

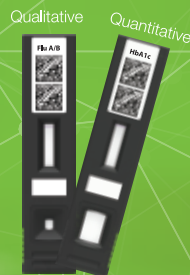
STANDARD F

Fluorescent Immunoassay System

STANDARD F100

STANDARD F200

STANDARD F2400

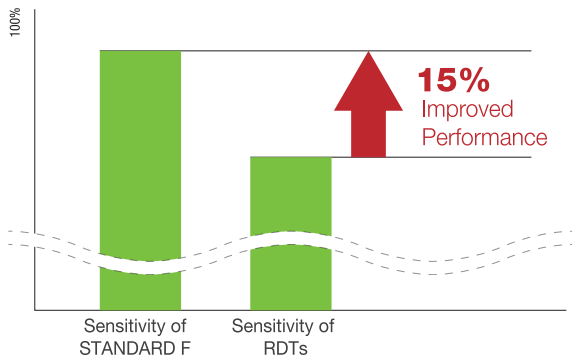


Higher sensitivity through fluorescent immunoassay

STANDARD F is a fluorescent immunoassay system that uses fluorescent europium as a detector.

Higher sensitivity than the existing RDTs could be provided through advanced fluorescent detection with an UV LED energy source.

15% improved sensitivity than RDTs – Influenza



552 samples (53 positive, 499 negative) were used in a single-center prospective study conducted in Malaysia. The samples were confirmed by RT-qPCR and STANDARD F showed higher sensitivity compared to RDT.

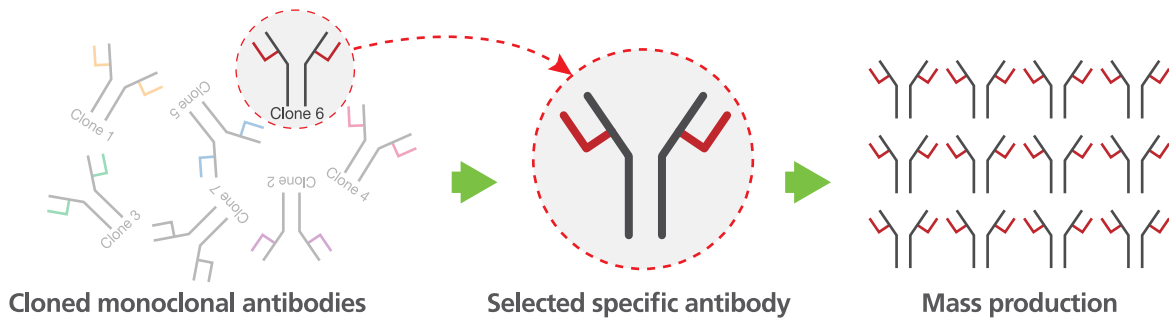
8 times lower LOD than RDTs – Influenza

Influenza A	STANDARD F		RDTs
dilution ratio	COI	Result	Result
2 ⁻¹	25.4	+	+
2 ⁻²	11.6	+	+
2 ⁻³	6	+	-
2 ⁻⁴	2.3	+	-
2 ⁻⁵	1.2	+	-
2 ⁻⁶	0.7	-	-

Influenza B	STANDARD F		RDTs
dilution ratio	COI	Result	Result
2 ⁻¹	17.9	+	+
2 ⁻²	14.1	+	+
2 ⁻³	8.5	+	-
2 ⁻⁴	4.2	+	-
2 ⁻⁵	2.2	+	-
2 ⁻⁶	1.0	+	-
2 ⁻⁷	0.5	-	-

Reference : Internal evaluation

Specific antibody screening techniques allow STANDARD F to have superior sensitivity and specificity.



STANDARD F Specification

Series	F 100	F 200	F 2400
Image			
Test method	Fluorescent immunoassay		
Analysis	Quantitative & Qualitative test		
Test capacity	1 test each	1 test each	70 Tests per hour Random access
Quick test mode	Available	Available	Not Available
Power	AC/DC adapter or Battery(AA x 4)	AC/DC adapter	Power Cable (SMPS adapted)
Display	Graphic LCD	7" Color Touch Screen	10" Color Touch Screen
Printer	External	Built-in	Built-in
LIS /HIS connectivity	Bluetooth classic	HL7 v2.6	HL7 v2.6
Auto-ID	2D barcode	2D barcode	2D barcode
Dimension (mm)	105 x 135 x 100	200 x 240 x 205	510 x 566 x 297
Accessories	Thermal printer	Keyboard Barcode scanner	Keyboard Barcode scanner
Weight	0.7 kg	2.5 kg	20 kg

Advantages of STANDARD F

User friendly interface
7" Color Touch Screen

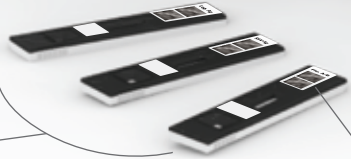
Convenient report
Built-in Printer

Compact desktop
200 x 240 x 205
2.5 kg

Graphic LCD
Result is presented clearly and concisely

Portable system
Battery(AA x 4)
or AC/DC adapter

Minimized risk of contamination
Keep the entrance shut unless the testing is in progress. The dust cover protects against contamination.



Variable test parameters
All the qualitative & quantitative assay menus are available for any F analyzer.

Convenient process
Auto coding procedure by recognizing 2D barcode

Hand held size
105 x 135 x 100
700 g



Connectivity
• Direct LIS/HIS
• HL7 v2.6



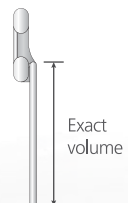
Calibration Set



Control Bead



Control Swab



Exact volume

Reliable result
Provide Calibration Set and Control reagent having more confidence in the result.

Accurate result
Take an accurate collection with Fixed volume dropper.

STANDARD F Analyzers are qualitative and quantitative fluorescent immunoassay systems and have been designed for easy and reliable measuring of various parameters. STANDARD F analyzers are differentiated into 3 different models that can be used depending on your workflow requirements. **Rapid, highly accurate and reliable results help you to reduce uncertainty of treatment and improve the quality of patients care.**

Technical Advantages

1. Simple and easy to use

Familiar lateral flow test platform

2. Europium-based fluorescent chemistry

Large Stoke's shift permits sensitive fluorescence detection and narrow emission peak permits multiplex detection.

3. Random access and No-coding via 2D barcode system

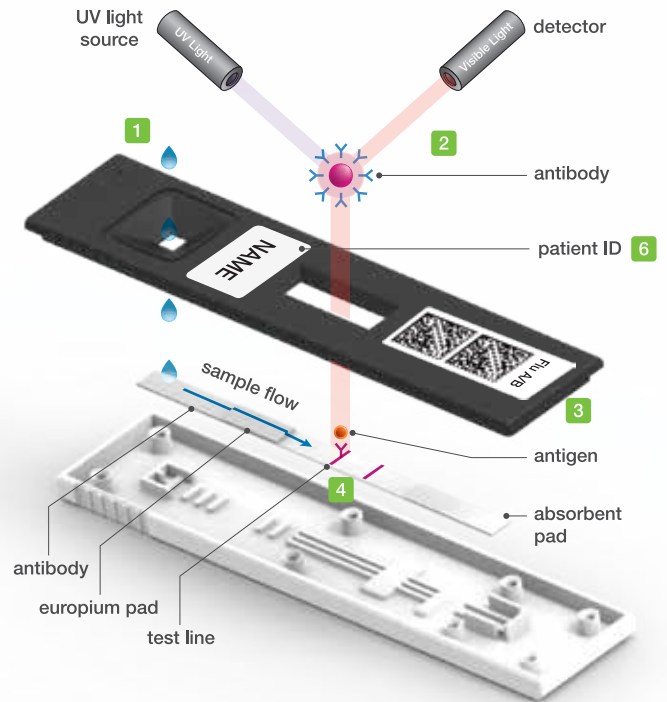
Automatic strip recognition (item, Lot No., serial No., coding information, expiry date)

4. Internal quality control

The control line checks that the test has progressed completely and correctly.

5. Time saving by early detection

In case of high titer samples, the analyzer automatically shows the test results in 1.5 minutes. (Influenza A/B)



6. Name awareness

STANDARD F Analyzer scans and prints a handwritten patient ID on the device, which allows of double checking the patient ID labeled on the sample.



Simple Test Procedure

■ STANDARD TEST mode

Automated procedure for a single test.



Insert the test device into the analyzer.



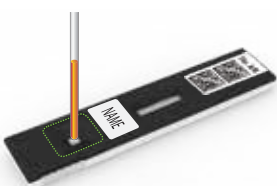
Apply the specimen into the test device.



The test result will be displayed automatically.

■ READ ONLY mode (only for the qualitative test items)

High-throughput procedure for multiple tests



Apply the specimen the test device.



Leave the test device outside of the analyzer for few minutes.

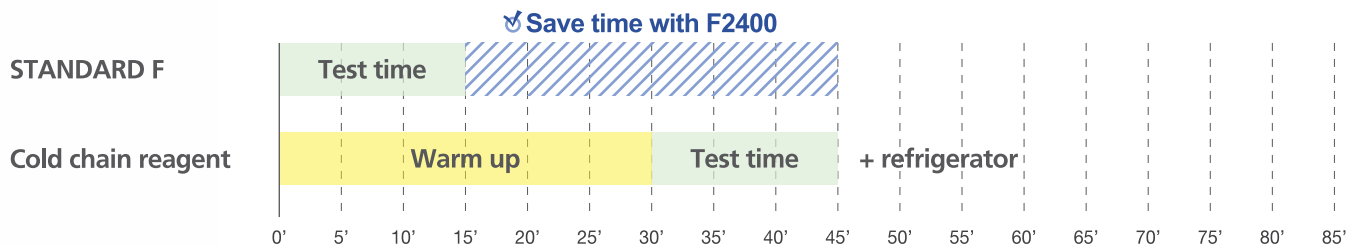


Insert the test device into the analyzer. The test result will be analyzed within 10 -15 seconds.

Advantages of STANDARD F2400

Fast and convenient diagnosis with STANDARD F2400 system

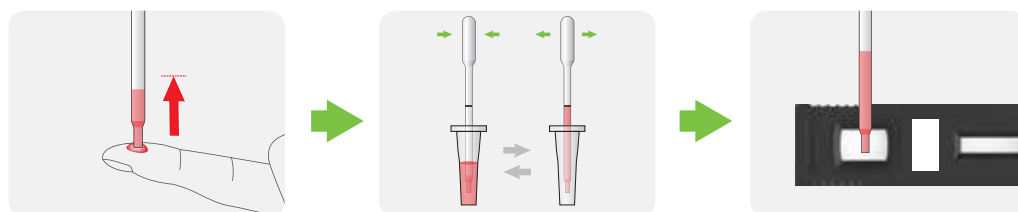
Room temperature storage : No need to preheat the test device. The moment you need it, test it right away!



Individual package : Efficient use of reagents as individual packaging

Only 3 steps : Collect ▶ Mix ▶ Drop

- No collection tubes
- No centrifuges
- No pipettes



Random access

2D barcode based data input enables the fully automatized workflow with random access. Once a test device is inserted, the test is automatically performed according to the protocols of each parameter through 2D barcode on the test device.

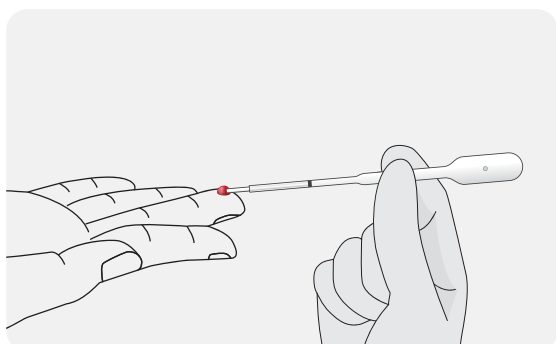
Input order	1	2	3	4	5	6
Test parameter	Influenza A/B	HbA1c	TnI	PCT	Legionella	CRP
Remaining time	11:02	00:32	8:58	4:08	13:36	2:41
Patient ID	Patient1	Patient2	Patient3	Patient4	Patient5	Patient6
Output order	5	1	4	3	6	2

High throughput

Through 24 inner slots of F2400, continuous test can be performed with up to 70 tests per hour of test capacity.

Small sample volume

Capillary whole blood use



LIS/HIS connectivity via HL7

Direct and immediate test result analysis through the own interface (Directional)



Over 45 quantitative and qualitative tests are available with F2400 analyzer

Quantitative parameter

Accurate results allow a high correlation with reference method

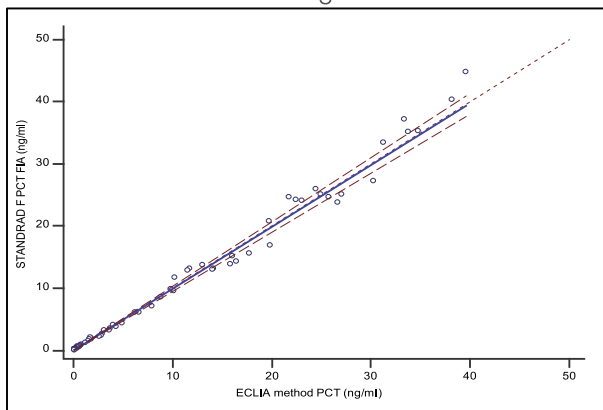


Fig.1. STANDARD F PCT FIA(y) compared to the Chemiluminescence immunoassay(x) with serum samples.

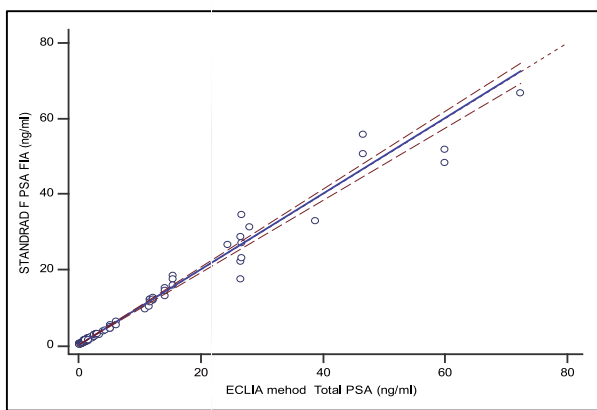


Fig.2. STANDARD F PSA FIA(y) compared to the Chemiluminescence immunoassay(x) with serum samples.

Qualitative parameter

Objective COI(Cut off index) provide semi-quantitative result

** 3% of Color scale result

VS

** The cut-off value for STANDARD F is COI 1.

Results tested with samples of the same concentration

Various parameters can be analyzed within 3-15minuts without sample pre-treatment.

Quantitative parameters	Qualitative parameters
<p>Cardiovascular</p> <ul style="list-style-type: none"> • CK-MB FIA • TnI FIA • NT-proBNP FIA • D-dimer FIA • hs-CRP <p>Inflammation</p> <ul style="list-style-type: none"> • PCT FIA • PCT FIA (Serum) • CRP <p>Tumor</p> <ul style="list-style-type: none"> • PSA FIA • iFOB FIA 	<p>Hormone</p> <ul style="list-style-type: none"> • β-hCG FIA • LH FIA • TSH FIA • TSH-II FIA • FT4 • T4 • Vitamin D FIA <p>Diabetes Monitoring</p> <ul style="list-style-type: none"> • HbA1c • U-Albumin FIA <p>Respiratory</p> <ul style="list-style-type: none"> • COVID19 Ag FIA • COVID19 IgM/IgG Combo FIA • COVID/Flu Ag Combo FIA * • SARS-CoV-2 nAb FIA* • Influenza A/B FIA • RSV Ag FIA • Strep A Ag FIA • Legionella Ag FIA • S. pneumoniae Ag FIA • Adeno Respi Ag FIA • TB-Feron FIA (IFN-gamma) <p>Blood-borne</p> <ul style="list-style-type: none"> • HIV Ag/Ab FIA <p>Hepatitis</p> <ul style="list-style-type: none"> • HCV Ab FIA • HAV IgM FIA <p>Vector-borne</p> <ul style="list-style-type: none"> • Dengue NS1 Ag FIA • Dengue IgM/IgG FIA • Zika Ag FIA • Zika IgM FIA • Chikungunya IgM/IgG FIA • Tsutsugamushi IgM/IgG FIA • Lyme IgM/IgG FIA <p>Gastrointestinal</p> <ul style="list-style-type: none"> • Norovirus Ag FIA • Rotavirus Ag • Rota/Adeno Ag • H. pylori Ag FIA • C. difficile GDH FIA • C. difficile Toxin A/B FIA <p>STI</p> <ul style="list-style-type: none"> • Syphilis Ab FIA

*Under development



Head Office C-4&5Floor, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Factory 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbukdo, 28161, REPUBLIC OF KOREA
Tel +82-31-300-0400 **Fax** +82-31-300-0499 **E-mail** sales@sdbiosensor.com **Website** www.sdbiosensor.com
 LEF-FSYST-EN / Rev.04 / 2020.08 © 2020 SD BIOSENSOR. All rights reserved.

STANDARD F Fluorescent Immunoassay System