

**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:

| <b>Similarities</b>       |  |  |
|---------------------------|--|--|
| <b>Item</b>               | <b>Device</b>  | <b>Predicate</b>   |
| Sample Type               | <b>HemosIL Calibration plasma</b><br>Citrated plasma   | <b>Assess Calibration Plasma</b><br>Citrated plasma  |
| Storage Conditions        | Refrigerate 2-8° C until expired   | Same   |
| <b>Differences</b>        |  |  |
| <b>Item</b>               | <b>Device</b>  | <b>Predicate</b>   |
| 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:*

| <b>Analyte</b>              | <b>Slope</b> | <b>R<sup>2</sup></b> | <b>Intercept</b> | <b>Sample Range</b> |
|-----------------------------|--------------|----------------------|------------------|---------------------|
| 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.

| <b>Analyte</b>        | <b>WHO Standard Code No.</b> |
|-----------------------|------------------------------|
| 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.