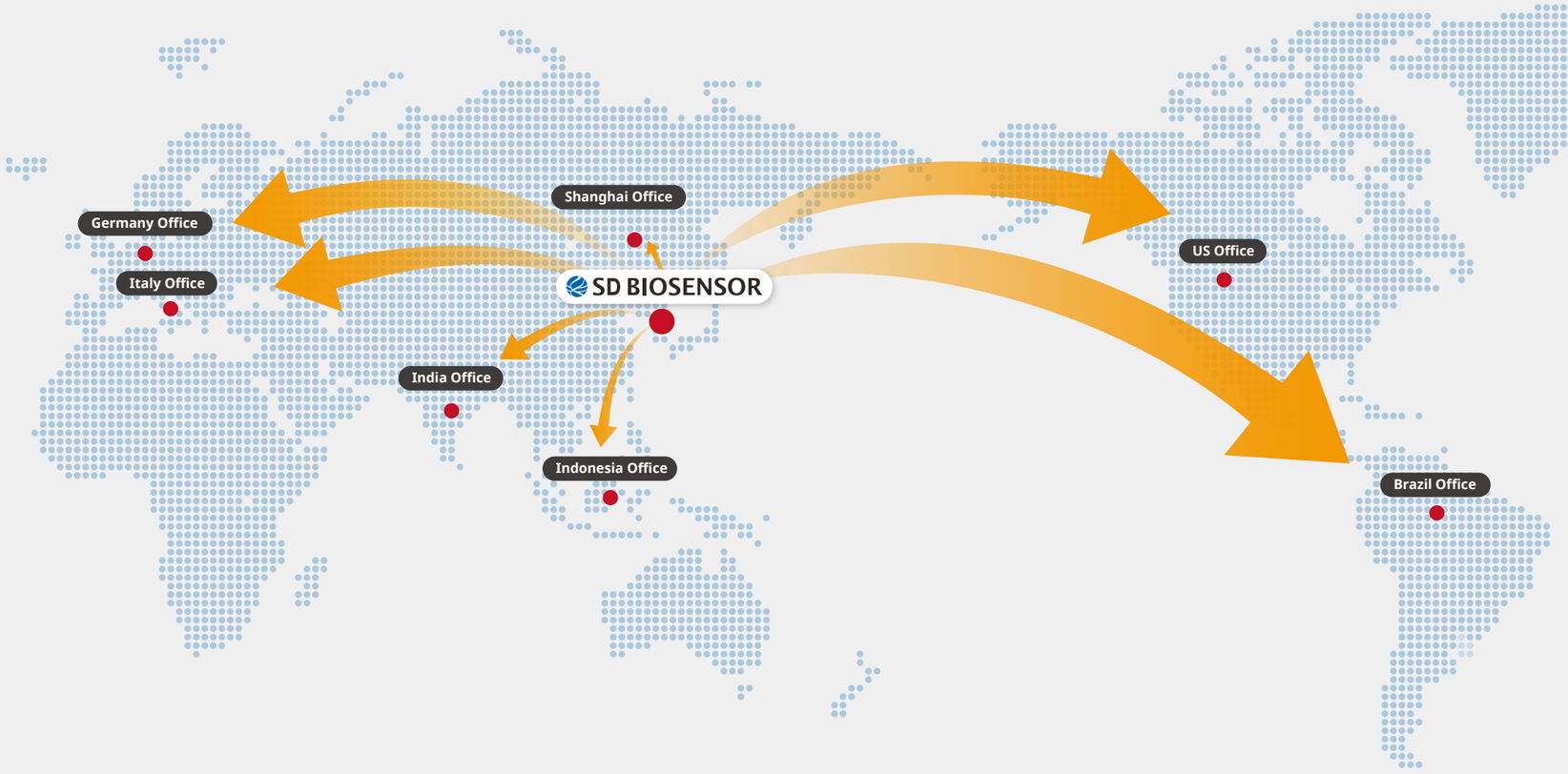
2021
- Obtained CE for STANDARD™ M10 and STANDARD™ M10 SARS-CoV-2
- Obtained FDA EUA Approval for COVID-19 At-Home Test
- Equity investment on CGMS specialized company
- Acquired Brazil IVD company
- Sales reached USD 1.5 billion
- Achieved the No.1 Bio/Pharmaceutical industry in Korea based on sales

2022 ~ to date
- Awarded for “2022 Korea Best Brand Awards” from Forbes Korea
- Acquired Germany professional IVD Products distributor
- Acquired Italy professional IVD Products distributor
- Expansion of STANDARD™ M10 cartridge automation facilities at the Jeungpyeong Factory

SD BIOSENSOR
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 expended from immuno-based IVD to POC MDx(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.

We are based in South Korea and have 7 global offices in India, Indonesia, China, U.S., Brazil, Germany and Italy. We also have more than 500 distribution partners in more than 120 countries, and the number is still growing.



Exporting
180 products

In **126** countries
517 dealers

COVID-19
1.94 Bn tests sold

SD BIOSENSOR, INC. Headquarter

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Factory 2 Pyeongtaek
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Factory 3 Gumi
Address 18-29, Cheomdangieop 2-ro, Sandong-eup, Gumi-si, Gyeongsangbuk-do, Republic of Korea

Factory 4 Jeungpyeong
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TABLE OF CONTENTS

01

STANDARD M

Molecular Diagnostics

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

STANDARD *M10*

Versatile Point-of-Care MDx Platform

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

qPCR + LAMP in One System

- Respiratory Infections
- Tuberculosis
- Arbovirus
- Gastrointestinal Infections
- Sexual Health
- Drug Resistance

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.

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
- Alternative operating system to PC (Window)
- 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

Assay Menu

Category	Products	Tests / Kit	Cat. no.
Respiratory Disease	STANDARD™ M10 SARS-CoV-2	10T	11COV10A
	STANDARD™ M10 SARS-CoV-2 *Turbo*	10T	11COV20A
	STANDARD™ M10 Flu/RSV/SARS-CoV-2	10T	11FLU10A
Tuberculosis	STANDARD™ M10 MDR-TB	10T	11MTB10A
	STANDARD™ M10 MTB/NTM	10T	11MTB20A
Sexual Health	STANDARD™ M10 HPV	10T	11HPV10A
Gastrointestinal Disease	STANDARD™ M10 *C. difficile*	10T	11CDC10A
Arbovirus	STANDARD™ M10 Arbovirus Panel	10T	11ARB10A

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

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

CE

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

Test type Professional Use Only
Specimen type Nasopharyngeal swab
Storage condition 2 ~ 28°C

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

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 SARS-CoV-2 *Turbo*	10 Tests	11COV20A

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

CE

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
- Real-time RT-PCR result in 1 hour
- One minute hands-on preparation
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Flu/RSV/SARS-CoV-2	10 Tests	11FLU10A

STANDARD *M10*
MDR-TB

CE

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

Test type	Professional Use Only
Specimen type	Pretreated normal sputum, sputum sediment sample
Storage condition	2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of *M. tuberculosis* and drug-resistance against rifampicin (RIF) and isoniazid (INH)
- Fast result in 75 minutes
- Simple sputum pretreatment process
- Room temperature storage

Ordering Information

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

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* and non-tuberculous mycobacteria(NTM) nucleic acids in human normal sputum or sputum sediment sample.

Test type	Professional Use Only
Specimen type	Pretreated normal sputum, sputum sediment sample
Storage condition	2 ~ 28°C

Advantage
- All-in-one cartridge (NA extraction + amplification)
- Simultaneous detection of *M. tuberculosis* and NTM
- Fast result in 77 minutes
- Simple sputum pretreatment process
- Room temperature storage

Ordering Information

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

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)
- One minute hands-on preparation
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 HPV	10 Tests	11HPV10A

STANDARD *M10*
C. difficile

CE

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

Test type	Professional Use Only
Specimen type	Unformed stool
Storage condition	2 ~ 28°C

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

Ordering Information

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

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(DENV), 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, ZIKV, CHIKV, YFV and WNV
- Serum / plasma sample
- Room temperature storage

Ordering Information

Products	Tests / Kit	Cat. No.
STANDARD M10 Arbovirus Panel	10 Tests	11ARB10A

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

nCoV Real-Time Detection Kit

FDA EUA CE MFDS

STANDARD M nCoV Real-Time Detection kit is used for identification and detection of SARS-CoV-2 ORF1ab (RdRp) gene and E gene in human nasopharyngeal swab, oropharyngeal swab and sputum specimens using reverse transcription(RT) real-time PCR.

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

Test Performance

Reference	Clinical Sensitivity	Clinical Specificity	Limit of Detection (LoD)
RT-PCR	100% (120/120, 95% CI: 96.97% -100%)	100% (157/157, 95% CI:97.68% -100%)	- ORF1ab (RdRp) gene- 0.5 copies/µl - E gene- 0.5 copies/µl

Ordering Information

Products	Tests / Kit	Cat. No.
M nCoV Real-Time Detection kit	96 Tests	11NCO10

STANDARD M

SARS-CoV-2/Variant I Real-Time Detection Kit CE

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

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

Test Performance

Concentration (copies/ml)	ORF1ab gene	N gene	S gene_ ins214EPE	S gene_E484A	Limit of Detection (LoD)
4.0 × 10^3 copies/ml	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)	- SARS-CoV-2 Wild Type ~ 1 copies/ µl - Omicron Variant ~ 2 copies/ µl
2.0 × 10^3 copies/ml	144/144 (100%)	144/144 (100%)	**141/144 (97.9%)**	**144/144 (100%)**	
1.0 × 10^3 copies/ml	**144/144 (100%)**	**143/144 (99.3%)**	124/144 (86.1%)	134/144 (93.1%)	
5.0 × 10^2 copies/ml	135/144 (93.8%)	134/144 (93.1%)	88/144 (61.1%)	125/144 (86.8%)	
2.5 × 10^2 copies/ml	104/144 (72.2%)	120/144 (83.3%)	51/144 (35.4%)	95/144 (66.0%)	

Ordering Information

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

SD BIOSENSOR

02

STANDARD F

Fluorescence immunoassay

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

STANDARD F Fluorescence immunodiagnosis

STANDARD F

Experience highly accurate FIA test with STANDARD F Analyzers

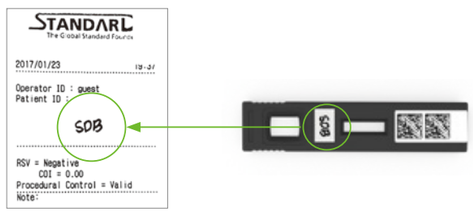
STANDARD F Analyzer is a next-generation fluorescent immunoassay system. It is a multi-parametric and random accessible immunoassay system providing accurate diagnostic results to your laboratory.

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

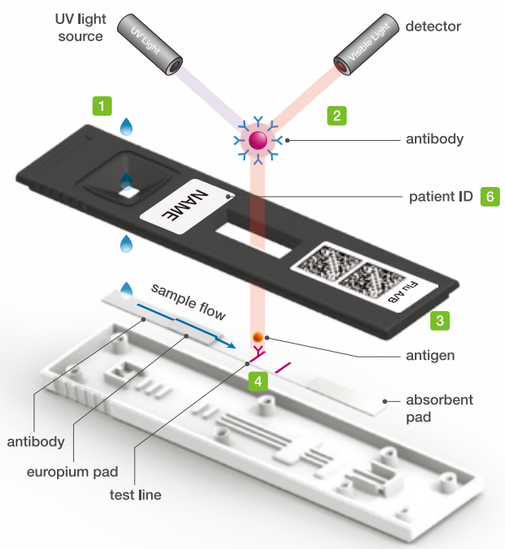
- High sensitivity and specificity
- Fast assay time
- Cost effective

Europium bead

- Strong signals
- Excellent stability
- Minimized interference

Parameter information

2D barcode contains all the information required for the test



CONNECTIVITY

Direct cable

- STANDARD F Analyzers connect with computer via the direct cable

Data share

- Via the cloud server

LIS/HIS connectivity

- Connect to the majority of existing information systems.

STANDARD

F2400

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

TECHNICAL SPECIFICATION

CE MFDS

Model	STANDARD™ F2400
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) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	510 x 566 x 297 mm
Weight	20.0 kg

STANDARD

F200

- 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

CE MFDS

Model	STANDARD™ F200
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative Tests
Test capacity	1 test
Test mode	STANDARD TEST, READ ONLY
Power	AC/DC Adapter
Display	7” Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	214.9 x 261 x 203 mm
Weight	2.5 kg

STANDARD

d-BLOCK Incubator

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

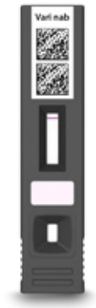
TECHNICAL SPECIFICATION

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

STANDARD F

SARS-CoV-2 Variant nAb FIA

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



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

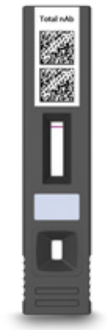
Ordering Information

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

STANDARD F

SARS-CoV-2 Total nAb FIA

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



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

Ordering Information

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

STANDARD F

COVID-19 Ag FIA

CE MFDS

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

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

Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
PCR	94.23%	100%

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-19 IgM/IgG Combo FIA

CE MFDS

STANDARD F COVID-19 IgM/IgG Combo FIA is the fluorescent immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma and whole blood.

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood (20 µl), Serum and Plasma (10 µl)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
PCR	100% (119/119) (≥7 days after symptom onset)	95.33% (143/150)

Ordering Information

Products	Tests / Kit	Cat. No.
F COVID-19 IgM/IgG Combo FIA	40 Tests	10COV50G
COVID-19 IgM/IgG Control	M Pos x 10 / G Pos x 10 / Neg x 10	10COVC20

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 nasal and nasopharyngeal swab specimens.

Test type	Professional use only
Specimen type	Nasal swab, Nasopharyngeal swab
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 (Nasal)	25 Tests	10COV70D
F COVID/Flu Ag Combo FIA	25 Tests	10COV71D
F COVID/Flu 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 : Internal evaluation

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

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 : Internal evaluation

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

Ordering Information

Products	Tests / Kit	Cat. No.
F Influenza A/B FIA	25 Tests	10INF20D
F Influenza A/B Control	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 : Clinical evaluation

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

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	100 µl
Testing time	5 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
Bacterial culture	95.0%	95.2%

Ordering Information

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

STANDARD F

Legionella Ag FIA

CE MFDS

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

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

Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
Fluorescent immunoassay	97.5%	98.5%

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 : Internal evaluation

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

Ordering Information

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

STANDARD F

Adeno Respi Ag FIA

CE

STANDARD F Adeno Respi FIA is the fl uorescence 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 volume	100µl of plasma (collected from sensitized whole blood in TB-Feron Tubes)
Dynamic range	0.145 ~ 10 IU/ml
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

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

STANDARD F

Dengue NS1 Ag FIA

CE

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

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

Test Performance

Reference : Internal evaluation

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

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 : Clinical evaluation

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

Ordering Information

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

STANDARD F

Zika Ag FIA

CE

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

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

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	96.3% (52/54)	97.4% (150/154)

Ordering Information

Products	Tests / Kit	Cat. No.
F Zika Ag FIA	25 Tests	10ZK10D
Zika Ag Control	Pos x 10 / Neg x 10	10ZIKC10

STANDARD F

Zika IgM FIA

CE

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

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

Test Performance

Reference : Clinical evaluation

Reference	Sensitivity	Specificity
ELISA	94.7% (36/38)	100% (74/74)

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 : Internal evaluation

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

Ordering Information

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

STANDARD F

Tsutsugamushi IgM/IgG FIA

CE

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

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

Test Performance

Reference : Clinical evaluation

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

Ordering Information

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

STANDARD F

Lyme IgM/IgG FIA

CE

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 : Internal evaluation

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

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	Liquid : 50-75 ul Solid : 50-75 mg
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference : Internal evaluation

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

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 Q

Rotavirus Ag

CE MFDS

STANDARD Q Rotavirus Ag Test is a Colloidal gold-based immunochromatographic assay for the detection of Rotavirus in human fecal sample. The test result can be determined visually and using the STANDARD F analyzers.

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 : Clinical evaluation

Reference	Sensitivity	Specificity
PCR & ELISA	100% (100/100)	100% (138/138)

Ordering Information

Products	Tests / Kit	Cat. No.
Q Rotavirus Ag	25 Tests	09ROT10D

STANDARD F

Rota/Adeno Ag FIA

CE

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

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

Ordering Information

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

STANDARD Q

Rota/Adeno Ag

CE MFDS

STANDARD Q Rota/Adeno Ag Test is a Colloidal gold-based immunochromatographic assay for simultaneous detection and differentiation of Rotavirus and Adenovirus in human fecal sample. The test result can be determined visually and using the STANDARD F analyzers.

Test type	Professional use only
Specimen type	Feces
Specimen volume	40-70 mg
Testing time	20 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Ordering Information

Products	Tests / Kit	Cat. No.
Q Rota/Adeno Ag	25 Tests	09ROT20D

STANDARD F

H. pylori Ag FIA

CE

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

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

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Internal Study	100% (5/5)	100% (150/150)

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 : Clinical evaluation

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

Ordering Information

Products	Tests / Kit	Cat. No.
F *C. difficile* GDH FIA	25 Tests	10CDG10D
C. difficile GDH Control	Pos x10 / 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 : Internal evaluation

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

Ordering Information

Products	Tests / Kit	Cat. No.
F *C. difficile* Toxin A/B FIA	25 Tests	10CDT10D
C. difficile Toxin A/B Control	Pos x10 / 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 : Internal evaluation

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

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 evaluation

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

Ordering Information

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

STANDARD F

HAV IgM FIA

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

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

Test Performance

Reference : Internal evaluation

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

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 : Internal evaluation

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

Ordering Information

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

STANDARD F

Syphilis Ab FIA

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

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

Test Performance

Reference : Internal evaluation

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

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

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

Method comparison

Reference : Internal evaluation

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

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

MFDS

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F U-Albumin FIA	
Correlation with ECLIA Method	**Differ(%)**
y=0.9837x + 0.8214, R^2=0.9927, n=70	within 10%

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 (Serum)

CE

STANDARD F PCT FIA (Serum) is a fluorescent immunoassay for the quantitative measurement of procalcitonin level in human serum. PCT helps assess the severity and prognosis of bacterial infections, and support early diagnosis of sepsis.

Test type	Professional use only
Specimen type	Serum
Specimen volume	50 µl
Measuring range	0.1 ~ 50 ng/ml
Reference range	< 0.5 ng/mL (SEPSIS) | <0.25 ng/mL (LRTI)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PCT (Serum)		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=0.9942x + 0.0158, R=0.9933, n=210	QCL=5.8% / QCM=6.5% / QCH=5.8%	within 12%

Ordering Information

Products	Tests / Kit	Cat. No.
F PCT FIA (Serum)	20 Tests	10PCT10B
F PCT Control	Lv1 x 10 / Lv2 x 10	10PCTC10

STANDARD F

PCT FIA

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

CRP

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CRP	
Correlation vs ECLIA Method	**Differ(%)**
y = 0.9977x + 0.519, R^2=0.9744, n=180	within 20%

Ordering Information

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

STANDARD F

TnI Pro FIA

CE

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TnI Pro FIA	
Correlation vs ECLIA Method	**Differ(%)**
y = 0.9704x + 47.971, R^2=0.9910, n=210	Within 25%

Ordering Information

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

STANDARD F

TnI/CK-MB Combo FIA

CE

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

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

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

TnI FIA

CE

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TnI FIA	
Correlation vs ECLIA Method	**Differ(%)**
y = 1.0056x - 0.0304, R^2=0.9902, n=210	Within 15% (Serum) / Within 20% (Whole blood)

Ordering Information

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

STANDARD F

CK-MB FIA

CE

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CK-MB FIA	
Correlation vs ECLIA Method	**Differ(%)**
y = 0.9937x - 0.047, R^2=0.9946, n=210	within 15%

Ordering Information

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

STANDARD F

D-dimer FIA

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F D-dimer FIA	
Correlation vs ECLIA Method	**Differ**
y = 0.9927x + 8.5607, R^2=0.9983, n=120	within 1.96SD

Ordering Information

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

STANDARD F

hs-CRP

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

NT-proBNP FIA

CE

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

Test type	Professional use only
Specimen type	Whole blood (EDTA), Serum
Specimen volume	100 µl
Measuring range	50 ~ 25,000 pg/mL
Reference range	• Acute HF Rule-out : <300 pg/mL • Symptomatic chronic HF Rule-out : <125 pg/mL (<75 yrs) <450 pg/mL (≥75 yrs)
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

Vitamin D FIA

CE

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

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

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

β-hCG FIA

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F β-hCG FIA	
Correlation vs ECLIA Method	**Differ(%)**
y=1.0161x-6.6452, R=0.9973, n=180	within 15%

Ordering Information

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

STANDARD F

LH FIA

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

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

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/L
Reference range	0.45 ~ 4.5 mIU/L
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

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

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/L
Reference range	0.45 ~ 4.5 mIU/L
Testing time	15 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

fT4

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

T4

CE MFDS

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F T4		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=1.0113x ~ 0.6502, R= 0.9943, n=120	QCL=7.7% / QCM=7.7% / QCH=8.0%	within 15%

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

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	50 µl
Measuring range	0.1-10 nmol/L
Reference range	1.3-3.1 nmol/L (0.8-2.0 ng/mL)
Testing time	25 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

Reference : Internal evaluation

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

Ordering Information

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

STANDARD F

PSA FIA

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

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

Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PSA FIA		
Correlation vs ECLIA Method	**CV%**	**Differ(%)**
y=0.9589x ~ 0.2336, R=0.9948, n=180	QCL=9.0% / QCM=8.0% / QCH=7.2%	within 15%

Ordering Information

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

STANDARD F

iFOB FIA

CE MFDS

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

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

Ordering Information

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

STANDARD Q

Rapid diagnostic test

03

STANDARD Q

Rapid diagnostic test

STANDARD Q provides rapid diagnostic products with high sensitivity and specificity through quality control from raw material development to production. STANDARD Q rapid diagnostic products have been globally recognized with 6 WHO-PQ-approved diagnostic products for Malaria, HIV, HCV and HIV/Syphilis, and 2 WHO approved diagnostic products for COVID-19(EUL) and Ebola (EUAL).

With fast development lead time, STANDARD Q COVID-19 Ag Test was the first COVID-19 rapid antigen test to be approved for WHO EUL in September, 2020.

STANDARD Q

COVID-19 Ag 2.0

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

COVID-19 Ag 2.0 (Nasal)

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

COVID-19 Ag Saliva

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 : Internal evaluation

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

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-19 Ag

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

COVID-19 Ag (Nasal)

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 : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	82.7%	99.1%

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 Ag Test 2.0	25 Tests	09COV31D

STANDARD Q

COVID-19 IgM/IgG Plus

Test type	Professional Use Only
Intended Use	Detection of specific IgM and IgG antibodies to SARS-CoV-2 virus
Specimen type	Venous whole blood, Capillary whole blood, Serum, Plasma
Specimen volume	Whole blood : 20 ul, Serum/Plasma : 10 ul
Testing time	10 ~ 15 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

Test Performance Reference : Internal evaluation

Reference	Sensitivity(≥ 7 days)	Specificity
RT-PCR	96.82% (152/157)	98.65% (219/222)

Ordering Information

Products	Tests / Kit	Cat. No.
Q COVID-19 IgM/IgG Plus	25 Tests	09COV70DM

STANDARD Q

COVID/Flu Ag Combo

CE

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 : Internal evaluation

Reference	Sensitivity	Specificity
SARS-CoV-2	92.73% (95%CI: 82.41% ~ 97.98%)	99.00% (95%CI: 99.09% ~ 100.00%)
Influenza A	100.00% (95%CI: 92.89% ~ 100.00%)	100.00% (95%CI: 96.38% ~ 100.00%)
Influenza B	96.88% (95%CI: 89.16% ~ 99.62%)	100.00% (95%CI: 96.38% ~ 100.00%)

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	10COVC30

STANDARD Q

COVID-19 Ag Home Test

MFDS

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD i-Q

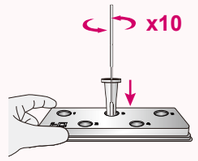
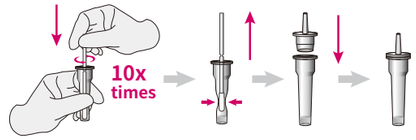
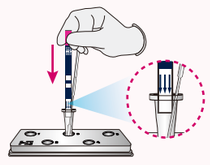
STANDARD i-Q is a new brand of SD BIOSENSOR that **pursues convenience and safety** while improving its performance as well.

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

Advantage

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

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

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

STANDARD i-Q COVID-19 Ag Home Test

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

Health Canada MFDS

Test Performance Reference : Internal evaluation

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

STANDARD i-Q COVID-19 Ag Test

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

Test Performance Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	83.33% (10/12)	100% (12/12)

STANDARD i-Q COVID-19 Ag Test 2.0

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

CE

STANDARD i-Q COVID/Flu Ag Combo Test

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

CE

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

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

CE

STANDARD Q MERS-CoV Ag

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

CE

Ordering Information

Products	Tests / Kit	Cat. No.
i-Q COVID-19 Ag Home Test	2 Tests	09COV120H
	5 Tests	09COV120J
	25 Tests	09COV120D
	25 Tests	09COV120DM
i-Q COVID-19 Ag Test	25 Tests	09COV200D
i-Q COVID-19 Ag Test 2.0 (NP)	25 Tests	09COV270D
i-Q COVID-19 Ag Test 2.0 (Oral)	25 Tests	09COV271D
i-Q COVID-19 Ag Test 2.0 (NS)	25 Tests	09COV272D
i-Q COVID/Flu Ag Combo Test	25 Tests	09COV280D
i-Q SARS-CoV-2 Spike IgG Test	25 Tests	09COV290D
Q MERS-CoV Ag	25 Tests	05MC10
COVID/Flu Ag Control swab	COVID Pos x 10, Flu Pos x 10, Neg x 10	10COVC30

STANDARD Q Influenza A/B

CE MFDS

Test type	Professional Use Only
Intended use	Detection of influenza A/B antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal wash / aspirate
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 : Internal evaluation

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%)

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 / Nasopharyngeal wash / aspirate
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 : Internal evaluation

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

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 : Internal evaluation

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

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	Nasal swab, 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 : Internal evaluation

Reference	Sensitivity	Specificity
PCR	100%	100%

Ordering Information

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

STANDARD Q

Ebola *Zaire* Ag

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

Dengue Duo

CE TGA

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

Test Performance Reference : Internal evaluation

	Reference	Sensitivity	Specificity
NS1	RT-PCR	92.9% (184/198)	98.7% (222/225)
IgM	ELISA	97.5% (77/79)	96.6% (346/358)
IgG	ELISA	97.2% (140/144)	96.2% (282/293)

Ordering Information

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

STANDARD Q

Dengue NS1 Ag

CE TGA

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

Test Performance Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	92.9% (184/198)	98.7% (222/225)

Ordering Information

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

STANDARD Q

Dengue IgM/IgG

CE TGA

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

Zika IgM

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

Chikungunya IgM/IgG

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

Yellow Fever IgM

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

Test Performance Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	88.3% (53/60)	96.1% (343/357)

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

STANDARD Q

ZIKV/DENV/CHIKV Fast Quad

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

STANDARD Q

Dengue/Chikungunya Trio

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

STANDARD Q

Zika/Dengue Fast Trio

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

Ordering Information

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

STANDARD Q

Malaria P.f Ag

WHO PQ CE

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

Malaria P.f/P.v Ag

WHO PQ CE

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

Test Performance Reference : Internal evaluation

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

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

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

Malaria/CRP Duo

CE

Test type	Professional Use Only
Intended use	Detection of Malaria P. falciparum specific HRP-2 and Plasmodium species (P. falciparum, vivax, ovale and malariae) specific pLDH & C-Reactive Protein (CRP)
Specimen type	Whole blood
Specimen volume	Mal: 5 µl / CRP: 10 µl
Testing time	Mal: 15 ~ 30 mins / CRP: 15 ~ 20 mins
Storage condition	2 ~ 30°C / 36 ~ 86°F

Test Performance Reference : Internal evaluation

	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)

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

Ordering Information

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

STANDARD Q

HIV/Syphilis Combo

WHO PQ

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

Test Performance

in accordance with CTS

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

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

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

Ordering Information

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

STANDARD Q

Syphilis Ab

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

HIV 1/2 Ab 3-Line

WHO PQ MFDS

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

Test Performance

in accordance with CTS

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

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

Ordering Information

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

STANDARD Q

HAV IgM

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

HCV Ab

WHO PQ CE MFDS

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

Test Performance

in accordance with CTS

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

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

Ordering Information

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

STANDARD Q

HBsAg

MFDS

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

Test Performance

Reference : Internal evaluation

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

Ordering Information

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

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 : Internal evaluation

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

Ordering Information

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

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 : Internal evaluation

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

Ordering Information

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

STANDARD Q

Norovirus Ag

CE

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

Ordering Information

Products	Tests / Kit	Cat. No.
Q Norovirus Ag Test	25 Tests	09NOR20D

STANDARD Q

Filariasis Ag

CE

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

Test Performance Reference : Internal evaluation

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

Ordering Information

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

STANDARD Q

TnI

CE

Test type	Professional Use Only
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 : Internal evaluation

Reference	Sensitivity	Specificity
ECLIA	98.4% (62/63)	99.37% (160/161)

Ordering Information

Products	Tests / Kit	Cat. No.
Q TnI Test	25 Tests	09TNI10D

04

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

Enzyme-Linked Immunosorbent assay

VECTOR BORNE DISEASE

STANDARD E

Dengue NS1 Ag ELISA

CE

Test type	Professional use only
Intended use	Detection of Dengue NS1 antigens
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
RT PCR	93.5% (58/62)	94.3% (66/70)

Ordering Information

Products	Tests / Kit	Cat. No.
E Dengue NS1 Ag ELISA	96 wells/Kit	07DEN10

STANDARD E

Dengue IgM ELISA

CE

Test type	Professional use only
Intended use	Detection of specific IgM to Dengue virus
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	98.2% (54/55)	95.4% (62/65)

Ordering Information

Products	Tests / Kit	Cat. No.
E Dengue IgM ELISA	96 wells/Kit	07DEN30

STANDARD E

Dengue IgG ELISA

CE

Test type	Professional use only
Intended use	Detection of specific IgG to Dengue virus
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	97.2% (140/144)	96.2% (282/293)

Ordering Information

Products	Tests / Kit	Cat. No.
E Dengue IgG ELISA	96 wells/Kit	07DEN20

STANDARD E

Zika IgM ELISA

CE

Test type	Professional use only
Intended use	Detection of specific IgM to Zika virus
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Test Performance

Reference : Internal evaluation

Reference	Sensitivity
RT PCR	96.0%(48/50)

Ordering Information

Products	Tests / Kit	Cat. No.
E Zika IgM ELISA	96 wells/Kit	07ZK30

STANDARD E

Chikungunya IgM ELISA

Test type	Professional use only
Intended use	Detection of specific IgM to Chikungunya virus
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Ordering Information

Products	Tests / Kit	Cat. No.
E Chikungunya IgM ELISA	96 wells/Kit	07CHI20

STANDARD E

Chikungunya IgG ELISA

Test type	Professional use only
Intended use	Detection of specific IgG to Chikungunya virus
Specimen type	Serum / Plasma
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Ordering Information

Products	Tests / Kit	Cat. No.
E Chikungunya IgG ELISA	96 wells/Kit	07CHI10

STANDARD E

Malaria Ag ELISA

CE

Test type	Professional use only
Intended use	Detection of Malaria *Plasmodium* sp. antigens
Specimen type	Whole blood
Storage condition	2 ~ 8°C / 36 ~ 46°F
Shelf life	15 months

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Microscopy	100%(41/41)	99.5%(200/201)

Ordering Information

Products	Tests / Kit	Cat. No.
E Malaria Ag ELISA	96 wells/Kit	07MAL10
	480 wells/Kit	07MAL10A

STANDARD E

TB-Feron ELISA

CE

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	15 months
Positive agreement rate with Q ELISA	98.4%
Negative agreement rate with Q ELISA	95.9%

Ordering Information

Products	Specimen	Tests / Kit	Cat. No.
E TB-Feron ELISA (2 plates)	Plasma	192 wells/Kit	07TBF10C
E TB-Feron Tubes 100	WB	Mitogen tube x 100	07TBFA10
E TB-Feron Tubes 200	WB	TB Antigen tube x 100 / Nil tube x 100	07TBFA20
E TB-Feron Tubes 300	WB	Mitogen tube x 100 / TB Antigen tube x 100 / Nil tube x 100	07TBFA30
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
Testing time	18 months
Storage condition	2 ~ 8°C / 36 ~ 46°F

Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Infection history	97% (97/100)	94.2% (81/86)

Ordering Information

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

05

Chronic Care

Blood Glucose Monitoring System & Chronic Care Analyzers
SD BIOSENSOR's Chronic Care provides accurate results by quantitatively measuring items related to chronic diseases such as blood sugar, cholesterol, HbA1c, and U-albumin using blood sample.

Chronic Care

Blood Glucose Monitoring System & Chronic Care Analyzers

STANDARD GlucoNavii® Elite

Blood Glucose (GDH-FAD) Monitoring System for Hospitals

CE

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

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

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

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

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

STANDARD GlucoNavii Elite Blood Glucose Meter

Size	80 x 150 x 16.2mm
Weight	170g
Measurement Result Range	10-600 mg/dL
Correction Method	Plasma correction
Sample Type	Capillary and venous whole blood
Sample Volume	Minimum 0.5 µl
Hematocrit Range	0% ~ 70%
Measurement Time	5 seconds
Measurement Method	Glucose Dehydrogenase Biosensor
Measurement Units	mg/dL or mmol/L
Memory	8GB (actual storing capacity 4GB)
BT Version	Bluetooth 5.0 (LE)
Storage Conditions	-20°C ~ 50°C
Operating Conditions	8 ~ 45°C / 10% ~ 93% RH
Power Consumption	- (100-240) V ~ , (50/60) Hz, 0.3 A (for Cradle charging) - 5 Vd.c., 1.0 A (for C-type cable charging) - 3.7 Vd.c., 1700 mAh (for Lithium Polymer battery pack)

STANDARD™ GlucoNavii® Elite Cradle

Size	142.8 x 100.8 x 101.5mm
Weight	200g
Power Supply	C-Type USB or Charging Adapter
External Ports	Adapter charging port, LAN port (data transfer)

STANDARD GlucoNavii® PRO

Blood Glucose (GDH-FAD) Monitoring System

CE

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, Venous (Professional Use Only)

Bluetooth Low Energy (Optional model)

Ordering Information

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

STANDARD GlucoNavii® GDH

Blood Glucose (GDH-FAD) Monitoring System

CE
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

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

NFC Function, Bluetooth Low Energy (Optional model)

FDA
CE
MFDS

Ordering Information

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

SD CHECK® GOLD 2

Convenient to use

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

MFDS

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

CodeFree Test Strip
- Compatible with CodeFree test strip

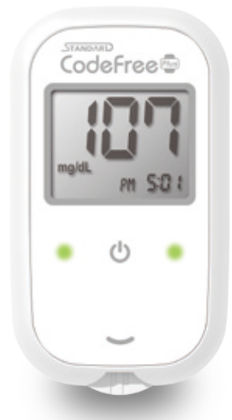
Color Customization
- OEM service is available

Data Transfer
- NFC or Bluetooth (optionally available)

No Coding
- Easy and accurate

Hypo Warning
- Helpful to warm hypoglycemia symptom

CE
MFDS



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

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 warm hypoglycemia

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

FDA
CE
MFDS

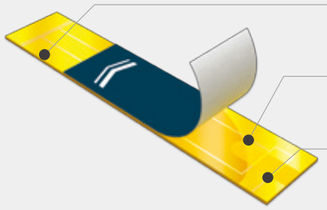
Ordering Information

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

BGMS Strip Advantages

99.9% gold electrode

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



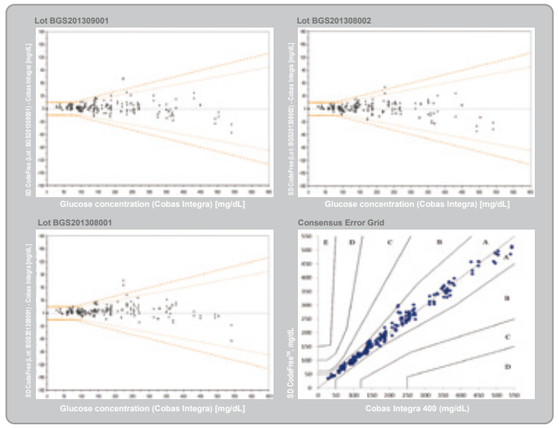
- **Wide Gold Electrode**
  Makes best accurate results
- **Laser patterning**
  Ensures an excellent precision
- **Fast Draw Technology**
  Makes test fast and easy

Performance

GOD Strip

SD Codefree™ blood glucose system complies with the system accuracy requirements of ISO 15197:2015 standard. 581 of 600 (96.8%) results meet the requirements.

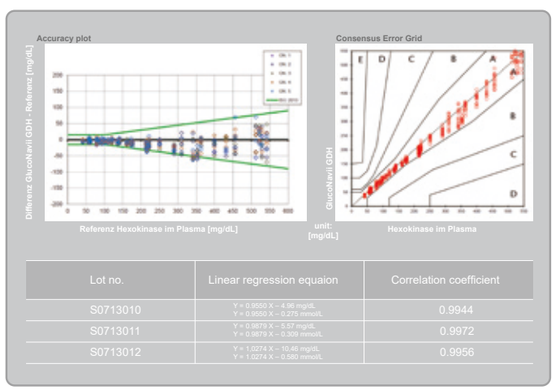
Investigative Site	Institut für Diabetes (IDT), Germany
Test system	SD Codefree™
Reference system	Cobas Integra 400 Plus
Samples	whole blood (capillary)



GDH Strip

STANDARD™ GlucoNaviI® GDH blood glucose system complies with the system accuracy requirements of ISO 15197:2015 standard. 591/600 (98.5%) results meet the requirements.

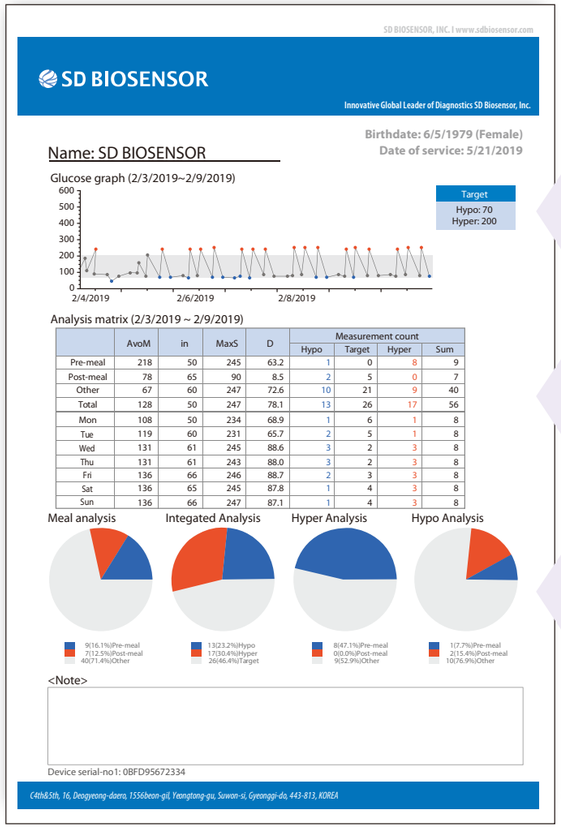
Investigative Site	IMCARMED Gmbh, Germany
Test system	STANDARD™ GlucoNaviI® GDH
Reference system	Hexokinase method
Samples	whole blood (capillary)



Lot no.	Linear regression equaion	Correlation coefficient
S0713010	Y = 0.9550 X – 4.96 mg/dL Y = 0.9550 X – 0.275 mmol/L	0.9944
S0713011	Y = 0.9879 X – 5.57 mg/dL Y = 0.9879 X – 0.309 mmol/L	0.9972
S0713012	Y = 1.0274 X – 10.46 mg/dL Y = 1.0274 X – 0.580 mmol/L	0.9956

STANDARD™ DMS (Diabetes Management Software)

STANDARD™ Diabetes Management Program systematically analyzes stored data within the SDB glucose meters to help efficient glucose management for diabetics. The program also benefits Healthcare professions by allowing more accurate evaluation of the patient' status, improving the quality of each checkup sessions.



	AvoM	in	MaxS	D	Measurement count			
					Hypo	Target	Hyper	Sum
Pre-meal	218	50	245	63.2	1	0	8	9
Post-meal	78	65	90	8.5	2	5	0	7
Other	67	60	247	72.6	10	21	9	40
Total	128	50	247	78.1	13	26	17	56
Mon	108	50	234	68.9	1	6	1	8
Tue	119	60	231	65.7	2	5	1	8
Wed	131	61	245	88.6	3	2	3	8
Thu	131	61	243	88.0	3	2	3	8
Fri	136	66	246	88.7	2	3	3	8
Sat	136	65	245	87.8	1	4	3	8
Sun	136	66	247	87.1	1	4	3	8

Trend Graph

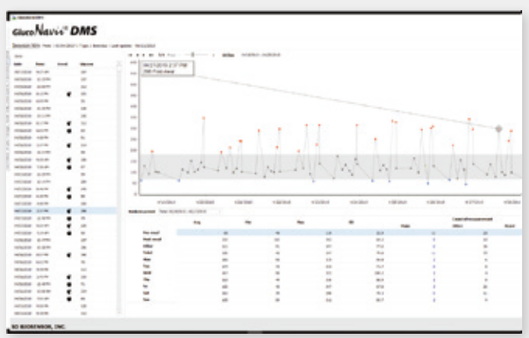
Able to monitor change in glucose level during designated period through dotted line of the graph.

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.



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Download "STANDARD™ DMS Program"

MultiCare

The Brilliant All in One Analyzer

CE MFDS

Method	Quantitative Immunochromatography
Dimension	163 mm x 96 mm x 52 mm
Weight	500g
Display	LCD
Data transfer	Mini USB cable, Bluetooth(optional)
Storage Capacity	999 Patient Data
Operating Temperature	15-32 °C / 59-90 °F
Humidity	30-80 %
Test kit storage temperature	2-30 °C / 36-86 °F
Optional Accessories	Thermal printer, Barcode Scanner

HbA1c

- Sample: Whole blood
- Volume: 5µl
- Range: 4.0-15.0 %
- Time: 3 mins.

CRP

- Sample: Whole blood, Serum, Plasma
- Volume: 5µl
- Range:
  - Whole blood: 3-150 mg/L
  - Serum, Plasma: 3-120 mg/L
- Time: 3 mins.

U-Albumin

- Sample: Urine
- Volume: 3µl
- Range: 5-300 mg/L
- Time: 3 mins.

Lipid Profile

- Sample: Whole blood, Serum, Plasma
- Volume: 35µl
- Range:
  ~ TC : 100 ~ 450 mg/dL
  ~ TG : 45 ~ 650 mg/dL
  ~ HDL : 25 ~ 95 mg/dL
- Time: 3 mins.

Ordering Information

Category	Products	Contents	Cat. no.
Analyzer	MultiCare Analyzer	1 Unit	03MA10
	MultiCare Analyzer (Bluetooth)	1 Unit	03MA20
Test device	MultiCare HbA1c Test Kit	20T	03MS10
	MultiCare U-Albumin Test Kit	20T	03MS20
	MultiCare CRP Test Kit	20T	03MS30
	MultiCare Lipid Profile Test kit	20T	03MS40

STANDARD LipidoCare

Small in size, Big in performance

FDA CE MFDS

Method	Lipid: Photometric Glucose: Electrochemical
Specimen type	Finger Stick, Venous-WB/Serum/Plasma (EDTA or heparin)
Sample volume	Single: 10µl / Lipid Profile: 35µl
Measuring range	TC: 100 ~ 450 mg/dL , HDL: 25 ~ 95 mg/dL, TG: 45 ~ 650 mg/dL Calculated LDL, LDL/HDL, TC/HDL, non-HDL, Glucose: 20 ~ 600 mg/dL
Measuring time	5 sec. (Glucose), 3 mins (Cholesterol)
Data transfer	Mini USB cable, Bluetooth(optional)
Test kit storage temperature	2 ~ 32°C (36 -90°F)
Shelf life	18 months

Ordering Information

Category	Products	Contents	Cat. no.
Analyzer	STANDARD LipidoCare Analyzer	1 Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1 Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip ~ Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip ~ TC	25T	02LS20
Control Solution	SDB Lipid Control Solution	Level 1x1/ Level 2x1	02LCS10

STANDARD G6PD

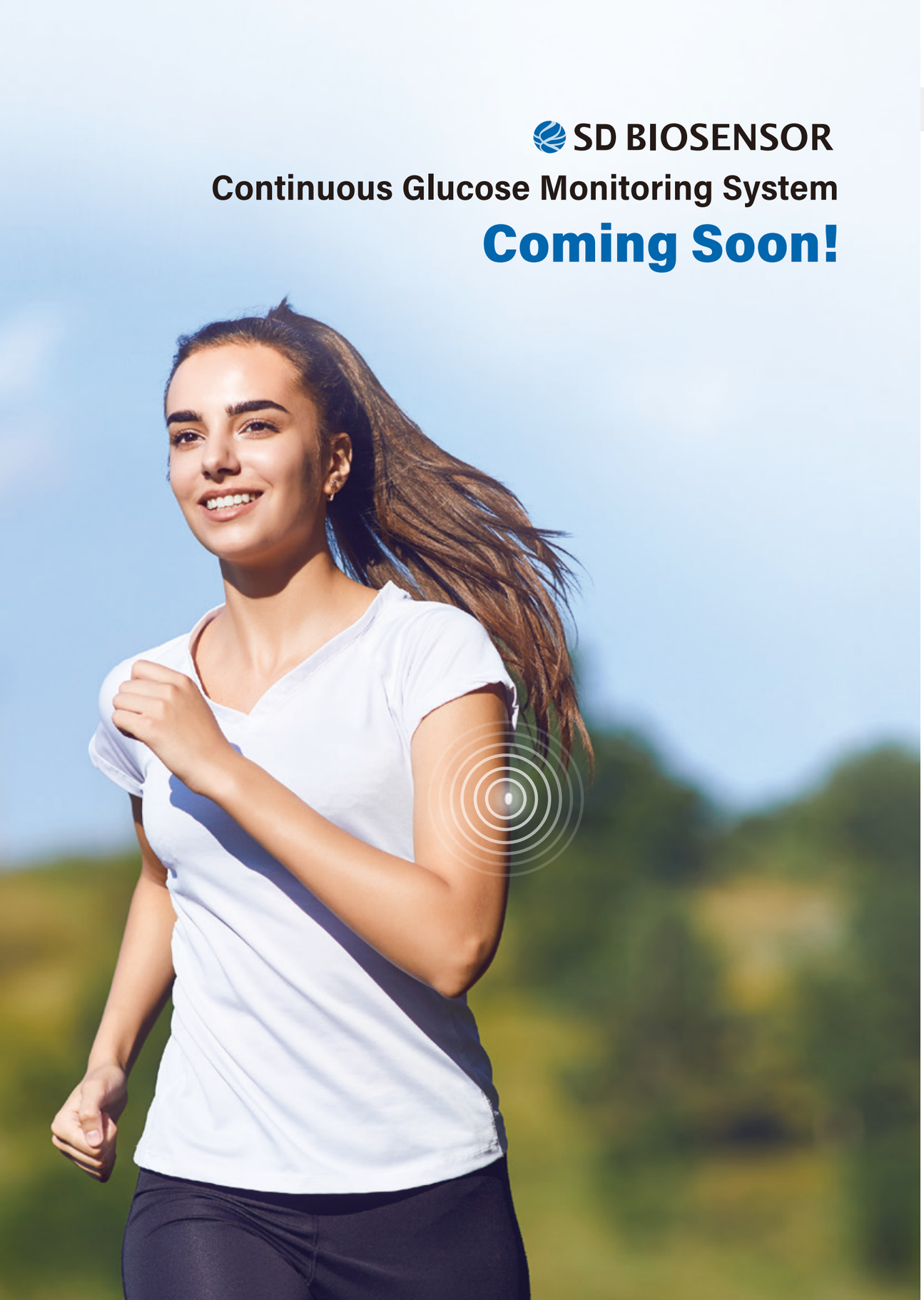
Quantitative G6PD enzyme activity analyzer

TGA CE

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

Ordering Information

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



Chronic Care Systems

BGMS (Blood Glucose Monitoring System)

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

STANDARD LipidoCare

Category	Products	Contents	Cat. no.
Analyzer	STANDARD LipidoCare Analyzer	1 Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1 Unit	02LA20G
Test device	STANDARD LipidoCare Lipid Test Strip ~ Lipid Profile	25T	02LS10A
	STANDARD LipidoCare Lipid Test Strip ~ TC	25T	02LS20
Control Solution	SDB Lipid Control Solution	Lv 1 x 1 / Lv 2 x 1	02LCS10

MultiCare

Category	Products	Contents	Cat. no.
Analyzer	MultiCare Analyzer	1 Unit	03MA10
	MultiCare Analyzer (Bluetooth)	1 Unit	03MA20
Test device	MultiCare HbA1c Test Kit	20T	03MS10
	MultiCare U-Albumin Test Kit	20T	03MS20
	MultiCare CRP Test Kit	20T	03MS30
	MultiCare Lipid Profile Test kit	20T	03MS40
Control Solution	SDB HbA1c Control Solution	Lv 1 x 10 / Lv 2 x 10	03ACS10
	SDB U-Albumin Control Solution	Lv 1 x 10 / Lv 2 x 10	03UCS10
	SDB CRP Control Solution	Lv 1 x 10 / Lv 2 x 10	03CCS10
	SDB Lipid Control Solution	Lv 1 x 1 / Lv 2 x 1	02LCS10

STANDARD G6PD

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

STANDARD M

Analyzer

Products	Contents	Dimension (W/L/H)	Weight	Cat. no.
STANDARD M10	1 M10 Console + 1 M10 Module	-	-	11M1010
STANDARD M10 Console	1 M10 Console	200 x 240 x 205mm	2.5Kg	11M1011
STANDARD M10 Module	1 M10 Module	220 x 184 x 73mm	1.9 kg	11M1012

Assay Menu

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. no.
Respiratory Disease	STANDARD™ M10 SARS-CoV-2	NP** swab	600 µl	30-60 min	10T	11COV10A
	STANDARD™ M10 SARS-CoV-2 *Turbo*	NP** swab	300 µl	30 min	10T	11COV20A
	STANDARD™ M10 Flu/RSV/SARS-CoV-2	NP** swab	300 µl	60 min	10T	11FLU10A
Tuberculosis	STANDARD™ M10 MDR-TB	Pretreated normal sputum/ sputum sediment sample	1,000 µl	75 min	10T	11MTB10A
	STANDARD™ M10 MTB/NTM	Pretreated normal sputum/ sputum sediment sample	1,000 µl	77 min	10T	11MTB20A
Sexual Health	STANDARD™ M10 HPV	Cervical swab	1,000 µl	90 min	10T	11HPV10A
Gastrointestinal Disease	STANDARD™ M10 *C. difficile*	Unformed stool	1,000 µl	90 min	10T	11CDC10A
Arbovirus	STANDARD™ M10 Arbovirus Panel	Serum / Plasma	600 µl	90 min	10T	11ARB10A

*Oro : Oropharyngeal, **NP : Nasopharyngeal

qPCR Reagent

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. no.
Respiratory Disease	STANDARD M SARS-CoV-2 Real-Time Detection Kit	NP** swab /Oro* swab	10 µl (Extracted RNA)	43 min	100T	11NCO30
	STANDARD M nCoV Real-Time Detection kit	NP** swab /Oro* swab /Sputum	10 µl (Extracted RNA)	90 min	96T	11NCO10
	STANDARD M SARS-CoV-2/Variant I Real-Time Detection Kit	NP** swab	10 µl (Extracted RNA)	60 min	100T	11NCO50

*Oro : Oropharyngeal, **NP : Nasopharyngeal

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	10 ea	11COVC10J

2022 SD BIOSENSOR ORDERING INFORMATION

STANDARD F

Analyzer

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

Parameters

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. no.
Qualitative assays						
Respiratory Disease	COVID-19 Ag FIA	NP**swab	-	15 mins	25T	10COV30D
		Nasal swab	-	15 mins	25T	10COV31D
	COVID-19 IgM/IgG Combo FIA	WB/S/P*	10-20 µl	15 mins	40T	10COV50G
	SARS-CoV-2 Variant nAb FIA	S/P*	100 µl	35 mins	20T	10COV120B
	SARS-CoV-2 Total nAb FIA	S/P*	100 µl	35 mins	20T	10COV120B
	COVID/Flu Ag Combo FIA	NP**swab	-	15 mins	25T	10COV71D
		Nasal swab	-	15 mins	25T	10COV70D
	Influenza A/B FIA	NP** swab /wash /aspirate	-	1.5-10 mins	25T	10INF20D
	RSV Ag FIA	NP** swab /wash /aspirate	-	5-15 mins	25T	10RSV10D
	Strep A Ag FIA	Throat swab	-	5 mins	25T	10STR10D
	Legionella Ag FIA	Urine	100 µl	5-15 mins	25T	10LEG10D
	S. *pneumoniae* Ag FIA	Urine, CSF	100 µl	5-10 mins	25T	10SPN10D
	Adeno Respi Ag FIA	NP**swab, Nasal swab	-	15 mins	25T	10ADE10D
	TB-Feron FIA (IFN-gamma)	Plasma	100 µl	15 mins	30 Devices	10TBF10E
Vector Borne Disease	Dengue NS1 Ag FIA	WB/S/P*	100 µl	5-15 mins	25T	10DEN10D
	Dengue IgM/IgG FIA	WB/S/P*	10 µl	15 mins	25T	10DEN20D
	Zika Ag FIA	WB/S/P*	100 µl	5-15 mins	25T	10ZK10D
	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
	Rotavirus Ag	Feces	40-70 mg	15 mins	25T	09ROT10D
	Rota/Adeno Ag FIA	Feces	50-75 mg	20 mins	25T	10ROT10D
	Rota/Adeno Ag	Feces	40-70 mg	20 mins	25T	09ROT20D
	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 (Serum)	Serum	50 µl	15 mins	20T	10PCT10B
	PCT FIA	WB/S/P*	100 µl	15 mins	20T	10PCT20B
	CRP	WB/S/P*	5 µl	3 mins	20T	10CRP10B
Cardiovascular Disease	TnI Pro FIA	WB/S*	100 µl	10 mins	20T	10HST20B
	TnI/CK-MB Combo FIA	WB/S*	100 µl	10 mins	20T	10TNI20B
	TnI FIA	WB/S*	100 µl	10 mins	20T	10TNI10B
	CK-MB FIA	WB/S*	100 µl	10 mins	20T	10CKM10B
	D-dimer FIA	WB/P*	10 µl	7 mins	20T	10DDI10B
	hs-CRP	WB/S/P*	5 µl	3 mins	20T	10HSC10B
	NT-proBNP FIA	WB/S*	100 µl	15 mins	20T	10NTP10B
Hormone	Vitamin D FIA	S/P*	35 µl	45 mins	20T	10VIT10B
	β-hCG FIA	WB/S*	50 µl	15 mins	20T	10BHC10B
	LH FIA	WB/S/P*	20 µl	15 mins	20T	10LH10B
Thyroid function	TSH-II FIA	WB/S*	35 µl	15 mins	20T	10TSH20B
	TSH FIA	Serum	100 µl	15 mins	20T	10TSH10B
	fT4	Serum	50 µl	15 mins	20T	10FT410B
	T4	Serum	50 µl	15 mins	20T	10T410B
	T3	Serum	100ul	25 mins	20T	10T310B
Tumor Marker	PSA FIA	WB/S/P*	WB: 20 µl, S/P: 100 µl	10 mins	20T	10PSA10B
	iFOB FIA	Feces	3 drops	5 mins	50T	10IFO10C

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

STANDARD Q

Parameters

Category	Products	Specimen	Specimen volume	Testing time	Tests / Kit	Cat. no.
Respiratory Disease	COVID-19 Ag 2.0	NP**swab	4 drops	15 ~ 30 mins	25T	09COV172D
	COVID-19 Ag 2.0 (Nasal)	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV173D
	COVID-19 Ag	NP**swab	3 drops	15 ~ 30 mins	25T	09COV30D
	COVID-19 Ag (Nasal)	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV31D
	COVID-19 IgM/IgG Plus	WB/S/P*	10 ~ 20 µl	15 ~ 30 mins	25T	09COV70DM
	COVID-19 Ag Saliva	Saliva with mucus	-	15 ~ 30 mins	25T	09COV90D
	COVID/Flu Ag Combo	NP** swab	4 drops	15 ~ 30 mins	25T	09COV102D
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	1T	09COV130
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	2T	09COV130H
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	5T	09COV130J
	COVID-19 Ag Home Test	Nasal swab	4 drops	15 ~ 30 mins	25T	09COV130D
	i-Q COVID-19 Ag Test	NP** swab	-	15 ~ 30 mins	25T	09COV200D
	i-Q COVID-19 Ag Test 2.0	NP** swab	-	15 ~ 30 mins	25T	09COV270D
	i-Q COVID-19 Ag Test 2.0	Oral swab	-	15 ~ 30 mins	25T	09COV271D
	i-Q COVID-19 Ag Test 2.0	Nasal swab	-	15 ~ 30 mins	25T	09COV272D
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	2T	09COV120H
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	5T	09COV120J
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	25T	09COV120D
	i-Q COVID-19 Ag Home Test	Nasal swab	-	15 ~ 30 mins	25T	09COV120DM
	i-Q SARS-CoV-2 Spike IgG Test	WB/S/P*	-	10 ~ 15 mins	25T	09COV290D
	i-Q COVID/Flu Ag Combo	NP** swab	-	15 ~ 30 mins	25T	09COV280D
	Influenza A/B	NP** swab /wash /aspirate	-	8-12 mins	25T	09INF40D
	RSV Ag	NP** swab /wash /aspirate	-	15 ~ 30 mins	25T	09RSV40D
	Strep A Ag	Throat swab	-	5-15 mins	25T	09STR40D
	Adeno Respi Ag	NP**swab, Nasal swab	4 drops	15 ~ 20 mins	25T	09ADE10D
	MERS-CoV Ag (strip)	NP** swab /wash /aspirate	-	15 ~ 30 mins	25T	05MC10
	TB MPT64 Ag	Liquid culture, Solid culture	-	10 ~ 15 mins	25T	09MPT10D
	Ebola Zaire Ag	WB/S/P*	100 µl	20-30 mins	25T	05EZ10
Vector Borne Disease	Dengue Duo	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15 ~ 20 mins	10T	09DEN30A
	Dengue NS1 Ag	WB/S/P*	100 µl	15 ~ 20 mins	25T	09DEN10D
	Dengue IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09DEN20D
	Zika IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09ZK40D
	Chikungunya IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09CHI20D
	Yellow Fever IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09YEL20D
	Arbo Panel I (Z/D/C/Y)	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK110U
	ZIKV/DENV/CHIKV Fast Quad	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK100A
	Dengue/Chikungunya Trio	WB/S/P*	NS1: 100 µl, IgM/IgG: 10 µl	15 ~ 20 mins	10T	09DEN40A
	Zika/Dengue Fast Trio	WB/S/P*	NS1: 100 µl, IgM: 10 µl	15 ~ 20 mins	10T	09ZK61A
	Malaria P.f Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL10D
	Malaria P.f/P.v Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL20D
	Malaria P.f/Pan Ag	WB	5 µl	15 ~ 30 mins	25T	09MAL30D
	Malaria/CRP Duo	WB	Mal: 5 µl / CRP: 10 µl	Mal: 15 ~ 30 mins CRP: 15 ~ 20 mins	25T	09MAL50D
	Leptospira IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09LEP10D
	Tsutsugamushi IgM/IgG	WB/S/P*	10 µl	15 ~ 20 mins	25T	09TSU10D
Blood Borne Disease	HIV/Syphilis Combo	WB/S/P*	WB: 20 µl, S/P: 10 µl	15 ~ 20 mins	25T	09HIV20D
	Syphilis Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	25T	09SYP10D
	Syphilis Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	100T	09SYP10FM
	HIV 1/2 Ab 3-Line	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09HIV30D
	HIV 1/2 Ab 3-Line (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	100T	09HIV30F
Hepatitis	HAV IgM	WB/S/P*	10 µl	15 ~ 20 mins	25T	09HAV10D
	HCV Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	25T	09HCV10D
	HCV Ab	S/P*	10 µl	5-20 mins	25T	09HCV20D
	HCV Ab (multi)	WB/S/P*	WB: 20 µl, S/P: 10 µl	5-20 mins	100T	09HCV20F
	HBsAg	WB/S/P*	100 µl	20-30 mins	25T	09HBS10D
	HBsAg	WB/S/P*	100 µl	20-30 mins	100T	09HBS10FM
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	25T	09AHB10D
	Anti-HBs	WB/S/P*	100 µl	15 ~ 30 mins	100T	09AHB10F
Gastrointestinal Disease	H. pylori Ab	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09HPY10D
	H. pylori Ag	Feces	40-70 mg	10 ~ 15 mins	25T	09HPY20D
	Norovirus Ag	Feces	40-70 mg	15 mins	25T	09NOR20D
Parasitic Disease	Filariasis Ag	WB/S/P*	WB: 20 µl, S/P: 10 µl	10 ~ 20 mins	25T	09FIL10D
Cardiovascular Disease	TnI	WB/S/P*	100 µl	15 ~ 20 mins	25T	09TNI10D

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

2022 SD BIOSENSOR ORDERING INFORMATION

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	10COVC30
	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
	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
	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
	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
	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 Control Swab	COVID Pos x10 / Flu Pos x10 / Neg x 10	18M	2 ~ 30°C / 36 ~ 86 °F	10COVC50
	Vitamin D Control	Lv1 x10 / Lv2 x10	36M	2 ~ 30°C / 36 ~ 86 °F	10VITC10
	PCT-02 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10PCTC20
	CRP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	03CCS10
	HbA1c Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	03ACS10
	U-Albumin Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10UALC10
	CK-MB Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10CKBC10
	TnI Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10TNIC10
	NT-proBNP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10NTPC10
	D-dimer Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10DDIC10
	hs-CRP Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10HSCC10
	β-hCG Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10BHCC10
	LH Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10LHC10
	TSH Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10TSHC10
	fT4 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10FT4C10
	T4 Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10T4C10
	T3 Control	Lv1 x 10 / Lv2 x 10	24M	2 ~ 30°C / 36 ~ 86 °F	10T3C10
	PSA Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10PSAC10
	iFOB Control	Lv1 x10 / Lv2 x10	18M	2 ~ 30°C / 36 ~ 86 °F	10IFOC10
	TB-Feron Control	Lv1 x10 / Lv2 x10 / Lv3 x 10	18M	2 ~ 30°C / 36 ~ 86 °F	10TBFC10
	Norovirus Ag Control	Pos x 10 / Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10NORC10
	Rota/Adeno Ag Control	Pos x 10 / Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10ROTC20
	SARS-CoV-2 nAb Control	Pos x 10 / Neg x 10	36M	2 ~ 30°C / 36 ~ 86 °F	10COVC40

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
Vector Borne Disease	Dengue NS1 Ag ELISA	S/P*	96T	07DEN10
	Dengue IgM ELISA	S/P*	96T	07DEN30
	Dengue IgG ELISA	S/P*	96T	07DEN20
	Zika IgM ELISA	S/P*	96T	07ZK30
	Chikungunya IgM ELISA	S/P*	96T	07CHI20
	Chikungunya IgG ELISA	S/P*	96T	07CHI10
	Malaria Ag ELISA	WB*	96T	07MAL10

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

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