SUNBIO 上海太阳生物

THROMBOSIS · HEMOSTASIS

PRODUCT MANUAL

WeChat E-catalog

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Rev.3/0

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ABOUT US

Founded in 2001, Shanghai Sun Biotech is fully dedicated to the development, manufacturing and sales of Coagulation Reagent Kits, Coagulation Analyzers as well as Coagulation Cuvettes. As a NMPA, ISO13485 and CE certified company, we have more than 10,000 m^2 of R&D and production bases for diagnostic reagents that meet GMP standards, and nearly 30,000 m^2 of R&D and production bases for medical instruments and medical consumables that meet medical equipment production standards.

Attaching great importance to scientific and technological innovation, it has successfully developed a series of thrombus and hemostasis diagnostic reagents, coagulation analyzers and medical consumables, mastered the core technology of products, and nearly 100 independent formed intellectual property rights including invention patents. With high quality products and excellent customer service, the company enjoys strong brand recognition in the industry. As one of the earliest Chinese companies to develop and produce coagulation diagnostic products, its products cover thousands of hospitals and research institutes in China, and other countries around the world.

25 years reagent manufacturing experience
12 years analyzer manufacturing experience

MAIN PRODUCTS

Medical Equipment

- Coagulation Analyzers

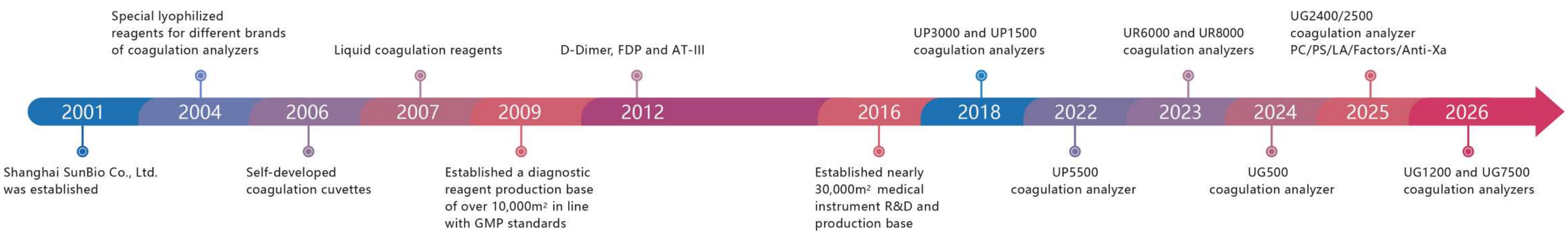
Clinical Diagnostic Reagents

- Coagulation Diagnostic Reagents
- Thrombus and Hemostasis Diagnostic Reagents
- Controls
- Cleaners

Medical Consumables

- Cuvettes

DEVELOPMENT HISTORY



Optical

Mechanical

Platelet Aggregation

It is designed with optical and mechanical principles, and can detect test items based on coagulation method, chromogenic method and immunobidmetry method. It can avoid the interference from hemolysis, icterus, lipemia samples.

UG SERIES

coagulation analyzer

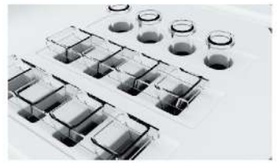
UG 500 SEMI-AUTOMATED COAGULATION ANALYZER

Processing Capability

- Detection Channel: 4 mechanical + 2 optical
- Mixing Position: 1
- Reagent Position: 4 (incubation positions)+2 (room temperature)
- Cuvette loading: 12 mechanical cuvettes +4 optical cuvettes

Advantages

- **Principle**
  Mechanical+Optical
- **Analysis method**
  Coagulation method, Chromogenic substrate assay, Immunoturbidimetry
- **Independent mixing position**
  Mix samples and reagents thoroughly and automatically
- **LCD operation screen**
  Enables convenient operation with intelligent human-computer interaction



UG 2400/2500 AUTOMATED COAGULATION ANALYZER

Processing Capability

- **PT:** 376Ts/h
- **D-Dimer:** 189Ts/h
- **Detection Channel:** 26 (full-wavelength)
- **Sample Position:** 60
- **Reagent Position:** 42 (refrigeration)+5 (room temperature)
- **Probe:** 1 sample probe, 1 reagent probe (cap piercing configurable)
- **Cuvette loading:** 1500 Pcs

Advantages

- **Optical-mechanical coagulation detection**
  Optical and mechanical dual-method detection, automatically switching to suitable detection channels for severe haemolysis, icterus and lipemia samples
- **Platelet aggregation test**
  Combined primary haemostasis and secondary haemostasis detection, with the function of coagulation testing and platelet aggregation test
- **Sample quality inspection**
  HIL monitoring, volume check, clot detection
- **Scheduled Power On/Off**
  Automatic startup and self-check at the scheduled time
- **Support child mode**
  Rapid and accurate analysis of micro plasma
- **Five wavelength design**
  340nm, 405nm, 570nm, 660nm, 800nm, estimate the test results of haemolysis, icterus and lipemia samples comprehensively

UP SERIES AUTOMATED COAGULATION ANALYZER

The UP series is a series of automated coagulation analyzers independently developed and produced by Sunbio for clinical coagulation diagnostic tests. Based on more than 20 years of reagent manufacturing experience, it creates a new era of SUNBIO automated instruments.

Automation **Precision** **Humanization**

It integrates coagulation method, chromogenic method and immunoassay method into one, which can satisfy the simultaneous detection of the three methodologies, and provide accurate and reliable results for routine blood coagulation detection and analysis in the laboratory.

UP SERIES

Automated coagulation analyzer

UP 1500 AUTOMATED COAGULATION ANALYZER

UP 1500 Automated Coagulation Analyzer is the first fully automated coagulation analyzer independently developed and originally designed by Sunbio, which realizes the overall supply of the whole product line of coagulation diagnostic reagents, coagulation analyzers and medical consumables.

Processing Capability
PT: 280Ts/h
D-Dimer: 100Ts/h
Detection Channel: 19
Sample Position: 48
Reagent Position: 22 (refrigeration)
+7 (room temperature)
Probe: 1 sample probe, 1 reagent probe

Advantages

- **Continuous Cuvette Supply**
  Equipped with automatic cuvette selection and transfer system, saving test preparation time
- **Built-in Scan Code**
  The built-in barcode recognition system reduces the tedious work of manually entering information
- **Emergency Priority**
  Enables priority detection of emergency samples in any position without downtime
- **Real-time Storage**
  Large-capacity storage offers, real-time display, storage and printing of test status and results
- **Precision Parts**
  Precision components, high-precision drive control

UP 3000 AUTOMATED COAGULATION ANALYZER

UP 3000 is an innovatively designed automated coagulation analyzer. It adopts the design concept of dual reagent probes and dual wavelengths to effectively avoid cross-contamination and endogenous interference. The sample plate design with more sample positions can meet the daily testing needs of large hospitals.

Processing Capability
PT: 300Ts/h
D-Dimer: 120Ts/h
Detection Channel: 21
Sample Position: 80
Reagent Position: 28 (refrigeration)
+5 (room temperature)
Probe: 1 sample probe, 2 reagent probes

Advantages

- **Double Reagent Probes**
  Independent dual-reagent probe design, flexible sample addition, effectively avoiding cross-contamination
- **Retest Function**
  Automatically performs retests for samples with abnormal data to ensure result repeatability and reliability
- **Precision Adding**
  Sensitive and precise adding system to ensure the accuracy of micro-adding and experimental results
- **Optimized Detection**
  Multi-methodological testing to meet the diverse project testing needs of laboratories
- **Stable Function**
  Modular integrated design ensures safe experimental operation and consistently provides accurate results

UP 5500 AUTOMATED COAGULATION ANALYZER

The **UP 5500** automated coagulation analyzer continues the excellent quality of the UP series, the high-throughput design of orbital injection, and realizes flexible processing of batch and sporadic samples and lean management of workflow.

Processing Capability
PT/APTT/FIB/TT: 420Ts/h
D-Dimer: 420Ts/h
Detection Channel: 20 (full-wavelength)
Sample Position: 100
Reagent Position: 28 (refrigeration) +5 (room temperature)
Probe: 1 sample probe, 2 reagent probes

Advantages

- **Full Inspection Channel**
  With 20 full-wavelength detection channels, it can simultaneously detect coagulation, immunoassay, and chromogenic methods
- **Three Probes Design**
  Adopts three probes design to avoid cross contamination
- **Batch Pre-warming**
  Independent pre-warming module for batch incubation of 32 samples simultaneously
- **Automatic Injection**
  Sample racks can be automatically loaded into the loading position
- **Plenty of Serving Cuvettes**
  2000 cuvettes can be loaded in a single time, ensuring the needs of large-scale sample detection

UR SERIES AUTOMATED COAGULATION ANALYZER

The UR series is a series of automated coagulation analyzers with faster speed,higher efficiency and more intelligent functions aiming at clinical pain points and needs. New era, new concept, UR series will lead a new fashion of thrombosis and hemostasis diagnosis.

› Fastest › Intelligence › Biosafety

UR series pushes coagulation diagnostic performance and detection speed to a new level and makes important breakthroughs in intelligent control and biosafety. In particular, UR8000 automated coagulation analyzer has the fastest throughput in the world so far, which greatly improves the detection efficiency and shortens TAT time.

UR SERIES

Automated coagulation analyzer

UR 6000 AUTOMATED COAGULATION ANALYZER

UR 6000 automated coagulation analyzer owes the functions of monitoring HIL samples, puncturing capped blood collection tubes and connecting pipeline on the base of routine analysis.

Processing Capability
PT/APTT/FIB/TT: 450Ts/h
D-Dimer: 450Ts/h
Detection Channel: 20 (full-wavelength)
Sample Position: 108 (front injection), 400 (side injection)
Reagent Position: 28 (refrigeration) + 6 (room temperature)
Probe: 2 sample probes, 2 reagent probes

Advantages

- **Intelligent monitoring**
  Monitoring hemolysis, lipaemia and icterus samples before test and switching suitable wavelength to detect to avoid interference.
- **Mixing study**
  Automated APTT mixing study.
- **High biosafety**
  Puncturing capped blood collection tubes directly, reducing the generation of aerosols during capping and improving biological safety.
- **Connect to lab automation system**
  It can be connected to lab automation system and realize remote control.
- **Bulk loading**
  Maximum capacity of 2000 cuvettes on board, sufficient sample and reagent positions and independent pre-warming module ensure the need of large-scale sample detection.

UR 8000 AUTOMATED COAGULATION ANALYZER

UR 8000 automated coagulation analyzer adopts innovative design concept to get to 900Ts/h, which is the fastest speed all around the word until now.

Processing Capability
PT/APTT/FIB/TT: 900 Ts/h
D-Dimer: 900Ts/h
Detection Channel: 40 (full-wavelength)
Sample Position: 108 (front injection), 400 (side injection)
Reagent Position: 56 (refrigeration) + 11 (room temperature)
Probe: 3 sample probes, 4 reagent probes

Advantages

- **Fastest in the world**
  Dual independent detection system, 900Ts/h throughput is the fastest worldwide.
- **Intelligent monitoring**
  Monitoring hemolysis, lipaemia and icterus samples before test automatically and switching suitable wavelength to detect to avoid interference.
- **Mixing study**
  Automated APTT mixing study.
- **High biosafety**
  Puncturing capped blood collection tubes directly, reducing the generation of aerosols during capping and improving biological safety.
- **Connecting lab automation system**
  It can be connected to lab automation system and realize remote control.
- **Bulk loading**
  Maximum capacity of 2000 cuvettes on board, sufficient sample and reagent positions and independent pre-warming module ensure the need of large-scale sample detection.

Ingenuity

Efficiency

Flexibility

UL-2000 LAS laboratory automation system is equipped with input/output module, centrifuge module, decapper module and track. The UL-2000 LAS laboratory automation system can connect to our UR series automated coagulation analyzer to maximize pre-processing capabilities.

The UL-2000 LAS Laboratory Automated system performs efficient pre-processing functions in a small footprint. It can realize a detection workstation for thrombosis and hemostasis.

UL-2000 LAS

Coagulation Lab Automation

UL-2000 LAS

Coagulation Lab Automation

Advantages

- **Input & Output module**
  Loading capacity: 400 tubes
  Customized sample area: normal sample, abnormal sample, STAT sample
- **Centrifuge module**
  Equipped with refrigerated centrifuges
  Designed with customized centrifuge parameters
- **Decapper module**
  Built-in cap collection with full-load sensing
  Prevents aerosol contamination
- **Track module**
  Built-in RFID chip to realize sample traceability
  The break-apart track allows flexible layout
- **Analysis Module**
  Supports on-orbit sample aspiration
  Equipped with automatic cap-piercing technology
- **Laboratory Intelligent System Software**
  Automatic result review
  Intelligent remote control

TEST ITEMS

Method	Test	
Coagulation Method	Prothrombin Time	PT
	Activated Partial Thromboplastin Time	APTT
	Fibrinogen	FIB
	Thrombin Time	TT
	Protein S	PS
	Lupus Anticoagulant	LA
	Factor Detection	Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ
Chromogenic Substrate Method	Protein C	PC
	Antithrombin Ⅲ	AT-III
	Anti-Xa	Anti-Xa
Immunoturbidimetric Method	D-Dimer	D-Dimer
	Fibrin (ogen) Degradation Products	FDP
.....		

TECHNICAL SPECIFICATIONS

Principle	Coagulation Method、Chromogenic Method、Immunoassay Method
Light Source	LED cold light source, maintenance free
Coagulation Curve	With
Data Storage	100,000 sample results and coagulation curves
Precision Management	Choose L-J management or X-bar management, day-to-day difference series, day-to-day difference binary quality control chart
Cuvettes	500~2000
Barcode Reader	With build-in barcode read system in both sample position and reagent position
STAT	Priority testing in any sample position

Micro Sampling	5μL
Quality Control	X-bar control, L-J control multi-rule quality control
Calibration Curve	Automatic dilution setting, multi-point calibration curve, INR calibration curve, calibration curve can be automatically switched
Instrument Interface	With RS232 interface, connecting LIS/HIS
Printer	Print through external printer
Noise Level	<85dBA
Power Requirements	Voltage: 200-240V Frequency: 50Hz
Operating Environment	Ambient temperature: 10-30℃ Relative humidity: ≤80% Atmospheric pressure: 70-106kPa

REAGENTS AND CONSUMABLES

Meet your more needs for thrombosis and hemostasis experiments, and provide you with a complete set of clinical solutions.

Good Stability **High Sensitivity** **Strong Anti-interference**

- Available for: SUNBIO, SYSMEX, Werfen, STAGO, SEKISUI, BE.....

Professional Coagulation Diagnostic Reagents

▸▸ SCREENING TESTS - PT

Test Principle

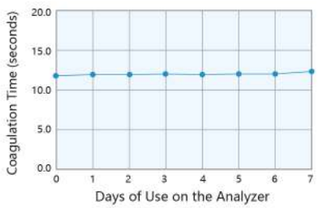
The coagulation process is triggered by incubation of plasma with an optimal amount of thromboplastin and calcium. The time to formation of afibrin clot is then measured.

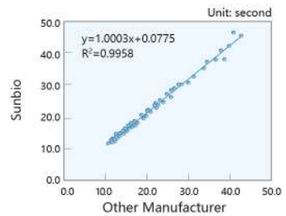
Summary and Explanation

- **The PT value is higher than the expected value in the following clinical states:** congenital deficiency of factors II, V, VII, X, hypofibrinogenemia or afibrinogenmia, disseminated intravascular coagulation (DIC), primary fibrinolysis, VitK deficiencies, liver disease, oral anticoagulants, heparin, fibrinogen degradation products (FDP) therapy, etc.
- **The PT value is commonly lower than the expected value in the following clinical states:** congenital increase of coagulation factor V, oral contraceptives, hypercoagulability, thrombotic disease, etc.

Performance Advantage

- **Excellent stability:** Unopened lyophilized reagents are stable for 3 years when stored at 2℃ to 8℃, and once redissolved, PT reagents are stable for 7 days at 2℃ to 8℃. Higher between-run precision (CV is 2.38%), higher sensitivity (ISI value 0.9-1.10).
- **Good correlation:** compared with an international mainstream manufacturer.





Specification

Item No.	Product Name	Test Method	Specification	Remarks
8000E	Determination of Prothrombin Time	Coagulation	PT Reagent: 10×2.0mL PT Buffer: 1×21mL	ISI 1.0～1.2
8001E	Determination of Prothrombin Time	Coagulation	PT Reagent: 10×4.0mL PT Buffer: 1×41mL	ISI 1.0～1.2
8002E	Determination of Prothrombin Time	Coagulation	PT Reagent: 10×10.0mL PT Buffer: 1×101mL	ISI 1.0～1.2
Y8001E	Determination of Prothrombin Time	Coagulation	PT Reagent: 10×4.0mL	ISI 1.0～1.2
Y8002E	Determination of Prothrombin Time	Coagulation	PT Reagent: 10×10.0mL	ISI 1.0～1.2

▸▸ SCREENING TESTS - APTT (Silica)

Test Principle

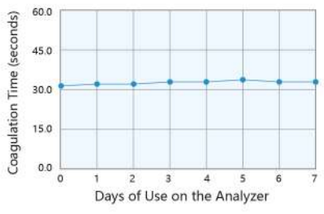
Factors of the intrinsic coagulation system are activated by incubating the plasma with the optimal amount of phospholipids and a surface activator. The addition of calcium ions triggers the coagulation process, and the clotting time is then measured.

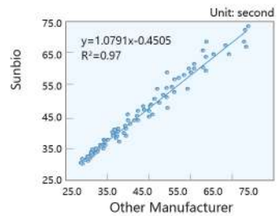
Summary and Explanation

- **The APTT value is higher than the expected value in the following clinical states:** congenital deficiency of factors II, V, VIII, IX, XI, XII, hypofibrinogenemia or afibrinogenmia, increased fibrinolytic activity, and the presence of anticoagulant substances (eg, increased plasma heparin and oral Anticoagulants) , and the APTT also is important indicators for monitoring heparin therapy.
- **The APTT value is commonly lower than the expected value in the following clinical states:** hypercoagulable states, thrombotic disease, myocardial infarction, unstable angina, cerebrovascular disease, pulmonary infarction, deep vein thrombosis, pregnancy- induced hypertension syndrome, nephrotic syndrome, etc.

Performance Advantage

- **Excellent stability:** Lyophilized reagent, vacuum preserved, valid for 3 years， and once redissolved, APTT reagents are stable for 7 days at 2℃ to 8℃.
- **Good correlation:** compared with an international mainstream manufacturer.





Specification

Item No.	Product Name	Test Method	Specification
8013E	Determination of Activated Partial Thromboplastin Time(Silica)	Coagulation	APTT Reagent: 10×4.0mL 0.025mol/L $CaCl_2$: 1×51mL
8014E	Determination of Activated Partial Thromboplastin Time(Silica)	Coagulation	APTT Reagent: 10×4.0mL 0.025mol/L $CaCl_2$: 10×6.0mL
8015E	Determination of Activated Partial Thromboplastin Time(Silica)	Coagulation	APTT Reagent: 10×5.0mL 0.025mol/L $CaCl_2$: 1×51mL
8016E	Determination of Activated Partial Thromboplastin Time(Silica)	Coagulation	APTT Reagent: 10×5.0mL 0.025mol/L $CaCl_2$: 10×6.0mL

▸▸ SCREENING TESTS - APTT (Ellagic Acid)

Test Principle

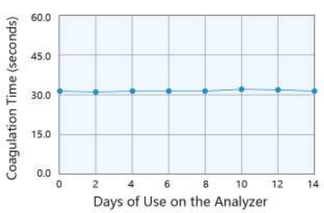
Factors of the intrinsic coagulation system are activated by incubating the plasma with the optimal amount of phospholipids and a surface activator. The addition of calcium ions triggers the coagulation process, and the clotting time is then measured.

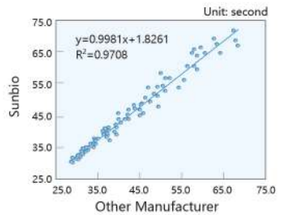
Summary and Explanation

- **The APTT value is higher than the expected value in the following clinical states:** congenital deciency of factors II, V, VIII, IX, XI, XII, hypofibrinogenemia or afibrinogenmia, increased fibrinolytic activity, and the presence of anticoagulant substances (eg, increased plasma heparin and oral Anticoagulants) , and the APTT also is important indicators for monitoring heparin therapy.
- **The APTT value is commonly lower than the expected value in the following clinical states:** hypercoagulable states, thrombotic disease, myocardial infarction, unstable angina, cerebrovascular disease, pulmonary infarction, deep vein thrombosis, pregnancy- induced hypertension syndrome, nephrotic syndrome, etc.

Performance Advantage

- **Excellent stability:** Liquid reagent is stable for 14 days at 2℃ to 8℃, and it can be immediately used without dissolve process . Unopened reagents are stable until the expiration date for 15 months when stored at 2℃ to 8℃.
- **Good correlation:** compared with an international mainstream manufacturer.





Specification

Item No.	Product Name	Test Method	Specification
8010E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTT Reagent: 10×2.0mL 0.025mol/L $CaCl_2$: 1×51mL
8011E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTTReagent: 10×4.0mL 0.025mol/L $CaCl_2$: 1×51mL
8012E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTTReagent: 10×4.0mL 0.025mol/L $CaCl_2$: 10×6.0mL
8019E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTT Reagent: 10×10.0mL 0.025mol/L $CaCl_2$: 1×101mL
8020E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTT Reagent: 10×10.0mL 0.025mol/L $CaCl_2$: 10×11.0mL
Y8012E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTT Reagent: 10×5.0mL 0.025mol/L $CaCl_2$: 1×51mL
Y8017E	Determination of Activated Partial Thromboplastin Time(Ellagic Acid)	Coagulation	APTT Reagent: 10×5.0mL 0.025mol/L $CaCl_2$: 10×6.0mL

▸▸ SCREENING TESTS - FIB

Test Principle

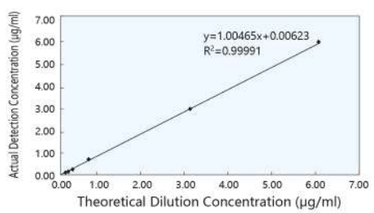
The enzyme thrombin converts the soluble plasma protein fibrinogen into its insoluble, fibrin. The clotting time for diluted plasma is inversely proportional to the fibrinogen concentration of the plasma. By using this principle, Clauss developed a simple procedure for determining fibrinogen based on measuring the clotting time of diluted plasma after the addition of thrombin. The clotting time obtained in this manner is then compared with that of a standardized fibrinogen preparation.

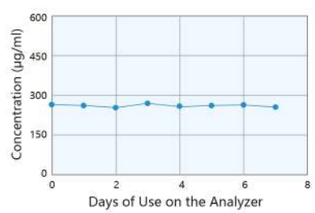
Summary and Explanation

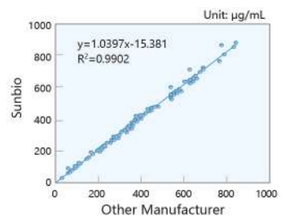
- An increase of FIB level is found in the case of diabetes, diabetic acidosis, atherosclerosis, acute infectious disease, acute nephritis, uremia, shock, mild hepatitis and postoperative patients, etc.
- A decrease of FIB level is found in the case of disseminated intravascular coagulation (DIC), primary fibrinolysis, severe hepatitis and cirrhosis, etc.

Performance Advantage

- **Excellent stability:** Unopened lyophilized reagents are stable for 3 years when stored at 2℃ to 8℃, and once redissolved, reagents are stable for 7 days at 2℃ to 8℃.
- **Good correlation:** compared with an international mainstream manufacturer.
- **Wide linear range:** 0.8-8g/L







Specification

Item No.	Product Name	Test Method	Specification
8031E / Y8031E	Determination of Fibrinogen	Coagulation	FIB Reagent: 6×2.0mL Imidazole Buffer Solution: 3×34mL Calibration Plasma: 1×1.0mL
8032E / Y8032E	Determination of Fibrinogen	Coagulation	FIB Reagent: 6×5.0mL Imidazole Buffer Solution: 3×34mL Calibration Plasma: 1×1.0mL
8033E / Y8033E	Determination of Fibrinogen	Coagulation	FIB Reagent: 10×2.0mL Imidazole Buffer Solution: 3×34mL
8035E / Y8035E	Determination of Fibrinogen	Coagulation	FIB Reagent: 10×5.0mL Imidazole Buffer Solution: 3×34mL

▸▸ SCREENING TESTS - TT

Test Principle

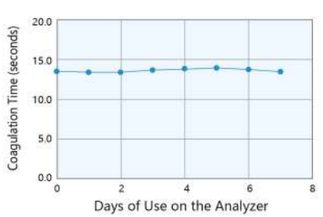
Thrombin converts fibrinogen which is contained in the plasma sample into fibrin, whereupon a clot form. The time to clot formation is measured.

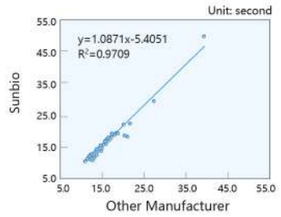
Summary and Explanation

◦ **The TT values is higher than the expected value in the following clinical states:** increase of heparin or existence of heparinoids, systemic lupus erythematosus (SLE), liver disease, nephropathy, hypofibrinogenemia or afibrinogenemia, dysfibrinogenemia, increase of fibrinogen degradation products (FDP), globulinemia, increase of immunoglobulins, etc.

Performance Advantage

- **Excellent stability:** Unopened lyophilized reagents are stable for 3 years when stored at 2℃ to 8℃, and once redissolved, reagents are stable for 7 days at 2℃ to 8℃.
- **Good correlation:** compared with an international mainstream manufacturer.





Specification

Item No.	Product Name	Test Method	Specification
8021E	Determination of Thrombin Time	Coagulation	TT Reagent: 10×5.0mL TT Buffer: 1×51mL
8022E	Determination of Thrombin Time	Coagulation	TT Reagent: 10×10.0mL TT Buffer: 1×101mL
Y8020E	Determination of Thrombin Time	Coagulation	TT Reagent: 10×4.0mL
Y8025E	Determination of Thrombin Time	Coagulation	TT Reagent: 10×10.0mL

▸▸ FIBRIN DEGRADATION PRODUCTS - D-Dimer

Test Principle

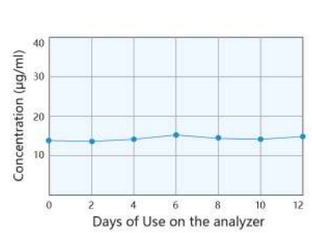
This Kit is based on the latex immunoturbidimetry method. The D-Dimer monoclonal antibody-coated on latex microparticles reacts with D-Dimer in plasma to cause agglutination of the latex microparticles, leading to an increase in turbidity of the reaction medium. This increase in turbidity is reflected by an increase in light absorbance. Subsequently, the D-Dimer level is measured by detecting the variation of light absorbance.

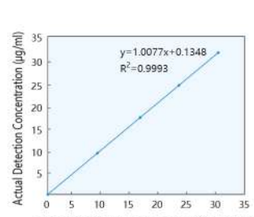
Summary and Explanation

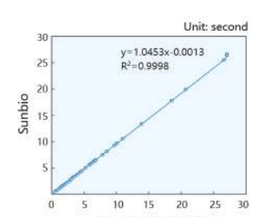
◦ **Elevated values of D-Dimer is clinically indicated:** Formation or increase of D-Dimer in human blood indicates that both the coagulation and fibrinolysis systems have been activated. It can be taken as one of the important biomarkers in thrombogenesis. It is also a valuable indicator to distinguish between primary fibrinolysis and secondary fibrinolysis and to monitor thrombolytic therapy. Elevation of D-Dimer in the blood is also an important indicator in the diagnosis of thrombotic disease, such as disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT), pulmonary embolism (PE), cerebrovascular disease, myocardial infarction and severe hepatitis, etc.

Performance Advantage

- **Excellent stability:** Unopened reagents are stable for 18 months when stored at 2℃ to 8℃, and once redissolved, reagents are stable for 12 days at 2℃ to 8℃, D-Dimer Calibrator or QC is stable for 7 days at 2℃ to 8℃ .
- **Good correlation:** compared with an international mainstream manufacturer.
- **Wide linear range:** High concentration samples do not need to be re-dilutes again (0.25~30.0μg/ml).







Specification

Item No.	Product Name	Test Method	Specification
8042E	Determination of D-Dimer	Immunoturbidimetric Assay	Reagent: R1:5×3.0mL R2: 5×3.0mL Diluent: 1×55mL Calibrator: 6×0.5mL
N8042E	Determination of D-Dimer	Immunoturbidimetric Assay	Reagent: R1:5×3.0mL R2:5×3.0mL Diluent: 1×55mL
8045E	Determination of D-Dimer	Immunoturbidimetric Assay	Reagent: R1:5×5.0mL R2: 5×5.0mL Diluent: 1×55mL Calibrator: 6×0.5mL
N8045E	Determination of D-Dimer	Immunoturbidimetric Assay	Reagent: R1:5×5.0mL R2: 5×5.0mL Diluent: 1×55mL

▸▸ FIBRIN(OGEN) DEGRADATION PRODUCTS - FDP

Test Principle

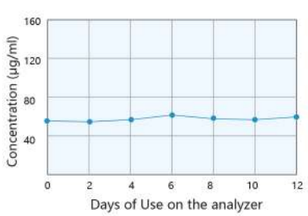
The Kit is based on the latex immunoturbidimetry method. The FDP monoclonal antibody-coated on latex microparticles reacts with FDP in plasma to cause agglutination of the latex microparticles, leading to an increase in turbidity of the reaction medium. This increase in turbidity is reflected by an increase in light absorbance. Subsequently, the FDP level is measured by detecting the variation of light absorbance.

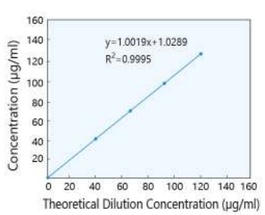
Summary and Explanation

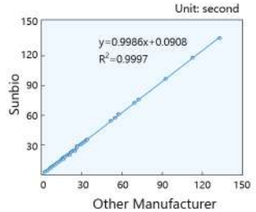
- The increase of FDP indicates hyperfibrinolysis in the blood. Detection of increase of FDP is significant in diagnosing and treating the disorders of or related to the fibrinolytic system and in monitoring thrombolytic therapy. Elevation of FDP in the blood is also an important indicator in diagnosis, treatment and monitoring of various thrombotic and bleeding diseases, such as disseminated intravascular coagulation (DIC) and deep venous thrombosis (DVT).

Performance Advantage

- **Excellent stability:** Unopened reagents are stable for 18 months when stored at 2℃ to 8℃, and once redissolved, reagents are stable for 12 days at 2℃ to 8℃, D-Dimer Calibrator or QC is stable for 7 days at 2℃ to 8℃ .
- **Good correlation:** compared with an international mainstream manufacturer.
- **Wide linear range:** 2.5~120.0μg/ml







Specification

Item No.	Product Name	Test Method	Specification
8047E	Determination of Fibrin/Fibrinogen Degradation Products	Immunoturbidimetric Assay	Reagent: R1:5×3.0mL R2: 5×3.0mL Diluent: 1×55mL Calibrator: 6×0.5mL
N8047E	Determination of Fibrin/Fibrinogen Degradation Products	Immunoturbidimetric Assay	Reagent: R1:5×3.0mL R2: 5×3.0mL Diluent: 1×55mL
8050E	Determination of Fibrin/Fibrinogen Degradation Products	Immunoturbidimetric Assay	Reagent: R1:5×5.0mL R2: 5×5.0mL Diluent: 1×55mL Calibrator: 6×0.5mL
N8050E	Determination of Fibrin/Fibrinogen Degradation Products	Immunoturbidimetric Assay	Reagent: R1:5×5.0mL R2: 5×5.0mL Diluent: 1×55mL

▸▸ COAGULATION FACTORS - II , V , VII, VIII, IX, X , XI, XII

Test Principle

The determination of extrinsic coagulation factors II, V, VII, and X adopts the principle of coagulation method. In the original time (PT) test, the plasma coagulation time was negatively correlated with the activity of coagulation factors in the sample to be tested.

The determination of intrinsic coagulation factors VIII, IX, XI and XII adopts the principle of coagulation method, and the sample to be tested is mixed with the corresponding factor-deficient plasma for activation. Partial thromboplastin time (APTT) test. Plasma clotting time is negatively correlated with coagulation factor activity in the sample to be tested.

Summary and Explanation

- **Elevated coagulation factor VIII can be seen in the following clinical conditions:** thrombotic complications, coronary atherosclerosis, renal failure, diabetes mellitus, general inflammation; Elevated coagulation factor VIII is a risk factor for thrombosis, especially venous thrombosis.
- **Decreased coagulation factors can be seen in the following clinical conditions:** congenital coagulation factor deficiency (factor VIII deficiency is hemophilia A, factor IX deficiency is hemophilia B), factor inhibitors, vitamin K deficiency, liver disease, disseminated intravascular coagulation (DIC), hyperfibrinolysis, oral anticoagulation, etc.

Performance Advantage

- **Estability:** Stable for at least 8 hours after reconstitution at 2-8°C, 15-25°C, and onboard (≤20°C)
- **Linearity range:** Up to 150%, extendable to 300% after dilution
- **Accuracy:** Relative deviation ≤±15%
- **Repeatability:** CV ≤10%
- **Batch Difference:** CV ≤10%
- **Detection Limit:** Factor XI ≤4%, Factor XII ≤7%, other factors ≤5%

Specification

Item No.	Product Name	Test Method	Specification
8150E / 8151E	Coagulation Factor II Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8155E / 8156E	Coagulation Factor V Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8160E / 8161E	Coagulation Factor VII Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8165E / 8166E	Coagulation Factor VIII Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8170E / 8171E	Coagulation Factor IX Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8175E / 8176E	Coagulation Factor X Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8180E / 8181E	Coagulation Factor XI Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL
8185E / 8186E	Coagulation Factor XII Deficient Plasma	Coagulation	10×1.0mL / 5×1.0mL

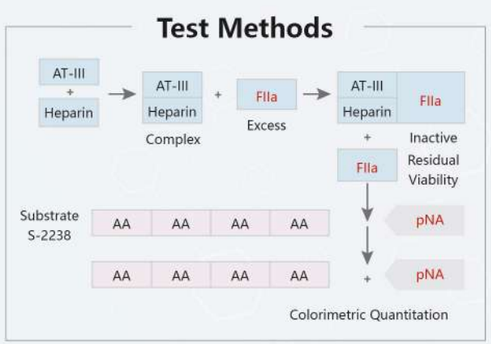
▸▸ THROMBOPHILIA - AT-III

Test Principle

The AT-III in the sample is converted by heparin into an immediate inhibitor and inactivates the thrombin present. The residual thrombin content is determined in a kinetic test measuring the increase in absorbance at 405nm. The absorbance change is inversely correlated to the AT-III activity in the sample.

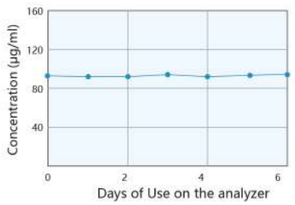
Summary and Explanation

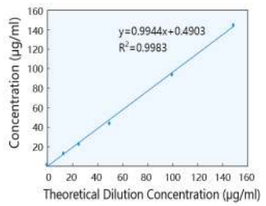
- The increased AT-III levels usually appear in hemophilia and oral anticoagulation therapy.
- The decrease AT-III levels normally occur in disseminated intravascular coagulation (DIC), deep venous thrombosis (DVT), pulmonary embolism (PE), cerebrovascular disease, liver disease, nephrosis and pregnancy-induced hypertension (PIH).

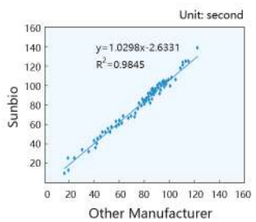


Performance Advantage

- **Excellent stability:** Unopened reagents are stable until the expiration date for 2 years when stored at 2℃ to 8℃, and once redissolved, reagents are stable for 5 days at 2℃ to 8℃, AT-III Calibrator is stable for 8 hours at 2℃ to 8℃ .
- **Good correlation:** compared with an international mainstream manufacturer.
- **Wide linear range:** 0~150%







Specification

Item No.	Product Name	Test Method	Specification
8070E	Determination of Antithrombin Ⅲ	Chromogenic Substrate Assay	AT III R1: 5×6.0mL AT III R2: 5×4.0mL AT III R1 Solvent: 1×31mL AT III Calibrator: 1×1.0mL

▸▸ THROMBOPHILIA - PROTEIN C (PC)

Test Principle

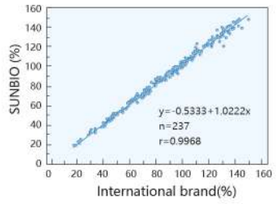
PC determination adopts the principle of chromogenic substrate method. PC activator is added to the sample, and the PC is activated to activate protein (APC). Then, APC acts on the specific chromogenic substrate to cleave the chromogenic group. The color depth is positively correlated with the amount of PC activity.

Summary and Explanation

- **Protein C deficiency** has been found to be associated with an increased risk of venous thrombosis and hereditary. The decrease PC levels also normally occur in disseminated intravascular coagulation (DIC), liver disease, malignant tumors, Vitamin K deficiency, coumarin therapy and acute respiratory distress syndrome (ARDS), etc.

Performance Advantage

- **Good correlation:** the test result is highly correlated to the international brand.
- **Excellent stability:** lyophilized, stable at 2~8℃ for 90 days after reconstitution.
- **Wide linear range:** 10-150%, r≥0.99.
- **Strong anti-interference:** not influenced by hemolysis, icterus, and lipemia, etc.
- **Supporting QC:** provide SUNBIO Normal and Low Protein C Control.
- **Wide compatibility:** suitable for SUNBIO, SYSMEX, Werfen, SEKISUI, STAGO coagulation analyzers.



Specification

Item No.	Product Name	Test Method	Specification
8090E	Determination of Protein C	Chromogenic Substrate Assay	PC R1: 5×3.0mL PC R2: 5×3.0mL PC Diluent: 2×30mL PC Calibrator: 1×1.0mL
N8090E	Determination of Protein C	Chromogenic Substrate Assay	PC R1: 5×3.0mL PC R2: 5×3.0mL PC Diluent: 2×30mL

▸▸ THROMBOPHILIA - PROTEIN S (PS)

Test Principle

The PS determination adopts the principle of coagulation method. Adding PS-deficient matrix plasma (providing sufficient fibrinogen, coagulation factor V and other essential coagulation factors) to the sample can promote the activation of PC, which can inhibit the effect of factor Va. And the coagulation time of plasma was positively correlated with free PS (FPS) activity.

Summary and Explanation

- **Decreased PS is commonly occurred in the following clinical conditions:** venous thrombosis due to hereditary PS deficiency, liver disease, coumarin therapy, L-asparaginase therapy, pregnancy, oral contraceptives, estrogen therapy and elevated plasma C4bBP levels in acute phase reactions.

▸▸ THROMBOPHILIA - LUPUS ANTICOAGULANT (LA)

Test Principle

LA adopts the principle of coagulation method: it is composed of lupus anticoagulant screening reagent and lupus anticoagulant confirmation reagent. In the presence of calcium ions, the viper in the reagent Snake Venom Activator (RVV-X) can activate coagulation factor X, which causes blood to clot.

The phospholipid content of the lupus anticoagulant screening reagent is low, and if LA is present in the sample, the plasma clotting time is prolonged.

High concentrations of phospholipids in the lupus anticoagulant confirmatory reagent can neutralize LA in plasma and normalize plasma time.

Summary and Explanation

- **Elevated LA can be seen in the following clinical conditions:** antiphospholipid syndrome (APS), autoimmune disease (systemic lupus erythematosus), thrombosis, recurrent spontaneous abortion and infection.

▸▸ ANTICOAGULATION THERAPY - ANTI-Xa (Anti-Xa)

Test Principle

The Anti-Xa determination adopts the principle of chromogenic substrate method. Excess AT-III is added to the sample to be tested, so that AT-III and heparin in plasma form a complex, and then excess factor Xa is added to form an AT-III-heparin-Xa complex, and the remaining Xa The factor acts on the specific chromophoric substrate to cleave the chromogenic group. And the color depth is inversely proportional to the concentration of heparin.

Summary and Explanation

- **Clinical application:** It is used to monitor the efficacy of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) for the prevention and treatment of thrombotic diseases, more accurately achieve anticoagulation treatment goals, and reduce the probability of bleeding and thrombosis.

▸▸ Thrombomodulin (TM)

Test Principle

The TM assay utilises its properties as a transmembrane protein of endothelial cells. Soluble TM (sTM) in plasma is detected by a double-antibody sandwich assay: the antigen is captured by a coated anti-TM antibody, which is then conjugated to a labelled secondary antibody for luminescence quantification.

Summary and Explanation

- **Elevated:** TM is produced by vascular endothelial cells and is involved in the regulation of the coagulation and fibrinolytic systems. Elevated TM is usually indicative of endothelial injury or inflammatory response, and is commonly seen in diseases such as DIC, sepsis, neoplasms and acute coronary syndromes. In patients with sepsis, TM is significantly elevated, suggesting endothelial injury and activation of the coagulation system.
- **Decreased**: less common, may indicate impaired TM function or significant anticoagulant effect.

▸▸ Thrombin-antithrombin complexes (TAT)

Test Principle

TAT is detected by chemiluminescent enzyme immunoassay, which takes advantage of the specific binding of thrombin to antithrombin (AT-III) to form a complex. In the assay, magnetic particles coated with anti-TAT antibody bind to TAT in plasma and its concentration is quantified by a luminescent substrate reaction.

Summary and Explanation

- **Elevated:** associated with advancing age, pregnancy, septicemia, disseminated intravascular coagulation, multiple trauma, acute pancreatitis, acute and chronic leukemia, preëclampsia, acute and chronic liver disease, and other predisposing causes of thrombosis. Increased levels are also reported during heparin and fibrinolytic therapy.
- **Decreased:** can also indicate the resolution of a thrombotic event. TAT levels are markedly reduced in the first 24 hours after receiving oral anticoagulants.

▸▸ α2-Plasmininhibitor-Plasmin Complex (PIC)

Test Principle

The PIC assay is based on the characterisation of fibrinolytic enzymes in complex with their inhibitor α2-antifibrinolytic enzyme (α2-PI). A chemiluminescent assay was used to capture PIC in plasma using anti-PIC monoclonal antibody-coated magnetic particles and quantify it by enzymatic luminescence.

Summary and Explanation

- **Elevated:** reflects the activation of the fibrinolytic system, suggesting hyperfibrinolysis. Elevated PIC is commonly seen in acute ischaemic stroke, sepsis, DIC and other diseases, and its level is closely related to the severity of the disease. For example, in patients with sepsis, PIC is significantly elevated, suggesting hyperfibrinolysis. Elevated PIC is also associated with vascular invasion in patients with tumours.
- **Decreased:** usually suggests inhibition of the fibrinolytic system and may be associated with insufficient fibrinolytic activity.

▸▸ tissue plasminogen activator-inhibitor Complex (tPAIC)

Test Principle

The t-PAIC assay is based on the characterisation of t-PA in a 1:1 complex with PAI-1. Competitive chemiluminescence is used: t-PAIC in the sample competes with the labelled antigen to bind immobilised antibodies, which are quantified by the inverse ratio of the luminescent signal.

Summary and Explanation

- **Elevated:** reflects activation of the fibrinolytic system, suggesting vascular endothelial damage and hyperfibrinolysis. t-PAIC is commonly elevated in DIC, sepsis, acute leukaemia, malignancy and venous thromboembolism. For example, in patients with sepsis, t-PAIC is significantly elevated, suggesting abnormal activation of the fibrinolytic system.
- **Decreased:** less common, may suggest inhibition of the fibrinolytic system or reduced t-PA activity.

▸▸ QUALITY CONTROL

Used to check the performance of analytical instruments or methods, it is a stable substances used to verify the performance of analytical instruments or methods.

Specification

Item No.	Product Name	Specification
240E	Coagulation Control Level 1 (For PT, APTT, TT, FIB, AT-III)	10×1.0mL
241E	Coagulation Control Level 1(For PT, APTT, TT, FIB, AT-III)	5×1.0mL
245E	Coagulation Control Level 2(For PT, APTT, TT, FIB, AT-III)	10×1.0mL
246E	Coagulation Control Level 2(For PT, APTT, TT, FIB, AT-III)	5×1.0mL
250E	Coagulation Control Level 3(For PT, APTT, TT, FIB, AT-III)	10×1.0mL
251E	Coagulation Control Level 3(For PT, APTT, TT, FIB, AT-III)	5×1.0mL
2081E	D-Dimer Control Low	10×0.5mL
2083E	D-Dimer Control High	10×0.5mL
2086E	FDP Control Low	10×0.5mL
2088E	FDP Control High	10×0.5mL
275E	Protein C Control Normal	10×1.0mL
280E	Protein C Control Low	10×1.0mL
265E	LA Control Negative	10×1.0mL
268E	LA Control Positive	10×1.0mL
295E	UF Heparin Control Low	10×1.0mL
298E	UF Heparin Control High	10×1.0mL
351E	LMW Heparin Control Low	10×1.0mL
354E	LMW Heparin Control High	10×1.0mL
357E	Heparin Calibrator	5 heparin concentration×1.0mL
375E	Protein S Control Normal	10×1.0mL
380E	Protein S Control Abnormal	10×1.0mL
440E	Coagulation Factor Control Normal (For factor Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ)	10×1.0mL
445E	Coagulation Factor Control Abnormal (For factor Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ)	10×1.0mL
450E	Coagulation Factor Calibration Plasma(For factor Ⅱ, Ⅴ, Ⅶ, Ⅷ, Ⅸ, Ⅹ, Ⅺ, Ⅻ)	10×1.0mL

▸▸ SUNBIO CLEANER

Coagulation analyzer Cleaner: mainly includes SUNMED Cleaner I, SUNMED Cleaner II, SUNMED Clean III, SUNMED Rinse Solution.

Product use: used in conjunction with UP, UR, UG series coagulation analyzers and UL-2000LAS lab automation syetem .

Specification

Item No.	Product Name	Remarks	Specification
8060E	SUNMED Concentrated Rinse Solution	Available for SUNBIO	500mL
8061E	SUNMED Concentrated Rinse Solution	Available for SUNBIO	2x5000mL
8062E	SUNMED Clean I	Available for SUNBIO	50mL
8063E	SUNMED Clean II	Available for SUNBIO	12x15mL
8065E	Rinse Solution	Available for SUNBIO	2x5000mL
8066E	SUNMED Clean III	Available for SUNBIO	10x15mL
8075E	Cleaning Solution	SUNMED Clean I	50mL
8076E	Cleaning Solution	SUNMED Clean II	12x15mL
8077E	Cleaning Solution	SUNMED Clean III	10x15mL
8078E	Cleaning Solution	Rinse Solution	2x5000mL
8079E	Cleaning Solution	SUNMED Concentrated Rinse Solution	500mL
8080E	Cleaning Solution	SUNMED Concentrated Rinse Solution	2x5000mL

▸▸ SUITABLE FOR ALL BRANDS OF COAGULATION ANALYZER CLEANING SOLUTION

Including SYSMEX, IL, STAGO, SEKISUI, BE, TECO, etc.

Specification

Item No.	Product Name	Specification
2060E	SYSMEX Cleaner I	50mL
2061E	SYSMEX Cleaner II	500mL
2062E	SYSMEX Cleaner II	5000mL
2063E	SYSMEX CS Cleaner I	10×50mL
2066E	SYSMEX CN Cleaner	2000mL
1052E	IL Reference Cleaner (ACL 100-7000)	500mL
1053E	IL Reference Cleaner (ACL 8000, 9000, ELITE)	1000mL
1054E	IL Reference Cleaner A (ACL Advance, Futura, TOP)	500mL
1055E	IL Reference Cleaner B (ACL Advance, Futura, TOP)	80mL
1056E	IL Rinse Solution (ACL Advance, Futura)	2000mL
1057E	IL Rinse Solution (ACL TOP, Advance, Futura)	3×4000mL
3060E	STAGO Clean	8×2500mL
3061E	STAGO Special Clean	12×15mL
C261E	Sekisui Medical Cleaner	500mL
C262E	Sekisui Medical Cleaner	10×15mL
4060E	BE Cleaner	50mL
4061E	BE Cleaner	1000mL
6060E	TECO Cleaner A	500mL
6062E	TECO Cleaner B	4×1250mL
R562E	Rayto Cleaner	30mL
R560E	Rayto Rinse Solution	8×2500mL
260E	Precil Rinse Solution	8×2500mL
261E	Precil Cleaner	12×15mL
262E	Precil Cleaner	50mL
465E	Beijing Succeeder Rinse Solution	8×2500mL
466E	Beijing Succeeder Cleaner	12×15mL

▸▸ SUNBIO CUVETTE

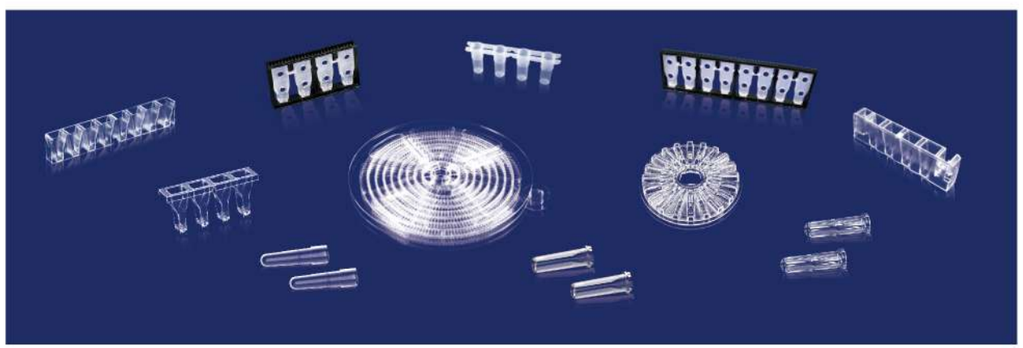
- UP/UR/UG Series Cuvette

Specifications

Item No.	Product name	Remarks	Specification
BS01E	Cuvettes	Available for UP1500 · 3000 · 5000 · 5500 UR 6000 · 8000 UG 2400 · 2410 · 2500 · 2510	12000 pcs/ctn
BS02E	Cuvettes	Available for UG 500 (mechanical)	1050 pcs/ctn
BS03E	Cuvettes	Available for UG 2400 · 2410 · 2500 · 2510 (mechanical)	2304 pcs/ctn
BS04E	Cuvettes	Available for UG 2500 · 2510 (platelet aggregation)	2304 pcs/ctn
BS05E	Cuvettes	Available for UG 500 (optical)	3000 pcs/ctn
S001E	0.5mL Sample Cup		2000 pcs/ctn
S002E	2.0mL Sample Cup		2000 pcs/ctn
S003E	2.0mL Micro Sample Cup		3000 pcs/ctn

▸▸ SUITABLE FOR ALL BRANDS OF COAGULATION ANALYZER CUVETTES

Including IL cuvette, STAGO cuvette, SYSMEX cuvette, Sekisui cuvette, BE cuvette, Hitachi cuvette...



Provide cuvettes (OEM/ODM) suitable for various brands of coagulation analyzers

Specifications

Item No.	Applicable Models	Specification
BC01	Sekisui Medical CP 2000 · 3000 Coagulation Analyzers	5000 Pcs
BH01	Hitachi 3500 Biochemical System	5000 Pcs
B016	SYSMEX CA 50 · 510 · 530 · 550 · 620 660 · 1500 · 7000 · 8000 Coagulation Analyzers	11400 Pcs
B018	SYSMEX CS 1300 · 1600 · 2000i 2100i · 2400 · 2500 · 5100 Coagulation Analyzers	12000 Pcs
RB059	RAYTO RAC 030 · 050 · 100 · 120 1800 · 1830 · 2800 Coagulation Analyzers	11400 Pcs
B010	IL ACL 100 · 200 · 3000 · 7000 8000 · 9000 · ELITE Coagulation Analyzers	264 Pcs
B011	ACL Advance · Futura Coagulation Analyzers	1800 Pcs
B012	IL ACL TOP Coagulation Analyzers	1000 Pcs
B001	BE Compact · Compact-X Rack Rotor · Compact-XR Coagulation Analyzers (Including Magnetic Beads)	1740 Pcs
B002	BE TRT Four-channel Coagulation Analyzers (Including Magnetic Beads)	2400 Pcs
B003	BE TRT Double-channel Coagulation Analyzers (Including Magnetic Beads)	4800 Pcs
B005	BE Thrombolyzer-XRM Coagulation Analyzers (Including Magnetic Beads)	1160 Pcs
B025	STAGO STA-4 Semi-automatic Coagulation Analyzers (Including Magnetic Beads)	1050 Pcs
B026	STAGO Compact · Compact CT Compact Max R Evolution · R Max Fully Automatic Coagulation Analyzer (Including Magnetic Beads)	6000 Pcs
B075	Beijing Succeeder SF-8000 · 8050 Fully Automated Coagulation Analyzers (Including Magnetic Beads)	6000 Pcs
B083	TECO Coatron Fully Automated Coagulation Analyzers	2000 Pcs
B028	Precil C2000-4 Semi-automatic Coagulation Analyzers (Including Magnetic Beads)	1050 Pcs
B029	Precil C2000-A Fully Automatic Coagulation Analyzer (Including Magnetic Beads)	6000 Pcs