

Reagents

Item	Product Name	Constituent Reagent Name	Code	Package	Storage	Shelf life
PT	Coagpia PT-N	Thromboplastin Reagent	476051	10 × 4 mL	2-10°C	Two year after manufacturing
			482366	10 × 10 mL		
APTT	Coagpia APTT-N	APTT Regent	476068	10 × 4 mL		
			482373	10 × 10 mL		
		Calcium Chloride Solution	476075	10 × 4 mL		
			482380	10 × 10 mL		
Fbg	Nanopia Fbg	Thrombin Reagent	425721	10 × 3 mL		
			515439	10 × 10 mL		
		Sample Dilution Solution	425714	10 × 10 mL		
FDP	Nanopia P-FDP	P-FDP Buffer Solution 1 P-FDP Latex Reagent 2	421198	CP set R1 1 × 10.5 mL R2 1 × 10 mL		
D-dimer	Nanopia D-dimer	D-dimer Buffer Solution 1 D-dimer Latex Reagent 2	421228	CP set R1 1 × 10.5 mL R2 1 × 10 mL		

* CP set is dedicated package for CP3000 and Coapresta 2000.

Calibrator

Product Name	Code	Package	Storage	Shelf life
Coagpia Calibrator N	476082	10 × 1.0 mL	2-8°C	Two year after manufacturing
FDP Calibrator N	468049	5 conc. × 0.5 mL	2-10°C	
D-dimer Calibrator	346903	6 conc. × 0.5 mL	2-10°C	

* This is not an In-Vitro Diagnostic under Japanese Pharmaceutical Law.

Control

Product Name	Code	Package	Storage	Shelf life
Coagpia Control P-N	476099	5 × 2 conc. × 1.0 mL	2-8°C	Two year after manufacturing
FDP Control	337123	3 × 2 conc. × 1.0 mL	2-10°C	

* This is not an In-Vitro Diagnostic under Japanese Pharmaceutical Law.

Dilution

Product Name	Code	Package	Storage	Shelf life
Coagpia Fbg Sample Dilution Solution	425714	10 × 10mL	2-10°C	Two year after manufacturing

* “Nanopia”, “Coagpia” and “Coapresta” are trademarks or registered trademarks of SEKISUI MEDICAL CO., LTD. in Japan and/or other countries.

* “CP2000” in the data: “Coapresta 2000”



Automated Coagulation Analyzer CP3000
Instrument & Reagent

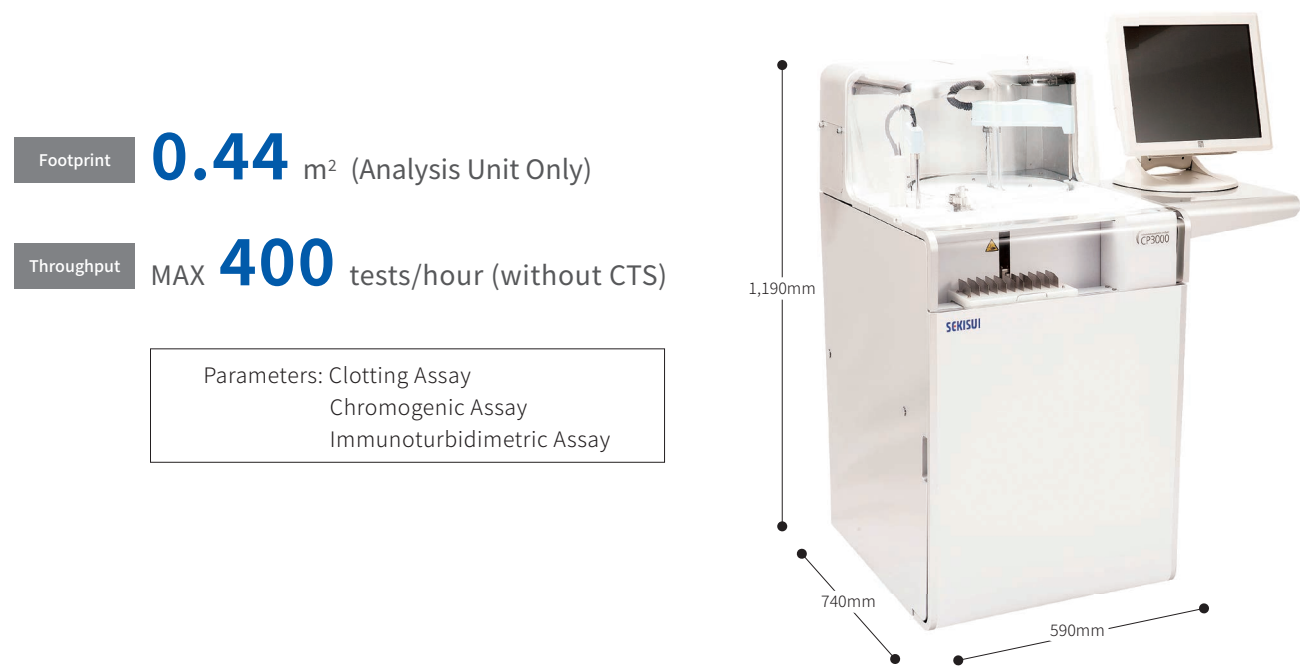


Manufacturer:
SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan

We offer a variety of “saving” features achieving efficiency by through streamlining.

Small-footprint floor model

analyzer allowing installation anywhere



Product Specifications

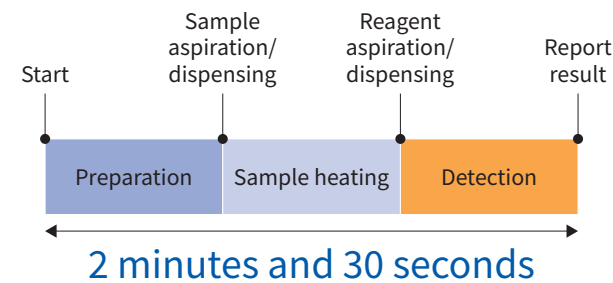
* Specifications are subject to change without notice

Item	Descriptions
Throughput	Clotting tests: Max. 400 tests/hour (without CTS) Photometric tests: Max. 200 tests/hour
Analysis Principle	Light scattering photometry, optical density method
Simultaneous test items	Max. 20 test items
Parameters	Max. 60 parameters (clotting: 30 / photometric: 30)
- Clotting assays	PT, APTT, Fbg, LA, Factor (II , V , VII, VIII, IX, X , XI, XII)
- Chromogenic assays	Heparin, AT, APL, PLG, PC
- Immunoturbidimetric assays	FDP, D-dimer, SF, PIC, PAI-1, TAT *Please contact your local distributor for full details of Sekisui reagents available on the CP3000 instrument
Max. Sample Number	50 (Can be added, even during analysis; includes STAT lanes)
Reagent Compartments	Refrigerated: 30 ports + Room temperature: 9 ports
Calibration Curve	Automatic dilution options; Multi-point calibration curve; INR calibration curve Automatic switching between calibration curves
Light Source	Clotting: LED 660 nm, Photometric: halogen lamp 405/570/730 nm
Data Storage	2.5 years
Quality Control	Daily time - series; Daily twin plot
Operation part*	17-inch color touch panel
Barcode Readers:	
- Reagent Code Reader	Built-in
- 2D Code Reader*	Hand-held
- Sample Code Reader	Built-in
Dimensions/Weight	W590 × D740 × H1190 mm/ Approx. 185 kg (Without CTS) W590 × D915 × H1190 mm/ Approx. 200 kg (With CTS)
Main power supply	AC220V ±10%, 50/60 Hz

* Please note that the monitor, 2D Code Reader and printer are not included in some areas.

First Report Time

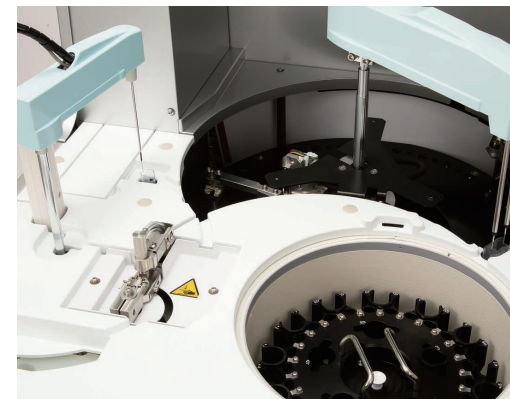
Only **2.5 minutes** from an inactive state to display of the first result Fast analyses with shorter turn-around times.



Energy-saving

Minimum water usage

Up to about 1,800 samples can be processed by continuous PT measurement.



Continuous Rack Loading

Samples can be added even during analysis without having to stop the measurement operation.

Open the cover, and just place racks

The device automatically collects the racks and loads sample information for sample processing. For re-testing, measured samples can be re-loaded, reducing the workload to search for measured samples. Samples in STAT lanes are also processed on a priority basis.



Automatic Reagent Scanning

Required reagent information, including item name, expiry date, lot No., and ISI value, is automatically registered.

Just set the reagents on a tray. The code reader built into the reagent tray automatically scans and registers all the codes* of the set reagents. (*Data matrix type)



Easy Operation Mode

All the options you need on one screen, allowing even first timers to carry out analyses in ease.

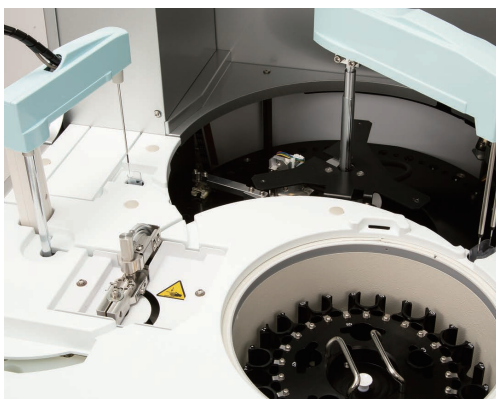


CTS (Closed Tube Sampling)

* Optional

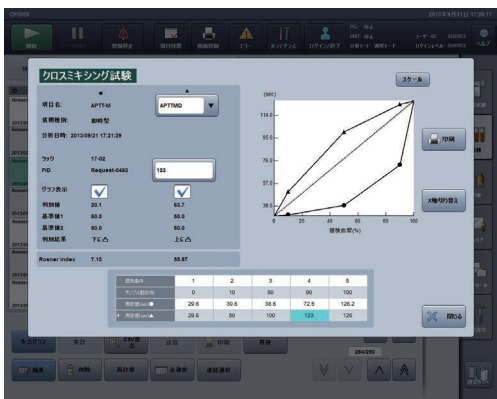
This function allows sampling without removing the cap of the blood collection tube. The innovative technology to pierce the cap of the blood collection tube maintains high-accuracy sampling.

The cap does not have to be removed from the tube during sampling, ensuring safe and reliable operation by preventing blood spillage when the cap is removed.



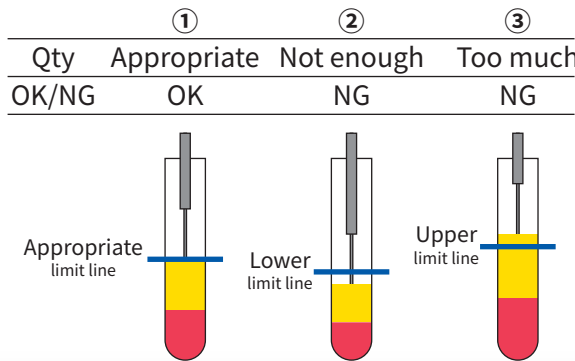
Cross-mixing Tests function

The measurement result of each immediate/deferred reaction is automatically displayed as a graph.



Sample Assessment Functions

At the time of the measurement, double-check for “Sample Volume Check” and “Turbidity Check” is performed to increase the reliability of the measured data.



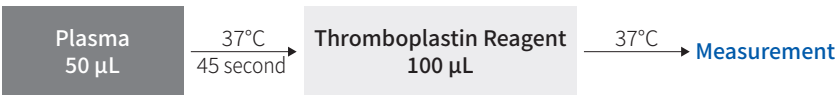
Prothrombin time assay kit

Coagpia PT-N

Feature

- Reagent with International Sensitivity Index ISI close to 1, Normal plasma PT is about 12 seconds.
- On-board stability after dissolution - about 9 days (Measured by CP3000.)

Measurement Method

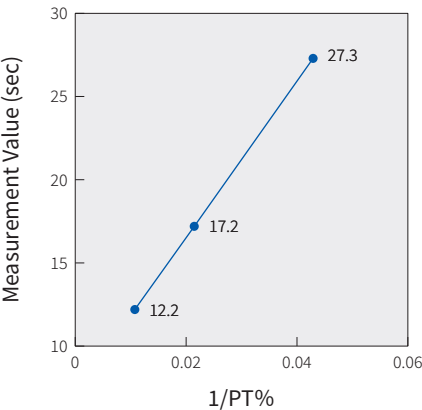


Data (CP3000)

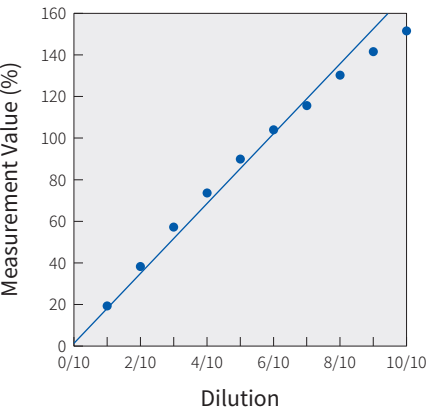
Precision

	Sample 1			Sample 2		
	sec	%	INR	sec	%	INR
n	10	10	10	10	10	10
Mean	12.26	91.92	1.036	21.17	33.37	1.765
S.D.	0.05	0.93	0.005	0.20	0.50	0.014
C.V.(%)	0.42	1.01	0.50	0.95	1.50	0.81
Max.	12.3	93.0	1.04	21.4	34.3	1.78
Min.	12.2	91.2	1.03	20.8	32.8	1.74
Range	0.1	1.8	0.01	0.6	1.5	0.04

Calibration Curve

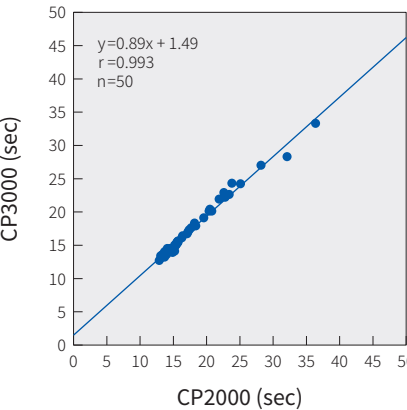


Linearity

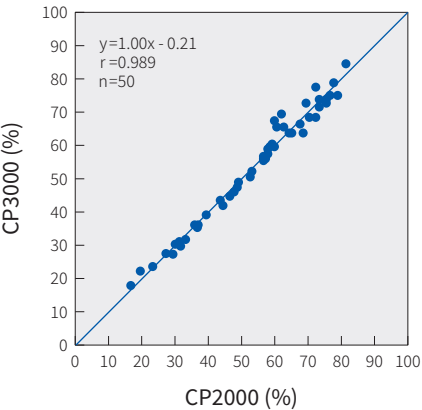


Correlation between CP3000 and CP2000

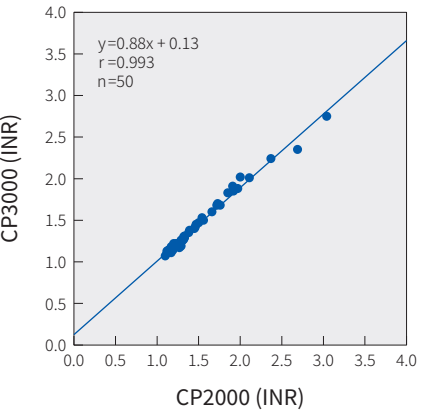
PT (sec)



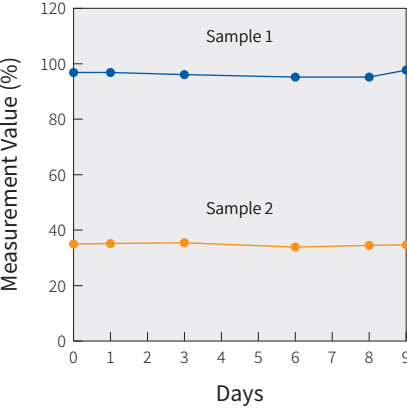
PT (%)



PT (INR)



On-board Stability



Interference

	Concentration	Measurement Value (%)	
		Normal Plasma	Added Plasma
Free Bilirubin	25 mg/dL	95.9	96.9
Conjugated Bilirubin	25 mg/dL	94.9	94.0
Hemoglobin	500 mg/dL	95.9	98.9
Chyle	Formazin Turbidity	96.0	96.9

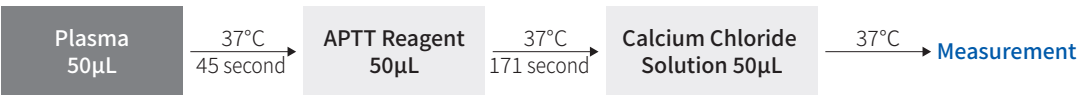
Activated partial thromboplastin time assay kit

Coagpia APTT-N

Feature

- Good LA sensitivity – can be detected LA by cross-mixing tests (mixing tests)
- Good heparin sensitivity and factor sensitivity
- Good stability - no precipitation occurs as ellagic acid is used as the activator.

Measurement Method



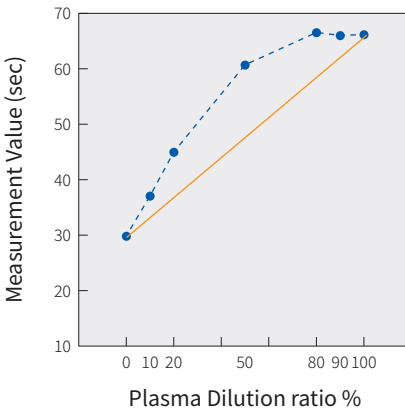
Data (CP3000)

Precision

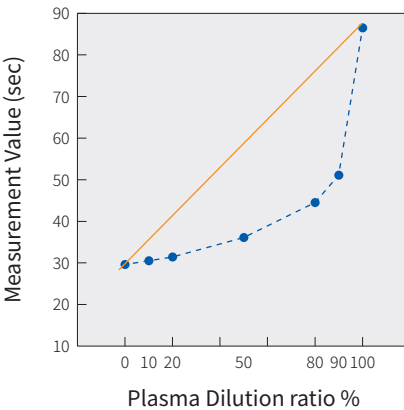
	Sample 1		Sample 2	
	sec	sec	sec	sec
n	10	10	10	10
Mean	27.79		57.55	
S.D.	0.11		0.3	
C.V.(%)	0.40		0.6	
Max.	27.9		58.3	
Min.	27.6		57.0	
Range	0.3		1.3	

LA sensitivity (Cross mixing test)

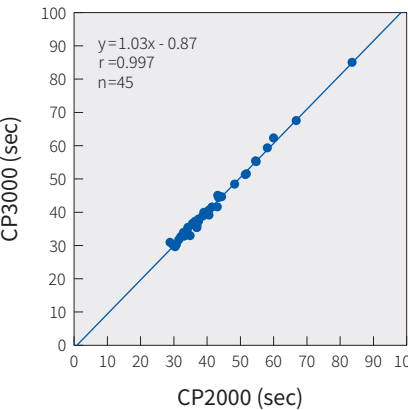
LA positive sample (Immediate Reaction)



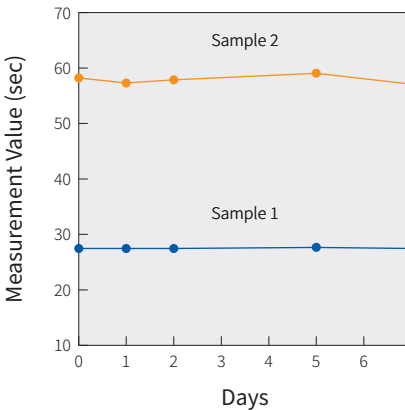
Factor Deficient Plasma (Immediate Reaction)



Correlation between CP3000 and CP2000



On-board Stability



Interference

	Concentration	Measurement Value (sec)	
		Normal Plasma	Added Plasma
Free Bilirubin	25 mg/dL	29.2	30.4
Conjugated Bilirubin	25 mg/dL	30.2	30.6
Hemoglobin	500 mg/dL	29.9	29.9
Chyle	Formazin Turbidity	29.9	30.3

Fibrinogen kit

Coagpia Fbg

- Feature
- Excellent stability

• Does not affect measurement up to 8 U/mL of sodium heparin

• Wide measurement range: 40–800 mg/dL

• Calibrator compliant with WHO standard

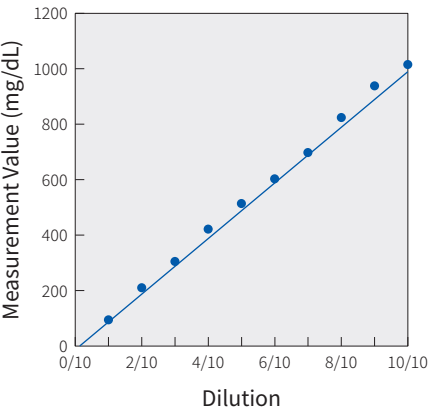


Data (CP3000)

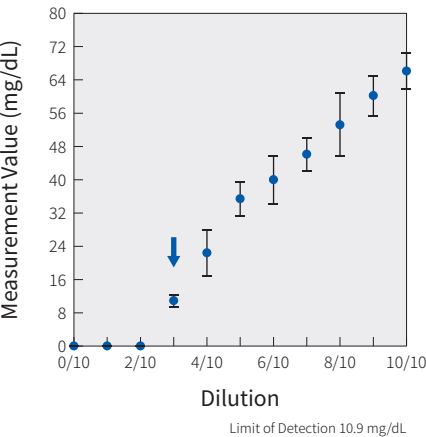
Precision

	Sample 1	Sample 2
	mg/dL	mg/dL
n	10	10
Mean	265.42	89.35
S.D.	3.64	2.34
C.V.(%)	1.37	2.62
Max.	269.9	93.4
Min.	257.6	84.6
Range	12.3	8.8

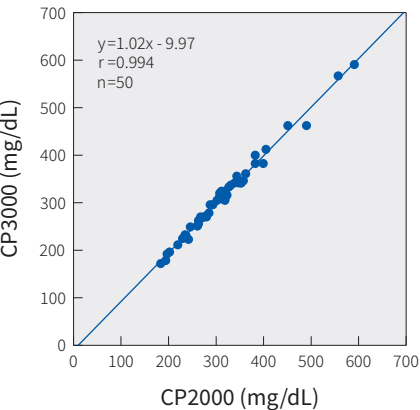
Linearity



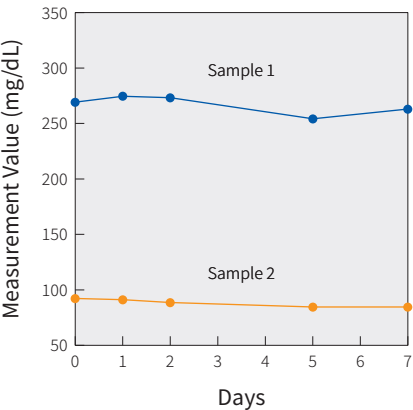
Limit of detection



Correlation between CP3000 and CP2000



On-board Stability



Interference

	Concentration	Measurement Value (mg/dL)	
		Normal Plasma	Added Plasma
Free Bilirubin	25 mg/dL	379.3	382.0
Conjugated Bilirubin	25 mg/dL	365.8	368.4
Hemoglobin	500 mg/dL	353.3	363.2
Chyle	Formazin Turbidity	363.2	360.7

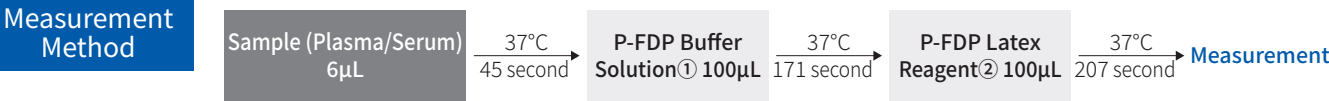
Fibrin/fibrinogen degradation products assay kit

Nanopia P-FDP

- Feature
- Both plasma and serum can be measured

• In the DIC diagnostic criteria, the concordance rate between the serum-specific FDP measurement reagent and Nanopia P-FDP (plasma FDP) scores is good.

• Wide measurement range: 2.5–120 μg/mL

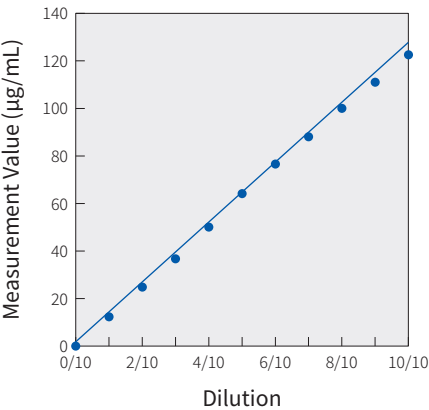


Data (CP3000)

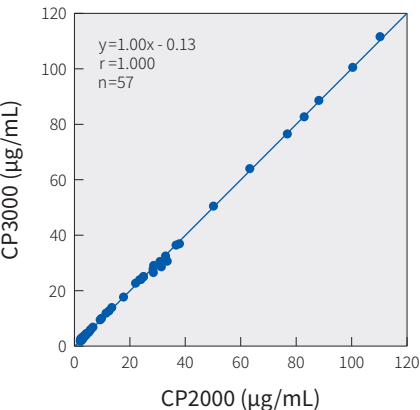
Precision

	Sample 1	Sample 2
	μg/mL	μg/mL
n	10	10
Mean	10.75	31.37
S.D.	0.21	0.45
C.V.(%)	1.97	1.44
Max.	11.2	32.1
Min.	10.4	30.8
Range	0.8	1.3

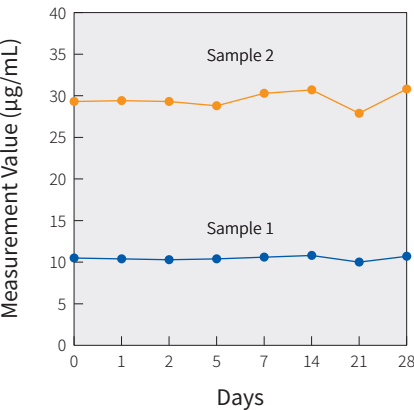
Linearity



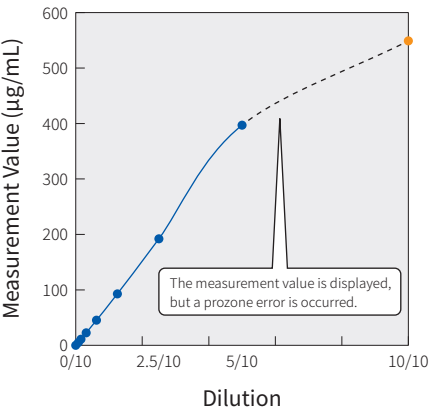
Correlation between CP3000 and CP2000



On-board Stability



Prozone

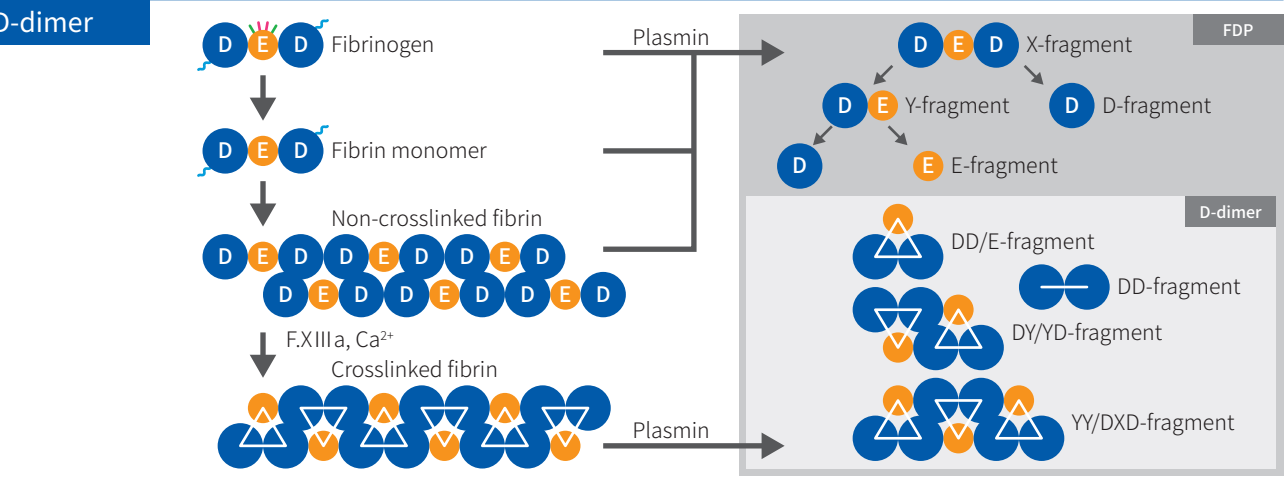
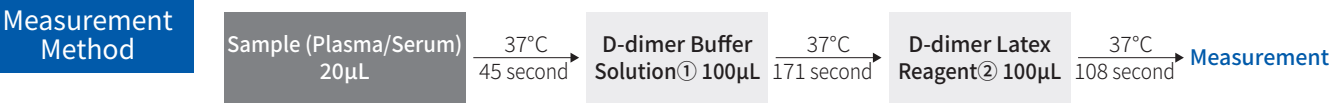


Interference

	Concentration	Measurement Value (μg/mL)	
		Normal Plasma	Added Plasma
Free Bilirubin	25 mg/dL	5.7	5.7
Conjugated Bilirubin	25 mg/dL	5.8	5.8
Hemoglobin	500 mg/dL	5.7	5.7
Chyle	Formazin Turbidity	5.9	5.6
Intralipos	5%	6.1	6.0
Rheumatoid Factor	500 IU/mL	6.2	6.4

Nanopia D-dimer

- Feature
- Wide measurement range: 0.5–60 µg/mL
 - Captures all D-dimer fragments

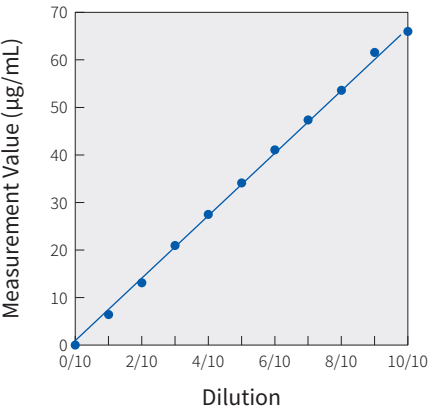


Data (CP3000)

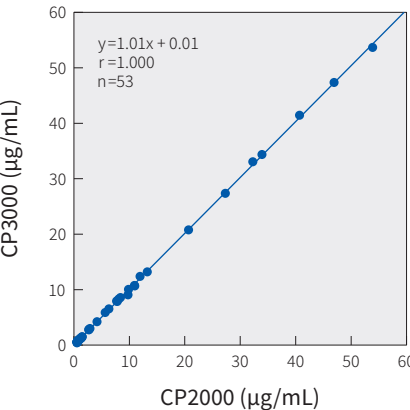
Precision

	Sample 1	Sample 2
	µg/mL	µg/mL
n	10	10
Mean	3.65	12.44
S.D.	0.04	0.13
C.V.(%)	1.03	1.05
Max.	3.7	12.7
Min.	3.6	12.2
Range	0.1	0.5

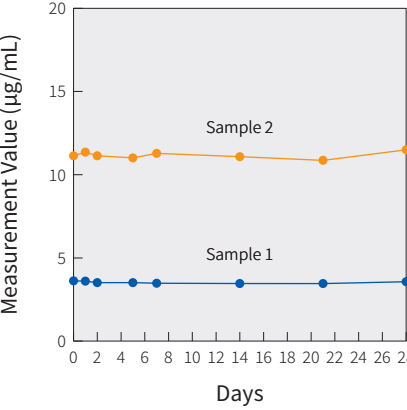
Linearity



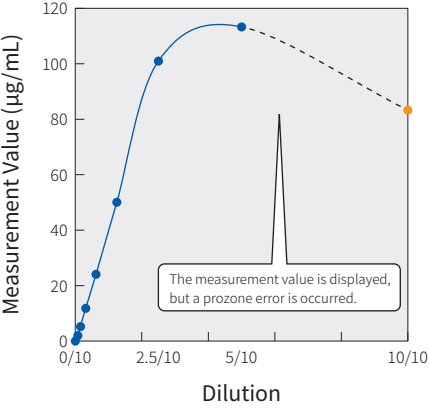
Correlation between CP3000 and CP2000



On-board Stability



Prozone



Interference

	Concentration	Measurement Value (µg/mL)	
		Normal Plasma	Added Plasma
Free Bilirubin	25 mg/dL	6.7	6.8
Conjugated Bilirubin	25 mg/dL	6.7	6.8
Hemoglobin	500 mg/dL	6.7	6.8
Chyle	Formazin Turbidity	6.8	6.5
Intralipos	5%	7.0	6.6
Rheumatoid Factor	500 IU/mL	7.3	7.3