

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

A. 510(k) Number:

K040359

B. Analyte:

Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C, Protein S, von Willebrand Factor, Factors II, V, VII, VIII, IX, X, XI, XII

C. Type of Test:

N/A

D. Applicant:

Instrumentation Laboratory Company

E. Proprietary and Established Names:

HemosIL Special Test Control Level 1 & 2

F. Regulatory Information:

1. Regulation section:
864.5425
2. Classification:
Class II
3. Product Code:
JPA
4. Panel:
Hematology (81)

G. Intended Use:

HemosIL Special Test Control Level 1 & 2 is human plasma used for quality control as follows:

- In the abnormal range of the chromogenic tests (Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Factor VIII) and Free Protein S assay on the IL Coagulation Systems
 - Of von Willebrand Factor assay in the normal (Level 1) and abnormal (Level 2) on the IL Coagulation Systems
 - Of factor assays (clotting) in the abnormal range (Level 2) on the IL Coagulation Systems
1. Indication for use:
HemosIL Special Test Control Level 1 & 2 is human plasma used for quality control as follows:

- In the abnormal range of the chromogenic tests (Antithrombin, Plasminogen, Plasmin Inhibitor, Protein C and Factor VIII) and Free Protein S assay on the IL Coagulation Systems
 - Of von Willebrand Factor assay in the normal (Level 1) and abnormal (Level 2) on the IL Coagulation Systems
 - Of factor assays (clotting) in the abnormal range (Level 2) on the IL Coagulation Systems
2. Special condition for use statement(s):
Not Applicable
 3. Special instrument Requirements:
HemosIL Special Test Control Level 1 & 2 is for use on the IL Coagulation Systems.

H. Device Description:

HemosIL Special Test Control Level 1 & 2 is lyophilized human plasma containing buffer and stabilizers.

I. Substantial Equivalence Information:

1. Predicate device name:
HemosIL Special Test Controls Level 1 & 2
2. Predicate K number:
K864271
3. Comparison with predicate:

Similarities		
Item	Predicate	Device
	<i>HemosIL Special Test Control Level 1 & 2 (K864271)</i>	<i>HemosIL Special Test Controls Level 1 & 2</i>
Intended use	For the quality control in the abnormal range of the chromogenic tests (Antithrombin, Plasminogen, Plasmin Inhibitor and Protein C) and Free Protein S. For the quality control of von Willebrand Factor assay in the normal (Level 1) and abnormal range (Level 2).	Same with addition of Factor VIII (Level 1 and 2), and the addition of a quality control for factor assays (clotting) in the abnormal range (Level 2).
Test Principle	Level 1: Abnormal levels for the chromogenic tests and the Free Protein assay in the range of 50-60% activity. It is intended for the assessment of precision and accuracy of the tests in the mid abnormal range.	Level 1: Same

	<p>Von Willebrand Factor values are within the normal range.</p> <p>Level 2: Abnormal levels for chromogenic test and the Free Protein S assay in the range of 20-30% activity. It is intended for the assessment of precision and accuracy of the chromogenic tests for patients undergoing thrombolytic therapy.</p> <p>Von Willebrand Factor values are in the low abnormal range.</p>	<p>Level 2: Abnormal levels for chromogenic test and the Free Protein S and factor assays (clotting) in the range of 20-40% activity. It is intended for the assessment of precision and accuracy of chromogenic tests for patients undergoing thrombolytic therapy.</p> <p>Same</p>
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J. Standard/Guidance Document Referenced (if applicable):

National Committee for Clinical Laboratory Standards, Preparation and Testing of Reagent Water in the Clinical Laboratory, NCCLS Document C3-A3; Vol 17 No 18

K. Test Principle:

Not Applicable

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

N/A

b. *Linearity/assay reportable range:*

N/A

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

The reported values in the product insert are determined over multiple runs on IL Coagulation Systems using a specific lot of reagent and against a Calibration Plasma House Standard, which is traceable to the current International Standards. See below:

Test	WHO Standard Code No.
Chromogenic Factor VIII*	House Calibrator Standard
Factor II	94/746
Factor V*	House Calibrator Standard
Factor VII	94/746
Factor VIII	97/586
Factor IX	94/746
Factor X	94/746
Factor XI*	House Calibrator Standard
Factor XII*	House Calibrator Standard

*For the tests where International Standards are not available, these parameters have been assigned against a House Standard which is traceable to a frozen normal plasma pool of 100 donors following an internal Quality Control Procedure.

- d. Detection limit:*
N/A
 - e. Analytical specificity:*
N/A
 - f. Assay cut-off:*
N/A
- 2. Comparison studies:
 - a. Method comparison with predicate device:*
N/A
 - b. Matrix comparison:*
N/A
- 3. Clinical studies:
 - a. Clinical sensitivity:*
N/A
 - b. Clinical specificity:*
N/A
 - c. Other clinical supportive data (when a and b are not applicable):*
- 4. Clinical cut-off:
N/A
- 5. Expected values/Reference range:
Refer to specific reagent inserts for performance characteristics. The reported ranges were determined over multiple runs on IL Coagulation Systems using specific lots of IL reagents. The mean of the control range determined in the user's laboratory may vary due to the lot of reagent used.

M. Conclusion:

Based on the review of the information provided, the HemosIL Special Test Control Level 1 & 2 is substantially equivalent (SE) to devices regulated under 21 CFR 864.5425, system, multipurpose for in vitro coagulation studies, product code JPA.