510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K150877

B. Purpose for Submission:

To introduce new pre-analytical features and software on the currently marketed ACL TOP Family (reference: K073377 and K091980 – LAS model).

C. Manufacturer and Instrument Name:

Instrumentation Laboratory (IL) Co., 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.

NOTE: CTS = Closed Tube Sample; LAS = Laboratory Automated System.

D. Type of Test or Tests Performed:

Clotting, chromogenic and immunological coagulation assays

E. System Descriptions:

1. Device Description:

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. The ACL TOP Family 50 Series instruments perform the following types of tests, using the same optical measuring wavelengths and test parameters as the predicate ACL TOP Family:

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

The ACL TOP Family 50 Series also offers new pre-analytical features not available on the predicate 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 new pre-analytical features and software are as follows:

Pre-Analytical HIL Check detects and measures interference caused by the presence of hemoglobin, bilirubin, and light scattering lipids in patient samples.

- H – Hemolysis (hemoglobin)
- I – Icterus (bilirubin)
- L – Lipemia (turbidity)

A third measurement wavelength at 535 nm and an additional emitter control channel have been introduced to support the new Pre-Analytical HIL Check feature.

Pre-Analytical Tube Fill Height (THF) Check 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.

Pre-Analytical Clog Detection is performed on all samples during aspiration. 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. A pressure transducer has been introduced to support this new Pre-Analytical Clog Detection feature.

Instrument software has been updated to support the new features.

2. Principles of Operation:

Following is an overview of the ACL TOP Family 50 Series control modules and analytical technology:

A. Control Module (CM)

The CM provides a user interface and operation control. It consists of a personal computer running Windows™ software, keyboard, touch screen display monitor, mouse, and communications interfaces to the AM and external devices/systems. The CM provides the major functionality associated with the user interface (UI) including data management, data reduction, LIS (Laboratory Information System) communications, sample identification, test materials management, fluid management, reporting, test tracking and QC management, and monitoring.

B. Analytical Module (AM)

The AM consists primarily of sample and reagent handling hardware. It processes reagents and auxiliary materials. It can perform coagulometric (turbidimetric), chromogenic (absorbance), and immunological measurements.

C. Coagulometric (Turbidimetric) Measurement

The principle of coagulometric (turbidimetric) clot detection is used in the system to measure and record the amount of time required for a plasma specimen to clot. This

technique assesses coagulation endpoint by measuring change in optical density.

Clot detection is based on the principle that light passing through a medium in which fibrinogen is converted to fibrin is absorbed by the fibrin strands. Light (405 nm or 671 nm) is transmitted through a sample onto a photodetector, which is positioned 180° to the source. Light absorption increases as fibrin clot formation progresses. Consequently, light transmittance through the sample continuously decreases and is measured by the photodetector. The corresponding electrical signal output from the photodetector changes according to the detected light. The signal output is processed via software through a series of algorithms to determine the clot point.

D. Chromogenic (Absorbance) Measurement

Chromogenic tests can be either direct or indirect.

- Direct test – Test where the analyte of interest (e.g. protein C, plasminogen) acts directly on a specified synthetic substrate.
- Indirect test – Test where the analyte of interest (antithrombin, plasmin inhibitor) reacts with a fixed quantity of enzyme to form inactive complexes. Under optimized test conditions, residual enzyme activity is then measured using a specific synthetic substrate.

In most cases, the reaction is monitored at 405 nm by the continuous release of paranitroaniline (pNA) from the synthetic substrate.

The chromogenic channels use the colorimetric principle of measuring absorbance in the cuvette. An optical sensor reads light (405 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of pNA. The amount of light reaching the photodetector is converted into an electrical signal that is proportional to the enzyme activity.

E. Immunological Measurements

The principle of immunological measurement is used on the system to directly measure and record the amount of an analyte. This technique assesses the physical concentration of the analyte (and not its activity) by measuring change in optical density. Although similar to the turbidimetric method, the immunological method relies on the formation of antigen-antibody complexes to affect light transmission. Immunological testing of the ACL TOP uses the 405 nm or the 671 nm channels depending on the test and the reagent formulation. Both the 405 nm and the 671 nm channels use the principle of measuring absorbance in the cuvette. An optical sensor reads the light (405 nm or 671 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of antigen-antibody complexes. The amount of light reaching the photodetector is converted into an electrical signal that is proportional or inversely proportional to the analyte concentration.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____x____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____x____

4. Specimen Identification:

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

5. 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.

6. Calibration:

   See (K041905, K090563)

7. Quality Control:

   See the corresponding 510(k) submission regarding the appropriate quality control material for the relevant assays: K021023, K021022, K021024, K931721, K050544, K040359, K041905.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes____x____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5400, Coagulation instrument

2. Classification:

Class II

3 Product code:

GKP, Instrument, Coagulation, Automated

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for 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 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.

2. Special Conditions for Use Statement(s):

For prescription use only

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

ACL TOP: K073377; K091980 for LAS model

2. Comparison with Predicate Device:

Similarities		
Item	Device ACL TOP Family 50 Series Models	Predicate ACL TOP Family Models
Trade Names	ACL TOP 750 ACL TOP 750 CTS ACL TOP 750 LAS ACL TOP 550 CTS ACL TOP 350 CTS	ACL TOP 700 (Base) ACL TOP 700 CTS ACL TOP 700 LAS ACL TOP 500 CTS ACL TOP 300 CTS
Indications for Use	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 in vitro	The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for in vitro diagnostic clinical use in the hemostasis laboratory for coagulation and/or

Similarities		
Item	Device ACL TOP Family 50 Series Models	Predicate ACL TOP Family Models
	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.	fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct hemostasis measurements and calculated parameters.
Sample Matrix	3.2% citrated plasma	Same
Test Methodology	The ACL TOP Family performs the following types of tests: 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

Differences		
Item	Device ACL TOP Family 50 Series Models	Predicate ACL TOP Family Models
Pre-Analytical HIL Check	Standard for all models A third measurement wavelength at 35 nm and an additional emitter control channel (all models) have been introduced to support this new feature	Not available
Pre-Analytical Tube Fill Height Check	Standard for all models	Not available
Pre-Analytical Clog Detection	Standard for all models A pressure transducer (all models) has been introduced to support this new feature.	Not available
Software	Windows 7	Windows XP
	Support for new features	Not applicable

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP5-A2. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

CLSI EP05-A3. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline. 2014.

CLSI EP06-A. Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. 2003.

CLSI EP09-A3. Measurement Procedure Comparison and Bias Estimation Using Patient Samples Approved Guideline. 3rd Ed.

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Method Comparison Study (External)

Method comparison studies were conducted at three external sites in the United States. 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. At the three external sites, patient samples were collected based on doctor's orders for each of the following test group categories:

- Prothrombin Time, Activated Partial Thromboplastin Time, Fibrinogen Clauss, Fib-RP (derived Fibrinogen)
- Antithrombin, Protein C, Free Protein S
- D-Dimer
- Factors (V, VII, VIII and IX)

Comparison results for all assays at all external sites passed acceptance criteria.

Measurand	**Slope Acceptance Criteria**	**r Acceptance Criteria**
Prothrombin Time	1.0±0.1	≥ 0.975
Derived Fibrinogen	1.0±0.2	≥ 0.950
APTT	1.0±0.1	≥ 0.975
Fibrinogen Clauss	1.0±0.1	≥ 0.975
D-Dimer	1.0±0.1	≥ 0.975
Antithrombin	1.0±0.1	≥ 0.950
Protein C	1.0±0.1	≥ 0.975
Free Protein S	1.0±0.1	≥ 0.975
Factor V	1.0±0.15	≥ 0.975
Factor VII	1.0±0.15	≥ 0.975
Factor VIII	1.0±0.15	≥ 0.950
Factor IX	1.0±0.15	≥ 0.950

Internal Method Comparison (Pre-Analytical HIL Check)

1. *Hemoglobin*
   The hemoglobin method comparison study demonstrated that hemoglobin results generated by the ACL TOP Family 50 Series (ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 and ACL TOP 750 CTS) match well with results from the comparator device, the HemoCue. The acceptance criteria for slope 1.0 ± 0.2 and r > 0.90 were met with all instrument models.

2. *Bilirubin*
   The bilirubin method comparison study demonstrated that bilirubin results generated by the ACL TOP Family 50 Series (ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 and ACL TOP 750 CTS) match well with results from the comparator device, the Envoy 500. The acceptance criteria for slope 1.0 + 0.2 and r > 0.90 were met with all instrument models.

   Testing used each of the three assays on the ACL TOP Family 50 Series:
   - Prothrombin Time (PT-RP) (HemosIL RecombiPlasTin 2G)
   - Activated Partial Thromboplastin Time (APTT-SS) (HemosIL SynthASil)
   - HIL (default automatically performed by the instrument when PT-RP and APTT-SS assays are not ordered)

3. *Lipemia (Turbidity)*
   Method comparison for lipemia was tested externally.

Internal Method Comparison: Hemoglobin - HemoCue vs. ACL TOP 50 with PT-RP

Reference (X)	**Hemocue**	**Hemocue**	**Hemocue**	**Hemocue**
Test (Y)	**PT-RP TOP 350 CTS**	**PT-RP TOP 550 CTS**	**PT-RP TOP 750**	**PT-RP TOP 750 CTS**
N	304	304	304	304
Slope	1.063	1.029	0.9765	0.9965
Slope 95%CI	1.002 to 1.124	0.9594 to 1.099	0.9187 to 1.034	0.9268 to 1.066
r	0.924	0.924	0.922	0.917
Intercept	-0.9360	1.376	1.883	1.825
Intercept 95% CI	-5.682 to 3.809	-4.203 to 6.956	-2.859 to 6.625	-3.305 to 6.956

Internal Method Comparison: Hemoglobin - HemoCue vs. ACL TOP 50 with APTT-SS

Reference (X)	**Hemocue**	**Hemocue**	**Hemocue**	**Hemocue**
Test (Y)	**APTT-SS TOP 350 CTS**	**APTT-SS TOP 550 CTS**	**APTT-SS TOP 750**	**APTT-SS TOP 750 CTS**
N	304	304	304	304
Slope	1.050	1.021	0.9790	1.007

Reference (X)	Hemocue	Hemocue	Hemocue	Hemocue
Test (Y)	APTT-SS TOP 350 CTS	APTT-SS TOP 550 CTS	APTT-SS TOP 750	APTT-SS TOP 750 CTS
Slope 95%CI	1.001 to 1.100	0.9591 to 1.083	0.9244 to 1.034	0.9254 to 1.088
r	0.929	0.925	0.925	0.924
Intercept	1.782	5.218	5.418	3.002
Intercept 95% CI	-2.548 to 6.112	0.02170 to 10.41	0.3579 to 10.48	-3.288 to 9.291

Internal Method Comparison: Hemoglobin - HemoCue vs. ACL TOP 50 with HIL

Reference (X)	Hemocue	Hemocue	Hemocue	Hemocue
Test (Y)	HIL TOP 350 CTS	HIL TOP 550 CTS	HIL TOP 750	HIL TOP 750 CTS
N	304	304	304	304
Slope	1.036	1.050	0.9651	1.016
Slope 95%CI	0.9424 to 1.129	0.9878 to 1.112	0.8980 to 1.032	0.9525 to 1.078
r	0.931	0.931	0.913	0.926
Intercept	4.708	3.149	5.592	3.738
Intercept 95% CI	-3.444 to 12.86	-1.921 to 8.218	0.3558 to 10.83	-1.403 to 8.879

Internal Method Comparison: Bilirubin - Envoy 500 vs. ACL TOP 50 with PT-RP

Reference (X)	Envoy	Envoy	Envoy	Envoy
Test (Y)	PT-RP TOP 350 CTS	PT-RP TOP 550 CTS	PT-RP TOP 750	PT-RP TOP 750 CTS
N	274	274	274	274
Slope	1.017	0.9820	0.9949	0.9987
Slope 95%CI	0.9749 to 1.059	0.9423 to 1.022	0.9485 to 1.041	0.9550 to 1.042
r	0.946	0.954	0.946	0.953
Intercept	1.789	1.889	1.960	1.543
Intercept 95% CI	1.476 to 2.103	1.588 to 2.189	1.612 to 2.308	1.243 to 1.843

Internal Method Comparison: Bilirubin - Envoy 500 vs. ACL TOP 50 with APTT-SS

Reference (X)	Envoy	Envoy	Envoy	Envoy
Test (Y)	APTT-SS TOP 350 CTS	APTT-SS TOP 550 CTS	APTT-SS TOP 750	APTT-SS TOP 750 CTS
N	274	274	274	274
Slope	1.000	0.9953	0.9869	0.9793
Slope 95%CI	0.9585 to 1.042	0.9534 to 1.037	0.9454 to 1.028	0.9256 to 1.033
r	0.952	0.952	0.947	0.951
Intercept	1.831	1.878	1.939	1.648
Intercept 95% CI	1.522 to 2.141	1.572 to 2.184	1.605 to 2.273	1.297 to 2.000

Internal Method Comparison: Bilirubin - Envoy 500 vs. ACL TOP 50 with HIL

Reference (X)	Envoy	Envoy	Envoy	Envoy
Test (Y)	**HIL TOP 350 CTS**	**HIL TOP 550 CTS**	**HIL TOP 750**	**HIL TOP 750 CTS**
N	274	274	274	274
Slope	0.9638	0.9804	0.9727	0.9779
Slope 95%CI	0.9158 to 1.012	0.9350 to 1.026	0.9297 to 1.016	0.9305 to 1.025
r	0.947	0.952	0.942	0.951
Intercept	1.865	1.834	1.953	1.587
Intercept 95% CI	1.538 to 2.193	1.505 to 2.162	1.628 to 2.278	1.273 to 1.901

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

External method comparison studies for the new Pre-Analytical HIL Check feature were conducted at three US sites with patient samples. 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. The Pre-Analytical HIL Check feature flagged sample results to alert instrument operators of potential HIL interference specific to the assays requested for a sample.

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%

b. Precision/Reproducibility:

Internal Precision

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. Testing included the following assays: PT (as well as

derived Fibrinogen), APTT, Fibrinogen Clauss, D-dimer, Antithrombin, Free Protein S (latex), Protein C (chromogenic), Factor V, Factor VII, Factor VIII, and Factor IX. 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. Precision results for all assays passed acceptance criteria.

Measurand	Control	Acceptance Criteria	Acceptance Criteria
Prothrombin Time (Seconds)	HemosIL Normal Control HemosIL High Abnormal Control	≤ 3.0 ≤ 5.0	≤ 3.0% ≤ 8.0%
Derived Fibrinogen (mg/dL)	HemosIL Normal Control HemosIL Low Fibrinogen Control	≤ 15.0 ≤ 15.0	≤ 15.0 ≤ 15.0
APTT (Seconds)	HemosIL Normal Control HemosIL High Abnormal Control	≤ 2.5 ≤ 4.0	≤ 3.5 ≤ 5.0
Fibrinogen Clauss (mg/dL)	HemosIL Normal Control HemosIL Low Fibrinogen Control	≤ 8.0 ≤ 8.0	≤ 10.0 ≤ 10.0
D-Dimer (ng/mL)	HemosIL D-Dimer Low Control HemosIL D-Dimer High Control	≤ 10.0 ≤ 8.0	≤ 12.0 ≤ 10.0
Antithrombin (%)	HemosIL Normal Control HemosIL Special Test Level 2	≤ 6.0 ≤ 15.0	≤ 8.0 ≤ 15.0
Protein C (%)	HemosIL Normal Control HemosIL Special Test Level 2	≤ 5.0 ≤ 10.0	≤ 6.0 ≤ 12.0
Free Protein S (%)	HemosIL Normal Control HemosIL Special Test Level 2	≤ 6.0 ≤ 10.0	≤ 8.0 ≤ 12.0

External Precision

An external 20-day precision study was performed at 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. Testing included the following assays: PT, APTT, Fibrinogen Clauss, D-dimer, Antithrombin, Free Protein S (latex), Protein C (chromogenic), Factor V, Factor VII, Factor VIII, and Factor IX. 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 ACL TOP 55 CTS model. Precision results for all assays at all external sites passed acceptance criteria (see acceptance criteria for internal precision study).

Reproducibility Study - External

An external 5-day precision study was performed at three US external 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. Testing included the following assays: PT (as well as

derived Fibrinogen), APTT, Fibrinogen Clauss, D-dimer, Antithrombin, Free Protein S (latex), Protein C (chromogenic), Factor V, Factor VII, Factor VIII, and Factor IX. 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 ACL TOP 550 CTS model. Reproducibility results for all assays at all external sites passed acceptance criteria (see acceptance criteria above for the internal precision study).

c. Linearity:

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. Linearity results for all assays on all instrument models passed the acceptance criteria of Slope 1.0 ± 0.1 and $r^2 \geq 0.960$.

d. Carryover:

Sample Carryover: Hemoglobin
Hemoglobin carryover was assess in an internal study using two pools prepared as follows: one with no interferent (Normal Pooled Plasma or NPP), and one with high levels of interferent (hemoglobin). A series of samples of each pool were run in the following sequence: NPP, NPP, interferent, interferent, interferent, interferent, and NPP on each model instrument. The results for the seventh cup (i.e., NPP) were compared to the NPP baseline results and percent difference was calculated by (test result-baseline/baseline) x 100. The hemoglobin carry over studies were performed on the ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 and ACL TOP 750 CTS. Results on all instruments passed the acceptance criteria of % change from baseline $\pm$15%.

Sample Carryover: Bilirubin
Bilirubin carryover was assessed in an internal study using two pools prepared as follows: one with no interferent (Normal Pooled Plasma or NPP), and one with high levels of interferent (bilirubin). A series of samples of each pool were run in the following sequence: NPP, NPP, interferent, interferent, interferent, interferent, and NPP on each model instrument. The results for the seventh cup (i.e., NPP) were compared to the NPP baseline results and percent difference was calculated by (test result-baseline/baseline) x 100. The bilirubin carry over studies were performed on the ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 and ACL TOP 750 CTS. Results on all instruments passed the acceptance criteria of % change from baseline $\leq$ (4 within-run SD/control mean) x100, using the within-run SD and control (or $\leq$19.6%).

Sample Carryover: Lipemia (Turbidity)
Lipemia carryover was assess in an internal study with two pools prepared as follows:

one with no interferent (Normal Pooled Plasma or NPP), and one with high levels of interferent (turbidity, i.e. lipemia). A series of samples of each pool were run in the following sequence: NPP, NPP, interferent, interferent, interferent, interferent, and NPP on each model instrument. The results for the seventh cup (i.e., NPP) were compared to the NPP baseline results and percent difference was calculated by (test result-baseline/baseline) x 100. The lipemia carry over studies were performed on the ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750 and ACL TOP 750 CTS. Results on all instruments passed the acceptance criteria of % change from baseline ±15%.

e. Interfering Substances:

Not applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

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.

Matrix Comparison
Matrix studies were conducted to compare paired samples from the same donor drawn in 3.2% sodium citrate (test) collection tubes and lithium heparin (comparator method) collection tubes on the HemoCue (Hemoglobin) and Envoy 500 (Total Bilirubin) analyzers as samples used in the internal method comparison. The matrix comparison study results support equivalent performance between the comparator devices (HemoCue and Envoy 500 analyzers) originally cleared sample matrix (lithium heparin) and 3.2% sodium citrate used in the internal method comparison study.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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