June 2, 2025

Sysmex America, Inc.
Esther John-Olotu
Regulatory Affairs Manager
577 Aptakisic Road
Lincolnshire, Illinois 60069

Re: K250965
Trade/Device Name: Automated Blood Coagulation Analyzer CN-Series (CN-6000)
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: March 28, 2025
Received: March 31, 2025

Dear Esther John-Olotu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MIN WU -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250965

Device Name
Automated Blood Coagulation Analyzer CN-Series (CN-6000)

Indications for Use *(Describe)*

The CN-Series (CN-6000) is a fully automated coagulation analyzer intended for in vitro diagnostic use in the clinical laboratory. The instrument analyzes citrated plasma samples (3.2 % sodium citrate) collected from venous blood, using clotting, chromogenic and immunoassay methods.

The performance of this device has not been established in neonate and pediatric patient populations

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

The assigned 510(k) number is: K250965

Submitter's name, address, telephone number, contact person, and date the summary was prepared:

Submitter's Name:	Sysmex America, Inc.
Submitter's Address:	577 Aptakisic Road Lincolnshire, IL 60069
Submitter's Telephone:	(404)957-3627
Submitter's Contact:	Esther John-Olotu
Date 510(k) Summary Prepared:	March 28, 2025

Name of the device, including the trade or proprietary name, the common or usual name, and the classification name:

Proprietary name:	Automated Blood Coagulation Analyzer CN-Series (CN-6000)
Common name:	Automated Blood Coagulation Analyzer
Regulation description:	Coagulation Instrument
Regulation Section:	21 CFR 864.5425
Device Class:	II
Product Code:	JPA

Predicate Device and 510(k) number:
Sysmex Automated Blood Coagulation Analyzer CS-5100 K150678

Description of the Device:

The CN-Series (CN-6000) coagulation analyzer is an automated blood coagulation instrument which can analyze samples using clotting, chromogenic and immunoassay methods. Analysis results are displayed on the IPU (Information Processing Unit) screen. They can be printed on external printers or transmitted to a host computer.

Sold separately from the instrument are the associated reagents, controls, calibrators, and consumable materials. The subject of this 510(k) notification is the analyzer together with the reagent applications which perform the coagulation tests:

- Prothrombin Time (PT) seconds and PT INR with Dade® Innovin®
- Activated Partial Thromboplastin Time (APTT) with Dade® Actin® FSL
- Fibrinogen (Fbg) with Dade® Thrombin Reagent
- Antithrombin (AT) with INNOVANCE® Antithrombin
- D-dimer with INNOVANCE® D-Dimer.

The analysis principles used on the instrument are reflected by the reagent application testing provided in this submission and are described in the table below. These reagents were selected to show the analytical technology of the instrument while also selecting commonly used applications in coagulation laboratories in the United States.

Reagent	Application	Methodology
Dade® Innovin®	PT, Prothrombin Time (seconds)	Clotting (extrinsic pathway)
	PT, Prothrombin Time (INR)	Clotting, calculated
Dade® Actin® FSL	APTT, Activated Partial Thromboplastin Time	Clotting (intrinsic pathway)
Dade® Thrombin Reagent	Fibrinogen quantitation	Clotting (common pathway)
INNOVANCE® Antithrombin	Antithrombin quantitation	Chromogenic
INNOVANCE® D-Dimer	D-dimer quantitation	Immunochemical

The intended environment of use is a clinical laboratory. The instrument and reagent applications are not labeled for home use nor for patient use.

Statement of Intended Use:

The CN-series (CN-6000) is a fully automated blood coagulation analyzer intended for in vitro diagnostic use in the clinical laboratory. The instrument analyzes citrated plasma samples (3.2% sodium citrate) collected from venous blood using clotting, chromogenic and immunoassay methods.

The performance of this device has not been established in neonate and pediatric patient populations.

Summary of Substantial Equivalence:

The CN-6000 uses the same principles of operation as the CS-5100 in using venous blood samples collected in 3.2% sodium citrate tubes to analyze clotting, chromogenic and immunoassay methods in the clinical laboratory.

The main similarities between the CN-6000 instrument and the CS-5100 are listed in the device comparison Table 1 and differences are in Table 2 below:

Table 1: Instrument Comparison – Similarities with Predicate Device

Analyzer Component	**Predicate Device** CS-5100 (K150678)	**Proposed Device** CN-6000
Intended Use	The Sysmex CS-5100 is a fully automated blood coagulation analyzer intended for in vitro diagnostic use using plasma collected from venous blood samples in 3.2% sodium citrate tubes to analyze clotting, chromogenic and immunoassay methods in the clinical laboratory. For determination of: • Prothrombin Time (PT) seconds and PT INR with Dade® Innovin® • Activated Partial Thromboplastin Time (APTT) with Dade® Actin® FSL • Fibrinogen (Fbg) with Dade® Thrombin Reagent • Antithrombin (AT) with INNOVANCE® Antithrombin • D-dimer with INNOVANCE® D-Dimer The performance of this device has not been established in neonate and pediatric patient populations.	The CN-6000 is a fully automated coagulation analyzer intended for in vitro diagnostic use in the clinical laboratory. The instrument analyzes citrated plasma samples (3.2 % sodium citrate) collected from venous blood, using clotting, chromogenic and immunoassay methods. The performance of this device has not been established in neonate and pediatric patient populations.
Sample type	Human plasma, 3.2% sodium citrate	Same
Application type	**Clotting Applications:** • Prothrombin Time (PT) seconds and PT INR with Dade® Innovin® • Activated Partial Thromboplastin Time (APTT) with Dade® Actin® FSL • Fibrinogen (Clauss) with Dade® Thrombin Reagent	Same
	Chromogenic Application: Antithrombin with INNOVANCE® Antithrombin	Same
	Immunoassay Application: D-dimer with INNOVANCE® D-Dimer	Same

Analyzer Component	**Predicate Device** CS-5100 (K150678)	**Proposed Device** CN-6000
Operating Principle	**Clotting/Chromogenic/Immunoassay:** Transmitted Light Detection (Absorbance) at 340, 405, 575, 660 or 800 nm.	Same
Specimen Processing	Automatic Pipetting and Dilution	Same
Random Access	Yes	Same
Liquid Level Sensing	Yes – Reagent and Sample	Same
Bar code reader	Reagent and Sample	Same
Sample Barcodes	ITF, NW-7 (CODABAR), CODE-39, JAN-13, JAN-8, CODE-128 and ISBT128	Same
STAT testing	Yes	Same
Sampling Capabilities	Normal and Micro Mode	Same
Cap Piercing	Cap Piercer	Same
Temperature Control	Sample incubation well: 37°C ± 1.0°C	Same
Pipetting Capabilities	Reagent probe: 20 - 200 µL Sample probe: 4 - 270 µL	Same
Reagent Mixing	Automatic	Same

Table 2 - Instrument Comparison – Differences with Predicate Device

Analyzer Component	**Predicate Device** CS-5100 (K150678)	**Proposed Device** CN-6000
Cleaning Solutions On-board	• CA-CLEAN I	• CN-COAGWASHER
External	• CA-CLEAN II • Dade® Owren's Buffer • Water	Same
Light Source	**Chromogenic & Immunochemical:** Halogen Lamp	LED

Analyzer Component	**Predicate Device** CS-5100 (K150678)	**Proposed Device** CN-6000
Probes	• 2 Sample probes • 3 Reagent probes	• 2 Sample probes • 2 Reagent probes
Reagent Cooling	• 10°C ± 2°C, when the ambient temperature is 20°C - 28°C. • 4°C - 15°C, when the ambient temperature is 15°C - 20°C or 28-30 °C	• 4°C - 12°C, when the ambient temperature is 15°C - 28°C • 4°C - 15°C, when the ambient temperature is 28°C - 30°C
Sampler	• 10 sample racks can be set simultaneously	• 5 sample racks can be set simultaneously

There are minor differences between the analyzers such as rinse and buffer solutions, light source, probes and reagent cooling. These differences do not impact the safety and performance of CN-6000.

Summary of Performance Testing:

A series of studies were performed that evaluated traditional laboratory performance characteristics. A summary of each study follows:

Method comparison:
Method comparison studies designed according to EP09C, 3rd edition CLSI Guideline were conducted at three clinical sites. Normal, abnormal samples, and samples at the medical decision levels were enrolled in order to adequately capture full spectrum of the analytical measuring interval (AMI). Samples were measured on both the predicate device (Sysmex® CS-5100) and the investigational device, CN-Series (CN-6000). Results were compared by Passing-Bablok regression analysis as well as Bland-Altman analysis. Results from each assay met the pre-established acceptance criteria. The following table shows a summary of Passing-Bablok regression analysis.

Application (AMI)	**Site A**	**Site B**	**Site C**	**Total Combined Sites**
Prothrombin Time with Dade® Innovin® (8.7 – 90.0 seconds)	N = 490 y = 1.012x – 0.134 r = 1.000	N = 168 y = 1.000x r = 0.999	N = 189 y = 1.020x – 0.206 r = 0.997	N = 847 y = 1.010x – 0.100 r = 0.999
Prothrombin Time (INR) with Dade® Innovin® (0.93 – 8.00 INR)	N = 472 y = 1.013x – 0.012 r = 1.000	N = 163 y = 1.000x r = 0.999	N = 178 y = 1.024x – 0.023 r = 0.996	N = 813 y = 1.010x – 0.010 r = 0.999

Application (AMI)	Site A	Site B	Site C	Total Combined Sites
Activated Partial Thromboplastin Time with Dade® Actin® FSL (20.0 – 139.0) seconds)	N = 401 y = 1.000x – 0.100 r = 0.997	N = 126 y = 0.961x + 1.093 r = 0.998	N = 111 y = 0.988x + 0.290 r = 0.994	N = 638 y = 0.993x + 0.088 r = 0.996
Fibrinogen quantitation with Dade® Thrombin Reagent (50 – 860 mg/dL)	N = 225 y = 1.067x + 4.517 r = 0.996	N = 121 y = 1.015x – 9.987 r = 0.998	N = 110 y = 1.077x – 11.731 r = 0.995	N = 456 y = 1.062x – 4.092 r = 0.993
Antithrombin quantitation with INNOVANCE® Antithrombin (9.0 – 128.0% of norm)	N = 221 y = 0.949x + 1.364 r = 0.997	N = 115 y = 0.988x – 2.119 r = 0.998	N = 114 y = 1.028x – 1.879 r = 0.997	N = 450 y = 0.984x – 0.998 r = 0.995
D-dimer quantitation with INNOVANCE® D-Dimer (0.19 – 35.20 mg/L FEU)	N = 194 y = 0.976x – 0.006 r = 0.998	N = 101 y = 0.897x + 0.030 r = 0.999	N = 100 y = 1.015x – 0.005 r = 0.998	N = 395 y = 0.959x + 0.007 r = 0.997

Precision:

Precision studies were conducted over twenty days, two runs per day, and two replicates per run for a total of eighty data points per assay. The study was conducted in accordance with recommendations of CLSI EP05-A3 using commercial QC materials and plasma pools reflecting medical decision levels. The precision data are summarized in the table below.

	Precision within-site					
			Repeatability		Within-Device/Lab Precision	
		Mean	SD [assay unit]	CV (%)	SD [assay unit]	Within Device/Lab CV (%)
Prothrombin Time (seconds) with Dade® Innovin®	Ci-Trol 1	11.0	0.07	0.7	0.08	0.8
	Ci-Trol 2	28.8	0.22	0.8	0.33	1.2
	Ci-Trol 3	46.6	0.36	0.8	0.75	1.6
	Plasma pool 1	10.3	0.07	0.6	0.09	0.9
	Plasma pool 2	15.4	0.09	0.6	0.16	1.0
	Plasma pool 3	19.4	0.1	0.5	0.19	1.0
	Plasma pool 4	38.6	0.09	0.2	0.46	1.2
	Plasma pool 5	49.6	0.18	0.4	0.79	1.6

	Precision within-site					
			Repeatability		Within-Device/Lab Precision	
		Mean	SD [assay unit]	CV (%)	SD [assay unit]	Within Device/Lab CV (%)
	Plasma pool 6	68.5	0.27	0.4	1.2	1.8
Prothrombin Time (INR) with Dade® Innovin®	Ci-Trol 1	1.03	0.007	0.7	0.008	0.8
	Ci-Trol 2	2.91	0.025	0.9	0.037	1.3
	Ci-Trol 3	4.90	0.042	0.9	0.085	1.7
	Plasma pool 1	1.01	0.005	0.5	0.009	0.9
	Plasma pool 2	2.28	0.011	0.5	0.027	1.2
	Plasma pool 3	3.18	0.011	0.4	0.041	1.3
	Plasma pool 4	5.11	0.021	0.4	0.096	1.9
	Plasma pool 5	7.41	0.042	0.6	0.162	2.2
Activated Partial Thromboplastin Time (APTT) (seconds) with Dade® Actin® FSL Activated PTT Reagent	Ci-Trol 1	26.6	0.11	0.4	0.2	0.7
	Ci-Trol 2	49.2	0.24	0.5	0.45	0.9
	Ci-Trol 3	61.2	0.39	0.6	0.74	1.2
	Plasma pool 1	27.9	0.08	0.3	0.18	0.6
	Plasma pool 2	44.4	0.29	0.7	1.15	2.6
	Plasma pool 3	88.8	0.33	0.4	0.63	0.7
	Plasma pool 4	122.3	1.06	0.9	1.64	1.3
Fibrinogen (mg/dL) with Dade® Thrombin Reagent	Ci-Trol 1	267	5.4	2.0	6.3	2.4
	Data-Fi Abnormal Fibrinogen Control	101	3.2	3.2	3.4	3.3
	Control Plasma N	238	5.6	2.4	5.9	2.5
	Control Plasma P	82	5	6.1	5.1	6.2
	Plasma pool 1	62	0.6	1.0	0.9	1.4
	Plasma pool 2	220	3	1.4	4.2	1.9
	Plasma pool 3	412	4.3	1.0	7.6	1.9
	Plasma pool 4	747	7.8	1.0	14.5	1.9
Antithrombin (%) with INNOVANCE® Antithrombin	Control Plasma N	93.5	1.28	1.4	1.45	1.6
	Control Plasma P	31.5	0.66	2.1	0.77	2.5
	Plasma pool 1	17.5	0.78	4.5	0.9	5.2

	Precision within-site					
			Repeatability		Within-Device/Lab Precision	
		Mean	SD [assay unit]	CV (%)	SD [assay unit]	Within Device/Lab CV (%)
	Plasma pool 2	40.9	0.78	1.9	0.79	1.9
	Plasma pool 3	104.0	0.95	0.9	1.85	1.8
	Plasma pool 4	116.3	1.41	1.2	1.91	1.6
D-Dimer (mg/L FEU) with INNOVANCE® D-Dimer	INNOVANCE D-Dimer Control 1	0.27	0.007	2.6	0.009	3.4
	INNOVANCE D-Dimer Control 2	2.46	0.046	1.9	0.078	3.2
	Plasma pool 1	0.19	0.008	4.2	0.011	5.8
	Plasma pool 2	0.48	0.013	2.8	0.022	4.5
	Plasma pool 3	2.46	0.042	1.7	0.08	3.3
	Plasma pool 4	28.62	0.524	1.8	0.919	3.2

Linearity & Measuring Range:

Linearity studies were performed for the following calibrated assays on the CN-series (CN-6000) coagulation analyzer: Fibrinogen with Dade® Thrombin Reagent, Antithrombin with INNOVANCE® Antithrombin, and D-dimer with INNOVANCE® D-Dimer. All reagents met the predetermined acceptance criteria and supported the Analytical Measuring Interval (AMI) claim. Studies were conducted as described in CLSI EP06 2nd Edition.

Application	Measured Linear Range	Analytical Measurement Interval
Prothrombin Time (seconds) with Dade® Innovin®	Not applicable	8.7 – 90.0 seconds
Prothrombin Time (INR) with Dade® Innovin®	Not applicable	0.93 – 8.00 INR
Activated Partial Thromboplastin Time (seconds) with Dade® Actin® FSL	Not applicable	20.0 – 139.0 seconds
Fibrinogen with Dade® Thrombin Reagent	38.4 – 900.2 mg/dL	50 – 860 mg/dL
Antithrombin with INNOVANCE® Antithrombin	7.56 – 130.42 % of norm.	9.0 – 128.0 % of norm.
D-dimer with INNOVANCE® D-Dimer	0.180 – 35.836 mg/L FEU	0.19 – 35.20 mg/L FEU

Interference Studies:

The interference study was performed on the CN-series (CN-6000) analyzer. The study was conducted with one reagent lot and five replicates per sample. All pre-established criteria were met, and the study demonstrated the proposed device has substantially equivalent optical performance related to hemolytic, icteric, lipemic, and Hydroxyethyl Starch (HES) potential interference in samples.

Reagent	Base pool	High Level without Interference				
		Hemoglobin	Conjugated Bilirubin	Unconjugated Bilirubin	Triglycerides	HES
Dade® Innovin® (seconds)	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
	Pathological (Prolonged)	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
Dade® Innovin® (INR)	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
	Pathological (High)	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
Dade® Actin® FSL Activated PTT Reagent	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
	Pathological (Prolonged)	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
Dade® Thrombin Reagent	Pathological (Low)	150 mg/dL	20 mg/dL	15 mg/dL	605 mg/dL	25.9 g/L
	Normal	561 mg/dL	44 mg/dL	66 mg/dL	605 mg/dL	31.4 g/L
	Pathological (High)	561 mg/dL	44 mg/dL	66 mg/dL	605 mg/dL	31.4 g/L
INNOVANCE® Antithrombin	Pathological (Low)	1100 mg/dL	44 mg/dL	66 mg/dL	495 mg/dL	-
	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	495 mg/dL	-
INNOVANCE® D-Dimer	Normal (Low)	1100 mg/dL	44 mg/dL	66 mg/dL	715 mg/dL	-
	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	715 mg/dL	-
	Pathological (High)	1100 mg/dL	44 mg/dL	66 mg/dL	715 mg/dL	-

Reagent Carryover:

This study has been designed in accordance with CLSI guidelines H57-A and EP10-A3-AMD. Two reagent lots were analyzed on the CN-series (CN-6000) analyzer. All results met the specified criteria, and the study showed that there was no reagent carryover effects from one application to another on the Automated Blood Coagulation Analyzer CN-6000.

Sample Carryover:

The sample carryover study evaluated the effects of possible contamination from one sample to the other and confirmed that the aspiration and washing of the sample probe on the CN series (CN-6000) reduces the likelihood of carryover contamination to negligible levels. The results of the sample carryover study met all specified criteria for PT, APTT, Fibrinogen, Antithrombin, and D-dimer quantitation assays.

Limit of Blank/Detection/Quantitation

The Limit of Blank study was designed in accordance with CLSI guideline EP17-A2 and CLSI guideline EP39-ED1. The studies were carried out on one analyzer with three calibrated assays, two different reagent lots, five replicates per run per day over three days for a total of 15 measurements per analyte-free (LOB) and low analyte (LOD/LOQ) samples.

Application	Measured LoB and LoD	Measured LoQ
Fibrinogen with Dade® Thrombin Reagent	Not applicable	LoQ – 36.1 mg/dL
Antithrombin with INNOVANCE® Antithrombin	LoB – 2.21% of norm. LoD – 2.95% of norm.	LoQ – 8.31% of norm.
D-Dimer with INNOVANCE® D-Dimer	LoB – 0.085 mg/L FEU LoD – 0.101 mg/L FEU	0.182 mg/L FEU

Factor Sensitivity (PT, APTT):

The factor sensitivity study was conducted in accordance with CLSI guideline H47 Ed3. Reagent sensitivity to factors V and VII was performed using two lots of Dade® Innovin®, and reagent sensitivity to factors VIII and IX was performed using two lots of Dade® Actin® FSL. The calculated factor sensitivity results were as follows:

Factor V: 40.8% - 44.5%
Factor VII: 45.8% - 48.3%
Factor VIII: 40.2% - 42.8%
Factor IX: 33.2%

Heparin Sensitivity (APTT):

A Heparin sensitivity study was conducted for APTT assay to assess instrument performance. Samples from patients receiving unfractionated heparin (UFH) therapy were measured with both the CN-6000 and CS-5100 coagulation analyzers using two APTT reagent lots. Passing-Bablok analysis for two lots yielded the following correlation.

- Lot 1: n = 56, y = 1.000x - 0.200, r = 0.9993
- Lot 2: n = 56, y = 0.981x - 0.313, r = 0.9995

Lupus Anticoagulant (LA) Sensitivity Study:

The LA sensitivity study was performed in-house evaluating 2 lots of Dade® Actin® FSL reagent on a total of 24 LA positive samples. The results for the study met the specified criteria.

Stability:

Reagents & Buffer Stability
Reagent stability was assessed for Dade® Innovin®, Dade® Actin® FSL, Dade® Thrombin, INNOVANCE® Antithrombin, INNOVANCE® D-Dimer, and Dade® Owren's Veronal Buffer. The manufacturer's claim for onboard stability for all reagents was met.

QC Stability
Studies were designed in accordance with CLSI guideline EP25. The manufacturer's claim for onboard stability for all QC materials was met.

High Dose Hook Effect
This study was designed in accordance with CLSI guideline EP34-ED1. The study was conducted with one reagent lot on one analyzer. The delta Optical Density, dOD, of each measurement, the presence of the antigen excess flag, and whether the instrument performed an automatic redilution (samples measuring 4.4mg/L FEU or less) were recorded for each sample.

The pre-established acceptance criterion of appropriate instrument flagging with "antigen excess", and no likelihood of reporting an erroneously low result due to High Dose Hook effect up to 500 mg/L FEU was confirmed. Therefore, the acceptance criterion was met for this study.

Matrix Comparison (Bridging Studies):

Auto-Dilution vs Manual Dilution:
The Auto-Dilution versus Manual dilution study performed on the CN-Series (CN-6000). Testing was performed for fibrinogen with Dade® Thrombin Reagent and D-Dimer with INNOVANCE® D-Dimer. A minimum of three samples per assay were tested, with five replicates per sample over three days. The pre-defined acceptance criteria were met for this study.

Uncapped Specimens vs Capped Specimens:
The objective of the uncapped versus capped specimens study was to determine equivalence of Prothrombin time (PT) with Dade® INNOVIN®, Activated partial thromboplastin time (APTT) with Dade® Actin® FSL, Fibrinogen with Dade® Thrombin Reagent, Antithrombin (AT) with INNOVANCE® Antithrombin and D-Dimer with INNOVANCE® D-Dimer results obtained from open (i.e., uncapped) blood collection tube samples versus closed (i.e., capped) blood collection tube samples. The pre-defined acceptance criteria were met.

Frozen Specimens vs Fresh Specimens:
The objective of the frozen versus fresh specimens study was to determine equivalency of

Prothrombin time (PT) with Dade® INNOVIN®, Activated partial thromboplastin time (APTT) with Dade® Actin® FSL, Fibrinogen with Dade® Thrombin Reagent, Antithrombin (AT) with INNOVANCE® Antithrombin and D-Dimer with INNOVANCE® D-Dimer results obtained from frozen human citrated plasma versus fresh human citrated plasma on the CN-6000 analyzer. The results for this study were determined to be acceptable.

Micro Mode vs Normal Mode Analysis:
The objective of the micro mode analysis versus normal mode analysis study was to assess comparability of Prothrombin time (PT) with Dade® INNOVIN®, Activated partial thromboplastin time (APTT) with Dade® Actin® FSL, Fibrinogen with Dade® Thrombin Reagent, Antithrombin (AT) with INNOVANCE® Antithrombin and D-Dimer with INNOVANCE® D-Dimer results measured in the micro mode and normal mode sample processing on the CN-6000 analyzer. The pre-established acceptance criteria were met.

Reference Range:
The Reference Interval study was designed to establish the normal reference ranges on the CN-Series (CN-6000) analyzer for the adult population using Dade® Innovin®, Dade® Actin® FSL, Dade® Thrombin, INNOVANCE® Antithrombin, and INNOVANCE® D-Dimer reagents. The study was conducted at three external clinical sites within the United States using adult samples.

Assay	Reference Interval
	Sysmex® CN-6000
Prothrombin Time (seconds) using Dade® Innovin	2.5^{th} – 97.5^{th} 9.9 – 12.3 (sec)
Prothrombin Time (INR) using Dade® Innovin	2.5^{th} – 97.5^{th} 0.93 – 1.16 (INR)
Activated Partial Thromboplastin Time using Dade® Actin® FSL	2.5^{th} – 97.5^{th} 23.8 – 32.0 (sec)
Fibrinogen quantitation using Dade® Thrombin Reagent	2.5^{th} – 97.5^{th} 192 – 440 (mg/dL)
Antithrombin quantitation using Dade® Thrombin Reagent	2.5^{th} – 97.5^{th} 83.7 – 121.6 (%)
D-Dimer quantitation using INNOVANCE® D-Dimer	minimum – 97.5^{th} < 0.19 – 1.27 (mg/L FEU)

Conclusion:
The CN-series (CN-6000) is similar to the CS-5100 in its intended use and system technological characteristics. There are minor differences in the number of probes, light source for the CN-series, rinse & buffer cleaning solutions, reagent cooling temperature and number of sample racks.

The list of assays used with the CN-series is the same as with the previously cleared assays in the CS-5100 (K150678).

The technological characteristics and operating principles of the CN-series are essentially the same as the predicate CS-5100. In addition, performance testing did not raise any issues with safety and effectiveness of the CN-series when compared with the CS-5100 instrument.

The data from the analytical and clinical testing supports that the CN-series (CN-6000) instrument is substantially equivalent to the previously cleared CS-5100 instrument (K150678), and the device is safe and effective for its intended use.