

# STANDARD™ F2400

Diagnosis can be performed anytime.

- Fluorescent immunoassay system
- 24 tests at once
- Optimized performance with fluorescent technology
- Ready-to-use reagents



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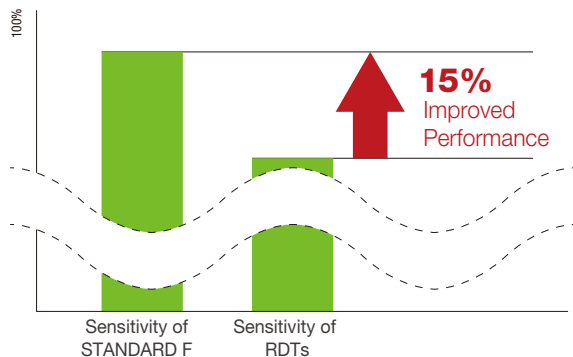
 STANDARD™

## Higher sensitivity through fluorescent readout

STANDARD F is a Fluorescent immunoassay system that uses fluorescent bead 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) in a single-center prospective study conducted in Malaysia. Discrepant results resolved by RT-qPCR

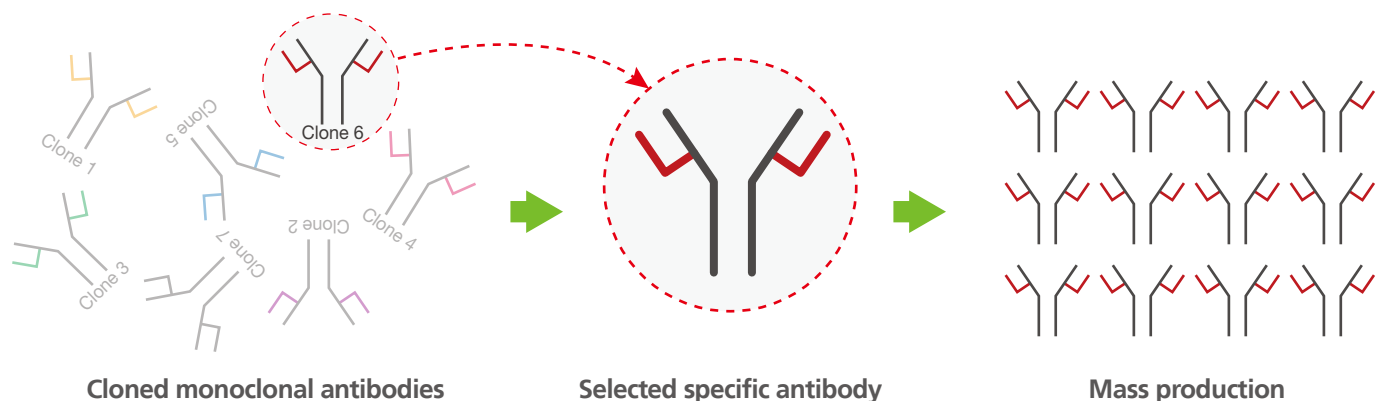
### 8 times lower LOD than RDTs

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

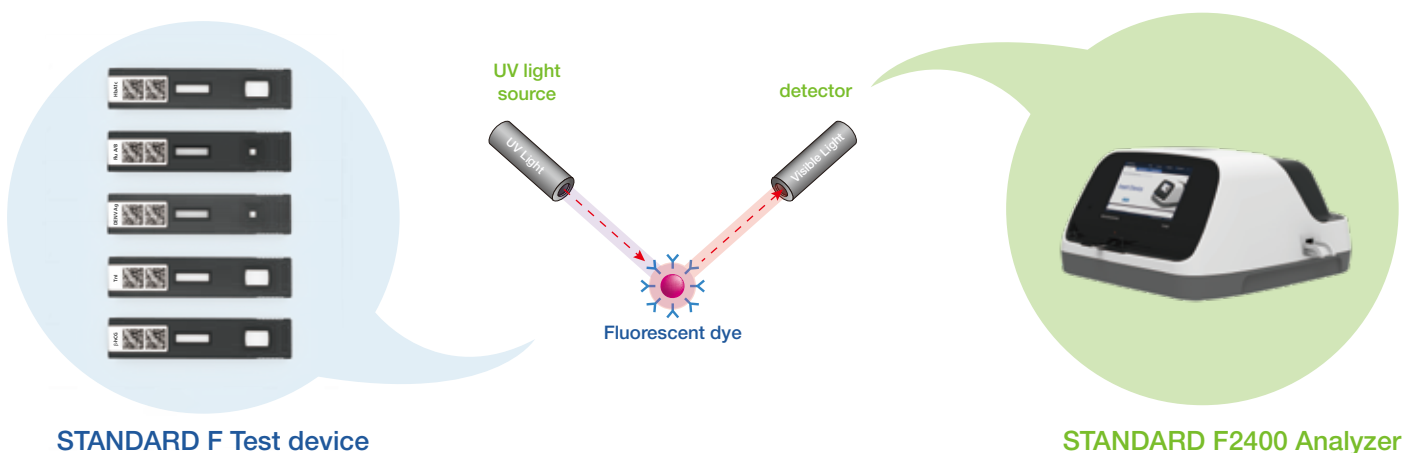
Influenza B	STANDARD F	RDTs
dilution ratio	COI	Result
2 <sup>-1</sup>	17.9	+
2 <sup>-2</sup>	14.1	+
2 <sup>-3</sup>	8.5	+
2 <sup>-4</sup>	4.2	+
2 <sup>-5</sup>	2.2	+
2 <sup>-6</sup>	1.0	+
2 <sup>-7</sup>	0.5	-

Reference : Internal evaluation

Our core technology is to select the most specific antibody and apply the mass production of the optimal antibodies. This core technology allows to improve not only sensitivity but also specificity of our STANDARD F.



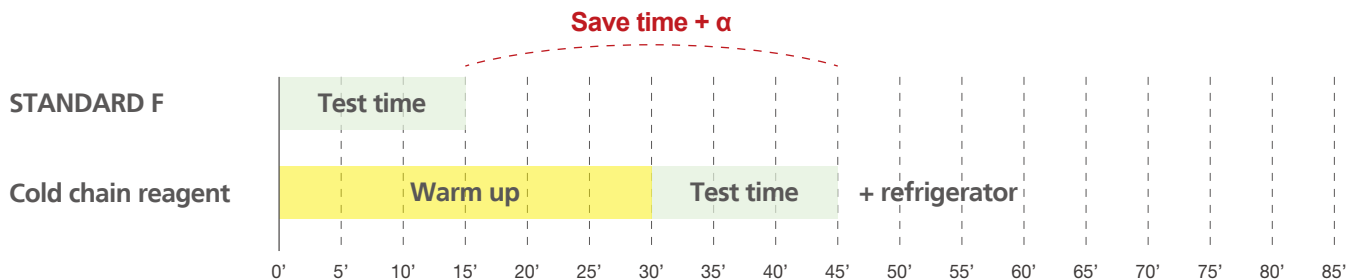
SD BIOSENSOR has well established infrastructures to develop raw materials as well as design medical equipment that detects raw materials precisely. Our researchers and engineers, who know well about the characteristics of our raw materials and equipment, maximize its synergy to produce the best quality products. SD BIOSENSOR's fully automated manufacturing systems are satisfied with MDSAP(ISO 13485:2003) and KGMP.



# Easy to Use

Fast and convenient diagnosis with flexible STANDARD F2400 system

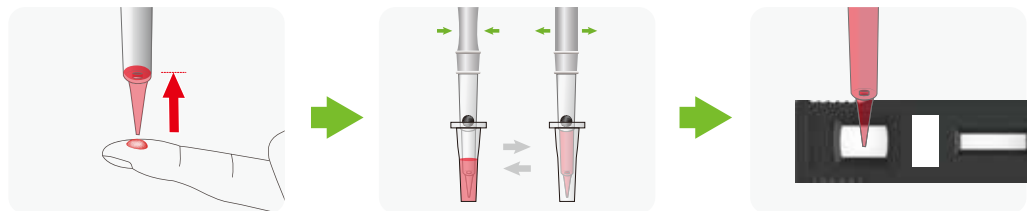
■ **Room temperature storage** : No need to preheat the reagents. The moment you need it, test it right away!



■ **Individual pack** : Efficient use of reagents as individual packaging

■ **Only 3 steps** : Collect ► Mix ► Drop

- ❌ No collection tubes
- ❌ No centrifuges
- ❌ No pipettes



■ **Random access**

Once a test device is inserted, the test is automatically performed according to the protocols of each parameter through 2D barcode technology.

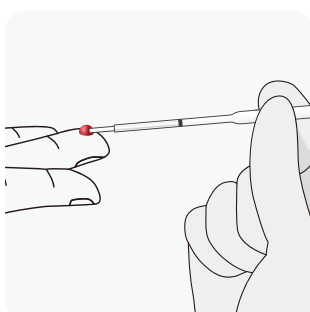
Input order	1	2	3	4	5	6
	Influenza A/B 11:02 Patient1	HbA1c 00:32 Patient2	TnI 8:58 Patient3	PCT 4:08 Patient4	Legionella 13:36 Patient5	CRP 2:41 Patient6
Output order	5	1	4	3	6	2

■ **Continual access**

Regardless of the test, continuous test can be performed and the capacity of the test is up to 70 tests per hour.

■ **Small sample volume**

Capillary whole blood capable



over  
50 parameters  
are available

■ **LIS/HIS connectivity**

Direct and immediate test result analysis through the own interface



Over 50 quantitative and qualitative tests are available with a single F2400 analyzer

## Quantitative parameter

Accurate results allow a high correlation with reference method results within CV 10%

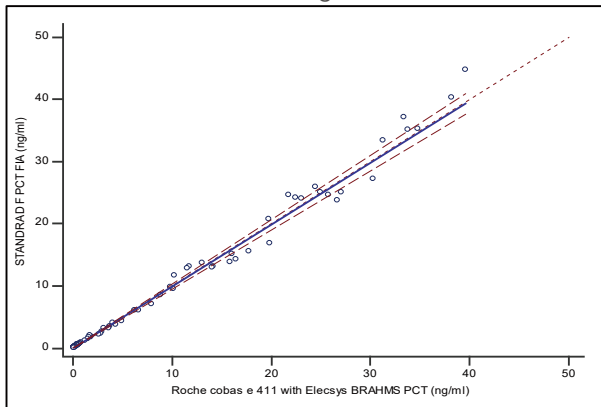


Fig.1. STANDARD F PCT FIA(y) compared to the Chemiluminescence immunoassay(x) with serum samples.

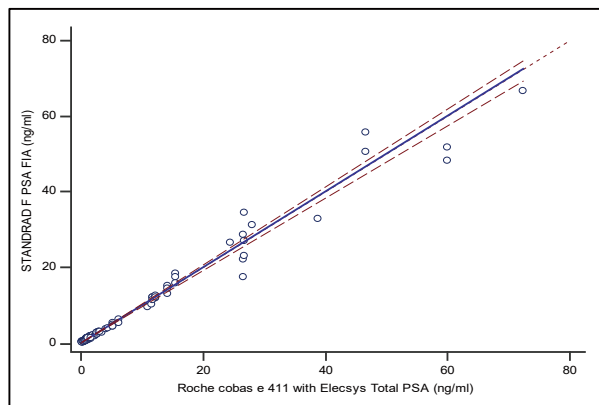



Fig.2. STANDARD F PSA FIA(y) compared to the Chemiluminescence immunoassay(x) with serum samples.

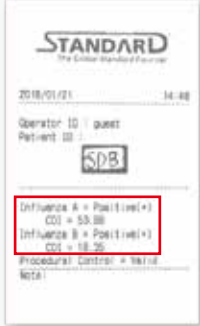
## Qualitative parameter

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

Results tested with samples of the same concentration



VS



\*\* 3% of Color scale result

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

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

### Quantitative parameters

#### Cardiovascular

- Tnl FIA
- CK-MB FIA
- hs-CRP FIA
- D-dimer FIA

#### Inflammation

- PCT FIA
- PCT FIA (Serum)
- CRP

#### Tumor

- PSA FIA

#### Hormone

- $\beta$  -hCG FIA
- LH FIA
- TSH FIA

#### Diabetes Monitoring

- HbA1c
- U-Albumin FIA

### Qualitative parameters

#### Respiratory

- Influenza A&B FIA
- RSV Ag FIA
- *Legionella* Ag FIA
- *S. pneumoniae* Ag FIA
- Strep A FIA

#### Blood-borne

- HCV Ab FIA

#### Vector-borne

- Dengue NS1
- Dengue IgM/IgG
- Chikungunya IgM/IgG
- Zika Ag
- Zika IgM

#### Gastrointestinal

- Rotavirus Ag
- Rota/Adeno Ag



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