# STANDARD F β-hCG FIA @SD BIOSENSOR

STANDARD F  $\beta$ -hCG FIA is a fluorescent immunoassay for the quantitative measurement of  $\beta$ -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.

- β-hCG is a hormone that can diagnose early pregnancy
- Automatic strip recognition by reading the information stored in 2D barcode
- Reagents can be stored at room temperature
- Serum and Whole blood samples available



Specification		
Specimen Type	Whole blood, Serum	
Specimen Volume	50 μl	
Measurement Range	5- 1500 mIU/ml	
Reference Range	$\geq 5.0 \text{ mIU/mI}$	
Testing Time	15 mins (Whole Blood) / 10 mins Serum	
Storage Conditions	2-30°C / 36-86°F	

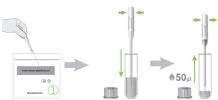
### METHODS OF SAMPLE COLLECTION



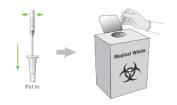
Whole Blood



### **TEST PROCEDURE**



Collect 50 µl of sample with a fixed volume pipette (50 µl) - [① labeled].



Dispense collected sample into the extraction buffer tube. Then, discard the used fixed volume pipette (50 µl).



Mix sample and buffer 2-3 times with the disposable dropper (100  $\mu$ l) - [② labeled]. Then, collect 100  $\mu$ l of sample mixture.



Apply the sample mixture into the sample well of the test device and immediately press the start button. The analyzer will automatically display the test result after 10 minutes for serum test and 15 minutes for whole blood test.

## **METHOD COMPARISON**

Reference Method vs β-hCG FIA		
Correlation vs ECLIA Method	y=1.0161x-6.6452; R=0.9968; n=180	
CV%	QCL=4.7% / QCM=4.7% / QCH=4.5%	
Differ (%)	Within 15%	

# ORDERING INFORMATION

Category	Product	Pack Size
Hormone	STANDARD F β-hCG FIA	20 Test
	STANDARD F β-hCG Control	Lv1 x 10 / Lv2 x 10



DARD SECTION

CE