



Food and Drug Administration
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December 13, 2015

Instrumentation Laboratory (IL) Co.
Carol Marble
Regulatory Affairs Director
180 Hartwell Road
Bedford, MA 01730

Re: K150877

Trade/Device Name: ACL TOP Family 50 Series Models: ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS

Regulation Number: 21 CFR 864.5400

Regulation Name: Coagulation Instrument

Regulatory Class: Class II

Product Code: GKP

Dated: November 12, 2015

Received: November 13, 2015

Dear Ms. Marble:

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 (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. 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.

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 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
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Enclosure

Indications for Use

510(k) Number (if known)

Device Name

ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS)

Indications for Use (Describe)

The ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS) 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 provide results for both direct hemostasis measurements and calculated parameters.

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.

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510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA
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Contact Person	Carol Marble, Regulatory Affairs Director Phone: 781-861-4467 Fax: 781-861-4207 Email: cmarble@ilww.com
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Preparation Date	November 12, 2015
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Device Trade Names	ACL TOP Family 50 Series Models: <ul style="list-style-type: none"> • ACL TOP 350 CTS • ACL TOP 550 CTS • ACL TOP 750 • ACL TOP 750 CTS • ACL TOP 750 LAS
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Regulatory Information	Classification: Class II Regulation No.: 21 CFR 864.5400 Common Name: Coagulation Instrument Panel: Hematology (81) Product Code: GKP
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Predicate Device	ACL TOP: K073377; K091980 for LAS model
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Device Indications for Use / Intended Use	The ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS) are bench top, fully automated, random access analyzers designed specifically for <i>in vitro</i> diagnostic clinical use 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.
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Description	
<p>The ACL TOP Family 50 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.</p> <p>The ACL TOP Family 50 Series instrument performs the following types of tests, using the same optical measuring wavelengths and test parameters as the predicate ACL TOP Family:</p> <ul style="list-style-type: none"> • Coagulometric (Turbidimetric) Measurements • Chromogenic (Absorbance) Measurements • Immunological Measurements <p>The ACL TOP Family 50 Series also offers new pre-analytical features not available on the current ACL TOP Family as described below. These features are not intended to replace laboratory quality policies. The features simply 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. The user will determine how to handle these situations (for example, by not reporting the results, or reporting the results with, or without, additional comments).</p>	
Pre-Analytical Features	<p>The <i>Pre-Analytical HIL Check</i> detects and measures interference caused by the presence of hemoglobin, bilirubin, and light scattering lipids in patient samples.</p> <ul style="list-style-type: none"> • H – Hemolysis (hemoglobin) • I – Icterus (bilirubin) • L – Lipemia (turbidity) <p>The <i>Pre-Analytical HIL Check</i> aids the coagulation laboratory in identifying and handling potential HIL interference issues. This feature flags samples to alert instrument operators of potential HIL interference specific to the tests requested for a sample.</p> <p>NOTES: There are <u>no</u> analytical claims for hemoglobin, bilirubin or turbidity analysis with the introduction of the <i>Pre-Analytical HIL Check</i>.</p> <p>Information provided by the check does <u>not</u> replace any interference information included in the package inserts of IL products.</p> <p>A third measurement wavelength @535 nm and an additional emitter control channel (all models) have been introduced to support the new <i>Pre-Analytical HIL Check</i> feature.</p> <hr/> <p>The <i>Pre-Analytical Tube Fill Height (THF) Check</i> aids laboratories by screening open and closed tube samples during the first sample aspiration to determine whether the tube fill meets the minimum level based on the tube manufacturer's recommendations.</p> <p>The fill height check for each patient sample occurs before the analytical testing process begins and thus there is no effect on patient test results.</p> <hr/> <p>A <i>Pre-Analytical Clog Detection</i> is performed on all samples during aspiration.</p> <p>A pre-analytical error or warning for fluidic obstruction is an indication for the user to review the sample integrity, following established laboratory sample quality procedures.</p> <p>A pressure transducer (all models) has been introduced to support this new <i>Pre-Analytical Clog Detection</i> feature.</p>

Comparison to Predicate		
Item	Predicate	New Device
Trade Names	ACL TOP Family Models <ul style="list-style-type: none"> • ACL TOP 700 (Base) • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS • ACL TOP 300 CTS 	ACL TOP Family 50 Series Models <ul style="list-style-type: none"> • ACL TOP 750 • ACL TOP 750 CTS • ACL TOP 750 LAS • ACL TOP 550 CTS • ACL TOP 350 CTS
Manufacturer	Instrumentation Laboratory Co.	Same
Product Code	GKP	Same
Regulation Section	864.5400	Same
Classification	Class II	Same
Regulation Description	Coagulation Instrument	Same
Similarities		
Indications for Use	<p>The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for <i>in vitro</i> diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.</p> <p>The system provides results for both direct hemostasis measurements and calculated parameters.</p>	<p>The ACL TOP Family 50 Series (ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS, ACL TOP 550 CTS and ACL TOP 350 CTS) are bench top, fully automated, random access analyzers designed specifically for <i>in vitro</i> diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.</p> <p>The systems provide results for both direct hemostasis measurements and calculated parameters.</p>
Matrix	3.2% Citrated Plasma	Same
Methodology	<p>The ACL TOP Family performs the following types of tests:</p> <ul style="list-style-type: none"> • Coagulometric (Turbidimetric) Measurements (405 nm or 671 nm) • Chromogenic (Absorbance) Measurements (405 nm) • Immunological Measurements (405 nm or 671 nm) 	Same
Test Menu	Clotting, chromogenic and immunological assays	Same
Quality Control	Automated QC	Same

Comparison to Predicate (Cont.)		
Item	Predicate	New Device
Trade Names	ACL TOP Family Models <ul style="list-style-type: none"> • ACL TOP 700 (Base) • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS • ACL TOP 300 CTS 	ACL TOP Family 50 Series Models <ul style="list-style-type: none"> • ACL TOP 750 • ACL TOP 750 CTS • ACL TOP 750 LAS • ACL TOP 550 CTS • ACL TOP 350 CTS
<i>Differences</i>		
Pre-Analytical HIL Check	Not Available	Standard for All Models A third measurement wavelength @535 nm and an additional emitter control channel (all models) have been introduced to support this new feature.
Pre-Analytical Tube Fill Height Check	Not Available	Standard for All Models
Pre-Analytical Clog Detection	Not Available	Standard for All Models A pressure transducer (all models) has been introduced to support this new feature.
Software	Windows XP	Windows 7
	Not Applicable	Support for new features

Performance Summary

Precision Study – Internal

In compliance with CLSI EP05-A2, an internal 20-day precision study was performed on an ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 CTS and ACL TOP 750, using 12 representative commercially available assays and their assayed control materials, as well as a prepared patient plasma pool. All materials were tested in duplicate, twice a day for 20 days, for a total of 80 replicates per level for each assay on each instrument model as summarized below.

HemosIL RecombiPlasTin 2G (K070005)				
Measurand: Prothrombin Time (Seconds)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.7	0.9	0.8	1.0
Total %CV (Observed)	1.2	1.7	2.2	1.5
Grand Mean (seconds)	11.47	22.03	38.67	30.40
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.6	0.8	0.9	0.7
Total %CV (Observed)	1.4	2.4	3.0	1.8
Grand Mean (seconds)	11.59	22.21	38.82	30.79
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.6	0.9	0.9	0.7
Total %CV (Observed)	1.4	2.0	2.9	1.5
Grand Mean (seconds)	11.51	22.25	38.76	30.66
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.6	1.0	0.6	0.8
Total %CV (Observed)	1.6	2.4	3.0	2.0
Grand Mean (seconds)	11.40	22.06	38.78	30.33

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL RecombiPlasTin 2G (K070005)				
Measurand: Derived Fibrinogen (mg/dL)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.4	1.3	2.9	2.7
Total %CV (Observed)	1.8	1.7	3.7	3.3
Grand Mean (mg/dL)	323.8	144.1	137.6	385.4
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL Low Fibrinogen Control	HemosIL Normal Control
N	80	80	80	80
Within-run %CV (Observed)	1.0	1.3	4.0	2.1
Total %CV (Observed)	1.5	1.7	4.4	2.2
Grand Mean (mg/dL)	320.8	143.6	137.0	379.2
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.1	1.5	4.4	3.1
Total %CV (Observed)	1.4	1.8	4.8	3.6
Grand Mean (mg/dL)	323.7	144.4	141.1	389.0
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.0	1.8	4.2	2.3
Total %CV (Observed)	1.5	1.9	4.2	2.3
Grand Mean (mg/dL)	320.1	139.8	133.9	384.4

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL SynthASil (K060688)				
Measurand: APTT (Seconds)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.7	0.8	0.60	1.4
Total %CV (Observed)	0.9	0.9	1.3	2.5
Grand Mean (seconds)	31.65	43.93	56.54	57.21
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.3	1.5	1.4	1.6
Total %CV (Observed)	1.4	1.6	1.7	2.0
Grand Mean (seconds)	32.09	44.60	57.65	58.46
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.8	0.9	1.1	1.2
Total %CV (Observed)	1.2	1.3	1.5	1.6
Grand Mean (seconds)	32.00	44.40	57.05	58.12
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Low Abnormal Control	HemosIL High Abnormal Control	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.3	1.2	1.5	1.7
Total %CV (Observed)	1.4	1.5	2.1	2.3
Grand Mean (seconds)	32.01	44.60	57.26	58.95

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Fibrinogen-C (K073367)			
Measurand: Fibrinogen Clauss (mg/dL)			
Model: ACL TOP 350 CTS			
Sample	HemosIL Normal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.7	3.4	2.5
Total %CV (Observed)	4.1	3.8	2.9
Grand Mean (mg/dL)	317.2	105.0	361.5
Model: ACL TOP 550 CTS			
Sample	HemosIL Normal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.9	5.5	2.3
Total %CV (Observed)	3.5	5.6	3.4
Grand Mean (mg/dL)	327.9	104.3	374.4
Model: ACL TOP 750 CTS			
Sample	HemosIL Normal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.4	4.8	2.2
Total %CV (Observed)	2.9	4.9	2.6
Grand Mean (mg/dL)	328.7	110.3	371.8
Model: ACL TOP 750			
Sample	HemosIL Normal Control	HemosIL Low Fibrinogen Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.4	4.5	1.8
Total %CV (Observed)	2.7	4.6	2.4
Grand Mean (mg/dL)	324.6	106.9	368.8

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL D-Dimer (K073042)			
Measurand: D-Dimer (ng/mL)			
Model: ACL TOP 350 CTS			
Sample	HemosIL D-Dimer Low Control	HemosIL D-Dimer High Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.9	2.9	8.5
Total %CV (Observed)	4.9	3.0	9.6
Grand Mean (ng/mL)	362.4	690.7	175.8
Model: ACL TOP 550 CTS			
Sample	HemosIL D-Dimer Low Control	HemosIL D-Dimer High Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	6.6	3.6	9.2
Total %CV (Observed)	7.1	3.7	11.4
Grand Mean (ng/mL)	367.6	698.1	175.0
Model: ACL TOP 750 CTS			
Sample	HemosIL D-Dimer Low Control	HemosIL D-Dimer High Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	4.3	2.5	6.1
Total %CV (Observed)	5.2	2.7	8.7
Grand Mean (ng/mL)	351.6	695.0	168.0
Model: ACL TOP 750			
Sample	HemosIL D-Dimer Low Control	HemosIL D-Dimer High Control	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	4.5	3.1	9.7
Total %CV (Observed)	5.6	3.2	10.5
Grand Mean (ng/mL)	328.4	658.8	149.3

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Liquid Antithrombin (K062431)				
Measurand: Antithrombin (%)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	2.5	4.1	8.9	2.4
Total %CV (Observed)	2.7	7.8	11.0	4.5
Grand Mean (%)	101.2	55.7	23.1	112.9
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	2.0	2.6	5.4	2.2
Total %CV (Observed)	2.8	5.4	7.9	4.0
Grand Mean (%)	103.5	58.6	28.4	114.9
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	2.0	2.5	6.6	2.0
Total %CV (Observed)	2.1	5.3	8.2	3.4
Grand Mean (%)	99.6	57.7	27.7	108.9
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.6	2.0	6.6	1.6
Total %CV (Observed)	2.2	4.9	7.4	3.1
Grand Mean (%)	98.7	56.7	26.7	109.7

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Protein C (K062430)				
Measurand: Protein C (%)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.6	1.1	1.6	1.2
Total %CV (Observed)	2.1	2.2	2.2	1.8
Grand Mean (%)	100.6	59.1	26.8	119.2
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.3	1.6	2.0	1.3
Total %CV (Observed)	1.6	2.1	2.3	2.2
Grand Mean (%)	101.3	59.1	25.9	120.2
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.2	1.2	1.2	1.1
Total %CV (Observed)	1.4	1.9	2.3	1.7
Grand Mean (%)	99.3	58.7	27.1	117.8
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.5	1.3	1.9	1.5
Total %CV (Observed)	2.1	2.3	2.3	1.8
Grand Mean (%)	100.6	58.0	25.3	120.0

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Free Protein S (K010379)				
Measurand: Free Protein S (%)				
Model: ACL TOP 350 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.3	1.4	1.7	1.1
Total %CV (Observed)	2.2	2.6	3.2	2.6
Grand Mean (%)	94.64	59.56	28.47	85.12
Model: ACL TOP 550 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	1.1	1.4	1.5	0.9
Total %CV (Observed)	2.8	2.8	2.8	2.6
Grand Mean (%)	93.76	59.21	28.48	84.65
Model: ACL TOP 750 CTS				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.8	1.4	1.8	0.8
Total %CV (Observed)	2.7	2.8	2.8	2.2
Grand Mean (%)	97.87	60.97	29.03	87.68
Model: ACL TOP 750				
Sample	HemosIL Normal Control	HemosIL Special Test Level 1	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80	80
Within-run %CV (Observed)	0.8	1.0	1.6	1.0
Total %CV (Observed)	2.6	2.4	2.8	2.6
Grand Mean (%)	96.10	59.81	28.10	86.95

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)			
Measurand: Factor V (%)			
Model: ACL TOP 350 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.8	2.9	3.8
Total %CV (Observed)	5.1	5.6	10.1
Grand Mean (%)	109.33	28.27	7.51
Model: ACL TOP 550 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	4.0	3.2	4.5
Total %CV (Observed)	5.8	5.8	9.1
Grand Mean (%)	110.04	27.32	7.79
Model: ACL TOP 750 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.6	2.5	2.6
Total %CV (Observed)	4.8	5.3	8.6
Grand Mean (%)	108.18	28.90	7.86
Model: ACL TOP 750			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	1.9	1.8	2.1
Total %CV (Observed)	3.9	4.7	8.3
Grand Mean (%)	108.65	28.86	7.80

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)			
Measurand: Factor VII (%)			
Model: ACL TOP 350 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.9	5.4	5.0
Total %CV (Observed)	4.2	5.9	6.2
Grand Mean (%)	86.69	18.39	11.73
Model: ACL TOP 550 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.9	4.8	5.5
Total %CV (Observed)	4.2	5.4	6.0
Grand Mean (%)	87.70	18.40	11.89
Model: ACL TOP 750 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.5	3.0	2.9
Total %CV (Observed)	3.2	4.9	5.1
Grand Mean (%)	83.59	19.27	12.36
Model: ACL TOP 750			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	1.6	1.7	2.3
Total %CV (Observed)	3.2	4.0	4.4
Grand Mean (%)	86.33	20.01	12.91

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)			
Measurand: Factor VIII (%)			
Model: ACL TOP 350 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.4	3.3	3.8
Total %CV (Observed)	3.9	4.2	7.6
Grand Mean (%)	87.66	24.39	6.91
Model: ACL TOP 550 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.9	4.0	4.9
Total %CV (Observed)	5.3	5.7	7.9
Grand Mean (%)	85.10	22.75	6.68
Model: ACL TOP 750 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.3	3.3	3.1
Total %CV (Observed)	4.1	4.7	6.8
Grand Mean (%)	86.49	24.60	7.09
Model: ACL TOP 750			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.2	3.4	3.6
Total %CV (Observed)	3.9	4.2	6.4
Grand Mean (%)	86.42	25.82	7.35

Performance Summary (Cont.)

Precision Study – Internal (Cont.)

HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)			
Measurand: Factor IX (%)			
Model: ACL TOP 350 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.8	3.0	3.5
Total %CV (Observed)	4.6	4.0	4.6
Grand Mean (%)	110.40	29.44	10.14
Model: ACL TOP 550 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	4.9	3.8	4.6
Total %CV (Observed)	6.5	4.8	5.8
Grand Mean (%)	107.06	29.03	10.74
Model: ACL TOP 750 CTS			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	3.9	4.3	3.7
Total %CV (Observed)	4.2	4.8	4.6
Grand Mean (%)	110.50	31.39	11.45
Model: ACL TOP 750			
Sample	HemosIL Normal Control	HemosIL Special Test Level 2	Plasma Pool
N	80	80	80
Within-run %CV (Observed)	2.5	3.2	2.9
Total %CV (Observed)	2.9	3.6	4.5
Grand Mean (%)	108.72	31.29	11.64

Performance Summary (Cont.)

Linearity Study – Internal

An internal linearity study was performed on an ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 CTS and ACL TOP 750, using 10 representative commercially available assays* and prepared plasma pool panels at a minimum of 9 levels. Each of the different panel levels was tested in quadruplicate on each instrument model with the resultant data supporting equivalent linearity range claims to the current ACL TOP Family.

***NOTE:** Linearity is not applicable to PT and APTT assays.

HemosIL RecombiPlasTin 2G (K070005)				
Measurand: Derived Fibrinogen (mg/dL)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	1.0222	1.0152	1.0147	1.015
Y-Intercept	15.296	13.272	15.901	16.143
r²	0.9894	0.9927	0.991	0.991
Range (mg/dL)	59-722	54-754	60-731	58-732
HemosIL Fibrinogen-C (K073367)				
Measurand: Fibrinogen Clauss (mg/dL)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	1.0529	1.0832	1.0691	1.0804
Y-Intercept	8.1556	1.5763	5.1815	5.3006
r²	0.9913	0.9891	0.9873	0.987
Range (mg/dL)	27-1207	30-1216	26-1165	30-1154
HemosIL D-Dimer (K073042)				
Measurand: D-Dimer (ng/mL)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9898	1.0195	1.0312	1.0217
Y-Intercept	143.83	93.588	83.203	74.254
r²	0.9781	0.9838	0.9837	0.9877
Range (ng/mL)	133-5415	122-5362	106-5383	95-5296

Performance Summary (Cont.)

Linearity Study – Internal (Cont.)

HemosIL Liquid Antithrombin (K062431)				
Measurand: Antithrombin (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9427	0.996	0.968	0.9652
Y-Intercept	3.4053	-1.3815	0.6826	0.6046
r²	0.9987	0.9997	0.9971	0.9993
Range (%)	9.3-158.0	6.0-152.0	6.5-157.8	6.8-159.0
HemosIL Protein C (K062430)				
Measurand: Protein C (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9956	1.0043	0.9972	1.0049
Y-Intercept	-1.1765	-2.6449	-2.3988	-1.4761
r²	0.9991	0.9991	0.9991	0.9995
Range (%)	5.5-160.5	4.0-158.8	4.5-163.8	5.8-166.5
HemosIL Free Protein S (K010379)				
Measurand: Free Protein S (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	1.03	1.0461	1.0414	1.0455
Y-Intercept	-4.8376	-6.169	-6.0499	-6.4417
r²	0.9983	0.9963	0.9974	0.998
Range (%)	10.4-325.3	9.8-318.1	9.7-309.1	9.3-309.8
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)				
Measurand: Factor V (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.974	0.972	0.924	0.9328
Y-Intercept	0.1607	0.4778	3.0972	3.6627
r²	0.9991	0.9984	0.9966	0.9969
Range (%)	0.4-157.6	0.3-151.2	0.3-159.6	0.3-154.3
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)				
Measurand: Factor VII (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9533	0.9698	0.9233	0.9136
Y-Intercept	1.4091	3.1770	4.4044	4.5945
r²	0.9987	0.9972	0.9965	0.9962
Range (%)	0.3-159.5	0.4-170.0	0.2-163.2	0.3-159.6

Performance Summary (Cont.)

Linearity Study – Internal (Cont.)

HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)				
Measurand: Factor VIII (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9842	1.0597	0.9903	0.9586
Y-Intercept	-0.8923	-2.4208	0.3118	2.1453
r ²	0.9991	0.999	0.9992	0.9969
Range (%)	0.2-151.6	0.3-159.9	0.1-160.5	0.3-150.6
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)				
Measurand: Factor IX (%)				
Instrument Model	ACL TOP 350 CTS	ACL TOP 550 CTS	ACL TOP 750 CTS	ACL TOP 750
Slope	0.9979	0.9913	0.9719	0.9999
Y-Intercept	-1.7626	-1.7805	0.6774	-0.8352
r ²	0.9993	0.9977	0.9989	0.9996
Range (%)	0.2-161.8	0.3-163.0	0.5-158.1	0.5-153.4

Performance Summary (Cont.)

Precision Study – External

An external 20-day precision study was performed at the same three US external sites on an ACL TOP 550 CTS by three different operators, using 11 representative commercially available assays each with two levels of assayed control materials. All materials were tested in duplicate, twice a day for 20 days, for a total of 80 replicates per level for each assay on each model as summarized below.

NOTE: Precision data for derived fibrinogen with HemosIL RecombiPlasTin 2G were not collected under the scope of this study

External Site No. 1						
Assay	Measurand	Control	N	Mean	Within-run CV%	Total CV%
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time (seconds)	HemosIL Normal Control	80	11.5	1.0%	1.6%
		HemosIL High Abnormal	80	40.8	1.4%	3.5%
HemosIL SynthASil (K060688)	APTT (Seconds)	HemosIL Normal Control	80	29.9	1.0%	1.2%
		HemosIL High Abnormal	80	52.5	1.4%	1.9%
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss (mg/dL)	HemosIL Normal Control	80	264	4.3%	4.5%
		HemosIL Low Fibrinogen	80	90	4.3%	4.7%
HemosIL D-Dimer (K073042)	D-Dimer (ng/mL)	HemosIL D-Dimer Low	80	344	6.9%	11.2%
		HemosIL D-Dimer High	80	739	2.8%	4.4%
HemosIL Liquid Antithrombin (K062431)	Antithrombin (%)	HemosIL Normal Control	80	100	2.1%	2.5%
		Special Test Level 2	80	23	6.0%	7.7%
HemosIL Protein C (K062430)	Protein C (%)	HemosIL Normal Control	80	99	1.4%	2.3%
		Special Test Level 2	80	26	3.8%	4.0%
HemosIL Free Protein S (K010379)	Free Protein S (%)	HemosIL Normal Control	80	99	1.9%	6.3%
		Special Test Level 2	80	30	3.0%	9.1%
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V (%)	HemosIL Normal Control	80	102	3.6%	6.7%
		Special Test Level 2	80	32	4.5%	6.7%
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII (%)	HemosIL Normal Control	80	103	3.2%	4.7%
		Special Test Level 2	80	26	3.8%	5.7%
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII (%)	HemosIL Normal Control	80	87	4.5%	9.1%
		Special Test Level 2	80	25	4.0%	12.6%
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX (%)	HemosIL Normal Control	80	102	4.7%	8.4%
		Special Test Level 2	80	31	9.2%	10.1%

Performance Summary (Cont.)

Precision Study – External (Cont.)

External Site No. 2						
Assay	Measurand	Control	N	Mean	Within-run CV%	Total CV%
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time (seconds)	HemosIL Normal Control	80	11.4	1.7%	2.3%
		HemosIL High Abnormal	80	38.7	1.5%	3.2%
HemosIL SynthASil (K060688)	APTT (Seconds)	HemosIL Normal Control	80	30.5	1.6%	1.8%
		HemosIL High Abnormal	80	55.9	1.6%	1.8%
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss (mg/dL)	HemosIL Normal Control	80	285	3.6%	4.4%
		HemosIL Low Fibrinogen	80	94	3.2%	4.7%
HemosIL D-Dimer (K073042)	D-Dimer (ng/mL)	HemosIL D-Dimer Low	80	333	5.0%	7.5%
		HemosIL D-Dimer High	80	712	2.6%	5.1%
HemosIL Liquid Antithrombin (K062431)	Antithrombin (%)	HemosIL Normal Control	80	93	1.7%	3.1%
		Special Test Level 2	80	25	6.1%	9.0%
HemosIL Protein C (K062430)	Protein C (%)	HemosIL Normal Control	80	93	1.5%	2.5%
		Special Test Level 2	80	24	1.8%	3.1%
HemosIL Free Protein S (K010379)	Free Protein S (%)	HemosIL Normal Control	80	92	2.4%	5.8%
		Special Test Level 2	80	29	3.1%	6.0%
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V (%)	HemosIL Normal Control	80	97	5.3%	7.3%
		Special Test Level 2	80	30	5.1%	6.9%
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII (%)	HemosIL Normal Control	80	90	3.2%	5.5%
		Special Test Level 2	80	23	3.1%	6.2%
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII (%)	HemosIL Normal Control	80	84	3.1%	6.4%
		Special Test Level 2	80	26	3.9%	7.8%
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX (%)	HemosIL Normal Control	80	101	4.9%	7.8%
		Special Test Level 2	80	31	4.8%	7.7%

Performance Summary (Cont.)

Precision Study – External (Cont.)

External Site No. 3						
Assay	Measurand	Control	N	Mean	Within-run CV%	Total CV%
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time (seconds)	HemosIL Normal Control	80	11	1.1%	2.5%
		HemosIL High Abnormal	80	39	4.8%	5.4%
HemosIL SynthASil (K060688)	APTT (Seconds)	HemosIL Normal Control	80	31	1.3%	2.2%
		HemosIL High Abnormal	80	54	1.8%	2.1%
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss (mg/dL)	HemosIL Normal Control	80	320	3.0%	4.6%
		HemosIL Low Fibrinogen	80	102	3.6%	6.3%
HemosIL D-Dimer (K073042)	D-Dimer (ng/mL)	HemosIL D-Dimer Low	80	398	4.5%	6.1%
		HemosIL D-Dimer High	80	725	3.8%	5.6%
HemosIL Liquid Antithrombin (K062431)	Antithrombin (%)	HemosIL Normal Control	80	94	2.3%	3.7%
		Special Test Level 2	80	22	5.1%	7.4%
HemosIL Protein C (K062430)	Protein C (%)	HemosIL Normal Control	80	94	1.8%	3.3%
		Special Test Level 2	80	24	2.7%	3.8%
HemosIL Free Protein S (K010379)	Free Protein S (%)	HemosIL Normal Control	80	95	3.8%	4.3%
		Special Test Level 2	80	28	2.0%	3.5%
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V (%)	HemosIL Normal Control	80	100	4.1%	7.5%
		Special Test Level 2	80	32	3.7%	9.6%
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII (%)	HemosIL Normal Control	80	81	2.7%	8.0%
		Special Test Level 2	80	21	2.2%	7.3%
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII (%)	HemosIL Normal Control	80	94	2.3%	5.4%
		Special Test Level 2	80	28	3.1%	4.7%
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX (%)	HemosIL Normal Control	80	107	3.5%	4.8%
		Special Test Level 2	80	34	4.1%	5.2%

Performance Summary (Cont.)

Reproducibility Study - External

An external 5-day precision study was performed at three US sites on an ACL TOP 550 CTS by three different operators, using the same lot of 12 representative commercially available assays, each with two levels of the same lot of assayed control materials. All materials were tested in triplicate, twice a day for 5 days, for a total of 30 replicates per level for each assay on each model as summarized below.

Site	Measurand	Level (unit)	N	Mean	Status	With-in Run			Total				
						%CV	Spec (%CV)	Status	%CV	Spec (%CV)	Status		
Site 1	PT	Normal Ctrl (Sec)	30	11.28	PASS	0.7%	≤	3.0%	Pass	1.9%	≤	3.0%	Pass
Site 2			30	11.33	PASS	0.7%	≤	3.0%	Pass	1.9%	≤	3.0%	Pass
Site 3			30	11.45	PASS	0.6%	≤	3.0%	Pass	1.1%	≤	3.0%	Pass
Site 1		Abnormal Ctrl (Sec)	30	38.50	PASS	2.1%	≤	5.0%	Pass	4.4%	≤	8.0%	Pass
Site 2			30	40.50	PASS	2.1%	≤	5.0%	Pass	3.7%	≤	8.0%	Pass
Site 3			30	39.83	PASS	1.8%	≤	5.0%	Pass	2.5%	≤	8.0%	Pass
Site 1	Derived Fib	Normal Ctrl (mg/dL)	30	324.0	PASS	1.2%	≤	15.0%	Pass	2.4%	≤	15.0%	Pass
Site 2			30	329.3	PASS	1.0%	≤	15.0%	Pass	1.1%	≤	15.0%	Pass
Site 3			30	337.5	PASS	0.7%	≤	15.0%	Pass	2.5%	≤	15.0%	Pass
Site 1		Low Fib Ctrl (mg/dL)	30	140.4	PASS	2.9%	≤	15.0%	Pass	3.8%	≤	15.0%	Pass
Site 2			30	145.4	PASS	3.7%	≤	15.0%	Pass	3.9%	≤	15.0%	Pass
Site 3			30	151.7	PASS	2.9%	≤	15.0%	Pass	3.0%	≤	15.0%	Pass
Site 1	APTT	NormalCtrl (Sec)	30	31.01	PASS	1.2%	≤	2.5%	Pass	1.2%	≤	3.5%	Pass
Site 2			30	30.62	PASS	1.3%	≤	2.5%	Pass	1.4%	≤	3.5%	Pass
Site 3			30	30.52	PASS	0.9%	≤	2.5%	Pass	1.3%	≤	3.5%	Pass
Site 1		Abnormal Ctrl (Sec)	30	55.55	PASS	1.4%	≤	4.0%	Pass	1.6%	≤	5.0%	Pass
Site 2			30	55.58	PASS	1.3%	≤	4.0%	Pass	1.5%	≤	5.0%	Pass
Site 3			30	54.99	PASS	1.7%	≤	4.0%	Pass	1.8%	≤	5.0%	Pass
Site 1	Fib-C	Normal Ctrl (mg/dL)	30	310.1	PASS	4.8%	≤	8.0%	Pass	4.8%	≤	10.0%	Pass
Site 2			30	327.0	PASS	3.0%	≤	8.0%	Pass	4.5%	≤	10.0%	Pass
Site 3			30	321.3	PASS	2.9%	≤	8.0%	Pass	4.4%	≤	10.0%	Pass
Site 1		Low Fib Ctrl (mg/dL)	30	100.2	PASS	3.7%	≤	8.0%	Pass	4.2%	≤	10.0%	Pass
Site 2			30	105.8	PASS	5.2%	≤	8.0%	Pass	5.9%	≤	10.0%	Pass
Site 3			30	106.6	PASS	3.3%	≤	8.0%	Pass	5.3%	≤	10.0%	Pass

Performance Summary (Cont.)

Reproducibility Study – External (Cont.)

Site	Measurand	Level (unit)	N	Mean	Status	With-in Run			Total		
						%CV	Spec (%CV)	Status	%CV	Spec (%CV)	Status
Site 1	D-Dimer	D-Dimer High (ng/mL)	30	710.1	PASS	3.3%	≤ 8.0%	Pass	3.4%	≤ 10.0%	Pass
Site 2			30	723	PASS	3.6%	≤ 8.0%	Pass	4.0%	≤ 10.0%	Pass
Site 3			30	748.8	PASS	3.6%	≤ 8.0%	Pass	3.6%	≤ 10.0%	Pass
Site 1		D-Dimer Low (ng/mL)	29	355.9	PASS	4.9%	≤ 10.0%	Pass	5.8%	≤ 12.0%	Pass
Site 2			30	361.3	PASS	4.2%	≤ 10.0%	Pass	5.6%	≤ 12.0%	Pass
Site 3			30	397.3	PASS	4.6%	≤ 10.0%	Pass	4.8%	≤ 12.0%	Pass
Site 1	Antithrombin	Normal Ctrl (%)	30	96.5	PASS	1.7%	≤ 6.0%	Pass	2.0%	≤ 8.0%	Pass
Site 2			30	97.6	PASS	1.9%	≤ 6.0%	Pass	2.1%	≤ 8.0%	Pass
Site 3			30	94.5	PASS	1.3%	≤ 6.0%	Pass	2.8%	≤ 8.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	23.4	PASS	7.1%	≤ 15.0%	Pass	7.6%	≤ 15.0%	Pass
Site 2			30	21.9	PASS	6.8%	≤ 15.0%	Pass	7.2%	≤ 15.0%	Pass
Site 3			30	22.2	PASS	5.9%	≤ 15.0%	Pass	6.2%	≤ 15.0%	Pass
Site 1	Protein C	Normal Ctrl (%)	30	97.2	PASS	1.6%	≤ 5.0%	Pass	1.8%	≤ 6.0%	Pass
Site 2			30	98.2	PASS	1.3%	≤ 5.0%	Pass	2.1%	≤ 6.0%	Pass
Site 3			30	97.6	PASS	1.4%	≤ 5.0%	Pass	3.0%	≤ 6.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	23.9	PASS	1.9%	≤ 10.0%	Pass	2.5%	≤ 12.0%	Pass
Site 2			30	24.7	PASS	2.1%	≤ 10.0%	Pass	2.5%	≤ 12.0%	Pass
Site 3			30	24.4	PASS	1.8%	≤ 10.0%	Pass	3.1%	≤ 12.0%	Pass
Site 1	Free Protein S	Normal Ctrl (%)	30	95.94	PASS	1.4%	≤ 6.0%	Pass	2.3%	≤ 8.0%	Pass
Site 2			30	97.53	PASS	1.4%	≤ 6.0%	Pass	2.2%	≤ 8.0%	Pass
Site 3			30	96.94	PASS	1.3%	≤ 6.0%	Pass	2.1%	≤ 8.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	25.09	PASS	3.4%	≤ 10.0%	Pass	3.4%	≤ 12.0%	Pass
Site 2			30	25.44	PASS	2.1%	≤ 10.0%	Pass	2.6%	≤ 12.0%	Pass
Site 3			30	24.23	PASS	2.6%	≤ 10.0%	Pass	3.8%	≤ 12.0%	Pass

Performance Summary (Cont.)

Reproducibility Study – External (Cont.)

Site	Measurand	Level (unit)	N	Mean	Status	With-in Run			Total				
						%CV	Spec (%CV)	Status	%CV	Spec (%CV)	Status		
Site 1	Factor V	Normal Ctrl (%)	30	95.01	PASS	3.3%	≤	10.0%	Pass	6.6%	≤	10.0%	Pass
Site 2			30	95.39	PASS	3.2%	≤	10.0%	Pass	5.2%	≤	10.0%	Pass
Site 3			30	100.87	PASS	3.7%	≤	10.0%	Pass	3.8%	≤	10.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	28.33	PASS	3.4%	≤	12.0%	Pass	8.1%	≤	14.0%	Pass
Site 2			30	28.96	PASS	3.7%	≤	12.0%	Pass	5.0%	≤	14.0%	Pass
Site 3			30	30.73	PASS	3.8%	≤	12.0%	Pass	5.8%	≤	14.0%	Pass
Site 1	Factor VII	Normal Ctrl (%)	30	89.55	PASS	2.6%	≤	10.0%	Pass	7.6%	≤	10.0%	Pass
Site 2			30	81.48	PASS	2.1%	≤	10.0%	Pass	5.7%	≤	10.0%	Pass
Site 3			30	86.39	PASS	2.8%	≤	10.0%	Pass	3.4%	≤	10.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	20.31	PASS	2.1%	≤	12.0%	Pass	6.5%	≤	14.0%	Pass
Site 2			30	19.53	PASS	1.9%	≤	12.0%	Pass	5.9%	≤	14.0%	Pass
Site 3			30	20.37	PASS	2.0%	≤	12.0%	Pass	3.9%	≤	14.0%	Pass
Site 1	Factor VIII	Normal Ctrl (%)	30	93.86	PASS	4.8%	≤	10.0%	Pass	4.8%	≤	10.0%	Pass
Site 2			30	91.13	PASS	2.8%	≤	10.0%	Pass	3.2%	≤	10.0%	Pass
Site 3			30	94.68	PASS	2.9%	≤	10.0%	Pass	4.0%	≤	10.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	27.13	PASS	5.8%	≤	12.0%	Pass	9.5%	≤	14.0%	Pass
Site 2			30	25.17	PASS	3.9%	≤	12.0%	Pass	4.6%	≤	14.0%	Pass
Site 3			30	27.20	PASS	3.4%	≤	12.0%	Pass	8.5%	≤	14.0%	Pass
Site 1	Factor IX	Normal Ctrl (%)	30	104.22	PASS	4.6%	≤	10.0%	Pass	5.2%	≤	10.0%	Pass
Site 2			30	104.72	PASS	3.8%	≤	10.0%	Pass	4.3%	≤	10.0%	Pass
Site 3			30	93.91	PASS	2.7%	≤	10.0%	Pass	3.7%	≤	10.0%	Pass
Site 1		Special Ctrl Level 2 (%)	30	29.85	PASS	4.6%	≤	12.0%	Pass	4.6%	≤	14.0%	Pass
Site 2			30	29.66	PASS	3.6%	≤	12.0%	Pass	3.9%	≤	14.0%	Pass
Site 3			30	28.83	PASS	2.9%	≤	12.0%	Pass	3.5%	≤	14.0%	Pass

Performance Summary (Cont.)

Method Comparison Study – External

Method comparison studies were conducted at three US external sites on patient samples following CLSI EP09-A3. Testing at each site compared a representative ACL TOP Family 50 Series model (ACL TOP 550 CTS) to an ACL TOP 500 model (predicate), using 12 representative commercially available assays. Summary statistics for each site are presented below.

NOTE: Results outside of the individual assay’s linear range, samples with incomplete information and samples with instrument errors were removed from final calculations.

External Site No. 1						
Assay	Measurand	Units	# of Samples	Slope	Intercept	r
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time	seconds	146	0.9350	0.7309	0.997
	Derived Fibrinogen	mg/dL	108	0.9883	-6.175	0.997
HemosIL SynthASil (K060688)	APTT	seconds	146	1.085	-3.396	0.998
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss	mg/dL	123	1.047	-15.23	0.983
HemosIL D-Dimer (K073042)	D-Dimer	ng/mL	76	0.9721	34.71	0.997
HemosIL Liquid Antithrombin (K062431)	Antithrombin	%	123	1.048	-3.627	0.972
HemosIL Protein C (K062430)	Protein C	%	118	0.9842	0.2767	0.992
HemosIL Free Protein S (K010379)	Free Protein S	%	121	1.003	-0.7447	0.995
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V	%	120	1.065	0.5548	0.976
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII	%	120	1.006	1.300	0.982
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII	%	86	1.014	-1.403	0.975
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX	%	104	0.9591	1.680	0.974

Performance Summary (Cont.)

Method Comparison Study – External (Cont.)

External Site No. 2						
Assay	Measurand	Units	# of Samples	Slope	Intercept	r
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time	seconds	120	0.9418	0.3975	0.996
	Derived Fibrinogen	mg/dL	97	0.9791	-5.815	0.997
HemosIL SynthASil (K060688)	APTT	seconds	121	0.9623	1.062	0.993
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss	mg/dL	111	0.9425	0.2688	0.981
HemosIL D-Dimer (K073042)	D-Dimer	ng/mL	61	0.9781	15.98	0.992
HemosIL Liquid Antithrombin (K062431)	Antithrombin	%	118	0.9588	5.163	0.990
HemosIL Protein C (K062430)	Protein C	%	116	1.007	0.6397	0.992
HemosIL Free Protein S (K010379)	Free Protein S	%	110	1.010	-0.5087	0.981
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V	%	117	0.9645	1.281	0.986
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII	%	118	0.8761	4.355	0.976
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII	%	64	0.9342	-1.471	0.944
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX	%	111	0.8773	-0.3883	0.962

Performance Summary (Cont.)

Method Comparison Study – External (Cont.)

External Site No. 3						
Assay	Measurand	Units	# of Samples	Slope	Intercept	r
HemosIL RecombiPlasTin 2G (K070005)	Prothrombin Time	seconds	127	0.9658	0.5089	0.995
	Derived Fibrinogen	mg/dL	124	1.005	-5.569	0.996
HemosIL SynthASil (K060688)	APTT	seconds	133	1.068	-1.871	0.998
HemosIL Fibrinogen-C (K073367)	Fibrinogen Clauss	mg/dL	130	0.9489	24.93	0.983
HemosIL D-Dimer (K073042)	D-Dimer	ng/mL	74	1.075	-11.65	0.998
HemosIL Liquid Antithrombin (K062431)	Antithrombin	%	122	0.9659	-3.377	0.978
HemosIL Protein C (K062430)	Protein C	%	117	0.9284	-0.9601	0.993
HemosIL Free Protein S (K010379)	Free Protein S	%	122	0.9443	0.6280	0.997
HemosIL Factor V Deficient Plasma (K023839) with HemosIL RecombiPlasTin 2G (K070005)	Factor V	%	121	0.9792	-0.1396	0.987
HemosIL Factor VII Deficient Plasma (K024082) with HemosIL RecombiPlasTin 2G (K070005)	Factor VII	%	116	0.9540	0.7169	0.991
HemosIL Factor VIII Deficient Plasma (K034007) with HemosIL SynthASil (K060688)	Factor VIII	%	75	1.004	3.088	0.972
HemosIL Factor IX Deficient Plasma (K031829) with HemosIL SynthASil (K060688)	Factor IX	%	107	1.025	0.8581	0.979

Performance Summary (Cont.)

Method Comparison Study – External (*Pre-Analytical HIL Check*)

External method comparison studies for the new *Pre-Analytical HIL Check* feature were also conducted at three US sites on patient samples following CLSI EP09-A3. Testing at each site compared a representative ACL TOP Family 50 Series model (ACL TOP 550 CTS) to the reference devices listed in the table below.

NOTES: The Pre-Analytical HIL Check feature flags sample results to alert instrument operators of potential HIL interference specific to the assays requested for a sample. There are no analytical claims for hemoglobin, bilirubin or turbidity analysis with the introduction of the *Pre-Analytical HIL Check*.

Information provided by the check does not replace any interference information included in the package inserts of IL products.

External Site No. 1						
Interferent	Reference	# of Samples	Units	Slope	Intercept	r
Hemoglobin	HemoCue (BK000043)	257	mg/dL	1.069	9.000	0.944
Bilirubin	Envoy 500 (K945271)	256	mg/dL	1.162	0.5738	0.963
Lipemia	Visual Matching	266	% Overall Matching			91%
External Site No. 2						
Interferent	Reference	# of Samples	Units	Slope	Intercept	r
Hemoglobin	HemoCue (BK000043)	244	mg/dL	1.068	14.92	0.957
Bilirubin	Envoy 500 (K945271)	249	mg/dL	1.160	0.8948	0.973
Lipemia	Visual Matching	257	% Overall Matching			93%
External Site No. 3						
Interferent	Reference	# of Samples	Units	Slope	Intercept	r
Hemoglobin	HemoCue (BK000043)	269	mg/dL	1.031	15.41	0.971
Bilirubin	Envoy 500 (K945271)	267	mg/dL	1.127	0.5977	0.952
Lipemia	Visual Matching	272	% Overall Matching			95%

Pre-Analytical Clog Detection Testing

A Pre-Analytical Clog Detection test was conducted internally on ACL TOP Family 50 Series model instruments (2 ACL TOP 350 CTS models; 2 ACL TOP 550 CTS models; 2 ACL TOP 750 models; 2 ACL TOP 750 CTS models; 1 ACL TOP 750 LAS model). All instrument models correctly detected an occluded sample probe.

Pre-Analytical Tube Fill Height Check Testing

A Pre-Analytical Tube Fill Height Check test was conducted internally on ACL TOP Family 50 Series model instruments (2 ACL TOP 350 CTS models; 2 ACL TOP 550 CTS models; 2 ACL TOP 750 models; 2 ACL TOP 750 CTS models). All instrument models correctly detected when tubes were underfilled.

Conclusion:

Based on the shared indications for use, operating principle, consumables, reagents, controls and calibrators, and considering the above summary performance data, the ACL TOP Family 50 Series with its new pre-analytical features can be concluded to be substantially equivalent to the cleared and currently marketed predicate device, ACL TOP Family.