Automated coagulation analyzer

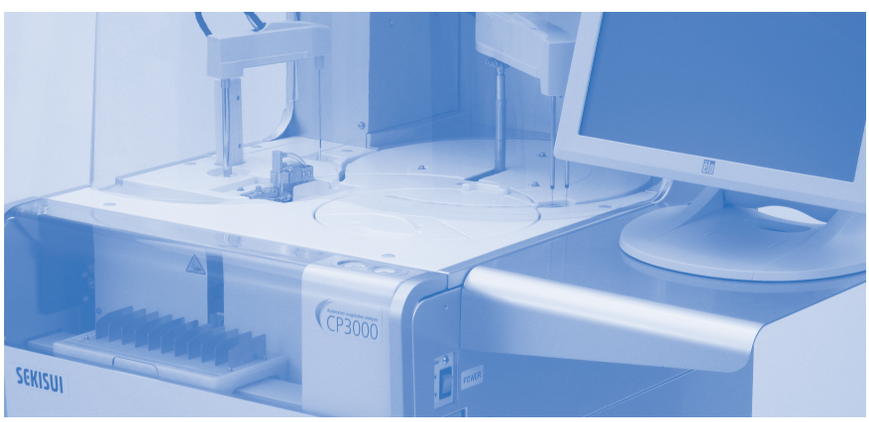
CP3000

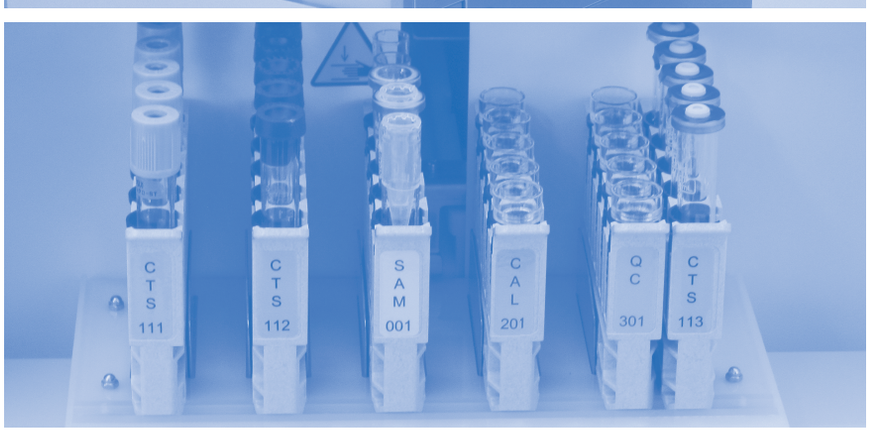
SEKISUI

Automated Coagulation Analyzer CP3000 and Related Products

Instrument & Reagent









* Refer to User Manual for warnings, precautions and limitations for proper use of the instrument.

Automated coagulation analyzer

CP3000

Our small Automated Coagulation Analyzer CP3000 delivers you fast and high quality assays, with various automated functions, and improves efficiency at your lab.

Footprint **0.44** m^2 (Unit only)

Throughput MAX **400** tests/hour (without CTS)

Assays: Clotting Assay
Chromogenic Assay
Immunoturbidimetric Assay



Product Specifications

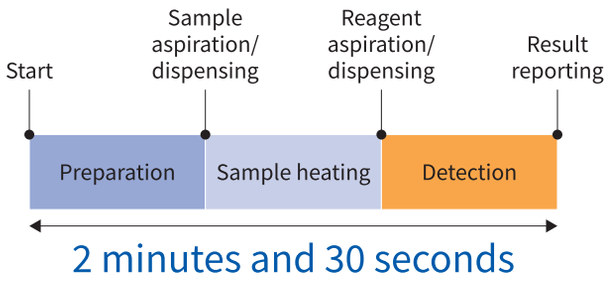
* Specifications are subject to change without notice

Feature	Descriptions
Throughput	Clotting tests: Max. 400 tests/hour (without CTS)　Photometric tests: Max. 200 tests/hour
Methods	Light scattering photometry, optical density method
Assays on-board	Max. 20
Assays	Max. 60 (clotting: 30 / photometric: 30)
	Available Assays
- 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
Sample capacity	50 (Can be loaded, even during analysis; includes STAT lanes)
Reagent capacity	Refrigerated: 30 positions + Room temperature: 9 ports
Calibration	Calibration types: Multi-point and INR. Automatedly dilutes one-point calibrator. Automatedly switches 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
Touch panel*	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 touch panel, the 2D Code Reader and the printer are not supplied in some areas.

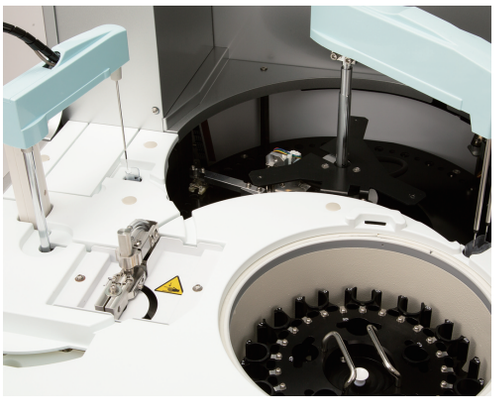
Time to first result

Only **2.5 minutes** are needed for the first result, shortening the turn-around time.



Environmental friendly specifications

CP3000 enhances energy saving and cost-effective operation.



Continuous Rack Loading

Samples can be loaded without stopping the assay.

Open the cover, and just place racks
The instrument automatically collects the racks and scans sample information. For re-testing, measured samples can be re-loaded, reducing the workload to search for measured samples. Samples in STAT lanes are processed on a priority basis.



Automatic Reagent Scanning

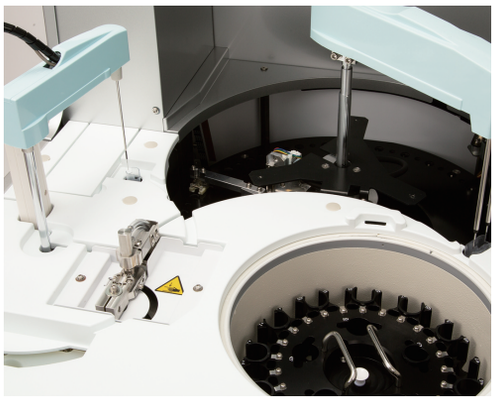
Just after placing reagent bottles, the reader, which is built-in the reagent tray, automatically scans Data Matrix codes and the reagent information including the name, expiry date, lot no. and ISI value is registered.



CTS (Closed Tube Sampling)

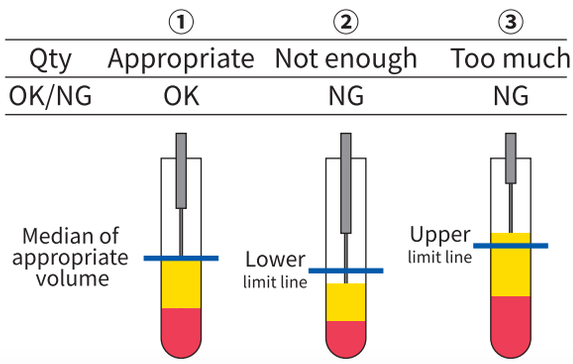
*** Optional**

A piercer, which pierces the caps of blood collection tubes, allows samples to be sucked without removing caps. This innovative technology ensures safe operation, preventing blood spillage.



Sample Volume Check

If sample volume in a tube is too much or small, the sample is not assayed. The probe sucks blood from the next tube, and the error flag “SampSH” is displayed on the [Result Data] screen.



User-friendly interfaces

Necessary information is indicated on a screen during assay, allowing various levels of users to operate.



Cross-mixing Test Function

Results from immediate and deferred reaction assays are plotted in a chart, helping cross-mixing test interpretation.



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.)

Assay Method

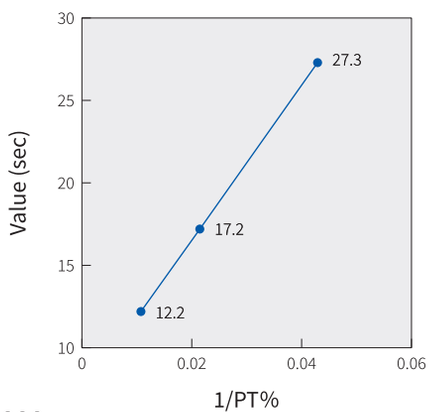
Plasma 50 µL → 37°C 45 seconds → Thromboplastin Reagent 100 µL → 37°C → Assay

Data (CP3000)

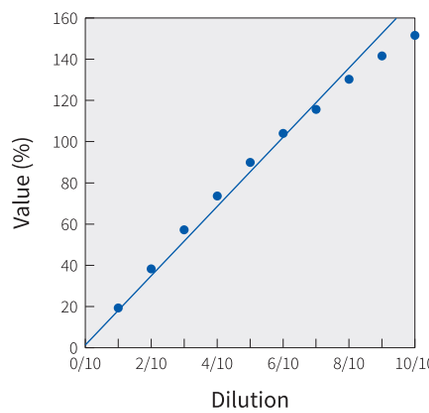
Precision

	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

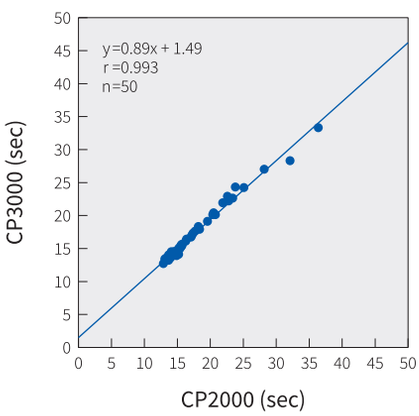


Linearity

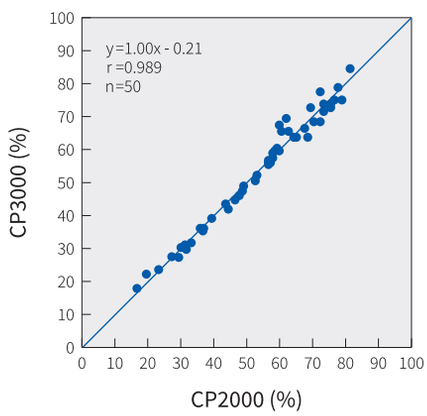


Correlation between CP3000 and CP2000

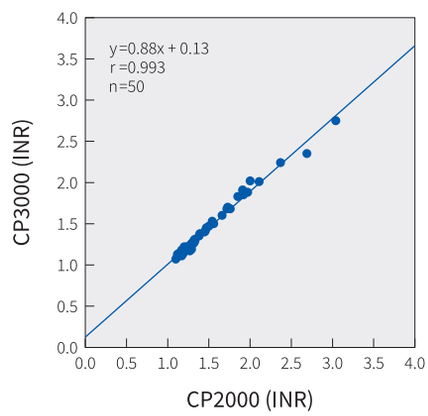
PT (sec)



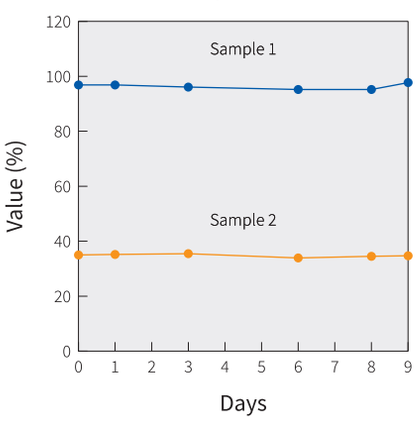
PT (%)



PT (INR)



On-board Stability



Interference

	Concentration	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.

Assay Method

Plasma 50µL → 37°C 45 seconds → APTT Reagent 50µL → 37°C 171 seconds → Calcium Chloride Solution 50µL → 37°C → Assay

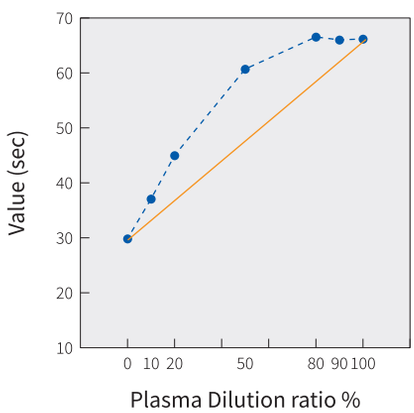
Data (CP3000)

Precision

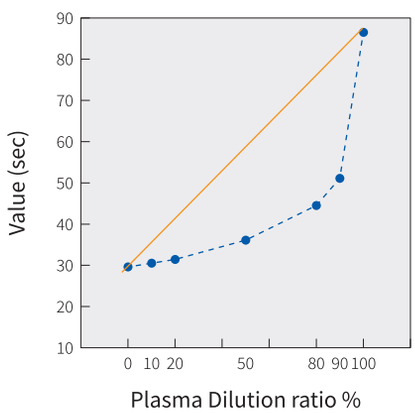
	Sample 1	Sample 2
	sec	sec
n	10	10
Mean	27.79	57.55
S.D.	0.11	0.3
C.V.(%)	0.40	0.6
Max.	27.9	58.3
Min.	27.6	57.0
Range	0.3	1.3

LA sensitivity (Cross mixing test)

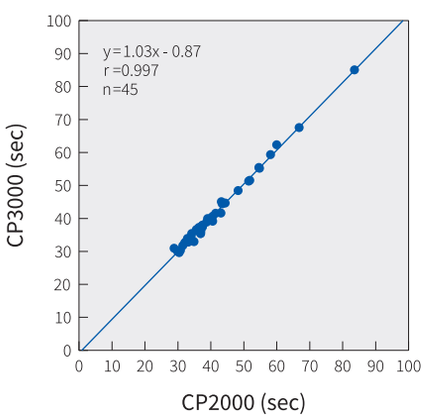
LA positive sample (Immediate Reaction)



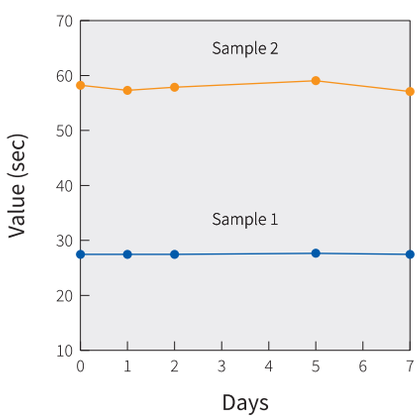
Factor Deficient Plasma (Immediate Reaction)



Correlation between CP3000 and CP2000



On-board Stability



Interference

	Concentration	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

Assay Method

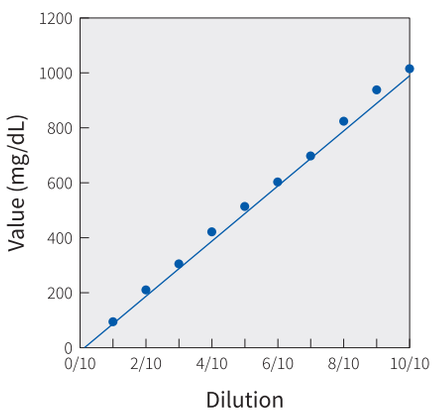
Sample (Plasma 10µL + Sample Dilution Solution 90µL) → 37°C 45 seconds → Thrombin Reagent 50µL → 37°C → Assay

Data (CP3000)

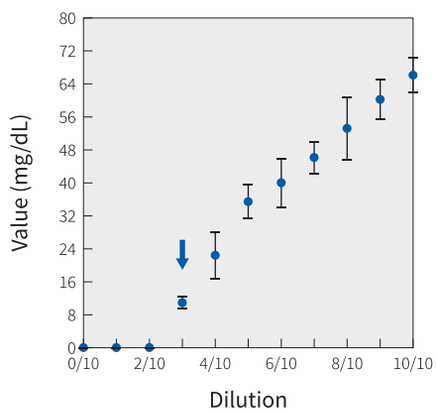
Precision

	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

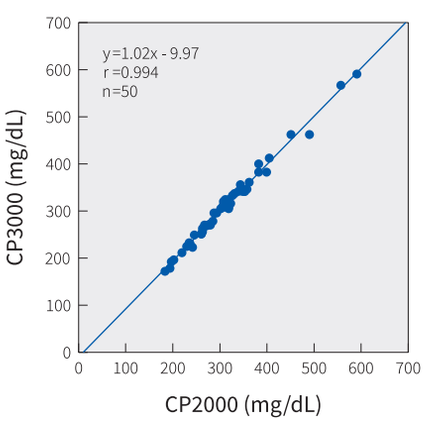


Limit of detection

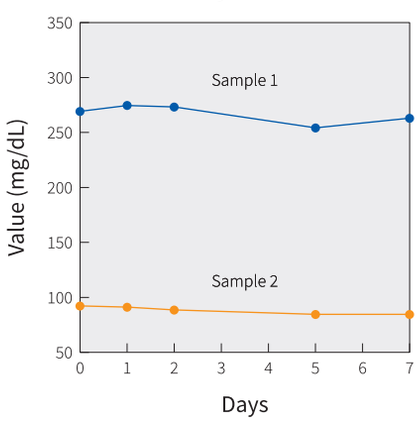


Limit of Detection 10.9 mg/dL

Correlation between CP3000 and CP2000



On-board Stability



Interference

	Concentration	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
- Wide measurement range: 2.5–120 µg/mL
- In the DIC diagnostic criteria, the concordance rate between the serum-specific FDP measurement reagent and Nanopia P-FDP (plasma FDP) scores is good.

Assay Method

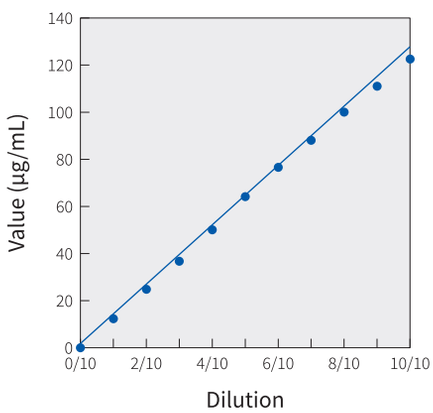
Sample (Plasma/Serum) 6µL → 37°C 45 seconds → P-FDP Buffer Solution① 100µL → 37°C 171 seconds → P-FDP Latex Reagent② 100µL → 37°C 207 seconds → Assay

Data (CP3000)

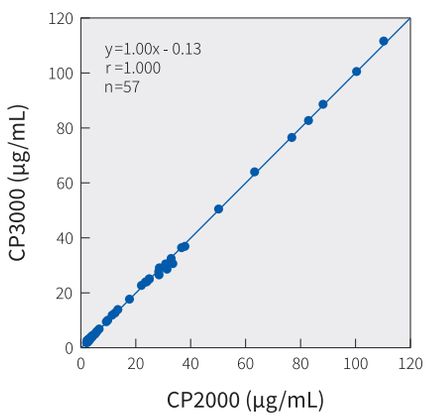
Precision

	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

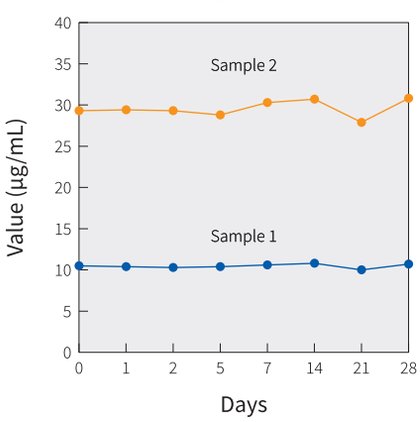
Linearity



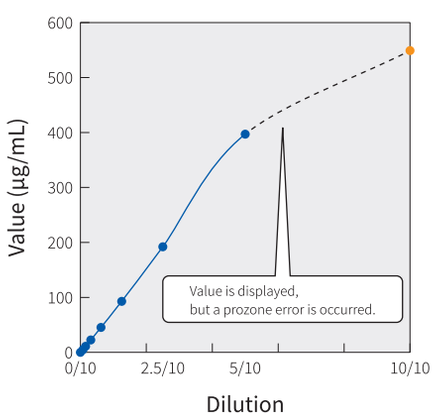
Correlation between CP3000 and CP2000



On-board Stability



Prozone



Interference

	Concentration	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

Fibrin degradation product assay kit

Nanopia D-dimer

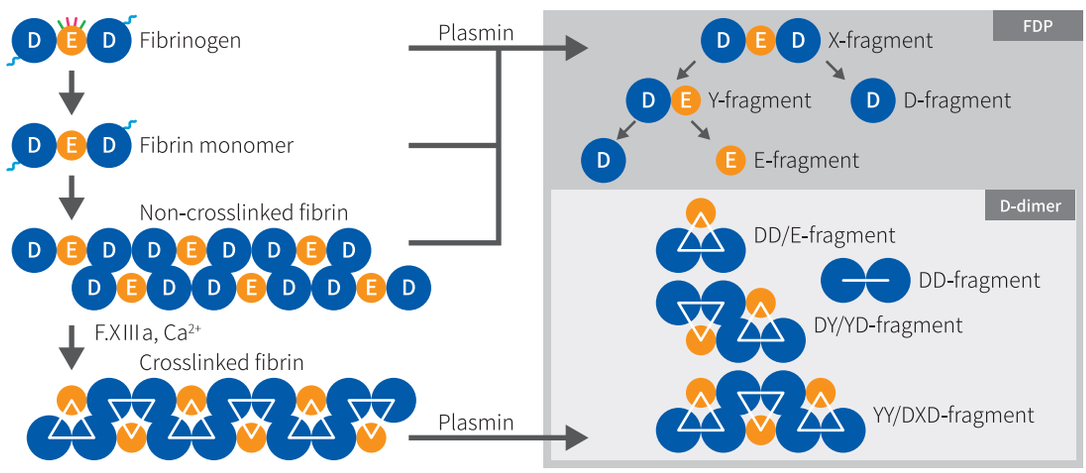
Feature

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

Assay Method

Sample (Plasma/Serum) 20µL → 37°C 45 seconds → D-dimer Buffer Solution① 100µL → 37°C 171 seconds → D-dimer Latex Reagent② 100µL → 37°C 108 seconds → Assay

D-dimer

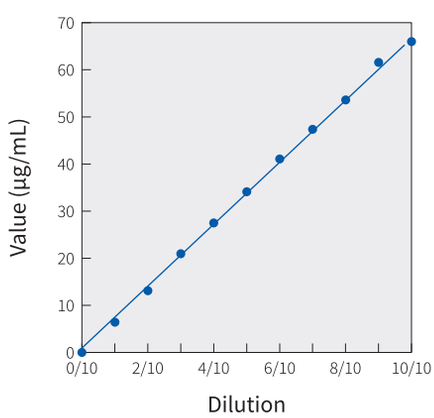


Data (CP3000)

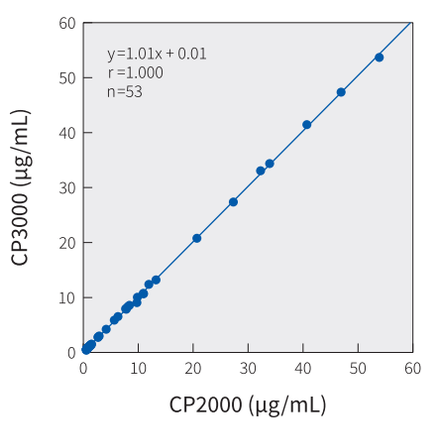
Precision

	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

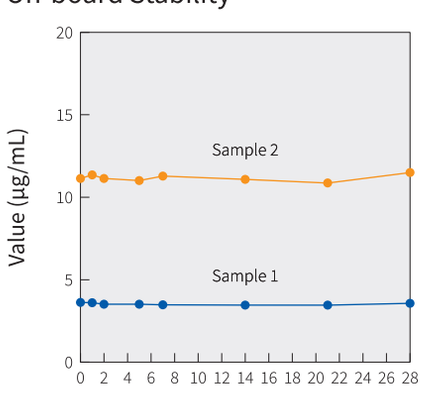
Linearity



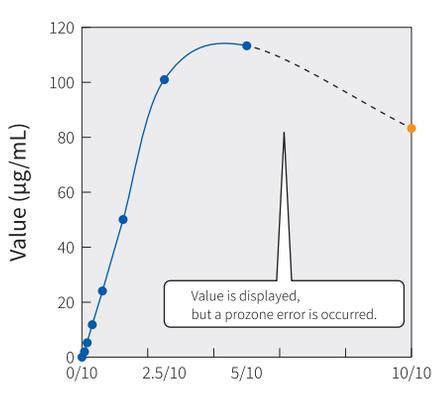
Correlation between CP3000 and CP2000



On-board Stability



Prozone



Interference

	Concentration	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

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 years 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	Coagpia 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		

Calibrators

Product Name	Code	Package	Storage	Shelf life
Calibrator N for Coagpia	476082	10 × 1.0 mL	2–8°C	Two years 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	

* Calibrators are not regulated as IVDs under Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices in Japan.

Controls

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

* Controls are not regulated as IVDs under Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices in Japan.

Diluent

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

* "Nanopia", "Coagpia" and "Coapresta" are trademarks or registered trademarks of SEKISUI MEDICAL CO., LTD. in Japan and/or other countries.
* CP2000 herein refers to Coapresta 2000.

* The performance claims herein have been those approved, certified or notified in Japan. The performance may vary with markets.
* CP3000 and its related reagents are not available in all markets; contact SEKISUI MEDICAL CO., LTD. about availability and registration status in your area.

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

CP3K-001
2503SC