510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K250965

B Applicant

Sysmex America, Inc.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JPA	Class II	21 CFR 864.5425 - Multipurpose System For In Vitro Coagulation Studies	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New automated coagulation analyzer evaluated with previously cleared assays

B Type of Test:

Quantitative coagulation tests

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The CN-Series (CN-6000) Automated Blood Coagulation Analyzer is a fully automated blood coagulation analyzer composed of a Main Unit, Information Processing Unit and Pneumatic Unit. The CN-Series (CN-6000) is for in vitro diagnostic use in clinical laboratories that can analyze a large volume of samples. The analyzer can analyze venous plasma samples collected in 3.2% sodium citrate. The instrument is capable of measuring the assays in a normal mode and a microsample mode. Results are displayed on the Information Processing Unit (IPU) screen and can be printed on external printers or transmitted to a host computer.

B Principle of Operation:

The CN-Series (CN-6000) is an automated blood coagulation instrument which can analyze samples using clotting, chromogenic and immunoassay methods. It performs testing analysis using mechanical, hydraulic, and electrical systems. The instrument uses associated reagents, controls, calibrators, and consumable materials to perform Prothrombin Time (PT) seconds and INR, Activated Partial Thromboplastin Time (APTT), Fibrinogen, Antithrombin, and D-dimer.

Sysmex CN-6000 Analysis Principles

Assay	Analyte	Methodology
Dade Innovin (K974343)	PT, Prothrombin Time (seconds)	Clotting (extrinsic pathway)
	PT, Prothrombin Time (INR)	Clotting, calculated
Dade Actin FSL (K863594)	APTT, Activated Partial Thromboplastin Time	Clotting (intrinsic pathway)
Dade Thrombin Reagent (K050928)	Fibrinogen quantitation	Clotting (common pathway)
INNOVANCE Antithrombin (K081769)	Antithrombin quantitation	Chromogenic
INNOVANCE D-Dimer (K093626)	D-dimer quantitation	Immunochemical

- Clotting method: Turbidity changes when fibrinogen is transformed into fibrin. This turbidity change is optically detected.
- Chromogenic method: Process of color emission by a chromogenic synthetic substrate based on the light absorbance change.
- Immunoassay method: Process of antibody-sensitive reagent reacting with antibodies based on the light absorbance change.

C Instrument Description Information:

1. Instrument Name:

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

2. Specimen Identification:

   Specimen identification can be identified manually or by a barcode reader.

3. Specimen Sampling and Handling:

   Automatic pipetting of a specimen in a normal mode and in a micro mode

4. Calibration:

   Calibration is an automated function of the CN-Series (CN-6000) coagulation analyzer. Reagents that require calibration are described in the reagent package insert.

5. Quality Control:

   The analyzer has two types of control methods: X-Bar control and L-J control, which are software tools used to monitor the performance of the instrument and reagents on a daily basis by analyzing samples with known values (quality control materials for each assay).

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sysmex Automated Blood Coagulation Analyzer CS-5100

B Predicate 510(k) Number(s):
K150678

C Comparison with Predicate(s):

Device & Predicate Device(s):	K250965	K150678
Device Trade Name	Automated Blood Coagulation Analyzer CN-Series (CN-6000)	Sysmex Automated Blood Coagulation Analyzer CS-5100

General Device Characteristic Similarities		
Intended Use/Indications For Use	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.	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.
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	Same

	Antithrombin	
	Immunoassay Application: D-dimer with INNOVANCE D-Dimer	Same
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
Bar code reader	Reagent and sample	Same
Liquid Level Sensing	Reagent and Sample	Same
Sampling Capabilities	Normal and Micro Mode	Same
Reagent Mixing	Automatic	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
General Device Characteristic Differences		
Cleaning Solution On-Board External	CN-Coagwasher	CA-Clean I CA-clean II Dade Owren's Buffer Water
Light Source	LED	Chromogenic & Immunochemical: Halogen Lamp
Probes	2 sample probes 2 reagent probes	2 sample probes 3 reagent probes
Reagent Cooling	4–12°C when the ambient temperature is 15 –28°C; 4–15°C when the ambient temperature is 28–30°C.	10±2°C when the ambient temperature is 20–28°C. 4–15°C when the ambient temperature is 15–20°C or 28–30 °C.
Sampler	5 sample racks can be set simultaneously	10 sample racks can be set simultaneously

VI Standards/Guidance Documents Referenced:

- CLSI EP06: Evaluation of the Linearity of Quantitative Measurement Procedures - Second Edition
- CLSI EP05-A3 (2014): Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP07: Interference Testing in Clinical Chemistry - Third Edition
- CLSI EP17-A2 (2012): Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second edition
- CLSI EP28-A3c (2010): Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition
- CLSI H47: One-Stage Prothrombin Time (PT) test and Activated Partial Thromboplastin time (APTT) Test - Third Edition
- IEC 60601-1-2 (2007): Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- IEC 61326-1 Edition 3.0 2020-10 electrical equipment for measurement control and laboratory use – EMC requirements Part 1: General requirements
- IEC 62471 First edition 2006: Photobiological safety of lamps and lamp systems
- ANSI AAMI IEC 62304:2006/A1:2016: Medical device software – software life cycle processes

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability (Within-lab)

A single site precision study was conducted with the 20 x 2 x 2 study design: testing each sample for 20 days with two replicates per run and two runs per day using one analyzer. Commercial quality control materials and human citrated plasma pools reflecting medical decision levels were used. Testing was performed with the PT (seconds), PT/INR, APTT, Fibrinogen, Antithrombin, and D-Dimer assays on one Sysmex CN-6000 instrument and one reagent lot using both normal mode and micro mode sampling.

Assay and Analyte List

Assay	Analyte
Dade Innovin (K974343)	PT, Prothrombin Time (seconds)
	PT, Prothrombin Time (INR)
Dade Actin FSL (K863594)	APTT, Activated Partial Thromboplastin Time
Dade Thrombin Reagent (K050928)	Fibrinogen quantitation
INNOVANCE Antithrombin (K081769)	Antithrombin quantitation
INNOVANCE D-Dimer (K093626)	D-dimer quantitation

Single-site Precision Result Summary (Normal Mode)

Analyte/Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT (seconds)	Plasma Pool 1	90	10.28	0.07	0.63	0.02	0.22	0.06	0.56	0.09	0.88
	Ci-Trol 1	90	10.96	0.07	0.65	0.03	0.31	0.03	0.29	0.08	0.77
	Plasma pool 2	90	15.38	0.09	0.57	0.03	0.21	0.13	0.84	0.16	1.04
	Plasma pool 3	90	19.36	0.10	0.51	0.09	0.45	0.13	0.69	0.19	0.97
	Ci-Trol 2	90	28.75	0.22	0.76	0.15	0.52	0.20	0.71	0.33	1.16
	Plasma Pool 4	90	38.56	0.09	0.23	0.24	0.61	0.38	0.99	0.46	1.19
	Ci-Trol 3	90	46.61	0.36	0.77	0.50	1.07	0.43	0.91	0.75	1.60
	Plasma Pool 5	90	49.57	0.18	0.37	0.50	1.00	0.59	1.19	0.79	1.60
	Plasma Pool 6	90	68.46	0.27	0.40	0.69	1.01	0.94	1.37	1.20	1.75
PT (INR)	Plasma Pool 1	90	1.01	0.01	0.52	0.01	0.57	0.00	0.42	0.01	0.88
	Ci-Trol 1	90	1.03	0.01	0.69	0.00	0.33	0.00	0.31	0.01	0.82
	Plasma Pool 2	90	2.28	0.01	0.49	0.01	0.48	0.02	0.98	0.03	1.19
	Ci-Trol 2	90	2.91	0.02	0.85	0.02	0.51	0.02	0.81	0.04	1.28
	Plasma Pool 3	90	3.18	0.01	0.36	0.02	0.73	0.03	1.02	0.04	1.30
	Ci-Trot 3	90	4.90	0.04	0.85	0.06	1.16	0.05	0.97	0.09	1.74
	Plasma Pool 4	90	5.11	0.02	0.41	0.06	1.10	0.07	1.46	0.10	1.87
	Plasma Pool 5	90	7.41	0.04	0.57	0.10	1.28	0.13	1.68	0.16	2.19
APTT (seconds)	Plasma Pool 1	90	26.55	0.11	0.43	0.13	0.47	0.10	0.37	0.20	0.74
	Ci-Trol 1	90	27.93	0.08	0.29	0.16	0.57	0.00	0.00	0.18	0.64
	Plasma Pool 2	90	44.38	0.29	0.66	1.04	2.33	0.41	0.93	1.15	2.60
	Ci-Trol 2	90	49.21	0.24	0.48	0.38	0.77	0.00	0.00	0.45	0.91
	Ci-Trol 3	90	61.24	0.39	0.64	0.63	1.03	0.00	0.00	0.74	1.21
	Plasma Pool 3	90	88.78	0.33	0.37	0.49	0.56	0.22	0.25	0.63	0.71
	Plasma Pool 4	90	122.27	1.06	0.87	1.25	1.02	0.00	0.00	1.64	1.34
Fibrinogen (mg/dL)	Plasma Pool 1	90	61.70	0.60	1.03	0.60	0.99	0.00	0.00	0.90	1.43
	Control Plasma P	90	81.70	5.00	6.11	0.00	0.00	1.00	1.20	5.10	6.22
	Data-Fi Abnormal Fibrinogen Control	90	101.00	3.20	3.17	1.10	1.04	0.00	0.00	3.40	3.34
	Plasma Pool 2	90	220.20	3.00	1.35	2.90	1.31	0.00	0.00	4.20	1.89
	Control Plasma N	90	237.60	5.60	2.35	1.90	0.79	0.00	0.00	5.90	2.48
	Ci-Trol 1	90	266.50	5.40	2.04	2.40	0.91	2.00	0.77	6.30	2.36
	Plasma Pool 3	90	412.40	4.30	1.04	6.10	1.48	1.70	0.40	7.60	1.85
	Plasma Pool 4	90	747.00	7.80	1.04	12.20	1.63	0.00	0.00	14.50	1.94
Antithrombin (% of norm)	Plasma Pool 1	90	17.46	0.78	4.49	0.00	0.00	0.44	2.55	0.90	5.16
	Control Plasma P	90	31.52	0.66	2.11	0.35	1.11	0.18	0.56	0.77	2.45
	Plasma Pool 2	90	39.60	0.78	1.91	0.00	0.00	0.09	0.22	0.79	1.92
	Control Plasma N	90	40.90	1.28	1.36	0.00	0.00	0.69	0.74	1.45	1.55
	Plasma Pool 3	90	93.52	0.95	0.92	1.33	1.28	0.86	0.83	1.85	1.78
	Plasma Pool 4	90	116.30	1.41	1.22	1.28	1.10	0.00	0.00	1.91	1.64
D-Dimer (mg/L FEU)	Plasma Pool 1	90	0.19	0.01	4.24	0.00	0.00	0.01	3.88	0.01	5.75
	INNOVANCE D-Dimer Control 1	90	0.27	0.01	2.61	0.01	2.16	0.00	0.00	0.01	3.39
	Plasma Pool 2	90	0.48	0.01	2.80	0.01	1.54	0.02	3.23	0.02	4.54
	Plasma Pool 3	90	2.46	0.05	1.89	0.06	2.51	0.01	0.27	0.08	3.16
	INNOVANCE D-Dimer Control 2	90	2.46	0.04	1.70	0.07	2.70	0.02	0.67	0.08	3.26

Analyte/Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
	Plasma Pool 4	90	28.62	0.52	1.83	0.67	2.32	0.36	1.25	0.92	3.21

Single-site Precision Result Summary (Micro Mode)

Analyte/Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT (seconds)	Plasma Pool 1	90	10.26	0.05	0.51	0.05	0.46	0.05	0.45	0.08	0.82
	Ci-Trol 1	90	10.94	0.06	0.59	0.04	0.40	0.01	0.12	0.08	0.72
	Plasma pool 2	90	15.31	0.07	0.44	0.05	0.31	0.12	0.77	0.14	0.94
	Plasma pool 3	90	19.22	0.10	0.53	0.07	0.34	0.11	0.59	0.17	0.86
	Ci-Trol 2	90	28.62	0.19	0.67	0.12	0.42	0.19	0.68	0.30	1.04
	Plasma Pool 4	90	38.82	0.08	0.21	0.31	0.80	0.38	0.98	0.50	1.29
	Ci-Trol 3	90	46.30	0.30	0.65	0.63	1.36	0.33	0.72	0.77	1.67
	Plasma Pool 5	90	49.16	0.29	0.59	0.40	0.81	0.71	1.45	0.87	1.76
	Plasma Pool 6	90	67.80	0.35	0.52	0.64	0.94	1.04	1.53	1.27	1.87
PT (INR)	Plasma Pool 1	90	1.01	0.01	0.59	0.01	0.52	0.01	0.48	0.01	0.92
	Ci-Trol 1	90	1.02	0.01	0.63	0.00	0.42	0.00	0.13	0.01	0.77
	Plasma Pool 2	90	2.27	0.01	0.56	0.01	0.52	0.01	0.78	0.02	1.09
	Ci-Trol 2	90	2.89	0.02	0.71	0.01	0.49	0.02	0.71	0.03	1.11
	Plasma Pool 3	90	3.16	0.02	0.56	0.02	0.89	0.02	0.76	0.04	1.30
	Ci-Trot 3	90	4.87	0.04	0.73	0.07	1.47	0.04	0.78	0.09	1.82
	Plasma Pool 4	90	5.07	0.03	0.61	0.06	1.26	0.06	1.16	0.09	1.82
	Plasma Pool 5	90	7.34	0.04	0.55	0.10	1.32	0.10	1.32	0.14	1.94
APTT (seconds)	Plasma Pool 1	90	26.40	0.10	0.36	0.14	0.53	0.08	0.30	0.19	0.71
	Ci-Trol 1	90	27.80	0.06	0.21	0.14	0.51	0.06	0.23	0.16	0.59
	Plasma Pool 2	90	43.16	0.25	0.59	0.90	2.09	0.00	0.00	0.94	2.17
	Ci-Trol 2	90	48.88	0.25	0.51	0.44	0.91	0.00	0.00	0.51	1.04
	Ci-Trol 3	90	61.06	0.40	0.66	0.71	1.16	0.00	0.00	0.82	1.34
	Plasma Pool 3	90	88.51	0.40	0.45	0.46	0.52	0.00	0.00	0.61	0.69
	Plasma Pool 4	90	120.38	1.33	1.11	0.59	0.49	0.00	0.00	1.46	1.21
Fibrinogen (mg/dL)	Plasma Pool 1	90	61.40	0.70	1.21	1.3	2.05	0.0	0.00	1.50	2.38
	Control Plasma P	90	79.10	5.40	6.87	0.0	0.00	0.6	0.81	5.50	6.92
	Data-Fi Abnormal Fibrinogen Control	90	103.00	3.40	3.34	1.20	1.13	0.00	0.00	3.60	3.53
	Plasma Pool 2	90	221.40	2.50	1.15	2.70	1.22	0.70	0.33	3.80	1.71
	Control Plasma N	90	240.20	4.00	1.67	3.20	1.33	1.40	0.58	5.30	2.22
	Ci-Trol 1	90	268.40	5.90	2.18	4.30	1.59	1.00	0.36	7.30	2.72
	Plasma Pool 3	90	412.60	5.50	1.33	5.20	1.26	2.00	0.49	7.80	1.90
	Plasma Pool 4	90	760.50	9.30	1.22	11.60	1.52	0.00	0.00	14.80	1.95
Antithrombin (% of norm)	Plasma Pool 1	90	18.10	0.74	4.11	0.41	2.26	0.00	0.00	0.85	4.68
	Control Plasma P	90	32.12	0.54	1.68	0.49	1.52	0.28	0.87	0.78	2.42
	Plasma Pool 2	90	41.65	0.52	1.26	0.45	1.09	0.32	0.76	0.76	1.83
	Control Plasma N	90	95.78	0.83	0.86	1.08	1.12	0.67	0.70	1.51	1.58
	Plasma Pool 3	90	106.46	0.74	0.69	1.47	1.39	0.29	0.28	1.67	1.57
	Plasma Pool 4	90	119.08	1.42	1.19	0.57	0.48	0.09	0.07	1.53	1.28
D-dimer	Plasma Pool 1	90	0.19	0.01	2.46	0.00	0.00	0.00	4.08	0.01	4.76

Analyte/Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Within-Laboratory	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV
(mg/L FEU)	INNOVANCE D-Dimer Control l	90	0.27	0.01	1.83	0.00	0.82	0.00	1.59	0.01	2.56
	Plasma Pool 2	90	0.48	0.01	2.18	0.01	1.32	0.02	3.49	0.02	4.32
	Plasma Pool 3	90	2.47	0.02	0.96	0.07	2.70	0.00	0.00	0.07	2.87
	INNOVANCE D-Dimer Control 2	90	2.47	0.04	1.47	0.06	2.38	0.00	0.00	0.07	2.80
	Plasma Pool 4	90	28.90	0.65	2.24	0.60	2.06	0.32	1.10	0.94	3.23

Reproducibility

The reproducibility study was performed at three clinical sites evaluating repeatability, between-run, between-day, between-site and reproducibility, using commercial QC materials and plasma pools reflecting medical decision levels in accordance with CLSI EP05-A3. Each sample was tested with three replicates per run, two runs per day for 5 days (5 x 2 x 3). Testing was performed with the PT (seconds), PT/INR, APTT, Fibrinogen, Antithrombin, and D-Dimer assays on one Sysmex CN-6000 instrument and one reagent lot per site using both normal mode and micro mode sampling.

Reproducibility Results Summary (Normal Mode)

Analyte/ Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT (seconds)	Plasma Pool 1	90	10.30	0.06	0.58	0.09	0.88	0.00	0.00	0.02	0.21	0.11	1.07
	Ci-Trol 1	90	11.10	0.08	0.72	0.06	0.56	0.03	0.24	0.07	0.61	0.12	1.12
	Plasma pool 2	90	15.30	0.06	0.40	0.15	0.99	0.03	0.17	0.05	0.30	0.17	1.12
	Plasma pool 3	90	19.00	0.10	0.54	0.19	1.02	0.04	0.23	0.10	0.55	0.25	1.30
	Ci-Trol 2	90	25.70	0.14	0.56	0.16	0.63	0.21	0.83	0.16	0.63	0.34	1.34
	Plasma Pool 4	90	36.40	0.08	0.23	0.34	0.92	0.26	0.71	0.48	1.32	0.65	1.77
	Ci-Trol 3	90	42.20	0.25	0.60	0.32	0.76	0.44	1.05	0.00	0.00	0.60	1.43
	Plasma Pool 5	90	47.00	0.25	0.53	0.70	1.49	0.45	0.95	0.15	0.32	0.88	1.87
	Plasma Pool 6	90	64.10	0.37	0.57	1.53	2.38	0.40	0.62	0.52	0.81	1.70	2.65
PT (INR)	Plasma Pool 1	90	1.00	0.01	0.56	0.01	0.86	0.00	0.37	0.02	2.14	0.02	2.41
	Ci-Trol 1	90	1.04	0.01	0.77	0.01	0.60	0.00	0.26	0.02	2.03	0.02	2.27
	Plasma Pool 2	90	2.24	0.01	0.30	0.02	0.74	0.02	0.79	0.05	2.40	0.06	2.65
	Ci-Trol 2	90	2.63	0.02	0.62	0.02	0.69	0.02	0.92	0.05	1.71	0.06	2.15
	Plasma Pool 3	90	3.13	0.01	0.45	0.04	1.33	0.03	0.93	0.06	2.04	0.08	2.64
	Ci-Trol 3	90	4.57	0.03	0.68	0.04	0.84	0.06	1.27	0.10	2.27	0.13	2.82
	Plasma Pool 4	90	4.99	0.03	0.54	0.08	1.57	0.07	1.45	0.07	1.36	0.13	2.59
	Plasma Pool 5	90	7.31	0.04	0.50	0.15	2.09	0.11	1.53	0.16	2.17	0.25	3.41
APTT (seconds)	Plasma Pool 1	90	27.00	0.07	0.25	0.17	0.62	0.00	0.00	0.15	0.54	10.23	0.86
	Ci-Trol 1	90	27.00	0.09	0.33	0.20	0.73	0.23	0.87	0.00	0.00	0.32	1.18
	Plasma Pool 2	90	42.90	0.26	0.61	0.90	2.10	0.00	0.00	0.77	1.80	1.22	2.83
	Ci-Trol 2	90	45.00	0.24	0.53	0.35	0.78	0.00	0.00	0.16	0.36	0.46	1.01
	Ci-Trol 3	90	59.10	0.45	0.76	0.50	0.84	0.23	0.39	0.25	0.43	0.75	1.27
	Plasma Pool 3	90	85.10	0.33	0.38	0.33	0.38	0.21	0.24	0.15	0.18	0.53	0.62
	Plasma Pool 4	90	121.20	1.08	0.89	1.33	1.10	0.00	0.00	0.00	0.00	1.72	1.42

Analyte/ Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Fibrinogen (mg/dL)	Plasma Pool 1	90	63	0.70	1.14	1.40	2.17	0.6	1.01	3.50	5.65	3.9	6.25
	Control Plasma P	90	83	3.10	3.75	0.60	0.75	0.00	0.00	2.60	3.13	4.1	4.95
	Data-Fi Abnormal Fibrinogen Control	90	106	3.20	2.96	2.10	2.02	0.70	0.62	6.00	5.63	7.10	6.70
	Plasma Pool 2	90	228	3.30	1.44	3.70	1.64	0.00	0.00	15.00	6.57	15.8	6.93
	Control Plasma N	90	244	4.70	1.94	2.80	1.13	0.00	0.00	13.60	5.57	14.6	6.00
	Ci-Trol 1	90	249	4.10	1.67	4.90	1.98	4.30	1.72	11.40	4.59	13.8	5.55
	Plasma Pool 3	90	416	4.90	1.17	3.80	0.92	4.10	0.98	15.90	3.83	17.6	4.22
	Plasma Pool 4	90	741	8.70	1.17	11.40	1.54	6.50	0.88	27.30	3.68	31.5	4.25
Antithrombin (% of norm)	Plasma Pool 1	90	17.80	0.64	3.62	0.19	1.07	0.45	2.52	0.73	4.10	1.09	6.12
	Control Plasma P	90	29.80	0.68	2.27	0.00	0.00	0.57	1.91	0.68	2.27	1.11	3.74
	Plasma Pool 2	90	39.40	0.56	1.42	1.06	2.70	0.00	0.00	0.00	0.00	1.20	3.05
	Control Plasma N	90	90.80	1.10	1.21	1.06	1.17	0.22	0.24	1.59	1.75	2.22	2.44
	Plasma Pool 3	90	101.80	1.13	1.11	1.27	1.25	0.32	0.31	1.76	1.73	2.47	2.42
	Plasma Pool 4	90	114.70	1.38	1.20	1.33	1.16	0.68	0.60	1.28	1.11	2.40	2.09
D-Dimer (mg/L FEU)	Plasma Pool 1	90	0.22	0.01	3.85	0.01	2.39	0.00	0.00	0.01	5.27	0.02	6.95
	INNOVANCE D-Dimer Control l	90	0.29	0.007	2.42	0.00	1.10	0.01	2.10	0.00	0.00	0.01	3.39
	Plasma Pool 2	90	0.46	0.02	4.60	0.01	2.73	0.001	1.56	0.02	4.29	0.03	7.03
	Plasma Pool 3	90	2.50	0.07	2.67	0.07	2.67	0.03	1.34	0.02	0.96	0.10	4.12
	INNOVANCE D-Dimer Control 2	90	2.54	0.06	2.44	0.11	4.48	0.05	1.98	0.05	1.83	0.15	5.77
	Plasma Pool 4	90	29.61	1.05	3.53	1.05	3.53	0.00	0.00	0.00	0.00	1.48	4.99

Reproducibility Results Summary (Micro Mode)

Analyte/ Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
PT (seconds)	Plasma Pool 1	90	10.30	0.06	0.58	0.10	0.92	0.00	0.00	0.00	0.00	0.11	1.09
	Ci-Trol 1	90	11.10	0.06	0.58	0.04	0.39	0.02	0.21	0.06	0.52	0.10	0.90
	Plasma pool 2	90	15.30	0.08	0.52	0.13	0.82	0.06	0.40	0.06	0.39	0.17	1.12
	Plasma pool 3	90	19.00	0.10	0.51	0.20	1.07	0.05	0.26	0.05	0.27	0.24	1.24
	Ci-Trol 2	90	25.60	0.18	0.69	0.22	0.86	0.12	0.47	0.11	0.42	0.32	1.27
	Plasma Pool 4	90	36.70	0.07	0.20	0.37	1.00	0.30	0.82	0.46	1.25	0.66	1.81
	Ci-Trol 3	90	41.90	0.27	0.65	0.48	1.15	0.30	0.72	0.11	0.25	0.64	1.52
	Plasma Pool 5	90	46.70	0.30	0.64	0.71	1.53	0.39	0.84	0.09	0.20	0.87	1.87
	Plasma Pool 6	90	63.80	0.32	0.51	1.36	2.12	0.75	1.17	0.00	0.00	1.58	2.48
PT (INR)	Plasma Pool 1	90	1.00	0.01	0.62	0.01	0.89	0.00	0.26	0.02	2.08	0.02	2.35
	Ci-Trol 1	90	1.03	0.01	0.62	0.00	0.42	0.00	0.23	0.02	1.96	0.02	2.11
	Plasma Pool 2	90	2.24	0.01	0.35	0.03	1.17	0.01	0.63	0.06	2.63	0.07	2.96
	Ci-Trol 2	90	2.62	0.02	0.75	0.03	0.96	0.02	0.56	0.05	1.98	0.06	2.40
	Plasma Pool 3	90	3.11	0.01	0.47	0.05	1.68	0.02	0.67	0.07	2.27	0.09	2.94
	Ci-Trot 3	90	4.54	0.03	0.71	0.059	1.29	0.04	0.79	0.10	2.14	0.12	2.72
	Plasma Pool 4	90	4.94	0.03	0.55	0.096	1.95	0.074	1.51	0.08	1.70	0.15	3.04
	Plasma Pool 5	90	7.26	0.04	0.56	0.178	2.46	0.071	0.98	0.16	2.24	0.255	3.51
APTT (seconds)	Plasma Pool 1	90	26.80	0.11	0.40	0.21	0.79	0.08	0.32	0.00	0.00	0.25	0.94
	Ci-Trol 1	90	26.90	0.08	0.30	0.21	0.78	0.00	0.00	0.16	0.60	0.28	1.03

Analyte/ Assay	Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Between-Site/Instrument		Reproducibility	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
	Plasma Pool 2	90	42.20	0.28	0.67	1.15	2.72	0.00	0.00	0.52	1.23	1.29	3.06
	Ci-Trol 2	90	44.90	0.27	0.61	0.27	0.60	0.08	0.18	0.20	0.45	0.44	0.98
	Ci-Trol 3	90	58.70	0.72	1.23	0.58	0.99	0.12	0.21	0.28	0.48	0.97	1.66
	Plasma Pool 3	90	84.80	0.46	0.55	0.41	0.49	0.00	0.00	0.22	0.26	0.66	0.78
	Plasma Pool 4	90	120.4	1.05	0.87	1.16	0.96	0.06	0.05	0.95	0.79	1.83	1.52
Fibrinogen (mg/dL)	Plasma Pool 1	90	63	1.00	1.51	2.00	3.10	0.70	1.13	4.10	6.49	4.70	7.44
	Control Plasma P	90	85	3.40	4.02	2.10	2.53	0.00	0.00	5.30	6.30	6.70	7.89
	Data-Fi Abnormal Fibrinogen Control	90	111	3.50	3.16	1.60	1.45	0.00	0.00	11.10	10.02	11.80	10.61
	Plasma Pool 2	90	230	4.10	1.77	5.80	2.50	2.50	1.08	19.00	8.27	20.50	8.88
	Control Plasma N	90	252	5.30	2.08	3.30	1.32	0.00	0.00	19.10	7.58	20.10	7.97
	Ci-Trol 1	90	257	6.80	2.63	4.70	1.82	4.00	1.55	18.10	7.03	20.30	7.88
	Plasma Pool 3	90	417	8.60	2.05	17.10	4.10	7.80	1.88	21.30	5.12	29.70	7.12
	Plasma Pool 4	90	762	18.30	2.40	12.20	1.60	9.40	1.23	52.00	6.83	57.30	7.51
Antithrombin (% of norm)	Plasma Pool 1	90	17.50	0.52	2.99	0.34	1.95	0.27	1.57	0.70	4.00	0.98	5.58
	Control Plasma P	90	29.90	0.67	2.25	0.49	1.63	0.30	0.99	0.51	1.72	1.02	3.41
	Plasma Pool 2	90	39.60	0.53	1.34	1.30	3.29	0.00	0.00	0.00	0.00	1.41	3.55
	Control Plasma N	90	91.20	0.97	1.06	0.91	1.00	0.00	0.00	1.60	1.76	2.08	2.28
	Plasma Pool 3	90	102.7	1.19	1.16	1.42	1.38	0.65	0.63	1.68	1.64	2.59	2.52
	Plasma Pool 4	90	115.5	1.39	1.20	2.28	1.97	0.00	0.00	0.92	0.79	2.82	2.44
D-Dimer (mg/L FEU)	Plasma Pool 1	90	0.22	0.01	4.33	0.00	1.78	0.00	0.75	0.01	4.48	0.01	6.52
	INNOVANCE D-Dimer Control l	90	0.29	0.01	2.40	0.00	1.10	0.01	2.57	0.00	0.00	0.01	3.68
	Plasma Pool 2	90	0.46	0.02	3.25	0.01	2.17	0.01	2.82	0.02	4.15	0.03	6.36
	Plasma Pool 3	90	2.49	0.05	2.15	0.05	2.18	0.06	2.45	0.05	1.81	0.11	4.32
	INNOVANCE D-Dimer Control 2	90	2.51	0.07	2.76	0.05	2.12	0.05	2.08	0.04	1.59	0.11	4.35
	Plasma Pool 4	90	29.97	0.80	2.66	1.18	3.92	0.36	1.18	0.51	1.70	1.55	5.17

2. Linearity:

This study was performed in accordance with CLSI EP06 *Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition* and CLSI EP34 *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition* to verify the established linear ranges of the cleared assays (Dade Thrombin Reagent, INNOVANCE Antithrombin, and INNOVANCE D-Dimer) on the Automated Blood Coagulation Analyzer CN-6000. Nine different dilutions were prepared for data analysis by mixing the high and low concentration pools spanning the targeted ranges including levels ± 10% of the Medical Decision Level (MDL). Each level was measured in five replicates with one lot for each assay. The linear ranges were verified such that all acceptance criteria were met.

Analyte/Assay	Linear Range
Fibrinogen (mg/dL) / Dade Thrombin Reagent	38.4–900.2
Antithrombin (% of norm) / INNOVANCE Antithrombin	7.6–130.4
D-dimer (mg/L FEU) / INNOVANCE D-Dimer	0.18– 35.84

3. Analytical Specificity/Interference:

This study was performed according to CLSI EP07 *Interference Testing in Clinical Chemistry, 3rd Edition*. The study was conducted with one reagent lot of each assay identified below. The interference of Hemoglobin, Bilirubin (conjugated and unconjugated), Triglycerides was assessed. Additional testing with Hydroxyethyl Starch (HES) was performed for Fibrinogen with Dade Thrombin Reagent. Pooled plasma samples including normal, factor and analyte deficient plasma, and D-Dimer purified antigen were used for this study. Each sample was evaluated with five replicates.

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

Assay	Sample	Concentration 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)					
Dade Innovin (INR)	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
	Pathological (high)					
Dade Actin FSL	Normal	1100 mg/dL	44 mg/dL	66 mg/dL	825 mg/dL	-
	Pathological (prolonged)					
Dade Thrombin Reagent	Pathological (low)	150 mg/dL	20 mg/dL	15 mg/dL	605 mg/dL	25.9 g/L
	Normal	561 mg/L	44 mg/dL	66 mg/dL	605 mg/dL	31.4 g/L
	Pathological (high)	561 mg/L	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					
INNOVANCE D-Dimer	Normal(low)	1100 mg/dL	44 mg/dL	66 mg/ dL	715 mg/dL	-
	Normal					
	Pathological (high)					

Lupus Anticoagulant (LA) Sensitivity for APTT

An in-house study of lupus sensitivity was conducted for Dade Actin FSL assay to assess instrument performance. Two lots of the assay and 24 LA positive samples were used in the study. All lupus samples yielded APTT results that exceeded the upper limit of the reference interval for both Dade Actin FSL lots.

Heparin Sensitivity for APTT

A Heparin sensitivity study was conducted for Dade Actin FSL to assess instrument performance. A minimum of 100 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. The Passing-Bablok regression analysis and Bland-Altman plots were performed to investigate the agreement between the two analyzers. The results demonstrated that the CN-6000 performance is comparable to CS-5100.

Factor Sensitivity for PT and APTT

Factor sensitivity study was conducted for PT and APTT to assess instrument performance. 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 coagulation factor sensitivity level of the PT and APTT assays on the CN-6000 coagulation analyzer was determined by comparing its results to the lower limit of the respective reference range. The results of the factor sensitivity study are presented below:

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

4. Assay Reportable Range:

Analyte/Assay	Reportable Range
Dade Innovin (second)	8.7 – 90.0
Dade Innovin (INR)	0.93 – 8.00
Dade Actin FSL (second)	20.0 – 139.0
Dade Thrombin Reagent (mg/dL)	50 – 860
INNOVANCE Antithrombin (% of norm)	9.0 – 128.0
INNOVANCE D-Dimer (mg/L FEU)	0.19 – 35.20

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

All assays are 510(k) cleared and traceability is specific to each assay performance.

The analytical value of calibrators and the assigned values of controls for the CS-5100 analyzer (K150678) have been applied to the CN-6000 analyzer. No changes have been made since the CS-5100 analyzer clearance.

On-board Reagent Stability

On-board reagent stability was assessed for Dade Innovin, Dade Actin FSL, Dade Thrombin, INNOVANCE Antithrombin, INNOVANCE D-Dimer and Dade Owren's veronal Buffer with one reagent lot, two different vial sizes, two different storage conditions (capped and uncapped), and four replicates per sample. The reagent lots selected spanned variations of the product self-life. Commercially available frozen plasma samples within a targeted range and quality control materials were used in this study. Results were analyzed by linear regression analysis. The shortest on-board stability time determined for all samples used with all test

batches was then considered the claimed on-board stability time. All reagents met the reagent manufacturer's specified target hours onboard the CN-6000.

6. Detection Limit:

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) studies were performed according to CLSI EP17-A2 *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures* by using two different reagent lots by each assay on one analyzer.

The LoB was determined by measuring four analyte-free plasma samples tested in five replicates over three days in a single run per day. The LoB was calculated as the 95th percentile using the non-parametric method for each lot as the dataset showed non-normal distribution. The claimed LoB was the highest 95th percentile value across the two lots.

The LoD was determined by measuring four low level plasma samples tested in replicates of five over three days in a single run per day. LoD was calculated as the LoB + 1.652 x SD of the replicates for the samples and the highest LoD across the two lots was the LoD claim.

The LoQ was determined by measuring four low level plasma samples tested in replicates of five over three days in a single run per day. The LoQ was defined as the lowest concentration of measurand that meets with in laboratory imprecision goal for each lot.

Analyte/Assay	**LoB**	**LoD**	**LoQ**
Fibrinogen (mg/dL) / Dade Thrombin Reagent	Not applicable	Not applicable	36.1
Antithrombin (% of norm)/ NOVANCE Antithrombin	2.21	2.95	8.31
D-Dimer (mg/L FEU) / INNOVANCE D-Dimer	0.085	0.101	0.182

7. Assay Cut-Off:

Refer to the relevant assay package insert.

8. Accuracy (Instrument):

Refer to Method Comparison Section.

9. Carry-Over:

Sample Carry-Over

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 analyzer's aspiration and washing of the sample probe between pipetting steps would

eliminate the possibility of contamination. The results of the sample carryover study met all specified criteria for tested PT, APTT, fibrinogen, antithrombin, and D-dimer assays.

Reagent Carry-Over

Reagent carryover was assessed to ensure there is no contamination from one assay application to another. Two reagent lots for each assay were analyzed on the CN-series (CN-6000) analyzer. Washing steps are included between all pipetting steps. The results were evaluated to confirm the absence of any reagent carryover of the applications and results were within the acceptance criteria. All possible carryover events were analyzed for all reagent components for the PT, APTT, fibrinogen, antithrombin, and D-dimer assays. All results met the specified acceptance criteria, and the study demonstrated that there was no reagent carryover effects from one application to another on the Automated Blood Coagulation Analyzer CN-6000.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison study was conducted at three external clinical laboratory sites in the U.S. Subjects over 18 years of age were enrolled with a minimum of 100 samples each site. 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 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.

Analyte/Assay	N	Range	r	Slope (95% CI)	Intercept (95% CI)
Prothrombin Time (sec) / Dade Innovin	847	9.7 – 82.8	0.999	1.01 (1.01, 1.01)	-0.10 (-0.14, 0.05)
Prothrombin Time (INR) / Dade Innovin	813	0.93 – 7.96	0.999	1.01 (1.01, 1.01)	-0.01 (-0.01, 0.01)
Activated Partial Thromboplastin Time (sec) / Dade Actin FSL	638	20.1 – 138.7	0.996	0.99 (0.99, 1.00)	0.09 (-0.10, 0.21)
Fibrinogen (mg/dL) / Dade Thrombin Reagent	456	58 – 838	0.993	1.06 (1.05, 1.07)	-4.09 (-7.62, 0.02)
Antithrombin (% of norm) / INNOVANCE Antithrombin	450	12.6 – 125.1	0.995	0.98 (0.98, 0.99)	-1.00 (-1.61, 0.32)
D-dimer (mg/L FEU) / INNOVANCE D-Dimer	395	0.19 – 30.78	0.997	0.96 (0.95, 0.97)	0.01 (-0.00, 0.01)

2. Matrix Comparison:

The objective of the study was to determine equivalency of frozen human citrated plasma versus fresh human citrated plasma on the CN-6000 analyzer by testing Dade INNOVIN,

Dade Actin FSL, Dade Thrombin Reagent, INNOVANCE Antithrombin and INNOVANCE D-Dimer assays. A minimum 100 samples covering the reportable range for each assay were assessed. Fresh samples were tested on the CN-6000 over at least five days. Frozen samples were tested after a minimum of seven days of frozen storage. For each assay, Pearson correlation coefficient, difference and % difference between frozen and fresh sample results were calculated. the Passing-Bablok regression analysis and Bland-Altman plots were also performed. The results of this study demonstrated the equivalency between fresh and frozen human citrated plasma samples.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Refer to the package insert of each assay.

E Expected Values/Reference Range:

The reference range study was designed to establish the normal reference ranges on the CN-Series (CN-6000) analyzer for the healthy population using Dade Innovin, Dade Actin FSL, Dade Thrombin, INNOVANCE Antithrombin, and INNOVANCE D-Dimer assays. The study was conducted at three external clinical sites in the U.S. The assay reference interval was established using a minimum of 60 normal donor/samples (approximately 30 males and 30 females) per site from consented healthy adult population (from ages 18 to 70). One reagent lot was used for each assay. The reference range is established by calculation of the 95% confidence interval 2.5–97.5 percentiles.

Analyte/Assay	Reference Interval
Prothrombin Time (sec) / Dade Innovin	9.9 – 12.3
Prothrombin Time (INR) / Dade Innovin	0.93 – 1.16
Activated Partial Thromboplastin Time (sec) / Dade Actin FSL	23.8 – 32.0
Fibrinogen quantitation (mg/dL) / Dade Thrombin Reagent	192 – 440
Antithrombin quantitation (% of norm) / Dade Thrombin Reagent	83.7 – 121.6
D-Dimer quantitation (mg/L FEU) / INNOVANCE D-Dimer	0.19 – 1.27

F Other Supportive Instrument Performance Characteristics Data:

Hook-Effect Study

This study was performed to evaluate the effect that a high concentration of sample may pose on an immunological method run on the Automated Blood Coagulation Analyzer CN-6000. The study was performed for immunological method, D-Dimer with INNOVANCE D-Dimer. The study was conducted with one lot of each assay on one analyzer. A high sample containing a concentration of approximately 500 mg/L FEU D-dimer was prepared and utilized to prepare nine additional surrogate samples using serial dilutions with single donor normal plasma as the diluent. Five replicates were performed for each of the 10 dilutions. All concentrations greater than 4.88 mg/L FEU were automatically re-diluted by the CN-6000 coagulation analyzer. The results showed that samples with high D-dimer levels can be diluted into the reportable range (no re-dilution range) of the assay. Reported results are correctly or flagged with antigen excess, confirming the acceptance criterion of no high dose hook effect up to 500 mg/L FEU for INNOVANCE D-Dimer.

Auto Dilution vs Manual Dilution

The Auto Dilution versus Manual dilution study was 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. Samples were tested using manual dilution followed by dilution with the analyzer. The pre-defined acceptance criteria were met for this study and demonstrated equivalency between auto dilution and manual dilution.

Closed tube vs. open tube performance

The study was performed to determine equivalent performance of the open (i.e., uncapped) versus closed (i.e., capped) blood collection tubes on the CN-Series (CN-6000). 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 were assessed. A minimum of 60 samples for each assay were included in this study with two sampling processes (capped sample

tube vs. uncapped sample tube) on one analyzer. For each assay, Pearson correlation coefficient, % difference, Passing-Bablok regression analysis and Bland-Altman plots were performed. The pre-defined acceptance criteria were met, indicating the open (i.e., uncapped) sample tube results are comparable to closed (i.e., capped) sample tube results on the CN-6000 analyzer.

Micro Mode vs Normal

The objective of the study was to assess comparability of the micro mode analysis versus normal mode analysis on the CN-Series (CN-6000). 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 were assessed. A minimum of 60 samples for each assay were included in this study for both modes on one analyzer. Each sample was measured in normal mode first and then measured in micro mode within 2 hours. For each assay, Pearson correlation coefficient, % difference, Passing-Bablok regression analysis and Bland-Altman plots were performed. The pre-defined acceptance criteria were met, indicating the micro mode is comparable to normal mode on the CN-6000 analyzer.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.