

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

A. 510(k) Number:

k113211

B. Purpose for Submission:

Addition of reconstituted freezing stability claims as well as update to Indications for Use to include use of the controls in the HemosIL dRVVT Screen/Confirm Assays

C. Measurand:

Controls for Lupus Anticoagulant (LA)

D. Type of Test:

Assayed Controls

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

HemosIL LA Positive Control

HemosIL LA Negative Control

G. Regulatory Information:

1. Regulation section:

21CFR §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 dRVVT Screen/dRVVT Confirm, HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

HemosIL LA Negative Control:

For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm, HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

2. Indication(s) for use:

Same as intended use.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:
 IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000;
 ACL Futura/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-phospholipid antibodies with added buffer. The device consists of 10 1-mL 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 10 1-mL vials of lyophilized controls per package.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 HemosIL LA Positive Control
 HemosIL LA Negative Control
2. Predicate 510(k) number(s):
 k102552
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	HemosIL LA Positive Control	Same
Analyte Tested	Lupus Anticoagulant	Same
Constituent Material	Lyophilized preparation from human donors exhibiting the presence of anti-phospholipid antibodies with added buffer	Same
Test System	IL coagulation system: ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000)	Same

Differences		
Item	Device	Predicate
	HemosIL LA Positive Control	Same
Intended Use	For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm , HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)]	For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)]

Differences		
Item	Device	Predicate
Reconstituted Freezing Stability	Stable for 3 weeks at -20°C in the closed original vial	No reconstituted frozen stability claim

Similarities		
Item	Device	Predicate
	HemosIL LA Negative Control	Same
Analyte Tested	Lupus Anticoagulant	Same
Constituent Material	Lyophilized preparation from human citrated platelet-poor plasma to make pooled normal plasma with added buffer	Same
Test System	IL coagulation system: ACL TOP Family, ACL ELITE/ELITE PRO/8/9/10000, ACL Futura/ACL Advance/ACL Advance, ACL Classic (100-7000)	Same

Differences		
Item	Device	Predicate
	HemosIL LA Negative Control	Same
Intended Use	For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL dRVVT Screen/dRVVT Confirm , HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)]	For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP Family; ACL ELITE/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)]
Reconstituted Freezing Stability	Stable for 3 weeks at -20°C in the closed original vial	No reconstituted frozen stability claim

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

- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material, June 7, 2007
- CLSI EP25-A: Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline (2009)

L. Test Principle:

LA Positive control is a lyophilized preparation from human donors with anti-phospholipid antibodies with added buffer. LA Negative control is a lyophilized preparation of a pool of normal human citrated platelet-poor plasma. The controls are used to assess the precision and accuracy of Lupus Anticoagulant (LA) assays

performed on IL Coagulation instrument platforms using HemosIL LA Reagents (LA dRVVT Screen/dRVVT Confirm, LAC Screen/LAC Confirm; Silica Clotting Time).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

To evaluate precision 9 vials were run over 1 day from 3 lots (27 samples total) for each control and were analyzed on the ACL TOP base analyzer with both the HemosIL dRVVT Screen and dRVVT Confirm assays. Normalized Ratios (NR) were calculated as described below. Acceptance criteria were set at a NR of ≥ 1.4 for the Positive Control, and a NR of ≤ 1.2 for the Negative Control. Both LA Controls met precision specifications.

To evaluate reproducibility, 2 lots of each Control were tested with a single lot of HemosIL dRVVT Screen and dRVVT Confirm assay on representative members of the instrument families for 20 days with 2 runs per day and 2 replicates for each run for each sample level (N=80 per level/instrument/lot).

Testing was done on the following instruments: ACL TOP/500CTS, ACL 10000, ACL Advance, and ACL Classic. Acceptance criteria for both within-run and total reproducibility were set at a CV $\leq 6\%$. Both LA Controls met reproducibility specifications.

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 is 24 months at 2-8°C.

After reconstitution the LA Controls are stable for 24 hours at 2-8°C and 21 days at -20°C in the closed original vials.

The on-board stability of the LA Controls after reconstitution are:

24 hours on the ACL TOP Family

4 hours on the ACL ELITE/ELITE PRO 8/9/10000

4 hours on the ACL Futura/ACL Advance

4 hours on the ACL Classic (100-7000) System

Freezing stability claim:

Fresh vials were reconstituted and assayed at time 0 at the same time that the frozen vials were thawed in a 37°C water bath. Two vials per time point per lot were pooled and assayed and the results were compared to the mean of the results from fresh vials at time 0. Each lot was assayed with the LAC Screen, LAC Confirm, SCT Screen, SCT Confirm, dRVVT Screen, and dRVVT Confirm assays.

Acceptance criteria are $\pm 10\%$ of the zero point.

$\% \text{Variation} = (\text{Test clot time (sec)} - (\text{Zero point clot time (sec)})) / \text{Zero point clot time (sec)} \times 100\%$

Because the LA Negative Controls were not stable at the 32 day time point, the 22 day time point was assayed and the acceptance criteria were met.

The LA Positive Controls was stable at the 32 day time point.

d. *Detection limit:*

Not applicable

