SD BIOSENSOR
PRODUCT CATALOG

POC *in-vitro* Total Platform Company

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

SD BIOSENSOR

www.rajbiosis.com
+91-998-3333-469

Raj Biosis Private Limited

02

STANDARD F

Fluorescence immunoassay

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

STANDARD F

Experience highly accurate FIA test with STANDARD F Analyzers

Raj Biosis Private Limited

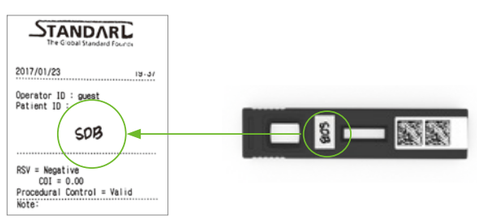
STANDARD F Analyzer is a next-generation fluorescent immunoassay system. It is a multi-parametric and random accessible immunoassay system providing accurate diagnostic results to your laboratory.

RANDOM ACCESS

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

PATIENT ID PRINTING SYSTEM

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



ASSAY PRINCIPLE

Fluorescent Immunoassay (FIA)

Specific Antigen or Antibody

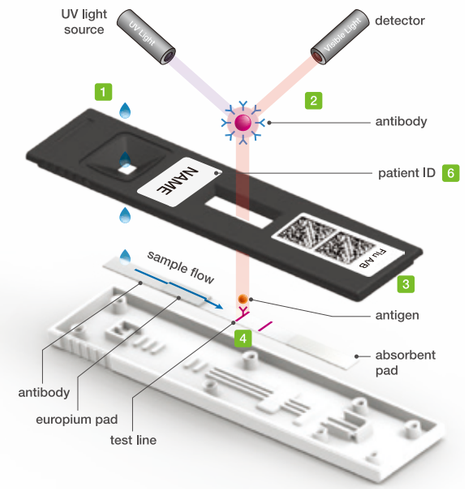
- High sensitivity and specificity
- Fast assay time
- Cost effective

Europium bead

- Strong signals
- Excellent stability
- Minimized interference

Parameter information

2D barcode contains all the information required for the test



CONNECTIVITY

LIS/HIS connectivity

Connect to the majority of existing information systems.

Data share

Via the cloud server

Direct cable

STANDARD F Analyzers connect with computer via the direct cable

STANDARD F | FLUORESCENT IMMUNOASSAY ANALYZER

STANDARD

F2400

CE MFDS

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

Raj Biosis Private Limited

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	10.1″ Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	510 x 566 x 297 mm
Weight	20.0 kg

STANDARD

F200

CE MFDS

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

Technical Specification

Model	STANDARD™ F2400
Test method	Fluorescent immunoassay (FIA)
Analysis	Quantitative / Qualitative Tests
Test capacity	1 Tests per hour
Test mode	STANDARD TEST, READ ONLY
Power	AC/DC Adapter
Display	7″ Color touch screen
Printer	Built-in
Connectivity	HL7 v2.6(PCD-01) / POCT1-A
Auto-ID	2D Barcode
Accessories	Keyboard / Barcode scanner
Dimension	214.9 x 261 x 203 mm
Weight	2.5 kg

STANDARD

d-BLOCK Incubator

CE

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

Raj Biosis Private Limited

Technical Specification

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

STANDARD F

SARS-CoV-2 Variant nAb FIA

CE

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

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

Ordering Information

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

STANDARD F

SARS-CoV-2 Total nAb FIA

CE

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

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

Ordering Information

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

STANDARD F

COVID-19 Ag FIA

CE MFDS

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

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

Test Performance

Reference	Sensitivity	Specificity
PCR	94.23%	100%

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

COVID-19 IgM/IgG Combo FIA

CE MFDS

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

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STANDARD F

COVID/Flu Ag Combo FIA

CE

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

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

Ordering Information

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

STANDARD F

Covi-FERON FIA

CE

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Influenza A/B FIA

CE MFDS

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

RSV Ag FIA

CE MFDS

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

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STANDARD F

Strep A Ag FIA

CE

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

Test type	Professional Use Only
Specimen type	Throat swab
Specimen volume	100 µl
Testing time	5 mins (Early detection available)
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Test Performance

Reference	Sensitivity	Specificity
Bacterial culture	95.0%	95.2%

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

Legionella Ag FIA

CE MFDS

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

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

Test Performance

Reference	Sensitivity	Specificity
Fluorescent immunoassay	97.5%	98.5%

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

S. pneumoniae Ag FIA

CE MFDS

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Adeno Respi Ag FIA

CE

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

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

Ordering Information

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

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STANDARD F

TB-Feron FIA (IFN-gamma)

CE

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

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

Ordering Information

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

STANDARD F

Dengue NS1 Ag FIA

CE

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Dengue IgM/IgG FIA

CE

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

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STANDARD F

Zika IgM FIA

CE

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

Chikungunya IgM/IgG FIA

CE

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Tsutsugamushi IgM/IgG FIA

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

Lyme IgM/IgG FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

Raj Biosis Private Limited

STANDARD F

Norovirus Ag Plus FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Rota/Adeno Ag FIA

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

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

Ordering Information

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

STANDARD F

H. pylori Ag FIA

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

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

Test Performance

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

Reference : Samsung Medical Center

Ordering Information

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

STANDARD F

C. difficile GDH FIA

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

Raj Biosis Private Limited

STANDARD F

C. difficile Toxin A/B FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Anti-HBs FIA

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

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

Ordering Information

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

STANDARD F

HBsAg FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

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STANDARD F

HCV Ab FIA

MFDS

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

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

Test Performance

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

Reference : Clinical evaluation

Ordering Information

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

STANDARD F

HAV IgM FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

HIV Ag/Ab FIA

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

Syphilis Ab FIA

CE

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

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

Test Performance

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

Reference : Internal evaluation

Ordering Information

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

Raj Biosis Private Limited

STANDARD F

HbA1c

CE NGSP IFCC MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

U-Albumin FIA

CE MFDS

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

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

Method comparison

Reference method vs STANDARD F HbA1c	
Correlation with ECLIA Method	**Differ(%)**
y=0.9837x + 0.8214, R^2=0.9927, n=70	within 10%

Reference : Internal evaluation

Ordering Information

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

STANDARD F

PCT FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

CRP

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

Raj Biosis Private Limited

STANDARD F

TnI Pro FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

TnI/CK-MB Combo FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

TnI FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

CK-MB FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

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STANDARD F

D-dimer FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

hs-CRP

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

NT-proBNP FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

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STANDARD F

Vitamin D FIA

CE

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

β-hCG FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

LH FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

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STANDARD F

TSH-II FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F

TSH FIA

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F
fT4

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F
T4

CE MFDS

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

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STANDARD F
T3

CE

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

Test type	Professional Use Only
Specimen type	Serum
Specimen volume	50 µl
Measuring range	0.1 ~ 10 nmol/L
Reference range	1.3 ~ 3.1 nmol/L (0.8 ~ 2.0 ng/mL)
Testing time	25 mins
Storage condition	2 ~ 30 °C / 36 ~ 86 °F

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F
PSA FIA

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

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

Method comparison

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

Reference : Internal evaluation

Ordering Information

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

STANDARD F
iFOB FIA

CE MFDS

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

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

Ordering Information

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