



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY**

I Background Information:

A 510(k) Number

K231031

B Applicant

Instrumentation Laboratory Company

C Proprietary and Established Names

ACL TOP Family 70 Series

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKP	Class II	21 CFR 864.5400 - Coagulation Instrument	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

To release the updated ACL TOP Family 50 Series models under the trade name ACL TOP Family 70 Series.

B Type of Test:

Clotting, chromogenic, and immunological coagulation assays

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570 and ACL TOP 770 / 770s / 770 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use by health care professionals in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The systems provide results for both direct hemostasis measurements and calculated parameters.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The ACL TOP Family 70 Series are fully automated coagulation analyzers that utilize the same intuitive software, the same consumables, reagents, calibrators and controls, and provide the same analytical methodology for routine and specialty assay result reporting as the predicate ACL TOP Family 50 Series.

The ACL TOP Family 70 Series instrument performs the following types of tests, using the same optical measuring wavelengths and test parameters as the predicate ACL TOP Family 50 Series:

- Coagulometric (Turbidimetric) Measurements
- Chromogenic (Absorbance) Measurements
- Immunological Measurements

The ACL TOP Family 70 Series also offers the same pre-analytical features available on the ACL TOP Family 50 Series. These features alert the instrument operator to a potential HIL (Hemoglobin, Icteric and Lipemia) interference situation specific to the assays requested for a sample, underfilled sample tubes or a detected clog.

B Instrument Description Information:

1. Instrument Name:

ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570, ACL TOP 770, ACL TOP 770s, ACL TOP 770 LAS)

2. Specimen Identification:

Samples, reagents, and diluents are identified by a barcode reader.

3. Specimen Sampling and Handling:

Draw blood into a light blue top tube containing 3.2% sodium citrate. Using other anticoagulants may cause invalid results. Fill to the proper level, indicated by a fill line on the tube. Gently invert six times to mix. Process immediately.

4. Calibration:

The ACL TOP instrument makes dilutions, adds reagents, and takes readings, then generates a calibration curve. The instrument can store the ten most recent calibrations. However, only one calibration can be validated at any time.

5. Quality Control:

The ACL TOP instrument provides a Quality Control (QC) program that allows user to monitor performance characteristics of an analytical system for precision and accuracy as well as alert user to sources of unacceptable analytical performance.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ACL Top Family 50 Series: ACL Top 350 CTS; ACL Top 550 CTS; ACL Top 750; ACL Top 750 CTS; ACL Top 750 LAS

B Predicate 510(k) Number(s):

K150877

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K231031</u>	<u>K150877</u>
Device Trade Name	ACL TOP Family 70 Series	ACL TOP Family 50 Series
General Device Characteristic Similarities		
Intended Use/Indications For Use	The ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570 and ACL TOP 770 / 770s / 770 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use by health care professionals in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The systems provide results for both direct hemostasis measurements and calculated parameters.	The ACL TOP Family 50 Series (ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The systems provides results for both direct hemostasis measurements and calculated parameters.
Test Methodology	<ul style="list-style-type: none"> • Coagulometric measurement • Chromogenic measurement • Immunological measurement 	Same
Wavelengths	<ul style="list-style-type: none"> • 405 nm • 535 nm 	Same

	<ul style="list-style-type: none"> • 671 nm 	
Test Menu	<ul style="list-style-type: none"> • Clotting Assays • Chromogenic Assays • Immunological Assays 	Same
Sample Matrix	3.2% citrated plasma	Same
Sample Handling	Cap piercing, onboard storage	Same
Fluidic Handling	Aspiration, dispense, mixing, rinse, clean, temperature control, bulk fluids	Same
Reaction and Detection	Optics, temperature control	Same
Quality Control	Automated QC	Same
Reagents, Controls and Calibrators	Packaging, formulation, performance claims in labeling	Same
Onboard Reagent Storage	Stirring, temperature control	Same
System Software	Hardware control, user interface except as noted in Differences below	Same
Pre-Analytical HIL Check	Standard for all models: Third measurement wavelength at 535 nm and an additional emitter control channel	Same
Tube Fill Height Check	Standard for all models	Same
Clog Detection	Standard for all models	Same
General Device Characteristic Differences		
External Skins and Chassis	On-market instrument appearance	Updated instrument appearance
Control Module	22-inch Color Touchscreen Monitor	17-inch Color Touchscreen Monitor
Software	<p>Software v1.3</p> <ul style="list-style-type: none"> • Designed for the ACL TOP Family 70 Series using predicate ACL TOP Family 50 Series SW v6.5 as a foundation • Updated Graphical User Interface (GUI) for aesthetics (e.g., higher resolution icons) • Added the Study Mode internal function to support laboratories in more efficiently meeting their 	Software v6.5

	<p>Quality System requirements. The Study Mode provides the interface for laboratories to organize and execute their internal performance studies, including collection of data for lot comparison, instrument comparison, or reference intervals.</p> <ul style="list-style-type: none"> • Added permission-based remote-control function for desktop sharing and remote software delivery and upgrades, utilizing security and privacy controls by design and installed by default. 	
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VI Standards/Guidance Documents Referenced:

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures (3rd Edition);
IEC 61326-1:2020: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements;
IEC 61326-2-6:2020: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: IVD medical equipment;
IEC 61010-1:2017: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements;
IEC 61010-2-101:2018 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: IVD medical equipment;
IEC 61010-2-010:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Heating;
IEC 60601-1-2:2020: Edition Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision testing was performed on selected representative assays to evaluate the following test methodologies:

- Latex agglutination
- Clotting (Calibrated)

- Clotting (Non-calibrated)
- Chromogenic (Calibrated)

These selected assays include HemosIL D-Dimer HS 500 (K172903), HemosIL Factor VIII deficient plasma (K034007), HemosIL RecombiPlasTin 2G (K070005), and HemosIL Liquid Anti-Xa (K213464) represent the highest volume used in the market for each test methodology.

D-Dimer Precision Study

Precision testing was performed for D-dimer with one reagent lot of HemosIL D-Dimer HS 500 using representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). For each material, testing was executed for 20 days at two runs per day, 2 replicates per run (n=80) per instrument model. Low and high controls, as well as two sample pools, were tested. All acceptance criteria for repeatability and within-laboratory precision were met.

ACL TOP 370 D-Dimer Precision Summary

Material	N	Mean (ng/mL FEU)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Control	80	710.7	38.8	5.5	0.0	0.0	18.8	2.6	43.1	6.1
High Control	80	2353.4	48.0	2.0	8.8	0.4	23.2	1.0	54.0	2.3
Cut-off Pool	80	619.8	24.5	4.0	0.0	0.0	13.1	2.1	27.8	4.5
High Pool	80	2373.8	33.1	1.4	14.4	0.6	13.8	0.6	38.6	1.6

ACL TOP 570 D-Dimer Precision Summary

Material	N	Mean (ng/mL FEU)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Control	80	674.3	34.4	5.1	4.8	0.7	8.5	1.3	35.8	5.3
High Control	80	2472.4	31.6	1.3	22.0	0.9	6.1	0.2	39.0	1.6
Cut-off Pool	80	590.2	36.7	6.2	11.8	2.0	0.0	0.0	38.5	6.5
High Pool	80	2529.5	21.7	0.9	19.0	0.8	0.0	0.0	28.8	1.1

ACL TOP 770 D-Dimer Precision Summary

Material	N	Mean (ng/mL FEU)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Control	80	676.9	30.5	4.5	0.0	0.0	10.2	1.5	32.2	4.8
High Control	80	2488.9	41.3	1.7	0.0	0.0	32.2	1.3	52.4	2.1
Cut-off Pool	80	569.9	36.5	6.4	0.0	0.0	6.4	1.1	37.1	6.5
High Pool	80	2486.6	50.2	2.0	0.0	0.0	0.0	0.0	50.2	2.0

D-Dimer Instrument-to-Instrument Variability

Material	N	Mean (ng/mL FEU)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Control	240	687.3	34.7	5.1	0.0	0.0	13.3	1.9	19.8	2.9	42.1	6.1
High Control	240	2438.2	40.9	1.7	11.0	0.5	23.2	1.0	73.6	3.0	88.0	3.6
Cut-off Pool	240	593.3	33.1	5.6	4.8	0.8	7.6	1.3	24.8	4.2	42.3	7.1
High Pool	240	2463.3	36.9	1.5	9.5	0.4	0.0	0.0	80.3	3.3	88.9	3.6

Factor VIII Precision Study

Precision testing was performed for factor VIII with one reagent lot of HemosIL Factor VIII deficient plasma using representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). For each material, testing was executed for 20 days at two runs per day, 2 replicates per run (n=80) per material per instrument model. Normal and abnormal controls, as well as two sample pools, were tested. All acceptance criteria for repeatability and within-laboratory precision were met.

ACL TOP 370 Factor VIII Precision Summary

Material	N	Mean (%)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	92.06	2.58	2.8	1.63	1.8	1.29	1.4	3.31	3.6
Abnormal Control	80	28.44	0.78	2.8	0.95	3.3	0.57	2.0	1.35	4.8
Plasma Pool 1	80	31.59	0.82	2.6	0.80	2.5	0.79	2.5	1.39	4.4
Plasma Pool 2	80	8.43	0.27	3.2	0.00	0.0	0.15	1.7	0.30	3.6

ACL TOP 570 Factor VIII Precision Summary

Material	N	Mean (%)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	92.66	2.67	2.9	2.26	2.4	0.00	0.0	3.50	3.8
Abnormal Control	80	28.78	0.64	2.2	0.87	3.0	0.00	0.0	1.08	3.7
Plasma Pool 1	80	32.45	2.54	7.8	0.00	0.0	0.66	2.0	2.62	8.1
Plasma Pool 2	80	9.01	0.22	2.4	0.13	1.5	0.20	2.2	0.32	3.6

ACL TOP 770 Factor VIII Precision Summary

Material	N	Mean (%)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	94.22	2.43	2.6	1.20	1.3	1.69	1.8	3.19	3.4
Abnormal Control	80	29.58	0.59	2.0	0.95	3.2	0.86	2.9	1.41	4.8
Plasma Pool 1	80	33.30	0.90	2.7	0.64	1.9	0.65	1.9	1.28	3.8
Plasma Pool 2	80	9.01	0.22	2.4	0.00	0.0	0.11	1.2	0.24	2.7

Factor VIII Instrument-to-Instrument Variability

Material	N	Mean (%)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	240	92.98	2.56	2.8	1.75	1.9	1.21	1.3	1.01	1.1	3.48	3.7
Abnormal Control	240	28.93	0.68	2.3	0.92	3.2	0.56	2.0	0.55	1.9	1.39	4.8
Plasma Pool 1	240	32.45	1.63	5.0	0.47	1.4	0.70	2.2	0.81	2.5	2.00	6.2
Plasma Pool 2	240	8.82	0.23	2.7	0.03	0.3	0.15	1.8	0.33	3.8	0.44	4.9

Prothrombin Time (PT) Precision Study

Precision testing was performed for prothrombin time (PT) with one reagent lot of HemosIL RecombiPlasTin 2G using representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). For each material, testing was executed for 20 days at two runs per day, 2 replicates per run (n=80) per material per instrument model. Three control levels, as well as one sample pool, were tested. All acceptance criteria for repeatability and within-laboratory precision were met.

ACL TOP 370 Prothrombin Time Precision Summary

Material	N	Mean (sec)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	11.97	0.09	0.8	0.09	0.8	0.16	1.4	0.21	1.7
Low Abn Control	80	23.23	0.19	0.8	0.44	1.9	0.66	2.8	0.81	3.5
High Abn Control	80	36.62	0.39	1.1	0.95	2.6	1.28	3.5	1.64	4.5
Plasma Pool	80	38.00	0.47	1.2	0.61	1.6	1.29	3.4	1.50	4.0

ACL TOP 570 Prothrombin Time Precision Summary

Material	N	Mean (sec)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	11.84	0.10	0.9	0.17	1.4	0.11	1.0	0.23	1.9
Low Abn Control	80	23.07	0.21	0.9	0.39	1.7	0.73	3.2	0.85	3.7
High Abn Control	80	36.72	0.30	0.8	1.01	2.8	1.42	3.9	1.77	4.8
Plasma Pool	80	37.82	0.40	1.1	0.88	2.3	1.14	3.0	1.50	4.0

ACL TOP 770 Prothrombin Time Precision Summary

Material	N	Mean (sec)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	11.94	0.07	0.6	0.10	0.9	0.17	1.4	0.21	1.8
Normal Control	80	23.24	0.15	0.7	0.37	1.6	0.75	3.2	0.85	3.7
Low Abn Control	80	36.93	0.29	0.8	0.89	2.4	1.57	4.3	1.83	5.0
High Abn Control	80	38.10	0.34	0.9	0.71	1.9	1.32	3.5	1.54	4.0

Prothrombin Time Instrument-to-Instrument Variability

Material	N	Mean (sec)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	240	11.92	0.09	0.8	0.13	1.0	0.15	1.3	0.06	0.5	0.22	1.9
Normal Control	240	23.18	0.19	0.8	0.40	1.7	0.72	3.1	0.00	0.0	0.84	3.6
Low Abn Control	240	36.76	0.33	0.9	0.95	2.6	1.43	3.9	0.00	0.0	1.75	4.8
High Abn Control	240	37.97	0.41	1.1	0.74	2.0	1.25	3.3	0.00	0.0	1.51	4.0

Fibrinogen Precision Study

Precision testing was performed for fibrinogen with one reagent lot of HemosIL RecombiPlasTin 2G using representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). For each material, testing was executed for 20 days at two runs per day, 2 replicates per run (n=80) per material per instrument model. Two control levels, as well as two sample pools, were tested. All acceptance criteria for repeatability and within-laboratory precision were met.

ACL TOP 370 Fibrinogen Precision Summary

Material	N	Mean (mg/dL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	347.9	3.7	1.1	3.2	0.9	11.4	3.3	12.4	3.6
Low Fib Control	80	144.4	5.3	3.6	4.0	2.8	2.7	1.8	7.1	4.9
Normal Pool	80	291.2	4.3	1.5	7.8	2.7	8.5	2.9	12.3	4.2
Abnormal Pool	80	139.0	3.2	2.3	3.5	2.5	4.8	3.5	6.8	4.9

ACL TOP 570 Fibrinogen Precision Summary

Material	N	Mean (mg/dL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	341.5	2.9	0.8	2.9	0.8	13.8	4.0	14.4	4.2
Low Fib Control	80	145.7	8.9	6.1	4.2	2.9	0.0	0.0	9.8	6.8
Normal Pool	80	287.5	3.3	1.1	5.9	2.1	8.2	2.9	10.7	3.7
Abnormal Pool	80	140.6	3.8	2.7	3.3	2.3	4.2	3.0	6.5	4.6

ACL TOP 770 Fibrinogen Precision Summary

Material	N	Mean (mg/dL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	80	339.1	3.1	0.9	2.6	0.8	12.6	3.7	13.2	3.9
Low Fib Control	80	140.7	9.0	6.4	5.7	4.0	4.1	2.9	11.4	8.1
Normal Pool	80	284.5	6.0	2.1	4.0	1.4	8.1	2.8	10.9	3.8
Abnormal Pool	80	136.9	5.9	4.3	0.0	0.0	3.5	2.6	6.8	5.0

Fibrinogen Instrument-to-Instrument Variability

Material	N	Mean (mg/dL)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Normal Control	240	342.9	3.2	0.9	2.9	0.8	12.6	3.7	3.5	1.0	13.8	4.0
Low Fib Control	240	143.6	7.9	5.5	4.7	3.3	2.5	1.7	2.2	1.6	9.8	6.8
Normal Pool	240	287.7	4.7	1.6	6.1	2.1	8.3	2.9	2.6	0.9	11.6	4.0
Abnormal Pool	240	138.8	4.4	3.2	2.8	2.0	4.2	3.0	1.4	1.0	6.9	4.9

Heparin Precision Study

Precision testing was performed for heparin with one reagent lot of HemosIL Liquid Anti-Xa using representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). For each material, testing was executed for 20 days at two runs per day, 2 replicates per run (n=80) per material per instrument model. Four control levels (2 for UF heparin; 2 for LMW heparin), as well as two sample pools (1 for UF heparin; 1 for LMW heparin), were tested. All acceptance criteria for repeatability and within-laboratory precision were met.

ACL TOP 370 Heparin Precision Summary

Material	N	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
UF Low Control	80	0.37	0.007	1.8	0.006	1.7	0.000	0.0	0.009	2.5
UF High Control	80	0.67	0.009	1.3	0.007	1.0	0.007	1.0	0.013	2.0
UF Pool	80	0.56	0.010	1.8	0.009	1.7	0.010	1.8	0.017	3.1
LMW High Control	80	1.53	0.022	1.4	0.019	1.3	0.005	0.3	0.030	1.9
LMW Low Control	80	0.61	0.016	2.7	0.012	2.0	0.000	0.0	0.020	3.3
LMW Pool	80	0.68	0.015	2.2	0.008	1.2	0.008	1.2	0.019	2.7

ACL TOP 570 Heparin Precision Summary

Material	N	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
UF Low Control	80	0.37	0.010	2.7	0.007	1.8	0.000	0.0	0.012	3.3
UF High Control	80	0.67	0.015	2.3	0.011	1.6	0.004	0.7	0.019	2.9
UF Pool	80	0.58	0.013	2.3	0.014	2.5	0.000	0.0	0.019	3.3
LMW High Control	80	1.54	0.027	1.7	0.056	3.6	0.000	0.0	0.062	4.0
LMW Low Control	80	0.61	0.018	2.9	0.021	3.4	0.005	0.9	0.028	4.6
LMW Pool	80	0.70	0.022	3.2	0.028	4.1	0.000	0.0	0.036	5.1

ACL TOP 770 Heparin Precision Summary

Material	N	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
UF Low Control	80	0.36	0.005	1.4	0.004	1.1	0.000	0.0	0.006	1.8
UF High Control	80	0.66	0.010	1.5	0.006	0.9	0.002	0.3	0.012	1.8
UF Pool	80	0.56	0.007	1.2	0.010	1.7	0.003	0.6	0.012	2.2
LMW High Control	80	1.50	0.029	1.9	0.008	0.5	0.015	1.0	0.033	2.2
LMW Low Control	80	0.58	0.013	2.2	0.007	1.3	0.003	0.5	0.015	2.6
LMW Pool	80	0.66	0.013	2.0	0.008	1.3	0.000	0.0	0.016	2.4

Heparin Instrument-to-Instrument Variability

Material	N	Mean (IU/mL)	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
UF Low Control	240	0.37	0.008	2.1	0.006	1.6	0.000	0.0	0.005	1.2	0.011	2.9
UF High Control	240	0.67	0.012	1.8	0.008	1.2	0.005	0.7	0.005	0.8	0.016	2.4
UF Pool	240	0.57	0.010	1.8	0.011	2.0	0.006	1.0	0.009	1.6	0.019	3.3
LMW High Control	240	1.53	0.026	1.7	0.034	2.2	0.000	0.0	0.023	1.5	0.049	3.2
LMW Low Control	240	0.60	0.016	2.6	0.015	2.4	0.000	0.0	0.014	2.3	0.026	4.3
LMW Pool	240	0.68	0.017	2.5	0.018	2.6	0.000	0.0	0.016	2.4	0.030	4.3

2. Linearity:

Refer to K150877

3. Analytical Specificity/Interference:

Refer to K150877

4. Accuracy (Instrument):

Method Comparison Studies

D-Dimer Method Comparison

A method comparison study for D-Dimer was performed with one lot of HemosIL D-Dimer HS 500 to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770) to a representative ACL TOP Family 50 Series model (ACL TOP 750 CTS). The study included 138 native clinical patient samples, spanning the assay's analytical measuring range (AMR) to demonstrate equivalent performance between the subject device and predicate device. The first replicate result on the candidate device (ACL TOP Family 70 Series models) was compared to the duplicate mean on the predicate device (ACL TOP Family 50 Series).

D-Dimer method comparison results are summarized in the table below. All acceptance criteria were met, supporting the comparable performance of the ACL TOP Family 70 Series (subject device) to the ACL TOP Family 50 Series (predicate device) with the representative latex agglutination assay.

D-Dimer Method Comparison Results Summary

Comparison	N	Range (ng/mL FEU)	r	Slope (95% CI)	Intercept (95% CI)
ACL TOP 370 vs. ACL TOP 750 CTS	119	233 to 106,815	0.998	1.006 (0.9936, 1.013)	5.701 (-16.66, 24.19)
ACL TOP 570 vs. ACL TOP 750 CTS	120	239 to 104,313	0.998	1.003 (0.9930, 1.014)	51.78 (27.91, 75.06)
ACL TOP 770 vs. ACL TOP 750 CTS	116	230 to 109,752	0.998	1.022 (1.005, 1.034)	0.557 (-37.66, 19.11)

Factor VIII Method Comparison Study

A method comparison study for factor VIII was performed with one lot of HemosIL Factor VIII deficient plasma (run with HemosIL SynthASil) to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770) to a representative ACL TOP Family 50 Series model (ACL TOP 750 CTS). The first replicate result on the candidate device (ACL TOP Family 70 Series models) was compared to the duplicate mean on the predicate device (ACL TOP Family 50 Series). The study included 148 samples spanning the assay’s AMR to demonstrate the equivalent performance between the subject and predicate devices.

Factor VIII method comparison results are summarized in the table below. All acceptance criteria were met, supporting the comparable performance of the ACL TOP Family 70 Series (subject device) to the ACL TOP Family 50 Series (predicate device) with the representative clotting (calibrated) assay.

Factor VIII Method Comparison Results Summary

Comparison	N	Range (% Activity)	r	Slope (95% CI)	Intercept (95% CI)
ACL TOP 370 vs. ACL TOP 750 CTS	104	0.5 to 156.6	0.998	1.001 (0.9849, 1.012)	-0.5437 (-1.766, -0.1074)
ACL TOP 570 vs. ACL TOP 750 CTS	104	0.5 to 148.4	0.996	1.024 (1.004, 1.043)	-0.5256 (-2.2118, -0.1011)
ACL TOP 770 vs. ACL TOP 750 CTS	104	0.7 to 153	0.998	1.006 (0.9954, 1.018)	-0.0587 (-0.3945, 0.0789)

Prothrombin Time (PT) Method Comparison Study

A method comparison study for prothrombin time (PT) was performed with one lot of HemosIL RecombiPlasTin 2G to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570 and ACL TOP 770 LAS) to a representative ACL TOP Family 50 Series model (ACL TOP 750 CTS). The first replicate result on the candidate device (ACL TOP Family 70 Series models) was compared to the duplicate mean on the predicate device (ACL TOP Family 50 Series). The study included

121 native patient samples, spanning the normal and abnormal range to demonstrate the equivalent performance between the subject and predicate devices.

Prothrombin Time method comparison results are summarized in the table below. All acceptance criteria were met, supporting the comparable performance of the ACL TOP Family 70 Series (subject device) to the ACL TOP Family 50 Series (predicate device) with the representative clotting (non-calibrated) assay.

Prothrombin Time Method Comparison Results Summary

Comparison	N	Range (Seconds)	r	Slope (95% CI)	Intercept (95% CI)
ACL TOP 370 vs. ACL TOP 750 CTS	115	10.5 to 56.1	0.999	1.000 (1.000, 1.009)	0.0500 (-0.1051, 0.050)
ACL TOP 570 vs. ACL TOP 750 CTS	116	10.45 to 55.7	1.000	1.000 (1.000, 1.011)	0.000 (-0.1550, 0.000)
ACL TOP 770 LAS vs. ACL TOP 750 CTS	116	10.5 to 56.6	1.000	1.012 (1.007, 1.018)	-0.0939 (-0.1690, -0.0196)

Fibrinogen Method Comparison Study

A method comparison study for fibrinogen was performed with one lot of HemosIL RecombiPlasTin 2G to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570 and ACL TOP 770 LAS) to a representative ACL TOP Family 50 Series model (ACL TOP 750 CTS). The first replicate result on the candidate device (ACL TOP Family 70 Series models) was compared to the duplicate mean on the predicate device (ACL TOP Family 50 Series). The study included 121 native patient samples, spanning the assay’s AMR to demonstrate the equivalent performance between the subject and predicate devices.

Fibrinogen method comparison results are summarized in the table below. All acceptance criteria were met, supporting the comparable performance of the ACL TOP Family 70 Series (subject device) to the ACL TOP Family 50 Series (predicate device) with the representative clotting (calibrated) assay.

Fibrinogen Method Comparison Summary of Passing-Bablok Regression Results

Comparison	N	Range (mg/dL)	r	Slope (95% CI)	Intercept (95% CI)
ACL TOP 370 vs. ACL TOP 750 CTS	113	68.0 to 653.0	0.999	1.003 (0.9961, 1.009)	4.963 (3.446, 6.907)
ACL TOP 570 vs. ACL TOP 750 CTS	114	68.0 to 660.0	0.997	1.007 (1.000, 1.014)	4.976 (2.604 to 7.000)
ACL TOP 770 LAS vs. ACL TOP 750 CTS	114	62.0 to 640.0	0.999	0.9756 (0.9693, 0.9831)	-1.122 (-3.644, 0.5549)

Heparin Method Comparison Study

Method comparison testing for heparin was performed with one lot of HemosIL Liquid Anti-Xa to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770) to a representative ACL TOP Family 50 Series

model (ACL TOP 750 CTS). The first replicate result on the candidate device (ACL TOP Family 70 Series models) was compared to the duplicate mean on the predicate device (ACL TOP Family 50 Series). The study included 260 samples spanning the assay's AMR to demonstrate the equivalent performance between the subject and predicate devices.

Heparin method comparison results are summarized in the table below. All acceptance criteria were met, supporting the comparable performance of the ACL TOP Family 70 Series (subject device) to the ACL TOP Family 50 Series (predicate device) with the representative chromogenic (calibrated) assay.

Heparin Method Comparison Summary of Passing-Bablok Regression Results

Comparison	N	Range (IU/mL)	r	Slope (95% CI)	Intercept (95% CI)
ACL TOP 370 vs. ACL TOP 750 CTS	209	0.03 to 1.98	0.997	0.9950 (0.9870, 1.000)	-0.0129 (-0.0200, -0.0058)
ACL TOP 570 vs. ACL TOP 750 CTS	204	0.03 to 2.06	0.997	1.005 (0.996, 1.020)	-0.0204 (-0.0306, -0.0100)
ACL TOP 770 vs. ACL TOP 750 CTS	207	0.03 to 1.98	0.999	0.9804 (0.9716, 0.9888)	-0.0145 (-0.0203, -0.0091)

5. Carry-Over:

Refer to K150877

B Other Supportive Instrument Performance Characteristics Data:

Refer to K150877

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.