

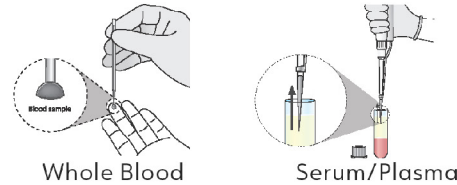
# STANDARD F PCT FIA SD BIOSENSOR

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.

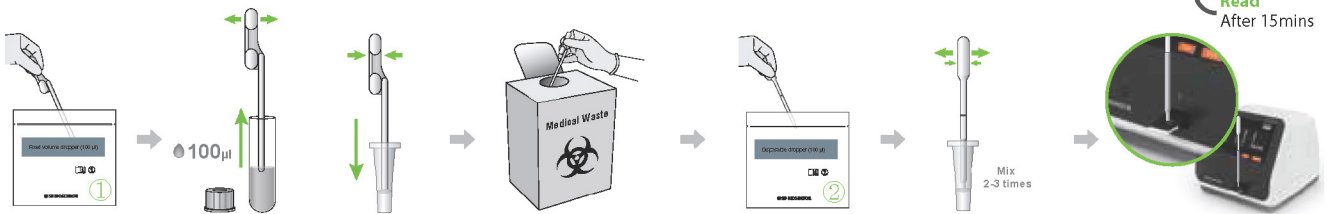


Specification	
Intended use	Quantitative measurement of PCT level to diagnose sepsis and bacterial infection
Specimen Type	Whole blood, Serum, Plasma
Specimen Volume	100 µl
Measurement Range	0.05 – 50 ng/ml
Testing Time	15 mins
Storage Condition	2 – 30°C / 36 – 86°F

## METHODS OF SAMPLE COLLECTION



## TEST PROCEDURE



Collect 100 µl of sample with a fixed volume dropper (100 µl).

Dispense collected sample into the extraction buffer tube. Then, discard the used fixed volume dropper (100 µl).

Mix sample and buffer 2-3 times with the disposable dropper (100 µl). Then collect 100 µl of sample mixture.

Apply the sample mixture into the sample well of the test device and immediately press the start button.

## INTERPRETATION OF RESULTS

### Diagnosis of Sepsis

PCT Levels (ng/mL)	Interpretation
<0.05	Normal
< 0.05 - 0.5	Low risk or local infection
> 0.5 – 2.0	Moderate risk for Sepsis
> 2.0 – 10.0	High risk for Sepsis
> 10.0	Severe sepsis or septic shock

### Diagnosis of Lower Respiratory Tract Infection

PCT Levels (ng/mL)	Interpretation
< 0.1	Normal
> 0.1 - 0.25	Bacterial infection unlikely
> 0.25 - 0.5	High likelihood of bacterial infection
> 0.5	Severe bacterial infection

## METHOD COMPARISON

### Reference Method vs STANDARD F PCT

Correlation vs Roche cobas	$Y=1.02147x + 0.0743; r= 0.9946; n=210$
CV%	QCL=7.5% / QCM=9.2% / QCH=8.9%
Differ(%)	Within 15%

## ORDERING INFORMATION

Category	Product	Pack Size
Inflammation	STANDARD F PCT FIA	20 Test
	STANDARD F PCT-02 Control	Lv1 x 10 / Lv2 x 10