2021 SD BIOSENSOR

PRODUCT CATALOG

STANDARD F
Fluorescent immunoassay

STANDARD Q
RDT Series

STANDARD E
ELISA Series

STANDARD M
Molecular diagnostics

Chronic Care
BGMS / MultiCare / LipidoCare / G6PD

SD BIOSENSOR

SD BIOSENSOR

PRODUCT CATALOG

2021

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.

STANDARD F
Fluorescent immunoassay
STANDARD Q
Rapid diagnostics test
CHALLENGE
EFFICIENCY
RELATIONSHIP
STANDARD E
ELISA
Chronic Care
BGMS/LipidoCare/ MultiCare

STANDARD M

Molecular diagnostics

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 (RDTs), 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.

SD BIOSENSOR's History of Innovation

Since 2010, SD BIOSENSOR has grown and evolved to make the world healthier through our innovative IVD products. Our goal is to be the global leading *In-vitro* diagnostics company. From starting with BGMS products, we have expanded our business to STANDARD Q (RDT), STANDARD F (FIA), STANDARD E (ELISA) and STANDARD M (POC 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

2010

- Established SD BIOSENSOR, Inc
- Obtained approval for Blood Glucose Self-Monitoring System "SD CodeFree" by U.S. FDA
- SD CHECK GOLD Health Canada and SFDA approved
- SD CodeFree Health Canada approved

2011

- Obtained CE Marking for and launched STANDARD LipidoCare
- Obtained CE Marking for and launched STANDARD Link 0.3

2012

- Established a branch office in India
- Obtained CE Marking for and launched STANDARD Mentor
- Won "The Customer Quality Satisfaction Awards" in 2012
- New construction of 2nd Production Factory in O-song Bio Techno Valley in Sejong-si, 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

- Obtained approval for STANDARD Mentor by U.S. FDA
- Met ISO15197 (2013) standards for STANDARD Mentor
- Met ISO15197 (2013) standards for STANDARD GlucoNavii NFC/GDH

2015

- Obtained MFDS approval for and launched STANDARD Mentor BT
- Developed Ebola Zaire Ag rapid diagnosis kit
- Developed 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

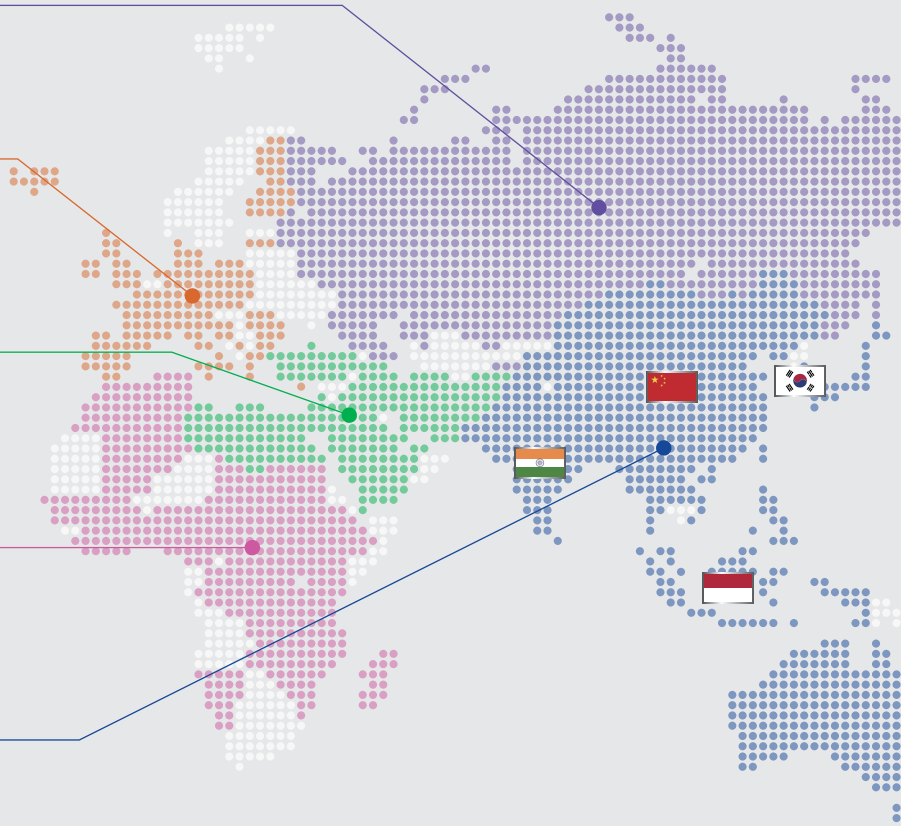
2019

- Listed on Global Fund/UNITAID Catalog with ERPD authorization
  - STANDARD G6PD
  - STANDARD Q HIV/Syphilis Combo
- Received CE mark for 'List A' product
  - STANDARD Q HCV Ab

SD BIOSENSOR

SD BIOSENSOR's 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 3 subsidiaries in India, Indonesia and China, and a branch in the U.S. We also have more than 130 distribution partners in more than 100 countries, and the number is still growing.



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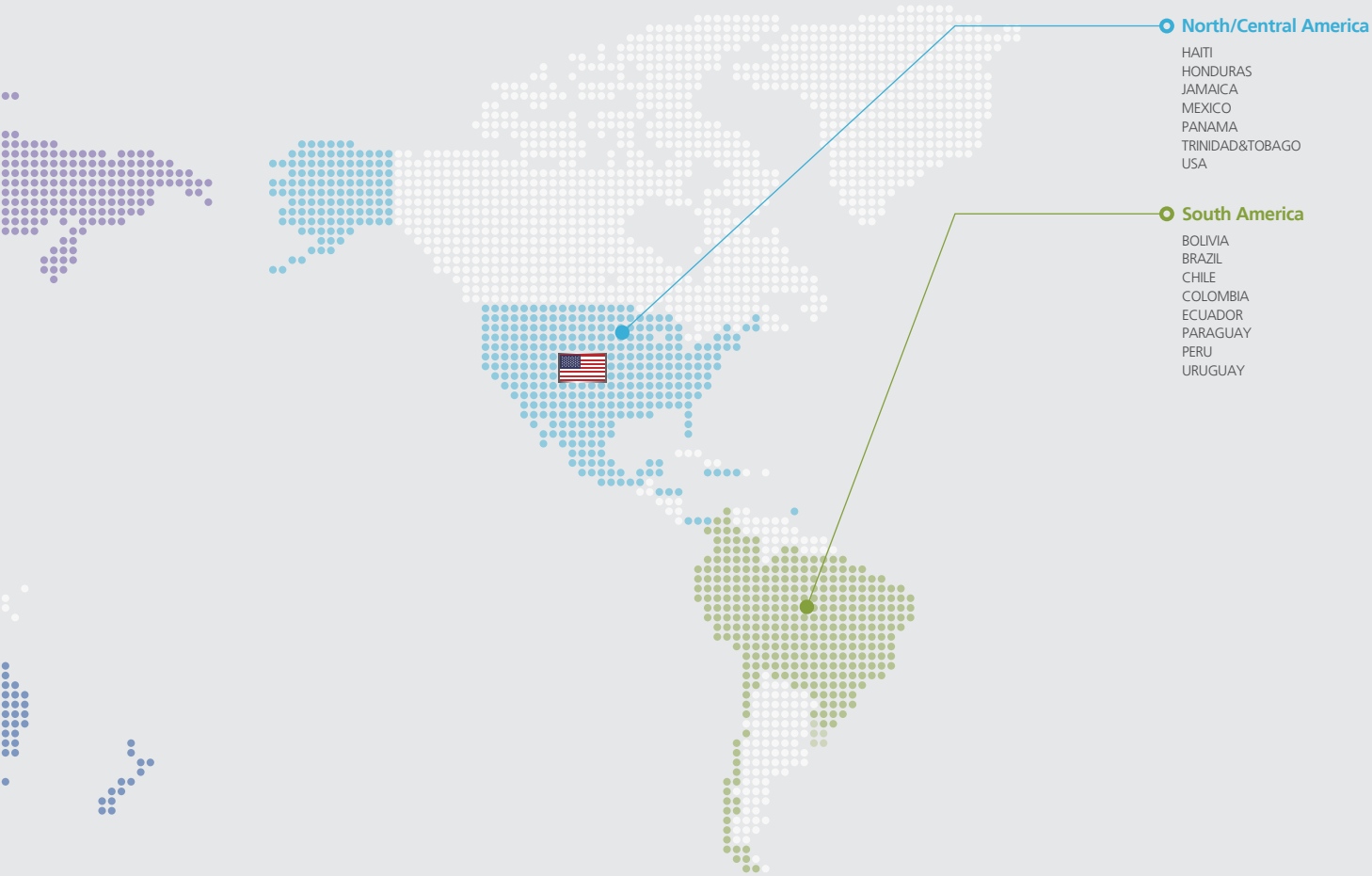

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STANDARD G6PD **77**

Test
Read Only
SD BIOSENSOR

STANDARD™

STANDARD F

STANDARD F will be
the **best diagnostic partner** of your laboratory.

STANDARD F

Fluorescent Immunoassay Analyzer

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.

Assay Principle

Fluorescent Immunoassay (FIA)

Specific Antigen or Antibody

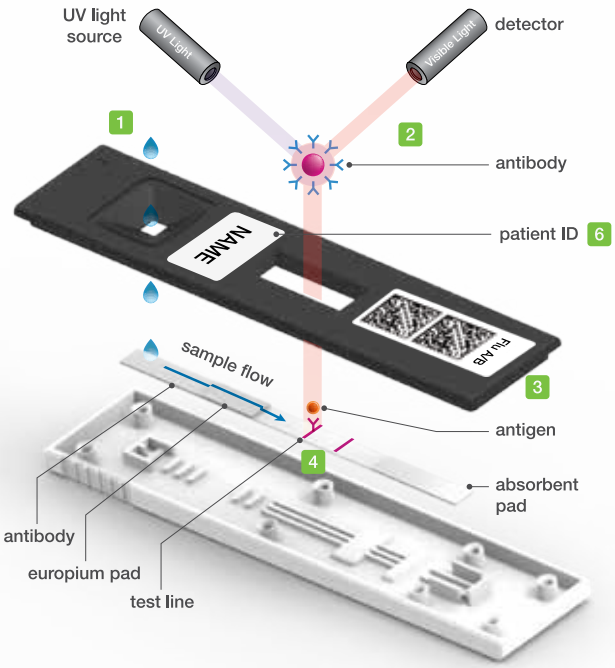
- High sensitivity and specificity
- Fast assay time
- Cost effective

Europium bead

- Strong signals
- Excellent stability
- Minimized interference

Parameter information

2D barcode contains all the information required for the test

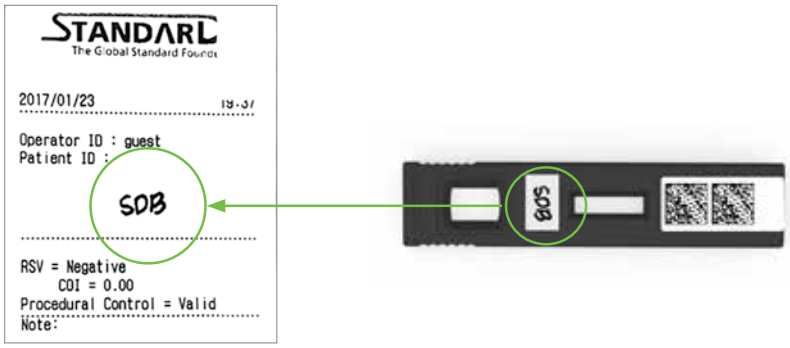


Random Access

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



Connectivity

Bluetooth

- F100 communicate with mobile via the bluetooth

Data share

- Via the cloud server

Direct cable

- STANDARD F Analyzers connect with computer via the direct cable

LIS/HIS connectivity

- Connect to the majority of existing information systems.

STANDARD F 2400

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

» Technical Specification

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" 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 F 200

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

» Technical Specification

Model	STANDARD™ F200
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	200 x 240 x 205 mm
Weight	2.5 kg

STANDARD F 100

» Fully portable POCT Analyzer
» F100 is a battery powered POCT analyzer. Its portable feature and accurate test result will improve the quality of the patient management.

» Technical Specification

Model	STANDARD™ F100
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative tests
Test capacity	1 test
Test mode	STANDARD TEST, READ ONLY
Power	Battery (AAx4) / AC/DC Adapter
Display	Graphic LCD
Printer	External
Connectivity	Bluetooth classic
Auto-ID	2D Barcode
Accessories	Thermal Printer
Dimension	105 x 135 x 100 mm
Weight	0.7 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 Parameters

SARS-CoV-2 nAb FIA

» Background

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

» Product Specification

Test type	Professional use only
Specimen type	Serum, Plasma(EDTA)
Specimen volume	100µl
Testing time	35 mins
Storage condition	2 – 30 °C / 36 - 86 °F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
VNT	100% (36/36)	Serum 99.0% (1,089/1,100), Plasma 98.8% (494/500)

» Ordering Information

Product	Pack Size	CAT No.
F SARS-CoV-2 nAb FIA	10 Sets/Kit (20 Tests)	10COV80B

STANDARD F COVID-19 Ag FIA

» Background

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.

» Product Specification

KOREA MFDS Approved

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	93.70% (106/111)	99.63% (538/543)

» Ordering Information

Product	Pack Size	CAT No.
F COVID-19 Ag FIA	25 Tests	10COV30D
F COVID-19 Ag FIA (Nasal)	25 Tests	10COV31D

COVID-19 IgM/IgG Combo FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	20μl,10μl
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

Product	Pack Size	CAT No.
F COVID-19 IgM/IgG Combo FIA	40 Tests	10COV50G

STANDARD F COVID/Flu Ag Combo FIA

» Background

STANDARD F COVID/Flu Ag Combo FIA is a 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 specimen.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F COVID/Flu Ag Combo FIA (Nasal)	25 Tests	10COV70D
F COVID/Flu Ag Combo FIA	25 Tests	10COV71D

STANDARD F Influenza A/B FIA

» Background

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.

» Product Specification

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

Product	Pack Size	CAT No.
F Influenza A/B FIA	25 Tests	10INF20D
Influenza A/B Control	Pos x 10 / Neg x 10	10INFC10

STANDARD F RSV Ag FIA

» Background

STANDARD F RSV Ag FIA test system can aid in making treatment decision, such as medicine prescribing and further diagnosis, in clinical settings.

» Product Specification

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 : Internal evaluation

Reference	Sensitivity	Specificity
RT-PCR	90.57% (48/53)	92.19% (118/128)

» Ordering Information

Product	Pack Size	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

» Background

STANDARD F Strep A Ag FIA test system (Analyzer + Test device) detects group A Streptococcal (Strep A) antigen through throat swabs of symptomatic patients or confirms Group A Streptococcal colonies that are recovered from culture.

» Product Specification

Test type	Professional use only
Specimen type	Throat swab
Specimen volume	100µl
Testing time	5 mins (Early detection available)
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Bacterial culture	93.3% (28/30)	95% (38/40)

» Ordering Information

Product	Pack Size	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

» Background

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 not affected by Rheumatoid factor.

» Product Specification

Test type	Professional use only
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Early detection available)
Storage condition	2 – 30 ℃ / 36 - 86 ℉

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Fluorescent immunoassay	97.67% (42/43)	99.38% (160/161)

» Ordering Information

Product	Pack Size	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

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Urine, CSF
Specimen volume	100µl
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

Product	Pack Size	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

» Background

STANDARD F Adeno Respi Ag FIA (Analyzer+Test device) is a commercially available rapid diagnostics test system. It can perform the test accurately and rapidly within 15 minutes with the STANDARD F analyzer.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F Adeno Respi Ag FIA	25 Tests	10ADE10D
Adeno Respi Ag Control	Positive control x 10 / Negative control x 10	10ADEC10

STANDARD F TB-Feron FIA (IFN-gamma)

» Background

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.

» Product Specification

CE

Test type	Professional use only
Product Name	STANDARD™ F TB-Feron FIA (IFN-gamma)
Test Method	Fluorescent Immunoassay
Sample 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 Tempera-ture	2-30°C / 36-86°F

» Test Performance

Reference : Internal evaluation

		Product Q(4 tubes format)		**Total**
		Positive	Negative	
STANDARD F TB-Feron FIA (IFN-gamma)	Positive	26	0	26
	Negative	2	26	28
Total		28	26	54

- Positive agreement (%): **93 %**
- Negative agreement (%): **100 %**
- Total agreement (%): **96.3 %**

» Ordering Information

Cat. No.	Product Name	Pack size
10TBF10E	F TB-Feron FIA (IFN-gamma)	30T/Kit
07TBFA40	TB-Feron Tube SPP	30 tubes
10TBFC10	F TB-Feron Control	Lv1 x 10 / Lv2 x 10 / Lv3 x 10

STANDARD F Dengue NS1 Ag FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
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

Product	Pack Size	CAT No.
F Dengue NS1 Ag FIA	25 Tests	10DEN10D

STANDARD F Dengue IgM/IgG FIA

» Background

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.

» Product Specification

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

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
F Dengue IgM/ IgG FIA	25 Tests	10DEN20D

STANDARD F Zika Ag FIA

» Background

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

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
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

Product	Pack Size	CAT No.
F Zika Ag FIA	25 Tests	10ZK10D

STANDARD F Zika IgM FIA

» Background

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.

» Product Specification

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

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
F Zika IgM FIA	25 Tests	10ZK30D

STANDARD F Chikungunya IgM/IgG FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10μl
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

Product	Pack Size	CAT No.
F Chikungunya IgM/IgG FIA	25 Tests	10CHI10D

STANDARD F Tsutsugamushi IgM/IgG FIA

» Background

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.

» Product Specification

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

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
F Tsutsugamushi IgM/IgG FIA	25 Tests	10TSU10D

VECTOR BORNE DISEASE

STANDARD F Lyme IgM/IgG FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
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

Product	Pack Size	CAT No.
F Lyme IgM/IgG FIA	25 Tests	10LYM10D

GASTROINTESTINAL DISEASE

STANDARD F Norovirus Ag FIA

» Background

STANDARD F Norovirus Ag FIA is a fluorescent immunoassay for the detection of Norovirus antigen in human fecal sample. The test kit is for *in vitro* use only.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F Norovirus Ag FIA	25 Tests	10NOR10D

STANDARD Q Rotavirus Ag

» Background

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.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
Q Rotavirus Ag	25 Tests	09ROT10D

STANDARD F Rota/Adeno Ag FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Feces
Specimen volume	50-75mg
Testing time	15 mins
Storage condition	2-8 °C/ 36-46 F

» Ordering Information

Product	Pack Size	CAT No.
F Rota/Adeno Ag FIA	25 Tests	10ROT10D

STANDARD Q Rota/Adeno Ag

» Background

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.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
Q Rota/Adeno Ag	25 Tests	09ROT20D

STANDARD F *H. pylori* Ag FIA

» Background

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

» Product Specification

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

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
F *H. pylori* Ag FIA	25 Tests	10HPY10D

STANDARD F *C. difficile* GDH FIA

» Background

STANDARD F *C. difficile* GDH FIA qualitatively analyzes *Clostridium difficile* Glutamate dehydrogenase (GDH) antigen in human feces.

» Product Specification

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

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
Culture GDH	95.24% (80/84)	100% (150/150)
EIA GDH (Well type)	100% (77/77)	100% (79/79)

» Ordering Information

Product	Pack Size	CAT No.
F *C. difficile* GDH FIA	25 Tests	10CDG10D

STANDARD F *C. difficile* Toxin A/B FIA

» Background

STANDARD F *C. difficile* Toxin A/B FIA qualitatively analyzes *C. difficile* Toxin A & B in human feces.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F *C. difficile* Toxin A/B FIA	25 Tests	10CDT10D

STANDARD F Anti-HBs FIA

» Background

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.

» Product Specification

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

Product	Pack Size	CAT No.
F Anti-HBs FIA	25 Tests	10AHB10D

STANDARD F HBsAg FIA

» Background

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

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F HBsAg FIA	25 Tests	10HBS10D

STANDARD F HCV Ab FIA

» Background

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 a fluorescent immunoassay for the detection of Hepatitis C virus (HCV) antibodies in human whole blood, serum, and plasma samples.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10μl
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	99.77% (439/440)	100% (1,210/1,210)

» Ordering Information

Product	Pack Size	CAT No.
F HCV Ab FIA	25 Tests	10HCV10D

STANDARD F HAV IgM FIA

» Background

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 a fluorescent immunoassay for the detection of hepatitis A virus IgM antibody in human whole blood, serum, and plasma samples.

» Product Specification

CE

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

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
CLIA	100% (98/98)	98.4% (189/192)

» Ordering Information

Product	Pack Size	CAT No.
F HAV IgM FIA	25 Tests	10HAV10D

BLOOD BORNE DISEASE

STANDARD F HIV Ag/Ab FIA

» Background

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.

» Product Specification

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

» Ordering Information

Product	Pack Size	CAT No.
F HIV Ag/Ab FIA	25 Tests	10HIV20D

STI

STANDARD F Syphilis Ab FIA

» Background

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 product transfusion. STANDARD F Syphilis Ab FIA is a fluorescent immunoassay for the detection of TP antibodies in human whole blood, serum, and plasma samples.

» Product Specification

CE

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	Whole blood: 20µl Serum/Plasma: 10µl
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

Product	Pack Size	CAT No.
F Syphilis Ab FIA	25 Tests	10SYP10D

STANDARD F HbA1c

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	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	y=0.9765x + 0.1254, R^2=0.9973, n=80
CV%	< 3%
Differ(%)	within 6% (NGSP criteria)

» Ordering Information

Product	Pack Size	CAT No.
F HbA1c	20 Tests	10A1C10B
SDB HbA1c Control	Lv1 x 10 / Lv2 x 10	03ACS10

STANDARD F U-Albumin FIA

» Background

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).

» Product Specification

Test type	Professional use only
Specimen type	Random urine
Specimen volume	3μl
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 Immu-noturbidimetric assay	y=0.9969x + 0.0181, R^2=0.9983, n=210
CV%	< 7%
Differ(%)	within 10%

» Ordering Information

Product	Pack Size	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)

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
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	y=0.9942x + 0.0158, R=0.9933, n=210
CV%	QCL=5.8% / QCM=6.5% / QCH=5.8%
Differ(%)	within 12%

» Ordering Information

Product	Pack Size	CAT No.
F PCT FIA (Serum)	20 Tests	10PCT10B
F PCT Control	Lv1 x 10 / Lv2 x 10	10PCTC10

STANDARD F PCT FIA

» Background

STANDARD F PCT FIA is a 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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
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	
Correlation vs ECLIA Method	y = 1.02147x +0.0743, R=0.9946, n=210
CV%	QCL=7.5% / QCM=9.2% / QCH=8.9%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F PCT FIA	20 Tests	10PCT20B
F PCT-02 Control	Lv1 x 10 / Lv2 x 10	10PCTC20

INFLAMMATION

STANDARD F CRP

» Background

STANDARD F CRP is an immunoassay for the quantitative measurement of C-reactive protein level in human serum, plasma and whole blood. CRP helps access the severity and prognosis of inflammation and infection.

» Product Specification

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

» Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CRP	
Correlation vs ECLIA Method	y=0.9884x + 0.2003, R=0.9840, n=120
CV%	QCL=7.7% / QCM=8.1% / QCH=7.6%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F CRP	20 Tests	10CRP10B
SDB CRP Control	Lv1 x 10 / Lv2 x 10	03CCS10

CARDIOVASCULAR DISEASE

STANDARD F CK-MB FIA

» Background

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).

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
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	y=0.9937x – 0.047, R=0.9973, n=210
CV%	QCL=6.0% / QCM=6.3% / QCH=7.0%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F CK-MB FIA	20 Tests	10CKM10B
F CK-MB Control	Lv1 x 10 / Lv2 x 10	10CKBC10

STANDARD F TnI FIA

» Background

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).

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
Measuring range	0.05 – 20 ng/mL
Reference range	< 0.16 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	y=0.9677x-0.0069, R=0.9918, n=120
CV%	QCL=8.8% / QCM=7.4% / QCH=7.1%
Differ(%)	Within 15% (Serum) / Within 20% (Whole blood)

» Ordering Information

Product	Pack Size	CAT No.
F TnI FIA	20 Tests	10TNI10B
F TnI Control	Lv1 x 10 / Lv2 x 10	10TNIC10

STANDARD F NT-proBNP FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(EDTA), Serum
Specimen volume	100µl
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	y=0.9842x + 11.036, R^2= 0.9694 n=180
CV%	QCL=11.3% / QCM=11.2% / QCH=11.3%
Differ(%)	15%

» Ordering Information

Product	Pack Size	CAT No.
F NT-proBNP FIA	20 Tests	10NTP10B
F NT-proBNP Control	Lv1 x 10 / Lv2 x 10	10NTPC10

STANDARD F D-dimer FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood(Sodium citrate), Plasma(Sodium citrate)
Specimen volume	10µl
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	y=1.0062x + 17.742, R=0.9920, n=120
CV%	QCL=6.8% / QCM=7.5% / QCH=8.8%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F D-dimer FIA	20 Tests	10DDI10B
F D-dimer Control	Lv1 x 10 / Lv2 x 10	10DDIC10

STANDARD F hs-CRP

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	5µl
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	y=0.9994x-0.01, R=0.9989, n=120
CV%	QCL=7.6% / QCM=9.7% / QCH=9.8%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F hs-CRP	20 Tests	10HSC10B
F hs-CRP Control	Lv1 x 10 / Lv2 x 10	10HSCC10

STANDARD F Vitamin D FIA

» Background

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

» Product Specification

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	Y = 0.937x +1.347, R = 0.960, n=100
CV%	QCL =5.3% / QCH = 6.3%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F Vitamin D FIA	20 Tests	10VIT10B

STANDARD F β-hCG FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum
Specimen volume	50µl
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	y=1.0161x-6.6452, R=0.9968, n=180
CV%	QCL=4.7% / QCM=4.7% / QCH=4.5%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F β-hCG FIA	20 Tests	10BHC10B
F β-hCG Control	Lv1 x 10 / Lv2 x 10	10BHCC10

STANDARD F LH FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	20µl
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	y=0.9916x + 0.0866, R=0.9921, n=210
CV%	QCL=8.3% / QCM=8.0% / QCH=8.2%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F LH FIA	20 Tests	10LH10B
F LH Control	Lv1 x 10 / Lv2 x 10	10LHC10

STANDARD F TSH-II FIA

» Background

STANDARD F TSH-II FIA is a 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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum
Specimen volume	35µl
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	y=0.9874 + 0.1170, R=0.9971 n=180
CV%	QCL=11.6% / QCM=12.0% / QCH=11.0%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F TSH-II FIA	20 Tests	10TSH20B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F TSH FIA

» Background

STANDARD F TSH FIA is a 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.

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	100µl
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	y=1.1097x – 0.5, R=0.9943, n=110
CV%	QCL=7.4% / QCM=6.5% / QCH=4.9%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F TSH FIA	20 Tests	10TSH10B
F TSH Control	Lv1 x 10 / Lv2 x 10	10TSHC10

STANDARD F fT4

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
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	y=1.002x – 0.1452, R= 0.9943 n=120
CV%	QCL=7.5% / QCM=8.0% / QCH=8.0%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F fT4	20 Tests	10FT410B
F fT4 Control	Lv1 x 10 / Lv2 x 10	10FT4C10

STANDARD F T4

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Serum
Specimen volume	50µl
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	y=1.0113x – 0.6502, R= 0.9943 n=120
CV%	QCL=7.7% / QCM=7.7% / QCH=8.0%
Differ(%)	Within 15%

» Ordering Information

Product	Pack Size	CAT No.
F T4	20 Tests	10T410B
F T4 Control	Lv1 x 10 / Lv2 x 10	10T4C10

STANDARD F PSA FIA

» Background

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.

» Product Specification

Test type	Professional use only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl (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	y=0.9589x – 0.2336, R=0.9948, n=180
CV%	QCL=9.0% / QCM=8.0% / QCH=7.2%
Differ(%)	within 15%

» Ordering Information

Product	Pack Size	CAT No.
F PSA FIA	20 Tests	10PSA10B
F PSA Control	Lv1 x 10 / Lv2 x 10	10PSAC10

STANDARD F iFOB FIA

» Background

STANDARD F iFOB FIA is a 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.

» Product Specification

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

Product	Pack Size	CAT No.
F iFOB FIA	50 Tests	10IFO10C
F iFOB Control	Lv1 x 10 / Lv2 x 10	10IFOC10

STANDARD Q POCT Parameters

STANDARD Q COVID-19 Ag

Test type	Professional Use Only
Specimen type	Nasopharyngeal swab, VTM
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%

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Test	25 Tests	09COV30D
Q COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID-19 Ag (Nasal)

Test type	Professional Use Only
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	97.12% (101/104)	100% (399/399)

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Test (Nasal)	25 Tests	09COV33D
Q COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID-19 IgM/IgG Plus

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma, Capillary whole blood
Specimen volume	Whole blood : 20ul, Serum/Plasma : 10ul
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%

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 IgM/IgG Combo Test	25 Tests	09COV70DM
COVID-19 IgM/IgG Control	Pos x 10, Neg x 10	09COV50G

STANDARD Q COVID-19 Ag Saliva

Test type	Professional Use Only
Specimen type	Saliva with mucus
Specimen volume	4 drops
Testing time	30 mins
Storage condition	2-30°C / 36-86°F

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Saliva Test	25 Tests	09COV90D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q COVID/Flu Ag Combo

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

» Ordering Information

Product	Pack Size	CAT No.
Q COVID/Flu Ag Combo Test	25 Tests	09COV100D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11
Influenza A/B Control	Pos x 10, Neg x 10	10INFC10

STANDARD Q COVID-19 Ag Home Test

Test type	Self-diagnostic test
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	82.5 (33/40)	100% (109/109)

» Ordering Information

Product	Pack Size	CAT No.
Q COVID-19 Ag Home Test	1 Test	09COV130
Q COVID-19 Ag Home Test	2 Test	09COV130H
Q COVID-19 Ag Home Test	5 Test	09COV130J
Q COVID-19 Ag Home Test	25 Test	09COV130D
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD i-Q COVID-19 Ag Home Test

Test type	Self-diagnostic test
Specimen type	Nasal swab
Testing time	15-30 mins
Storage condition	2-30°C / 36-86°F

» Ordering Information

Product	Pack Size	CAT No.
i-Q COVID-19 Ag Home Test	1 test	09COV121
i-Q COVID-19 Ag Home Test	2 test	09COV120H
COVID-19 Ag Control Swab	Pos x 10, Neg x 10	10COVC11

STANDARD Q Influenza A/B

CE

Test type	Professional Use Only
Intended use	Detection of influenza A/B antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal wash/aspirate
Testing time	8-12 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
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

Product	Pack Size	CAT No.
Q Influenza A/B Test	25 Tests	09INF40D
Influenza A/B Control	Pos x 10 / Neg x 10	10INFC10

STANDARD Q RSV Ag

CE

Test type	Professional Use Only
Intended use	Detection of Respiratory Syncytial Virus (RSV) antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal wash/aspirate
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
Q RSV Ag	25 Tests	09RSV40D
RSV Ag Control	Pos x 10 / Neg x 10	10RSVC10

STANDARD Q Strep A Ag

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 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
Q Strep A Ag	25 Tests	09STR40D
Strep A Ag Control	Pos x 10 / Neg x 10	10STRC10

STANDARD Q *Legionella* Ag

Test type	Professional Use Only
Intended use	Detection of *Legionella pneumophila* serogroup 1, 3, 5,6 and 8 antigens
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
DFA (Direct fluorescent-antibody testing)	97.6% (41/42)	100% (165/165)

» Ordering Information

Product	Pack Size	CAT No.
Q *Legionella* Ag	25 Tests	09LEG30D
Legionella Ag Control	Pos x 10 / Neg x 10	10LEGC10

STANDARD Q *S.pneumoniae* Ag

Test type	Professional Use Only
Specimen type	Urine
Specimen volume	100µl
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR	11/11 (100%)	98% (98/100)

» Ordering Information

Product	Pack Size	CAT No.
Q *S.pneumoniae* Ag	25 Tests	09SPN30D
S.pneumoniae Ag Control	Pos x 10 / Neg x 10	10SPNC10

STANDARD Q Adeno Respi Ag

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 (Do not read after 20 mins)
Storage condition	2 – 30°C / 36 - 86°F

» Ordering Information

Product	Pack Size	CAT No.
Q Adeno Respi Ag	25 Tests	09ADE10D
Adeno Respi Ag Control	Pos x 10 / Neg x 10	10ADEC10

STANDARD Q MERS-CoV Ag

Test type	Professional Use Only
Intended use	Detection of MERS-CoV antigens
Specimen type	Nasopharyngeal swab / Nasopharyngeal aspirate / lower respiratory tract aspirate
Testing time	15 mins (Do not read after 30 mins)
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	CAT No.
Q MERS-CoV Ag	25 Tests	05MC10

STANDARD Q TB MPT64 Ag

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 confirmed	100%	100%

» Ordering Information

Product	Pack Size	CAT No.
Q TB MPT64 Ag	25 Tests	09MPT10D

STANDARD Q Ebola *Zaire* Ag

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

Product	Pack Size	CAT No.
Q Ebola *Zaire* Ag	25 Tests	05EZ10

STANDARD Q Dengue Duo

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen & IgM/IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	NS1: 100µl, IgM/IgG: 10µl
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

Product	Pack Size	CAT No.
Q Dengue Duo Test	10 Tests	09DEN30A

STANDARD Q Dengue NS1 Ag

Test type	Professional Use Only
Intended use	Detection of Dengue NS1 antigen
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100µl
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

Product	Pack Size	CAT No.
Q Dengue NS1 Ag Test	25 Tests	09DEN10D

STANDARD Q Dengue IgM/IgG

Test type	Professional Use Only
Intended use	Detection of Dengue IgM and IgG antibodies
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
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

Product	Pack Size	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	10µl
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

Product	Pack Size	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	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
IgM	ELISA	100% (21/21)	97.7% (253/259)
IgG	ELISA	100% (21/21)	99.6% (258/259)

» Ordering Information

Product	Pack Size	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	10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	100% (8/8)	98.3% (173/177)

» Ordering Information

Product	Pack Size	CAT No.
Q Yellow Fever IgM Test	25 Tests	09YEL20D

STANDARD Q Arbovirus Multi Tests

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: 100µl, IgM : 10µl
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: 100µl, IgM : 10µl
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: 100µl, IgM/IgG : 10µl
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: 100µl, IgM : 10µl
Testing time	15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Ordering Information

Product	Pack Size	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 approved 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	5µl
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	99.59% (487/489)	100% (1104/1104)
Capillary whole blood	Microscopy	99.38% (322/324)	100% (256/256)

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria P.f Ag Test	25 Tests	09MAL10D

STANDARD Q Malaria P.f/P.v Ag

WHO PQ approved 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	5µl
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

Product	Pack Size	CAT No.
Q Malaria P.f/P.v Ag Test	25 Tests	09MAL20D

STANDARD Q Malaria P.f/Pan Ag

WHO PQ approved 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	5µl
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% (11/11)
		P.v, P.m. and P.o. confirmed specimen on Pan	100% (31/31)	

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria P.f/ Pan Ag Test	25 Tests	09MAL30D

STANDARD Q Malaria/CRP Duo

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: 5µl / CRP: 10µl
Testing time	Mal: 15-30 mins / CRP: 15-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
P.f	Microscopy	99.58% (476/478)	100% (1000/1000)
P.v, P.m. and P.o. confirmed specimen on Pan	Microscopy	100% (129/129)	
CRP	Immunoturbidimetric	87.5% (21/24)	100% (50/50)

» Ordering Information

Product	Pack Size	CAT No.
Q Malaria/CRP Duo Test	25 Tests	09MAL50D

STANDARD Q Leptospira IgM/IgG

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

» Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
ELISA	96.6% (29/30)	98.6% (143/145)

» Ordering Information

Product	Pack Size	CAT No.
Q Leptospira IgM/IgG Test	25 Tests	09LEP10D

STANDARD Q Tsutsugamushi IgM/IgG

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

» Ordering Information

Product	Pack Size	CAT No.
Q Tsutsugamushi IgM/IgG Test	25 Tests	09TSU10D

STANDARD Q HIV/Syphilis Combo

WHO PQ approved

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: 20µl, Serum/Plasma: 10µl
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 [95% CI]		**Specificity** [95% CI]	
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

Product	Pack Size	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: 20µl, Serum/Plasma: 10µl
Testing time	5-20 mins
Storage condition	2 – 40°C / 36 - 104°F

» Test Performance

Reference	Sensitivity	Specificity
RPR, ELISA, TPHA	100%(700/700)	100% (1,200/1,200)

Reference : Ghana - NPHRL(National Public Health and Reference Laboratory)
India - RPL (Rao's Pathlab)

» Ordering Information

Product	Pack Size	CAT No.
Q Syphilis Ab Test	25 Tests	09SYP10D
Q Syphilis Ab Test	100 Tests	09SYP10FM
Syphilis Ab Control	Pos x 10 / Neg x 10	10SYPC10

BLOOD BORNE DISEASE

STANDARD Q HIV 1/2 Ab 3-Line

WHO PQ approved

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: 20µl, Serum/Plasma: 10µl
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)
		Hospitalized patients	100.0% (200/200)
HIV-2 positive	100.0% (100/100)	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

Product	Contents	Pack Size	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	100 Tests	09HIV30F

HEPATITIS

STANDARD Q HAV IgM

CE

Test type	Professional Use Only
Intended use	Detection of Hepatitis A virus IgM antibody
Specimen type	Whole blood, Serum, Plasma
Specimen volume	10µl
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

Product	Pack Size	CAT No.
Q HAV IgM Test	25 Tests	09HAV10D

STANDARD Q HCV Ab

WHO PQ approved

Test type	Professional Use Only
Intended use	Detection of Hepatitis C virus antibody
Specimen type	Serum, Plasma
Specimen volume	10μl
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%** (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

Product	Contents	Pack Size	CAT No.	
Q HCV Ab Test	Device/Assay diluent/Capillary Tube	25 Tests	09HCV10D	
	Device/Assay diluent	25 Tests	09HCV20D	CE 0123
	Multi-Device/Assay diluent	100 Tests	09HCV20F	

STANDARD Q HBsAg

Test type	Professional Use Only
Intended use	Detection of Hepatitis B virus surface antigen (HBsAg)
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100μl
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

Product	Pack Size	CAT No.
Q HBsAg Test	25 Tests	09HBS10D

STANDARD Q Anti-HBs

Test type	Professional Use Only
Intended use	Detection of antibody against HBV surface antigen
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100μl
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

Product	Pack Size	CAT No.
Q Anti-HBs Test	25 Tests	09AHB10D
Q Anti-HBs Test	100 Tests	09AHB10F

STANDARD Q *H. pylori* Ab

Test type	Professional Use Only
Intended use	Detection of *Helicobacter pylori* antibody
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

» Ordering Information

Product	Pack Size	CAT No.
Q *H. pylori* Ab Test	25 Tests	09HPY10D

STANDARD Q *H. pylori* Ag

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 – 30°C / 36 - 86°F

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
Q *H. pylori* Ag Test	25 Tests	09HPY20D

STANDARD Q Norovirus Ag

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

» Ordering Information

Product	Pack Size	CAT No.
Q Norovirus Ag Test	25 Tests	09NOR20D

PARASITIC DISEASE

STANDARD Q Filariasis Ag

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	75μl
Testing time	10-20 mins
Storage condition	2-40°C / 36-104°F

» Ordering Information

Product	Pack Size	CAT No.
Q Filariasis Ag Test	25 Tests	09FIL10D

CARDIOVASCULAR DISEASE

STANDARD Q TnI

Test type	Professional Use Only
Specimen type	Whole blood, Serum, Plasma
Specimen volume	100μl
Testing time	15-20 mins
Storage condition	2-40°C / 36-104°F

» Test Performance

Reference : Internal evaluation

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

» Ordering Information

Product	Pack Size	CAT No.
Q TnI Test	25 Tests	09TNI10D

STANDARD E
Parameters

STANDARD E Dengue NS1 Ag ELISA

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

Product	Pack Size	CAT No.
E Dengue NS1 Ag ELISA	96 wells/Kit	07DEN10

STANDARD E Dengue IgM ELISA

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

Product	Pack Size	CAT No.
E Dengue IgM ELISA	96 wells/Kit	07DEN30

STANDARD E Dengue IgG ELISA

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

Product	Pack Size	CAT No.
E Dengue IgG ELISA	96 wells/Kit	07DEN20

STANDARD E Zika IgM ELISA

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	Specificity
RT-PCR	100% (60/60)

» Ordering Information

Product	Pack Size	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

Product	Pack Size	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

Product	Pack Size	CAT No.
E Chikungunya IgG ELISA	96 wells/Kit	07CHI10

VECTOR BORNE DISEASE

STANDARD E Malaria Ag ELISA

Test type	Professional use only
Intended use	Detection of *Plasmodium falciparum, P.vivax, P.ovale, P.malariae* and *P.knowlesi* species
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	96.36% (53/55)	97.0% (97/100)

» Ordering Information

Product	Pack Size	CAT No.
E Malaria Ag ELISA	96 wells/Kit	07MAL10
	480 wells/Kit	07MAL10A

RESPIRATORY DISEASE

STANDARD E TB-Feron ELISA

Test type	Professional use only
Intended use	Detection of specific to human IFN-γ antibody
Specimen type	Plasma (collected from sensitized whole blood in TB-Feron Tubes)
Storage condition	2 – 8°C / 36 - 46°F
Shelf life	15 months
Positive agreement rate with Q ELISA	98.4%
Negative agreement rate with Q ELISA	95.9%

» Ordering Information

Product	Specimen	Pack Size	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	07TBFA20
	WB	Nil tube x 100	
E TB-Feron Control		Lv1 x 15 / Lv2 x 15 / Lv3 x 15	07TBFC10

STANDARD M
Assay Menu

STANDARD M10

Versatile Point-of-Care MDx Platform

COMING SOON 2021

The 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.

» Clinical IVD Test Menu

Category	Product		Pack size	Cat. no.
Respiratory disease	STANDARD™ M10 SARS-CoV-2	Detection of SARS-CoV-2 causing COVID-19 in 45-60 minutes	10 tests	11COV10A
	STANDARD™ M10 SARS-CoV-2 20'	Rapid detection of SARS-CoV-2 causing COVID-19 in 20-30 minutes	10 tests	11COV20A
	STANDARD™ M10 Flu/SARS-CoV-2 20"	Rapid detection of SARS-CoV-2, Flu A&B in 20-30 minutes	10 tests	11COV30A
Tropical disease	STANDARD™ M10 Arbovirus 6 (ZIKV/DENV/CHIKV)	Detection and differenciation of Zika virus, Chikugunya virus, and Dengue virus 1~4 in 30 minutes	10 tests	11ARB10A
	STANDARD™ M10 ZIKV	Rapid detection of Zika virus in 30 minutes	10 tests	11ZIK10A
Tuberculosis	STANDARD™ M10 MDR-TB	Detection of mycobacterium tuberculosis(TB), rifampicin resistance mutation and isoniazid resistance mutation in 60 minutes	10 tests	11MTB10A
Virology	STANDARD™ M10 HIV-1 VL	Viral load testing of HIV-1 in serum or plasma using qPCR	10 tests	11HIV10A
	STANDARD™ M10 HBV VL	Viral load testing of HBV in serum or plasma using qPCR	10 tests	11HBV10A
	STANDARD™ M10 HCV VL	Viral load testing of HCV in serum or plasma using qPCR	10 tests	11HCV10A

STANDARD M nCoV Real-Time Detection kit

» Intended use

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.

KOREA MFDS EUA FDA

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

» Test Performance

Reference : Internal evaluation

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

Product	Pack Size	CAT No.
M nCoV Real-Time Detection kit	96 tests	11NCO10

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

» Intended use

STANDARD M Flu/SARS-CoV-2 Real-Time Detection Kit is a real-time reverse transcription PCR assay for the qualitative detection of Influenza A, Influenza B and SARS-CoV-2 nucleic acids in human nasopharyngeal swab, oropharyngeal swab, and sputum specimens.

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

» Ordering Information

Product	Pack Size	CAT No.
M Flu/SARS-CoV-2 Real-Time Detection Kit	96 tests	11NCO10

STANDARD M SPIN-X Viral RNA Extraction Kit

» Intended use

STANDARD M SPIN-X Viral RNA Extraction Kit is an in vitro diagnostic kit designed for the extraction of viral RNA from various human samples.

Test type	Professional Use Only
Specimen type	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	15~35 °C

» Ordering Information

Product	Pack Size	CAT No.
M SPIN-X Viral RNA Extraction Kit	100 tests	11SPN10

STANDARD M SPIN-X Viral DNA/RNA Extraction Kit

» Intended use

STANDARD M SPIN-X Viral DNA/RNA Extraction Kit is intended for the extraction, enrichment and purification of nucleic acids (DNA/RNA) from serum, plasma, whole blood, nasal swab, pharyngeal swab, nasopharyngeal swab and urogenital swab specimens.

Test type	Professional Use Only
Specimen type	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
Storage condition	8~25 °C

» Ordering Information

Product	Pack Size	CAT No.
M SPIN-X Viral DNA/RNA Extraction Kit	96 tests	11SPN20

Chronic Care Systems

BGMS

Simple & Accurate
Blood Glucose Monitoring System

Blood Glucose (GDH-FAD) Monitoring System

STANDARD GlucoNavii® PRO

» Advantage of STANDARD GlucoNavii ® PRO

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, Arterial, Neonatal(Professional Use Only)

Bluetooth Low Energy (Optional model)

CE 0123

Blood Glucose (GDH-FAD) Monitoring System

STANDARD GlucoNavii® GDH

» Advantage of STANDARD GlucoNavii ® GDH

Clinically Proven Accuracy
- Compliance with EN ISO15197:2015 standard

GDH-FAD
- Minimizing risk of interference

Broad HCT Range
- 0-70%

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

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

NFC Function (Optional)

CE 0123

» Ordering Information

Category	Product	Pack size	Cat. no.
STANDARD GlucoNavii GDH	STANDARD GlucoNavii GDH Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC30
	STANDARD GlucoNavii GDH Blood Glucose Monitoring System	1Unit	01GC32
	STANDARD GlucoNavii GDH Blood Glucose Test Strip	25T x 2	01GS30

The smallest blood volume

STANDARD Mentor

» Advantage of STANDARD Mentor

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 (Optional)

FDA

CE 0123

» Ordering Information

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

Convenient to use

SD CHECK GOLD 2

» Advantage of SD CHECK GOLD 2

No Coding
- Improved previous model

Wide Gold Electrode
- Conductive and stable for electrode reaction

Glucose Specific Detection
- Minimizing risk of interference

Adhere to Basic Function for blood glucose test

» Ordering Information

Category	Product	Pack size	Cat. no.
SD CHECK GOLD 2	SD CHECK GOLD 2 Blood Glucose Monitoring System	1Unit	01GC22
	SD CHECK GOLD 2 Blood Glucose Test Strip	50T x 1	01GS20C

Simply accurate

STANDARD CodeFree® Plus

» Advantage of STANDARD CodeFree Plus

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 0123

» Ordering Information

Category	Product	Pack size	Cat. no.
STANDARD CodeFree Plus	STANDARD CodeFree Plus Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC50
	STANDARD CodeFree Plus Blood Glucose Test Strip	25T x 2	01GS50

The best seller

SD CodeFree

» Advantage of SD CodeFree

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 0123

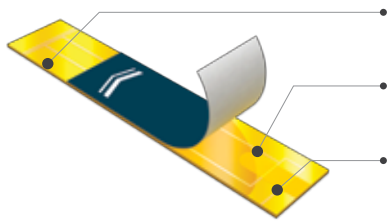
» Ordering Information

Category	Product	Pack size	Cat. no.
SD CodeFree	SD CodeFree Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC110
	SD CodeFree Blood Glucose Monitoring System	1Unit	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.



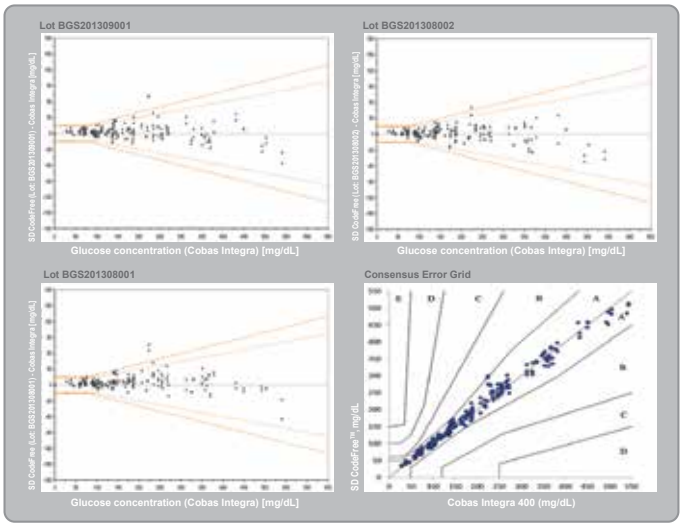
- **Wide Gold Electrode**
  Makes best accurate results
- **Laser patterning**
  Ensures an excellent precision
- **Fast Draw Technology**
  Makes test fast and easy

» Performance

GOD Strip

SD Codefree™ blood glucose system complies with the system accuracy requirements of ISO 15197:2013 standard. 581 of 600 (96.8%) results meet the requirements.

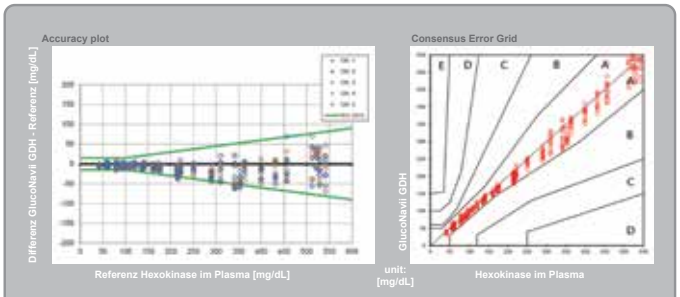
Investigative Site	Institut für Diabetes (IDT), Germany
Test system	SD Codefree™
Reference system	Cobas Integra 400 Plus
Samples	whole blood (capillary)



GDH Strip

STANDARD™ GlucoNavil® GDH blood glucose system complies with the system accuracy requirements of ISO 15197:2013 standard. 514 of 525 (97.9%) results meet the requirements.

Investigative Site	IMCARMED Gmbh, Germany
Test system	STANDARD™ GlucoNavil® 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

The Brilliant All in One Analyzer

MultiCare

» Product Specification

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	Product	Pack size	Cat. no.
Analyzer	MultiCare Analyzer	1Unit	03MA10
	MultiCare Analyzer (Bluetooth)	1Unit	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

Small in size, Big in performance

STANDARD LipidoCare

CE 0123

» Product Specification

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	Product	Pack size	Cat. no.
Analyzer	STANDARD LipidoCare Analyzer	1Unit	02LA10G
	STANDARD LipidoCare Analyzer (Bluetooth)	1Unit	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

Quantitative G6PD enzyme activity analyzer

STANDARD G6PD

CE

» Product Specification

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	12 months

» Ordering Information

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

2021 SD BIOSENSOR Ordering Information

STANDARD F

» Analyzer

Product	Pack size	Dimension (W/L/H)	Weight	Cat. no.
F2400	Unit	510 x 566 x 297mm	20.0Kg	10FA24
F200	Unit	200 x 240 x 205mm	2.5Kg	10FA20
F100	Unit	105 x 135 x 100mm	0.7Kg	10FA10

» Parameters

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Qualitative assays						
Respiratory Disease	COVID-19 Ag FIA NEW	NP**swab	4 drops	15 mins	25T	10COV30D
		Nasal swab			25T	10COV31D
	COVID-19 IgM/IgG Combo FIA NEW	WB/S/P*	10-20 µl	15 mins	25T	10COV50G
	SARS-CoV-2 nAb FIA NEW	S/P*	100 µl	15 mins	20T	10COV80B
	COVID/Flu Ag Combo FIA NEW	Nasal swab	4drops	15 mins	25T	10COV100D
	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	30T	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 FIA	Feces	40-70 mg	15 mins	25T	10NOR10D
	Rotavirus Ag	Feces	40-70 mg	15 mins	25T	09ROT10D
	Rota/Adeno Ag FIA NEW	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 NEW	WB/S/P*	100 µl	15 mins	25T	10AHB10D
	HBsAg FIA NEW	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	25T	10HAV10D
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	CK-MB FIA	WB/S*	100 µl	10 mins	20T	10CKM10B
	TnI FIA	WB/S*	100 µl	10 mins	20T	10TNI10B
	NT-proBNP FIA	WB/S*	100 µl	15 mins	20T	10NTP10B
	D-dimer FIA	WB/P*	10 µl	7 mins	20T	10DDI10B
	hs-CRP	WB/S/P*	5 µl	3 mins	20T	10HSC10B
Hormone	Vitamin D FIA NEW	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
	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
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	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	COVID-19 Ag NEW	NP**swab	3 drops	15-30 mins	25T	09COV30D
	COVID-19 Ag (Nasal) NEW	Nasal swab	4 drops	15-30 mins	25T	09COV31D
	COVID-19 IgM/IgG Plus NEW	WB/S/P*	10~20 µl	10-15 mins	25T	09COV70DM
	COVID-19 Ag Saliva NEW	Saliva with mucus	-	30 mins	25T	09COV90D
	COVID/Flu Ag Combo NEW	NP** swab /Nasal swab	4 drops	15-30 mins	25T	09COV100D
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	1T	09COV120
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	2T	09COV130H
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	5T	09COV130J
	COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	25T	09COV130D
	i-Q COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	1T	09COV121
	i-Q COVID-19 Ag Home Test NEW	Nasal swab	4 drops	15-30 mins	2T	09COV120H
	Influenza A/B	NP** swab /wash /aspirate	-	8-30 mins	25T	09INF40D
	RSV Ag	NP** swab /wash /aspirate	-	15-30 mins	25T	09RSV40D
	Strep A Ag	Throat swab	-	5-15 mins	25T	09STR40D
	Legionella Ag	Urine	100 µl	15-30 mins	25T	09LEG30D
	S. pneumoniae Ag	Urine	100 µl	15-30 mins	25T	09SPN30D
	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
	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
	Rotavirus Ag (QF)	Feces	40-70 mg	15-20 mins	25T	09ROT10D
	Rota/Adeno Ag (QF)	Feces	40-70 mg	20-25 mins	25T	09ROT20D
Parasitic Disease	Filariasis Ag NEW	WB/S/P*	75 µl	10-20 mins	25T	09FIL10D
Cardiovascular Disease	TnI NEW	WB/S/P*	100 µl	15-20 mins	25T	09TNI10D

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

» STANDARD Q & F Control Solution

Category	Product	Pack size	Shelf life	Storage	Cat. No.
STANDARD Q & F	COVID-19 Ag Control NEW	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10COVC10
	COVID-19 IgM/IgG Control NEW	M Pos x10 / G Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10COVC20
	H. pylori Ag Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 ℉	10HPYC10
	C. difficile Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 ℉	10CDGC10
	C. difficile Toxin A/B Control NEW	Pos x10 / Neg x10	36M	2 – 30℃ / 36 – 86 ℉	10CDTC10
	HBsAg Control NEW	Pos x10 / Neg x10	24M	2 – 30℃ / 36 – 86 ℉	10HBSC10
	Influenza A/B Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10INFC10
	RSV Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10RSVC10
	Strep A Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10STRC10
	Legionella Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10LEGC10
	S.pneumoniae Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10SPNC10
	Adeno Respi Ag Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10ADEC10
	Syphilis Ab Control	Pos x10 / Neg x10	18M	2 – 30℃ / 36 – 86 ℉	10SYPC10
STANDARD F	Vitamin D Control NEW	Lv1 x10 / Lv2 x10	36M	2 – 30℃ / 36 – 86 ℉	10VITC10
	PCT Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10PCTC10
	PCT-02 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10PCTC20
	CRP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	03CCS10
	HbA1c Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	03ACS10
	U-Albumin Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10UALC10
	CK-MB Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10CKBC10
	TnI Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10TNIC10
	NT-proBNP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10NTPC10
	D-dimer Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10DDIC10
	hs-CRP Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10HSCC10
	β-hCG Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10BHCC10
	LH Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10LHC10
	TSH Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10TSHC10
	fT4 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10FT4C10
	T4 Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10T4C10
	PSA Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10PSAC10
	iFOB Control	Lv1 x10 / Lv2 x10	18M	2 – 30℃ / 36 – 86 ℉	10IFOC10
	F TB-Feron Control	Lv1 x10 / Lv2 x10 / Lv3 x 10	18M	2 – 30℃ / 36 – 86 ℉	10TBFC10

STANDARD E

» Parameters

Category	Product	Specimen	Pack size	Cat. no.
Respiratory Disease	COVID-19 Total Ab ELISA NEW	S/P*	96 wells	07COV10
	SARS-CoV-2 nAb ELISA NEW	S/P*	96 wells	07COV30
	TB-Feron ELISA	P*	192wells	07TBF10C
	TB-Feron Tubes 100	WB*	100T (Mitogen Tube)	07TBFA10
	TB-Feron Tubes 200	WB*	100T (TB Antigen Tube)	07TBFA20
		WB*	100T (Nil Tube)	
	TB-Feron SPP	WB*	10T (Mitogen Tube)	07TBFA40
		WB*	10T (TB Antigen Tube)	
		WB*	10T (Nil Tube)	
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
		WB*	480T	07MAL10A

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

» STANDARD E Control Solution

Product	Pack size	Shelf life	Storage	Cat. No.
E TB-Feron Control	Lv1 x15 / Lv2 x15 / Lv3 x 15	18M	2 – 30℃ / 36 – 86 ℉	07TBFC10

STANDARD M

» Analyzer

Product	Contents	Dimension (W/L/H)	Weight	Cat. no.
M10	1 M10 Console + 1 M10 Module NEW			11M1010
M10 Console	1 M10 Console NEW	18x23x41cm	4kg	11M1011
M10 Module	1 M10 Module NEW	14x33x32cm	7.5kg	11M1012

» Assay Menu

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	SARS-CoV-2 NEW	NP** swab /Nasal swab /Throat swab	600 µl	40-60 min	10T	11COV10A
	SARS-CoV-2 20′ NEW	NP** swab /Nasal swab /Throat swab	600 µl	20-30 min	10T	11COV20A
	Flu/SARS-CoV-2 20′ NEW	NP** swab /Nasal swab /Throat swab	600 µl	20-30 min	10T	11COV30A

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

» qPCR Reagent

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	nCoV Real-Time Detection kit NEW (Real-Time RT-PCR reagent)"	NP** swab /Oro* swab /Sputum	10 µl (Extracted RNA)	90 min	96T	11NCO10
	Flu/SARS-CoV-2 Real-Time Detection Kit NEW (Real-Time RT-PCR reagent)"	NP** swab /Oro* swab /Sputum	10 µl (Extracted RNA)	90 min	96T	11NCO20

*Oro : Oropharyngeal, **NP : Nasopharyngeal

» NA Extraction Kit

Category	Product	Pack size	Cat. no.
NA Extraction Kit	SPIN-X Viral RNA Extraction Kit	96T	11NCO10
	SPIN-X Viral DNA/RNA Extraction Kit	96T	11NCO20

INCUBATOR

» Analyzer

Category	Product	Pack size	Cat. no.
Analyzer	d-BLOCK Incubator NEW	1 Unit	12INC10

Chronic Care Systems

» BGMS (Blood Glucose Monitoring System)

Category	Product	Pack size	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	Product	Pack size	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	Product	Pack size	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	Product	Pack size	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

SD BIOSENSOR

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SD BIOSENSOR

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