

**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

# 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.



# CHALLENGE EFFICIENCY RELATIONSHIP

## STANDARD F

Fluorescent  
immunoassay



## STANDARD Q

Rapid diagnostics test



## STANDARD E

ELISA



## Chronic Care

BGMS/LipidoCare/  
MultiCare

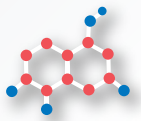


## Pursuing to be the global leading IVD company

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 M**

Molecular diagnostics



## 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 ◉ 2012 ◉ 2013 ◉ 2014

### 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 2<sup>nd</sup> 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 2<sup>nd</sup> 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.

### CIS

AZERBAIJAN  
GEORGIA  
KAZAKHSTAN  
RUSSIA  
TAJKISTAN

### Europe

AUSTRIA	FINLAND	KOSOVO	SLOVENIA
BOSNIA	FRANCE	LATVIA	SPAIN
BULGARIA	GERMANY	NETHERLANDS	SWITZERLAND
CROATIA	GREECE	POLAND	UK
CYPRUS	ICELAND	PORTUGAL	
CZECH	IRELAND	ROMANIA	
DENMARK	ITALY	SLOVAKIA	

### Middle East

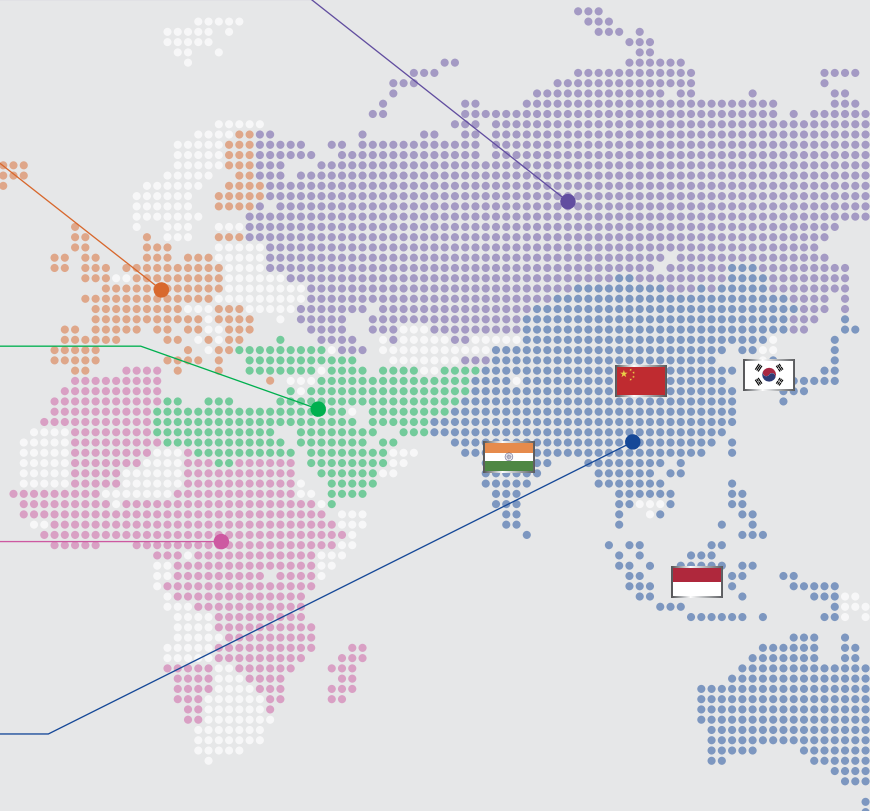
AFGHANISTAN	LIBYA
EGYPT	QATAR
IRAN	SAUDI ARABIA
IRAQ	TURKEY
ISRAEL	UAE
JORDAN	YEMEN
LEBANON	

### Africa

ALGERIA	CONGO	LIBERIA	NIGERIA	TUNISIA
BENIN	CÔTE D'IVOIRE	MADAGASCAR	RWANDA	UGANDA
BURKINA FASO	DRC	MALAWI	SENEGAL	ZAMBIA
BURUNDI	ETHIOPIA	MALI	SOUTH SUDAN	ZIMBABWE
CAMEROON	GHANA	MOROCCO	SUDAN	
CAR	GUINEA	MOZAMBIQUE	TANZANIA	
CHAD	KENYA	NAMIBIA	TOGO	

### Asia Pacific

AUSTRALIA	MALAYSIA	SINGAPORE
BANGLADESH	MONGOLIA	SOUTH KOREA
CHINA	MYANMAR	SRI LANKA
INDIA	NEPAL	TAIWAN
INDONESIA	NEW ZEALAND	THAILAND
JAPAN	PAKISTAN	TIMOR
LAOS	PHILIPPINES	VIETNAM







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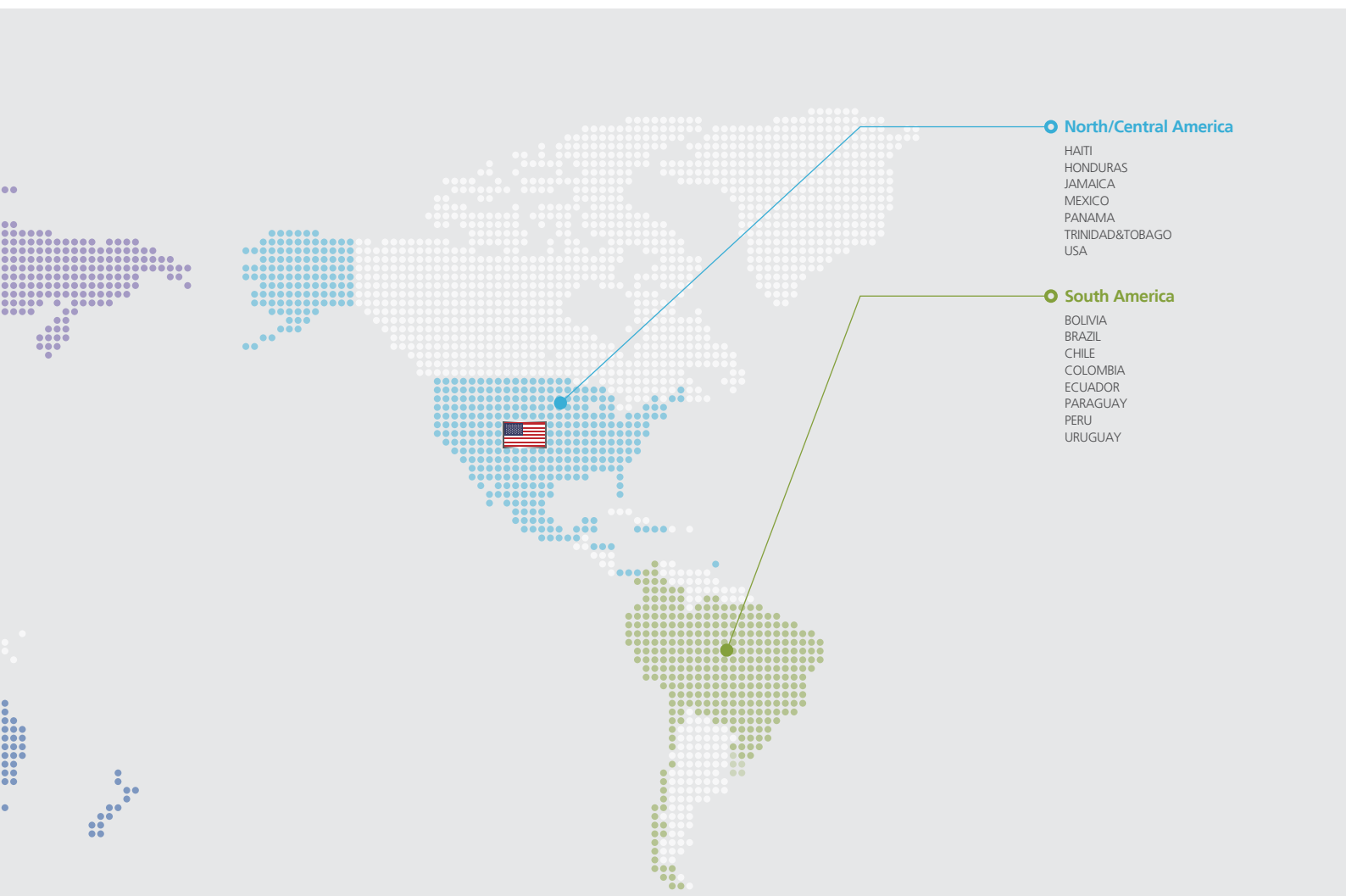
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#### North/Central America

- HAITI
- HONDURAS
- JAMAICA
- MEXICO
- PANAMA
- TRINIDAD&TOBAGO
- USA

#### South America

- BOLIVIA
- BRAZIL
- CHILE
- COLOMBIA
- ECUADOR
- PARAGUAY
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- URUGUAY

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- Rota/Adeno Ag
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- Influenza A/B
- RSV Ag
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- *S. pneumoniae* Ag
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- TB MPT64 Ag
- Ebola Zaire Ag

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## 03

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- Chikungunya IgG ELISA
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# 04

STANDARD M  
Molecular diagnostics

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# 06

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## STANDARD LipidoCare **77**

## STANDARD G6PD **77**



# 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



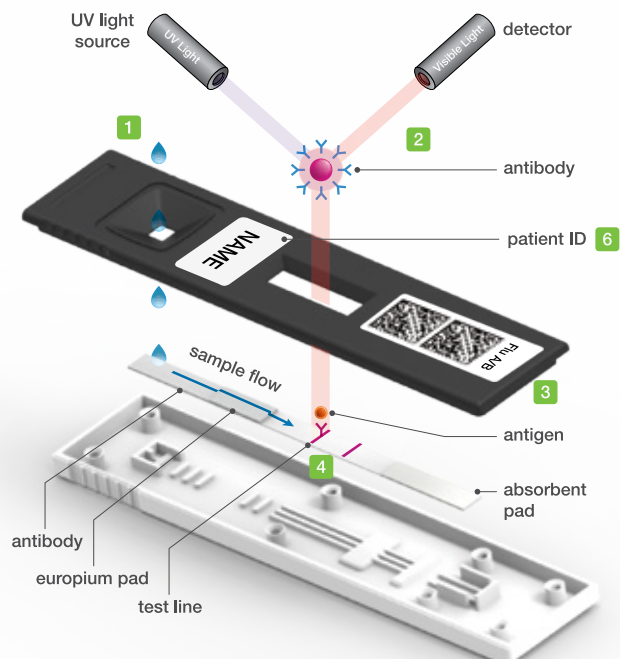
#### Europium bead

- Strong signals
- Excellent stability
- Minimized interference



#### Parameter information

2D barcode contains all the information required for the test



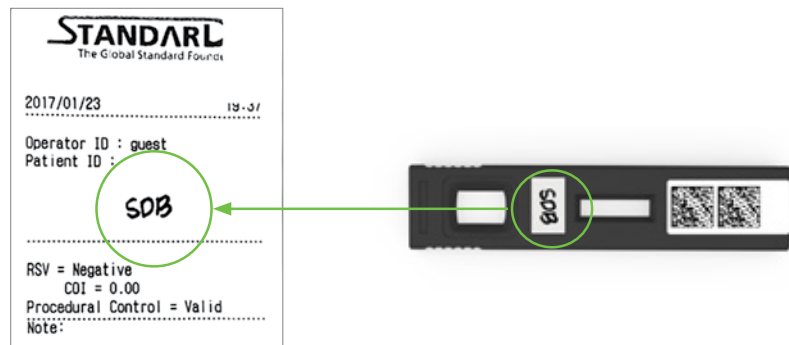
## Random Access

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



Mobile

### Data share

- Via the cloud server



### Direct cable

- STANDARD F Analyzers connect with computer via the direct cable



Personal computer



LIS/HIS

### 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**

## RESPIRATORY DISEASE

### STANDARD F 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Serum, Plasma(EDTA)
<b>Specimen volume</b>	100µl
<b>Testing time</b>	35 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Nasal swab, Nasopharyngeal swab / Transport media
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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

## RESPIRATORY DISEASE

### STANDARD F 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	20µl, 10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Nasal swab, Nasopharyngeal swab / Transport media
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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

## RESPIRATORY DISEASE

### 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Nasal swab / Nasopharyngeal swab / Nasopharyngeal wash / Nasopharyngeal aspirate / Transport media
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	10 mins (Early detection available)
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

#### » Test Performance

Reference : Internal evaluation

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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Nasopharyngeal swab / Nasopharyngeal aspirate / Nasopharyngeal wash / Transport media
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15 mins (Early detection available)
<b>Storage condition</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Throat swab
<b>Specimen volume</b>	100µl
<b>Testing time</b>	5 mins (Early detection available)
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

### » 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

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

### » 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Urine, CSF
<b>Specimen volume</b>	100µl
<b>Testing time</b>	10 mins (Early detection available)
<b>Storage condition</b>	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 <i>S. pneumoniae</i> Ag FIA	25 Tests	10SPN10D
<i>S. pneumoniae</i> 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Nasal swab, Nasopharyngeal swab
<b>Specimen volume</b>	4drops
<b>Testing time</b>	15 mins (Early detection available)
<b>Storage condition</b>	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- $\gamma$  (IFN- $\gamma$ ). The concentration of IFN- $\gamma$  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



<b>Test type</b>	Professional use only
<b>Product Name</b>	STANDARD™ F TB-Feron FIA (IFN-gamma)
<b>Test Method</b>	Fluorescent Immunoassay
<b>Sample volume</b>	100 $\mu$ l of plasma (collected from sensitized whole blood in TB-Feron Tubes)
<b>Dynamic range</b>	0.145 – 10 IU/ml
<b>Testing time</b>	15 mins
<b>Storage Temperature</b>	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)	30 Devices/Kit
07TBFA40	TB-Feron Tube SPP	30 Pcs/Kit (Nil tube x 10, TB Antigen tube x 10, and Mitogen tube x 10)
10TBFC10	F TB-Feron Control	Lv1 x 10 / Lv2 x 10 / Lv3 x 10

## VECTOR BORNE DISEASE

### 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	5 - 15 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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

## VECTOR BORNE DISEASE

### 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	5 - 15 mins
<b>Storage condition</b>	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



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

#### » Test Performance

Reference : Internal evaluation

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

#### » Ordering Information

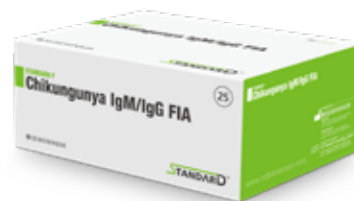
Product	Pack Size	CAT No.
F Zika IgM FIA	25 Tests	10ZK30D

## VECTOR BORNE DISEASE

### 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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



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

#### » Ordering Information

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

## GASTROINTESTINAL DISEASE

### 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



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

#### » Test Performance

Reference : Internal evaluation

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

#### » 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



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

#### » Ordering Information

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

## GASTROINTESTINAL DISEASE

### 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Feces
<b>Specimen volume</b>	40-70mg
<b>Testing time</b>	20 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Feces
<b>Specimen volume</b>	40-70mg
<b>Testing time</b>	10 mins
<b>Storage condition</b>	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 <i>H. pylori</i> Ag FIA	25 Tests	10HPY10D

## GASTROINTESTINAL DISEASE

### 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
Internal study	95.24% (80/84)	100% (77/77)

#### » Ordering Information

Product	Pack Size	CAT No.
F <i>C. difficile</i> 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

#### » Test Performance

Reference : Internal evaluation

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

#### » Ordering Information

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

## GASTROINTESTINAL DISEASE

### 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



<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100 µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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 fluorescent immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) present in whole blood, serum and plasma.



#### » Product Specification

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100 µl
<b>Testing time</b>	20 mins
<b>Storage condition</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins (5 mins early detection for strong positive sample)
<b>Storage condition</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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 2<sup>nd</sup> or 3<sup>rd</sup> 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	Whole blood: 20µl Serum/Plasma: 10µl
<b>Testing time</b>	15 mins (5 mins early detection for strong positive sample)
<b>Storage condition</b>	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	10SY10D

# CHRONIC DISEASE

## 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood
<b>Specimen volume</b>	5µl
<b>Measuring range</b>	4 – 15 % [NGSP], 20 – 140 mm/mol [IFCC]
<b>Reference range</b>	≤ 5.6% (Normal)   5.7 – 6.4% (Prediabetes)   ≥ 6.5% (Diabetes) 7% (ADA target for diabetes patients)
<b>Testing time</b>	3 mins
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F HbA1c	
<b>Correlation with HPLC</b>	$y=0.9765x + 0.1254, R^2=0.9973, n=80$
<b>CV%</b>	< 3%
<b>Differ(%)</b>	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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F U-Albumin FIA	
<b>Correlation with Immuno-turbidimetric assay</b>	$y=0.9969x + 0.0181, R^2=0.9983, n=210$
<b>CV%</b>	< 7%
<b>Differ(%)</b>	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

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

### » Method comparison

Reference : Internal evaluation

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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PCT	
<b>Correlation vs ECLIA Method</b>	$y = 1.02147x + 0.0743, R=0.9946, n=210$
<b>CV%</b>	QCL=7.5% / QCM=9.2% / QCH=8.9%
<b>Differ(%)</b>	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

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

#### » Method comparison

Reference : Internal evaluation

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

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

#### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F CK-MB FIA	
<b>Correlation vs ECLIA Method</b>	$y=0.9937x - 0.047$ , $R=0.9973$ , $n=210$
<b>CV%</b>	QCL=6.0% / QCM=6.3% / QCH=7.0%
<b>Differ(%)</b>	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



# CARDIOVASCULAR DISEASE

## 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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood(EDTA), Serum
<b>Specimen volume</b>	100µl
<b>Measuring range</b>	0.05 – 20 ng/mL
<b>Reference range</b>	< 0.16 ng/mL
<b>Testing time</b>	10 mins
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TnI FIA	
<b>Correlation vs ECLIA Method</b>	$y=0.9677x-0.0069$ , $R=0.9918$ , $n=120$
<b>CV%</b>	QCL=8.8% / QCM=7.4% / QCH=7.1%
<b>Differ(%)</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood(EDTA), Serum
<b>Specimen volume</b>	100µl
<b>Measuring range</b>	50 – 25,000 pg/mL
<b>Reference range</b>	<ul style="list-style-type: none"> <li>Acute HF Rule-out : &lt;300 pg/mL</li> <li>Symptomatic chronic HF Rule-out : &lt;125 pg/mL (&lt;75 yrs) &lt;450 pg/mL (≥75 yrs)</li> </ul>
<b>Testing time</b>	15 mins
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F NT-proBNP FIA	
<b>Correlation vs ECLIA Method</b>	$y=0.9842x + 11.036$ , $R^2= 0.9694$ $n=180$
<b>CV%</b>	QCL=11.3% / QCM=11.2% / QCH=11.3%
<b>Differ(%)</b>	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

# CARDIOVASCULAR DISEASE

## 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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F D-dimer FIA	
<b>Correlation vs ECLIA Method</b>	$y=1.0062x + 17.742, R=0.9920, n=120$
<b>CV%</b>	QCL=7.8% / QCM=8.0% / QCH=8.2%
<b>Differ(%)</b>	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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F hs-CRP	
<b>Correlation vs ECLIA Method</b>	$y=0.9994x-0.01, R=0.9989, n=120$
<b>CV%</b>	QCL=7.6% / QCM=9.7% / QCH=9.8%
<b>Differ(%)</b>	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



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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F Vitamin D FIA	
<b>Correlation vs ECLIA Method</b>	$Y = 0.937x + 1.347, R = 0.960, n=100$
<b>CV%</b>	QCL = 5.3% / QCH = 6.3%
<b>Differ(%)</b>	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



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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F β-hCG FIA	
<b>Correlation vs ECLIA Method</b>	$y = 1.0161x - 6.6452, R = 0.9968, n = 180$
<b>CV%</b>	QCL = 4.7% / QCM = 4.7% / QCH = 4.5%
<b>Differ(%)</b>	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

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



### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F LH FIA	
<b>Correlation vs ECLIA Method</b>	$y=0.9916x + 0.0866$ , $R=0.9921$ , $n=210$
<b>CV%</b>	QCL=8.3% / QCM=8.0% / QCH=8.2%
<b>Differ(%)</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Whole blood, Serum
<b>Specimen volume</b>	35µl
<b>Measuring range</b>	0.1 – 100 mIU/L
<b>Reference range</b>	0.45 – 4.5 mIU/L
<b>Testing time</b>	15 mins
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F



### » Method comparison

Reference : Internal evaluation

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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Serum
<b>Specimen volume</b>	100µl
<b>Measuring range</b>	0.1 – 100 mIU/L
<b>Reference range</b>	0.45 – 4.5 mIU/L
<b>Testing time</b>	15 mins
<b>Storage condition</b>	2 – 30 °C / 36 - 86 °F

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F TSH FIA	
<b>Correlation vs ECLIA Method</b>	$y=1.1097x - 0.5, R=0.9943, n=110$
<b>CV%</b>	QCL=7.4% / QCM=6.5% / QCH=4.9%
<b>Differ(%)</b>	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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F ft4	
<b>Correlation vs ECLIA Method</b>	$y=1.002x - 0.1452, R= 0.9943, n=120$
<b>CV%</b>	QCL=7.5% / QCM=8.0% / QCH=8.0%
<b>Differ(%)</b>	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 FT4 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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F T4	
<b>Correlation vs ECLIA Method</b>	$y=1.0113x - 0.6502, R= 0.9943$ n=120
<b>CV%</b>	QCL=7.7% / QCM=7.7% / QCH=8.0%
<b>Differ(%)</b>	Within 15%

### » Ordering Information

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

# TUMOR MARKER

## 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

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

### » Method comparison

Reference : Internal evaluation

Reference method vs STANDARD F PSA FIA	
<b>Correlation vs ECLIA Method</b>	$y=0.9589x - 0.2336, R=0.9948, n=180$
<b>CV%</b>	QCL=9.0% / QCM=8.0% / QCH=7.2%
<b>Differ(%)</b>	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

<b>Test type</b>	Professional use only
<b>Specimen type</b>	Feces
<b>Specimen volume</b>	3 drops
<b>Measuring range</b>	25 – 1,000 ng/mL (5 – 200 µg Hb/g feces)
<b>Reference range</b>	< 100 ng/mL (20 µg Hb/g feces)
<b>Testing time</b>	5 mins
<b>Storage condition</b>	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**

# RESPIRATORY DISEASE

## STANDARD Q COVID-19 Ag



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Nasopharyngeal swab, VTM
<b>Specimen volume</b>	3 drops
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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)



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Nasal swab
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Whole blood, Serum, Plasma, Capillary whole blood
<b>Specimen volume</b>	Whole blood : 20ul, Serum/Plasma : 10ul
<b>Testing time</b>	10 - 15 mins
<b>Storage condition</b>	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

## RESPIRATORY DISEASE

### STANDARD Q COVID-19 Ag Saliva



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Saliva with mucus
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	30 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Nasopharyngeal swab
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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

<b>Test type</b>	Self-diagnostic test
<b>Specimen type</b>	Nasal swab
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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



## RESPIRATORY DISEASE

### STANDARD i-Q COVID-19 Ag Home Test

<b>Test type</b>	Self-diagnostic test
<b>Specimen type</b>	Nasal swab
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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



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



#### » Test Performance

Reference : Internal evaluation

Reference	Sensitivity	Specificity
PCR	A: 97.44% (95% CI: 86.52-99.94%)	A: 100% (95% CI: 99.12-100.00%)
	B: 90.63% (95% CI: 74.98-98.02%)	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Respiratory Syncytial Virus (RSV) antigens
<b>Specimen type</b>	Nasopharyngeal swab / Nasopharyngeal wash/aspirate
<b>Testing time</b>	15 mins (Do not read after 30 mins)
<b>Storage condition</b>	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

# RESPIRATORY DISEASE

## STANDARD Q Strep A Ag



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Group A streptococcal antigens
<b>Specimen type</b>	Throat swab
<b>Testing time</b>	5 mins (Do not read after 15 mins)
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of <i>Legionella pneumophila</i> serogroup 1, 3, 5,6 and 8 antigens
<b>Specimen type</b>	Urine
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15 mins (Do not read after 30 mins)
<b>Storage condition</b>	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 <i>Legionella</i> Ag	25 Tests	09LEG30D
<i>Legionella</i> Ag Control	Pos x 10 / Neg x 10	10LEGC10

## STANDARD Q *S.pneumoniae* Ag



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Urine
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15 mins (Do not read after 30 mins)
<b>Storage condition</b>	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 <i>S.pneumoniae</i> Ag	25 Tests	09SPN30D
<i>S.pneumoniae</i> Ag Control	Pos x 10 / Neg x 10	10SPNC10

## RESPIRATORY DISEASE

### STANDARD Q Adeno Respi Ag



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of adenovirus antigens in respiratory specimens
<b>Specimen type</b>	Nasal swab, Nasopharyngeal swab
<b>Specimen volume</b>	4 drops
<b>Testing time</b>	15 mins (Do not read after 20 mins)
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of MERS-CoV antigens
<b>Specimen type</b>	Nasopharyngeal swab / Nasopharyngeal aspirate / lower respiratory tract aspirate
<b>Testing time</b>	15 mins (Do not read after 30 mins)
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Mycobacterium tuberculosis MPT64 antigen
<b>Specimen type</b>	Liquid culture, Solid culture
<b>Testing time</b>	10 mins (Do not read after 15 mins)
<b>Storage condition</b>	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

## RESPIRATORY DISEASE

### STANDARD Q Ebola Zaire Ag

CE



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

#### » Ordering Information

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

# VECTOR BORNE DISEASE

## STANDARD Q Dengue Duo



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Dengue NS1 antigen & IgM/IgG antibodies
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	NS1: 100µl, IgM/IgG: 10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Dengue NS1 antigen
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Dengue IgM and IgG antibodies
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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

# VECTOR BORNE DISEASE

## STANDARD Q Zika IgM



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Zika IgM antibody
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Chikungunya IgM and IgG antibodies
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Yellow Fever IgM antibody
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



## VECTOR BORNE DISEASE

### STANDARD Q Arbovirus Multi Tests

#### STANDARD Q Arbo Panel I (Z/D/C/Y) CE

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



#### STANDARD Q ZIKV/DENV/CHIKV Fast Quad CE

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



#### STANDARD Q Dengue/Chikungunya Trio CE

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



#### STANDARD Q Zika/Dengue Fast Trio CE

<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Dengue NS1 antigen and IgM specific to Zika or Dengue
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	NS1: 100µl, IgM: 10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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

# VECTOR BORNE DISEASE

## STANDARD Q Malaria P.f Ag

WHO PQ approved CE



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Malaria <i>Plasmodium falciparum</i> specific Histidine Rich Protein 2 (HRP-2)
<b>Specimen type</b>	Whole blood
<b>Specimen volume</b>	5µl
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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 Pf Ag Test	25 Tests	09MAL10D

## STANDARD Q Malaria P.f/P.v Ag

WHO PQ approved CE



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

### » Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
Venous whole blood	Microscopy	Pf 99.59% (487/489)	100% (1006/1006)
		Pv 100% (123/123)	
Capillary whole blood	Microscopy	Pf 99.38% (322/324)	100% (256/256)
		Pv 100% (25/25)	

### » Ordering Information

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

## STANDARD Q Malaria P.f/Pan Ag

WHO PQ approved CE



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

### » Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
Venous whole blood	Microscopy	Pf 99.58% (476/478)	100% (1000/1000)
		Pv, P.m. and P.o. confirmed specimen on Pan 100% (129/129)	
Capillary whole blood	Microscopy	Pf 99.68% (312/313)	100% (11/11)
		Pv, P.m. and P.o. confirmed specimen on Pan 100% (31/31)	

### » Ordering Information

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

## VECTOR BORNE DISEASE

### STANDARD Q Malaria/CRP Duo



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



#### » Test Performance

Reference : Internal evaluation

	Reference	Sensitivity	Specificity
Pf	Microscopy	99.58% (476/478)	
Pv, P.m. and Po. confirmed specimens on Pan	Microscopy	100% (129/129)	100% (1000/1000)
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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of <i>Leptospira interrogans</i> IgM and IgG antibodies
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



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



#### » Ordering Information

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

# BLOOD BORNE DISEASE

## STANDARD Q HIV/Syphilis Combo

WHO PQ  
approved

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



» **Test Performance** in accordance with CTS

Detection of HIV Ab			
Sensitivity [95% CI]		Specificity [95% CI]	
Total	<b>100.0%</b> [99.4-100.0%](637/637)	Total	<b>99.9%</b> [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 <i>Treponema pallidum</i> Ab			
Sensitivity [95% CI]		Specificity [95% CI]	
Total	<b>98.8%</b> [97.1-99.5%](395/400)	Total	<b>100.0%</b> [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

<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of specific antibodies to <i>Treponema pallidum</i>
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	Whole blood: 20µl, Serum/Plasma: 10µl
<b>Testing time</b>	5-20 mins
<b>Storage condition</b>	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

<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of specific antibodies to all isotypes of HIV-1/2
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	Whole blood: 20µl, Serum/Plasma: 10µl
<b>Testing time</b>	10-20 mins
<b>Storage condition</b>	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	<b>99.8%</b> [98.9-100.0%](500/501)	Total	<b>100.0%</b> [99.8-100.0%] (1,900/1,900)
HIV-1 positive	99.7% (360*/361)	EDTA plasma	100.0% (1,000/1,000)
HIV-1 positive (non-B subtypes**)	100.0% (40/40)	Whole blood	100.0% (500/500)
HIV-2 positive	100.0% (100/100)	Hospitalized patients	100.0% (200/200)
		Pregnant women	100.0% (200/200)

\* The missed sample was collected from a patient receiving HAART very soon after seroconversion phase.

\*\* non-B subtypes: A, A1, CRF01\_AE, CRF02\_AG, CRF06\_cpx, CRF36\_cpx, D, F1, F2, G, H, J, K, Group O

» **Ordering Information**

Product	Contents	Pack Size	CAT No.
	Device/Assay diluent/Capillary Tube/Lancet/Alcohol swab	25 Tests	09HIV30D
Q HIV 1/2 Ab 3-Line Test	Device/Assay diluent	25 Tests	09HIV30DM
	Multi-Device/Assay diluent	100 Tests	09HIV30F

## HEPATITIS

### STANDARD Q HAV IgM

CE

<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Hepatitis A virus IgM antibody
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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

# HEPATITIS

## STANDARD Q HCV Ab

WHO PQ  
approved



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Hepatitis C virus antibody
<b>Specimen type</b>	Serum, Plasma
<b>Specimen volume</b>	10µl
<b>Testing time</b>	5-20 mins
<b>Storage condition</b>	2 – 40°C / 36 - 104°F

» **Test Performance** in accordance with CTS

Detection of HCV Ab			
Sensitivity [95% CI]		Specificity [95% CI]	
Total	<b>100.0%</b> [99.1-100.0%](413/413)	Total	<b>97.67%</b> (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 <b>CE 0123</b>
	Multi-Device/Assay diluent	100 Tests	09HCV20F

## STANDARD Q HBsAg



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Hepatitis B virus surface antigen (HBsAg)
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	20-30 mins
<b>Storage condition</b>	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



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of antibody against HBV surface antigen
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15-30 mins
<b>Storage condition</b>	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



## GASTROINTESTINAL DISEASE

### STANDARD Q *H. pylori* Ab

CE



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

#### » Ordering Information

Product	Pack Size	CAT No.
Q <i>H. pylori</i> Ab Test	25 Tests	09HPY10D

### STANDARD Q *H. pylori* Ag

CE



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of <i>Helicobacter pylori</i> antigen
<b>Specimen type</b>	Feces
<b>Specimen volume</b>	40-70 mg
<b>Testing time</b>	10-15 mins
<b>Storage condition</b>	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 <i>H. pylori</i> Ag Test	25 Tests	09HPY20D

### STANDARD Q Norovirus Ag

CE



<b>Test type</b>	Professional Use Only
<b>Intended use</b>	Detection of Norovirus antigen
<b>Specimen type</b>	Feces
<b>Specimen volume</b>	40 - 70mg
<b>Testing time</b>	15 mins
<b>Storage condition</b>	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

CE



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	75µl
<b>Testing time</b>	10-20 mins
<b>Storage condition</b>	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

CE



<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Whole blood, Serum, Plasma
<b>Specimen volume</b>	100µl
<b>Testing time</b>	15-20 mins
<b>Storage condition</b>	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



A scientist wearing a white lab coat, a blue surgical mask, and safety glasses is working in a laboratory. The background is a soft-focus view of the scientist's face and upper body. In the foreground, there is a laboratory bench with various pieces of glassware. On the left, there is a clear Erlenmeyer flask containing a blue liquid. In the center and right, there are several petri dishes, some containing clear liquids and others containing blue substances. The overall lighting is cool and blue-toned.

# **STANDARD E Parameters**



# VECTOR BORNE DISEASE

## STANDARD E Dengue NS1 Ag ELISA



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of Dengue NS1 antigens
<b>Specimen type</b>	Serum / Plasma
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of specific IgM to Dengue virus
<b>Specimen type</b>	Serum / Plasma
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of specific IgG to Dengue virus
<b>Specimen type</b>	Serum / Plasma
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of specific IgM to Zika virus
<b>Specimen type</b>	Serum / Plasma
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



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



### » Ordering Information

Product	Pack Size	CAT No.
E Chikungunya IgM ELISA	96 wells/Kit	07CHI20

## STANDARD E Chikungunya IgG ELISA



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of specific IgG to Chikungunya virus
<b>Specimen type</b>	Serum / Plasma
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



<b>Test type</b>	Professional use only
<b>Intended use</b>	Detection of <i>Plasmodium falciparum</i> , <i>P.vivax</i> , <i>P.ovale</i> , <i>P.malariae</i> and <i>P.knowlesi</i> species
<b>Specimen type</b>	Whole blood
<b>Storage condition</b>	2 – 8°C / 36 - 46°F
<b>Shelf life</b>	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



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

“

**Real-time PCR**

+

**LAMP****in one system**

”



# 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 differentiation 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



## RESPIRATORY DISEASE

### 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.

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



CE

✓ KOREA MFDS EUA FDA

#### » 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.

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



CE

#### » Ordering Information

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

## NA EXTRACTION KIT

### 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.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
<b>Storage condition</b>	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.

<b>Test type</b>	Professional Use Only
<b>Specimen type</b>	Plasma, Serum, Nasopharyngeal swab, Oropharyngeal swab, Sputum
<b>Storage condition</b>	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 Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC30
STANDARD GlucoNavii GDH	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)**



### » Ordering Information

Category	Product	Pack size	Cat. no.
	STANDARD Mentor Blood Glucose Monitoring System (Test strips x 10)	1Unit	01GC210
STANDARD Mentor	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 Blood Glucose Monitoring System	1Unit	01GC22
SD CHECK GOLD 2	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



## » 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



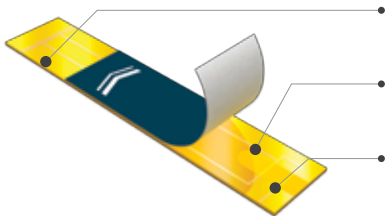
## » Ordering Information

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

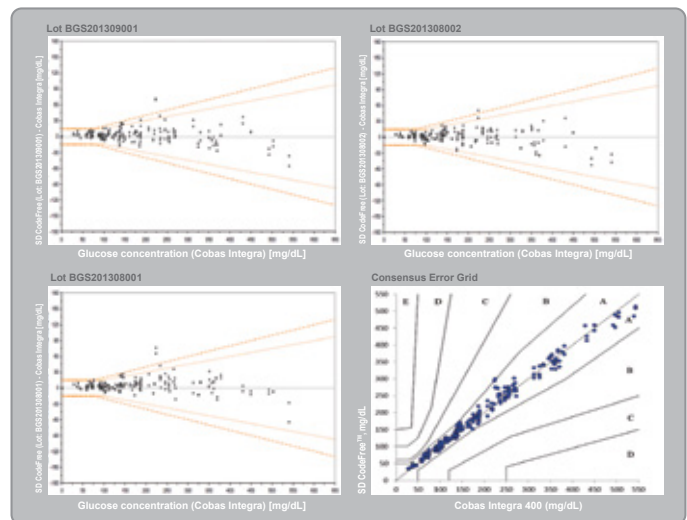
Makes test fast and easy

## » 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.

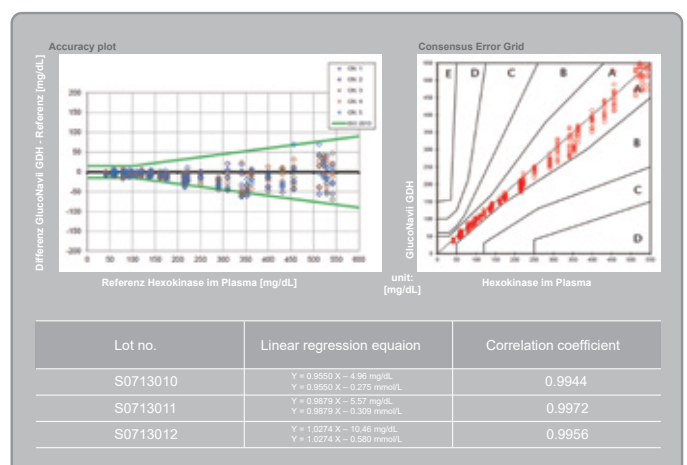
<b>Investigative Site</b>	Institut für Diabetes (IDT), Germany
<b>Test system</b>	SD Codefree™
<b>Reference system</b>	Cobas Integra 400 Plus
<b>Samples</b>	whole blood (capillary)



### 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.

<b>Investigative Site</b>	IMCARMED GmbH, Germany
<b>Test system</b>	STANDARD™ GlucoNavil® GDH
<b>Reference system</b>	Hexokinase method
<b>Samples</b>	whole blood (capillary)



The Brilliant All in One Analyzer

## MultiCare



### » Product Specification

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

<b>Method</b>	Lipid: Photometric / Glucose: Electrochemical
<b>Specimen type</b>	Finger Stick, Venous-WB/Serum/Plasma (EDTA or heparin)
<b>Sample volume</b>	Single: 10µl / Lipid Profile: 35µl
<b>Measuring range</b>	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
<b>Measuring time</b>	5 sec. (Glucose), 3 mins (Cholesterol)
<b>Data transfer</b>	Mini USB cable, Bluetooth(optional)
<b>Test kit storage temperature</b>	2 - 32°C (36 -90°F)
<b>Shelf life</b>	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

<b>Method</b>	Colorimetric
<b>Specimen type</b>	Whole blood
<b>Sample volume</b>	10µl
<b>Measuring range</b>	Total hemoglobin: 4-25 g/dL    G6PD: 0-20 U/g Hb
<b>Measuring time</b>	2 mins
<b>Test kit storage temperature</b>	2-30°C / 36 - 86°F
<b>Shelf life</b>	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.
<b>Qualitative assays</b>						
Respiratory Disease	COVID-19 Ag FIA <sup>NEW</sup>	NP**swab	4 drops	15 mins	25T	10COV30D
		Nasal swab			25T	10COV31D
	COVID-19 IgM/IgG Combo FIA <sup>NEW</sup>	WB/S/P*	10-20 µl	15 mins	25T	10COV50G
	SARS-CoV-2 nAb FIA <sup>NEW</sup>	S/P*	100 µl	15 mins	20T	10COV80B
	COVID/Flu Ag Combo FIA <sup>NEW</sup>	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
Vector Borne Disease	Adeno Respi Ag FIA	NP**swab, Nasal swab	-	15 mins	25T	10ADE10D
	TB-Feron FIA (IFN-gamma)	Plasma	100 µl	15 mins	30 Devices	10TBF10E
	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
Gastrointestinal Disease	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
	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 <sup>NEW</sup>	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
Hepatitis	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
	Anti-HBs FIA <sup>NEW</sup>	WB/S/P*	100 µl	15 mins	25T	10AHB10D
	HBsAg FIA <sup>NEW</sup>	WB/S/P*	100 µl	20 mins	25T	10HBS10D
Blood Borne Disease	HCV Ab FIA	WB/S/P*	10 µl	15 mins	25T	10HCV10D
	HAV IgM FIA	WB/S/P*	10 µl	15 mins	25T	10HAV10D
STI	HIV Ag/Ab FIA	WB/S/P*	100 µl	15 mins	25T	10HIV20D
	Syphilis Ab FIA	WB/S/P*	WB: 20 µl, S/P: 10 µl	15 mins	25T	10SYP10D
<b>Quantitative assays</b>						
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 <sup>NEW</sup>	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 <sup>NEW</sup>	NP**swab	3 drops	15-30 mins	25T	09COV30D	
	COVID-19 Ag (Nasal) <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	25T	09COV31D	
	COVID-19 IgM/IgG Plus <sup>NEW</sup>	WB/S/P*	10~20 µl	10-15 mins	25T	09COV70DM	
	COVID-19 Ag Saliva <sup>NEW</sup>	Saliva with mucus	-	30 mins	25T	09COV90D	
	COVID/Flu Ag Combo <sup>NEW</sup>	NP** swab /Nasal swab	4 drops	15-30 mins	25T	09COV100D	
	COVID-19 Ag Home Test <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	1T	09COV120	
	COVID-19 Ag Home Test <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	2T	09COV130H	
	COVID-19 Ag Home Test <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	5T	09COV130J	
	COVID-19 Ag Home Test <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	25T	09COV130D	
	i-Q COVID-19 Ag Home Test <sup>NEW</sup>	Nasal swab	4 drops	15-30 mins	1T	09COV121	
	i-Q COVID-19 Ag Home Test <sup>NEW</sup>	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	
	Vector Borne Disease	Ebola Zaire Ag	WB/S/P*	100 µl	20-30 mins	25T	05EZ10
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 Pf Ag		WB	5 µl	15-30 mins	25T	09MAL10D	
Malaria Pf/Pv Ag		WB	5 µl	15-30 mins	25T	09MAL20D	
Malaria Pf/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 <sup>NEW</sup>	WB/S/P*	75 µl	10-20 mins	25T	09FIL10D	
Cardiovascular Disease	TnI <sup>NEW</sup>	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 <b>NEW</b>	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10COVC10
	COVID-19 IgM/IgG Control <b>NEW</b>	M Pos x10 / G Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10COVC20
	H. pylori Ag Control <b>NEW</b>	Pos x10 / Neg x10	36M	2 – 30°C / 36 – 86 °F	10HPYC10
	C. difficile Control <b>NEW</b>	Pos x10 / Neg x10	36M	2 – 30°C / 36 – 86 °F	10CDGC10
	C. difficile Toxin A/B Control <b>NEW</b>	Pos x10 / Neg x10	36M	2 – 30°C / 36 – 86 °F	10CDTC10
	HBsAg Control <b>NEW</b>	Pos x10 / Neg x10	24M	2 – 30°C / 36 – 86 °F	10HBSC10
	Influenza A/B Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10INFC10
	RSV Ag Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10RSVC10
	Strep A Ag Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10STRC10
	Legionella Ag Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10LEGC10
	S.pneumoniae Ag Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10SPNC10
	Adeno Respi Ag Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10ADEC10
	Syphilis Ab Control	Pos x10 / Neg x10	18M	2 – 30°C / 36 – 86 °F	10SYPC10
	Vitamin D Control <b>NEW</b>	Lv1 x10 / Lv2 x10	36M	2 – 30°C / 36 – 86 °F	10VTC10
	STANDARD F	PCT Control	Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F
PCT-02 Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10PCTC20
CRP Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	03CCS10
HbA1c Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	03ACS10
U-Albumin Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10UALC10
CK-MB Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10CKBC10
Tnl Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10TNIC10
NT-proBNP Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10NTPC10
D-dimer Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10DDIC10
hs-CRP Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10HSCC10
β-hCG Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10BHCC10
LH Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10LHC10
TSH Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10TSHC10
ft4 Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10FT4C10
T4 Control		Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10T4C10
PSA Control	Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10PSAC10	
iFOB Control	Lv1 x10 / Lv2 x10	18M	2 – 30°C / 36 – 86 °F	10IFOC10	
F TB-Feron Control	Lv1 x10 / Lv2 x10 / Lv3 x 10	18M	2 – 30°C / 36 – 86 °F	10TBFC10	

## STANDARD E

### » Parameters

Category	Product	Specimen	Pack size	Cat. no.
Respiratory Disease	COVID-19 Total Ab ELISA <b>NEW</b>	S/P*	96 wells	07COV10
	SARS-CoV-2 nAb ELISA <b>NEW</b>	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
	TB-Feron SPP	WB*	10T (Mitogen Tube)	07TBFA40
		WB*	10T (TB Antigen Tube)	
	Vector Borne Disease	Dengue NS1 Ag ELISA	S/P*	96T
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°C / 36 – 86 °F	07TBFC10

## STANDARD M

### » Analyzer

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

### » Assay Menu

Category	Product	Specimen	Specimen volume	Testing time	Pack size	Cat. no.
Respiratory Disease	SARS-CoV-2 <sup>NEW</sup>	NP** swab /Nasal swab /Throat swab	600 µl	40-60 min	10T	11COV10A
	SARS-CoV-2 20' <sup>NEW</sup>	NP** swab /Nasal swab /Throat swab	600 µl	20-30 min	10T	11COV20A
	Flu/SARS-CoV-2 20' <sup>NEW</sup>	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 <sup>NEW</sup> (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 <sup>NEW</sup> (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 <sup>NEW</sup>	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 Blood Glucose Monitoring System (Test strips x 10)	1 Unit	01GC30
STANDARD GlucoNavii GDH	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 CHECK GOLD 2	SD CodeFree Blood Glucose Test Strip	25T x 2	01GS11
	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
	MultiCare HbA1c Test Kit	20T	03MS10
Test device	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





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