510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k102552

B. Purpose for Submission:
Clearance for HemosIL® LA Positive Control and HemosIL® LA Negative Control for Lupus Anticoagulant assays

C. Measurand:
Controls for Lupus anticoagulant (LA)

D. Type of Test:
Assayed controls

E. Applicant:
Instrumentation Laboratories Co.

F. Proprietary and Established Names:
HemosIL® LA Positive Control
HemosIL® LA Negative Control

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.5425 - Multipurpose system for in vitro coagulation studies
2. Classification:
   Class II
3. Product code:
   GGN (Plasma, Coagulation Control)
   GGC (Plasma Control, Abnormal)
   GIZ (Plasma Control, Normal)
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   HemosIL® LA Positive Control
   For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL Screen/LAC; Silica Clotting Time) on IL Coagulation systems [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000)].

   HemosIL® LA Negative Control
   For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL Screen/LAC; Silica Clotting Time) on IL Coagulation systems [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000)].

   The controls assess the precision and accuracy of Lupus Anticoagulant (LA) tests performed on IL Coagulation Systems using HemosIL LA assays.

2. Indication(s) for use:
   Same as above
3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   For use on IL Coagulation systems [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000)]

I. Device Description:

HemosIL® LA Positive Control is a lyophilized preparation from human donors exhibiting the presence of anti-phospholipids antibodies with added buffer. The device consists of ten-1ml vials of lyophilized controls per package.

HemosIL® LA Negative Control is a lyophilized preparation using human citrated platelet-poor plasma to make pooled normal plasma with added buffer. The device consists of ten-1ml vials of lyophilized controls per package.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   American Diagnsotica LAtrol Normal Control
   American Diagnsotica LAtrol Abnormal Control
2. Predicate 510(k) number(s):
   k935254
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	HemosIL® LA Positive Control	**LAtrol Abnormal Control**
Intended Use	For use as a positive quality control for HemosIL Lupus Anticoagulant assays	Same
Analyte Tested	Lupus Anticoagulant	Same
Format/Matrix	Lyophilized Plasma	Same

Differences		
Item	Device	Predicate
	HemosIL® LA Positive Control	**LAtrol Abnormal Control**
Constituent Material	Lyophilized preparation from human donors exhibiting the presence of anti-phospholipids antibodies with added buffer.	Lyophilized preparation of a lupus anticoagulant plasma with buffer.
Reconstituted Stability	Stable for 24 hours at 2-8°C	Stable for 8 hours at 2-8°C
Test System	IL coagulation system: [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000].	Manual tilt-tube method or semi-automated method using ST4 or BBL fibrometer, and most automated analyzers

Similarities		
Item	Device	Predicate
	HemosIL® LA Negative Control	**LAtrol Normal Control**
Intended Use	For use as a negative quality control for HemosIL Lupus Anticoagulants assays	Same
Analyte Tested	Lupus Anticoagulant	Same
Format/Matrix	Lyophilized Plasma	**Same**

Differences		
Item	Device	Predicate
	HemosIL® LA Negative Control	**LAtrol Normal Control**
Constituent Material	Lyophilized preparation using human citrated platelet-poor plasma to make pooled normal plasma with added buffer.	Lyophilized preparation of multi-donor normal plasma with buffer.
Reconstituted Stability	Stable for 24 hours at 2-8°C	Stable for 8 hours at 2-8°C
Test System	IL coagulation system: [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000].	Manual tilt-tube method or semi-automated method using ST4 or BBL fibrometer, and most automated analyzers

K. Standard/Guidance Document Referenced (if applicable):

- Guidance Document on Assayed and Unassayed Quality Control Material, June 7, 2007.
- CLSI EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods, 2nd Edition, 2004.
- CSLI C3-A4: Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline. Fourth Edition, Vol.26 No. 22

L. Test Principle:

LA Positive control and the LA Negative control are lyophilized preparations from human donor with anti-phospholipid antibodies with added buffer and human citrated platelet poor plasma used to assess the precision and accuracy of Lupus Anticoagulant (LA) assays performed on the IL Coagulation instrument platform using HemosIL LA reagents (LA Screen and Confirm).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability was demonstrated by testing within-run and between-run precision on two lots each of lyophilized controls according to procedures outlined under CLSI E5-A2 guidelines.

Reproducibility was conducted on two lots of each level of control. A total of 80 samples were run based on two replicates per run for two runs per day over 20 days per instrument over seven instrument platforms.

Precision studies for both controls were run with the designated assays on the following IL Coagulation instrument platforms:

- ACL TOP: HemosIL LAC Screen/LAC Confirm & HemosIL Silica Clotting Time
- ACL TOP 500 CTS: HemosIL LAC Screen/LAC Confirm & HemosIL Silica Clotting Time
- ACL 1000: HemosIL LAC Screen/LAC Confirm & HemosIL Silica Clotting Time
- ACL Advance: HemosIL LAC Screen/LAC Confirm & HemosIL Silica Clotting Time
- ACL 6000: HemosIL LAC Screen/LAC Confirm Only
- ACL 3000: HemosIL LAC Screen/LAC Confirm Only
- ACL 300+: HemosIL LAC Screen/LAC Confirm Only

Summary of precision study is as follows:

LA Controls	n	Within Run CV	Total CV	Normalized Ratio (run)
LA Negative Control	80	<6%	≤ 6%	<1.1 for LAC <1.16 for SCT
LA Positive Control	80	<6%	≤ 6%	≥ 1.40 for LAC and SCT

b. Linearity/assay reportable range:
Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Stability:
The lyophilized shelf life for the LA controls are stable at 2-8°C up to 24 months. After reconstitution, the LA controls are stable at 2-8°C for up to 24 hours. The on board stability of LA controls after reconstitution are as follows:

24 hours on the ACL TOP Family
4 hours on the ACL ELITE/ELITE PRO 8/9/1000
4 hours on the ACL Futura/ACL Advance
4 hours on the ACL Classic (100-7000) System

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable
   b. Matrix comparaison:
   Not applicable
3. Clinical studies:
   a. Clinical Sensitivity:
   Not applicable
   b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
The expected values were based on determined normalized ratios (NR) from the product inserts for IL LA test assays (LA Screen and LA Confirm) on IL Coagulation systems [ACL TOP Family, ACL ELITE®/ELITE PRO/8/9/1000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000].

Expected values were determined for the LA Positive and Negative controls using HemosIL LAC Screen and Confirm, and HemosIL Silica Clotting reagents verified by a control acceptance protocol. The expected values were determined from LA Negative control (N=288) and Positive control (N=288) studies applied on three LA assays over four instrument platforms to confirm value assignment:

Controls	**Expected Values**		
	Instrument Family	LAC Screen/Confirm	Silica Clotting Time
LA Negative Control	ACL TOP Line	<1.1	<1.16
LA Negative Control	ACL Advance, Elite, Elite PRO, Futura, Classic Lines	<1.2	No testing for the Classic line
LA Negative Control	ACL Elite, Elite PRO		<1.20
LA Negative Control	ACL Advance, Futura		<1.24
LA Positive Control	ACL Advance, Elite, Elite PRO, Futura, Classic Lines	≥1.40	No testing for the Classic line ≥ 1.40

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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