Reagents

Item	Product Name	Constituent Reagent Name	Code	Package	Storage	Shelf life
DT		Thrombonlastin Doogont	476051	$10 \times 4 \mathrm{mL}$		
PI	Coagpia PT-N	Thromboplastin Reagent	482366	10 × 10 mL		
		ADTT Percent	476068	$10 \times 4 \mathrm{mL}$		Two years after manufacturing
	Coognia ADTT N	AFTTRegent	482373	10 × 10 mL		
APTI	Coagpia APTI-N	Calaium Chlarida Calutian	476075	10 × 4 mL		
		Calcium Chionde Solution	482380	10 × 10 mL	2-10°C	
	Coagpia Fbg	Thrombin Reagent	425721	10 × 3 mL		
Fbg			515439	10 × 10 mL		
		Sample Dilution Solution	425714	10 × 10 mL		
		P-FDP Buffer Solution 1	421100	CP set R1 1 × 10.5 mL		
FDP	Nanopia P-FDP Р-	P-FDP Latex Reagent 2	421198	R2 1 $ imes$ 10 mL		
Daliasar	Negaria D. dimar	D-dimer Buffer Solution 1	421220	CP set R1 1 × 10.5 mL		
D-aimer	Nanopia D-dimer	D-dimer Latex Reagent 2	421228	R2 1 $ imes$ 10 mL		

Calibrators

Product Name	Code	Package	Storage	Shelf life
Calibrator N for Coagpia	476082	10 imes1.0 mL	2-8°C	
FDP Calibrator N	468049	5 conc. × 0.5 mL	2-10°C	Two years after manufacturing
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. $\times 1.0$ mL	2-8°C	Two years after manufacturing
FDP Control	337123	3×2 conc. $\times 1.0$ 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 imes 10 mL	2-10°C	Two years after manufacturing			
	* "Nanania" "Caagnia" and "Caaprasta" are tradomarks or registered tradomarks of SEKISUI MEDICAL COLITE 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



Automated Coagulation Analyzer CP3000 and Related Products Instrument & Reagent





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

2503SC





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



Assays: Clotting Assay

Chromogenic Assay

Immunoturbidimetric Assay



Product Specifications

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 \times D915 \times 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.



User-friendly interfaces

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

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.



Cross-mixing Test Function

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

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.



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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.)

37°C → Assay

Linearity 160

140

120

100

80

0/10

2/10

Value (%)

Assay Method



Data (CP3000)

Precision Sample 1 Sample 2 sec % INR sec % INR 10 10 10 10 10 10 n : 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



Correlation between CP3000 and CP2000



Sample 1

Sample 2

On-board Stability

120

100

80

20

Value (%) 60





CP2000 (INR)

4/10 6/10 8/10 10/10

Interference

	Concentration	Value	e (%)
	Concentration	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









1 2

	Concentration	Value	(sec)
	Concentration	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

Assay Method

Sample / Plasma + Sample Dilution Solution 10uL 90µL

Thrombin Reagent 37°C → Assay 37°C 45 seconds 50µL

• Calibrator compliant with WHO standard

Data (CP3000)

Precision





Feature • Both plasma and serum can be measured and Nanopia P-FDP (plasma FDP) scores is good. Assay Method ample (Plasma/Serum 37°C 6uL

Data (CP3000)

	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



Correlation between CP3000 and CP2000



On-board Stability

Sample 1

Sample 2

3 4

Days

5 6

350

300

250

200

150

100

50

0 1 2

Value (mg/dL)

Interference

	Constantion	Value (mg/dL)
	Concentration	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

 Wide measurement range: 2.5–120 μg/mL • In the DIC diagnostic criteria, the concordance rate between the serum-specific FDP measurement reagent

Interference

	Concentration	Value (μg/mL)
	Concentration	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

Dilution

Nanopia D-dimer

Sample 1

.

0 2 4 6 8 10 12 14 16 18 20 22 24 26 28

Days

Feature

 \bullet Wide measurement range: 0.5–60 $\mu g/mL$



Value is displayed,

5/10

Dilution

but a prozone error is occurred.

10/10

20

0

0/10

2.5/10

Rheumatoid Factor 500 IU/mL

7.3

7.3