

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K041905

B. Purpose for Submission:

To seek clearance for HemosIL Calibration plasma designed for calibration of coagulation assays on IL and ELECTRA Coagulation Systems.

C. Analyte:

PT, Fibrinogen, Single Factors, von Willebrand Factor, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, and as a reference plasma for APTT and TT.

D. Type of Test:

Quantitative clotting assay

E. Applicant:

Instrumentation Laboratory Company

F. Proprietary and Established Names:

HemosIL Calibration plasma

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1150
2. Classification:
Class II
3. Product Code:
JIX
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
HemosIL Calibration plasma is intended for the calibration of coagulation assays on IL and ELECTRA Coagulation Systems.
2. Indication(s) for use:
Used for the determination of PT, Fibrinogen, Single Factors, von Willebrand Factor, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, and as a reference plasma for APTT and TT.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

Not applicable

I. Device Description:

HemosIL Calibration plasma is calibration plasma is lyophilized human plasma prepared using citrated plasma plasmapheresed from healthy donors containing buffers, stabilizers and preservatives to maintain the characteristics of a normal plasma pool.

J. Substantial Equivalence Information:1. Predicate device name(s):

(a) HemosIL Assayed Reference Plasma – Normal (for ELECTRA) Series Analyzers)

(b) Assess Calibration Plasma (for ACL Family of Analyzers)

2. Predicate K number(s):

(a) K905203

(b) K002400

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample Type	HemosIL Calibration plasma	Assess Calibration Plasma
	Citrated plasma	Citrated plasma
Storage Conditions	Refrigerate 2-8° C until expired	Same
Differences		
Item	Device	Predicate
Composition/Manufacturing	Lyophilized citrated plasma plasmapheresed from healthy human donors containing buffer (Hepes), dextran and preservatives: ciprofloxacin and sodium omadine.	Lyophilized citrated human plasma containing buffer (Hepes), dextran and glycine (no preservatives).
Assigned Values	Same list as Assess Calibration Plasma with the addition of: APTT, PT, & TT.	Antithrombin, Factors, Fibrinogen, Alpha-2-Antiplasmin, Plasminogen, Protein C, Protein S, von Willebrand Factor

K. Standard/Guidance Document Referenced (if applicable):**L. Test Principle:**

Not applicable

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

Precision testing was performed as part of the value assignment process by running HemosIL Calibration plasma in replicates of eight on four different IL coagulation instruments (n=32) with the IL reagent listed below. The within-run, between-run and total %CV were calculated per NCCLS Document EP5-T2. All analytes met their specification for within-run %CV.

CV ranges for IL reagents and IL coagulation instruments (n=32)

Analyte	Within-run %CV	Between-run %CV	Total %CV	Within-Run CV Specification
APTT (seconds)	0.35-1.85	0.43-2.17	0.74-5.52	≤ 5 %
Antithrombin (%)	1.09-2.31	0.00-4.02	1.79-7.28	≤ 10 %
Factor II (%)	1.81-8.70	0.00-5.42	1.81-10.25	≤ 10 %
Factor V (%)	1.31-3.67	1.58-4.47	2.31-5.79	≤ 10 %
Factor VII (%)	1.26-3.68	1.27-4.56	1.80-5.86	≤ 10 %
Factor VIII (%)	4.21-6.65	1.27-4.63	4.47-8.10	≤ 10 %
Factor IX (%)	2.62-9.09	2.03-2.80	3.80-9.32	≤ 10 %
Factor X (%)	0.96-2.73	0.93-2.82	1.34-3.34	≤ 10 %
Factor XI (%)	3.11-7.06	0.76-6.28	3.20-9.45	≤ 10 %
Factor XII (%)	1.62-6.09	0.51-7.56	2.35-9.70	≤ 10 %
Factor VIII chromogenic (%)	1.65-2.63	0.32-2.87	1.69-3.89	≤ 10 %
Fibrinogen-Clauss (mg/dl)	1.98-6.72	1.16-3.18	2.41-6.82	≤ 15 %
Fibrinogen PT-based (mg/dl)	2.03-5.91	0.00-6.28	2.07-7.53	≤ 15 %
Plasmin Inhibitor (%)	1.65-3.16	1.49-6.38	2.51-7.11	≤ 10 %
Plasminogen (%)	0.81-3.37	1.55-2.57	2.22-3.81	≤ 10 %
Protein C (%)	1.42-6.96	1.52-10.61	2.07-12.50	≤ 10 %
Protein S (%)	2.14-3.66	1.53-4.36	2.64-5.51	≤ 10 %
PT (seconds)	0.61-3.20	0.00-2.12	0.91-3.37	≤ 5 %
TT (seconds)	1.27-3.76	0.00-3.22	2.10-3.95	≤ 7 %
von Willebrand Factor (%)	1.13-2.88	0.25-1.80	1.16-3.40	≤ 10 %

b. Linearity/assay reportable range:

Analyte	Slope	R ²	Intercept	Sample Range
Antithrombin (%)	0.9897	1.000	3.7142	19.7-113 %
Plasmin Inhibitor (%)	1.0462	1.000	-2.5797	31.0-109 %
Plasminogen (%)	0.8763	1.000	3.1824	17.0-141 %
Protein C (%)	1.0155	1.000	0.1110	24.1-132 %
Protein S (%)	0.9643	1.000	-0.5825	13.9-109 %
VWF (%)	0.9141	1.000	1.7586	6.0-171 %
Factor V (%) with PT	0.9886	1.000	0.3342	1.91-131 %
Factor VIII (%) with APTT	1.1103	1.000	-0.3741	0.36-134 %
Factor VIII (%) Chromogenic	1.0711	1.000	5.6404	3.44-163 %
Fibrinogen (mg/dl) Clauss	0.9532	0.9964	8.2089	98.2-601 mg/dl

c. Traceability (controls, calibrators, or method):

The analyte values for HemosIL Calibration plasma have traceability to the International Standards listed below. If an International Standard is not available, then a House Standard is assigned against a pool of 100 normal donors.

Analyte	WHO Standard Code No.
Antithrombin	93/768
Factor II	94/746
Factor V	House Standard
Factor VII	94/746
Factor VIII	97/586
Factor IX	99/826
Factor X	94/746
Factor XI	House Standard
Factor XII	House Standard
Fibrinogen (Derived)	98/612
Fibrinogen (Clauss)	89/644
Plasmin Inhibitor	House Standard
Plasminogen	House Standard
Protein C	86/622
Protein S	93/590
Von Willebrand Factor	97/586

- 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 comparison:*
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):*

Stability:

Reconstituted stability testing was performed to support the following package insert claims for the new HemosIL Calibration plasma:

- 24 hours at 2-8°C in the original vial for PT, Fibrinogen, APTT, TT, Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S
- 8 hours at 2-8°C in the original vial for the remaining parameters (Factors)
- 24 hours at -20°C in the original vial for PT and APTT

A shelf-life stability study is ongoing at 2-8°C using three different lots of HemosIL Calibration plasma. At time intervals of 0, 6 mo., 12 mo., 18 mo., 24 mo., 30 mo., and 36 mo., HemosIL Calibration plasma was run in quadruplicate and the results compared to the baseline at time zero. The results to date support a 36-month shelf life for HemosIL Calibration plasma.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Conclusion:

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