

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

A. 510(k) Number:

K082859

B. Purpose for Submission:

New Submission

C. Measurand:

PT, APTT, Fibrinogen

D. Type of Test:

Quantitative

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

HemosIL Routine Control Level 1, 2, and 3

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

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

HemosIL Routine Control Level 1 is for the quality control of coagulation assays in the normal range. The product is intended in the assessment of precision and accuracy for PT, APTT, and Fibrinogen tests performed on coagulation systems.

HemosIL Routine Control Level 2 is for the quality control of coagulation assays in the low abnormal range. The product is intended in the assessment of precision and accuracy for PT, and APTT tests performed on coagulation systems.

HemosIL Routine Control Level 1 is for the quality control of coagulation assays in the high abnormal range. The product is intended in the assessment of precision and accuracy for PT, and APTT tests performed on coagulation systems.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

N/A

4. Special instrument requirements:

N/A

I. Device Description:

The HemosIL Routine Control Level 1 is a lyophilized product prepared using human citrated plasma from healthy donors. It contains buffer, stabilizers and preservatives.

The HemosIL Routine Control Level 2 is a lyophilized product prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified, by means of a dedicated process, to stimulate an abnormal coagulation sample. It contains buffer and stabilizers. No preservatives are included.

The HemosIL Routine Control Level 3 is a lyophilized product prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified, by means of a dedicated process, to stimulate an abnormal coagulation sample. It contains buffer and stabilizers. No preservatives are included

J. Substantial Equivalence Information:

1. Predicate device name(s):

K021023 HemosIL Normal Control

K021022 HemosIL Low Abnormal Control

K021024 HemosIL High Abnormal Control

2. Predicate 510(k) number(s):

See Above

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use: For the quality control of coagulation assays in the normal, low abnormal, and high abnormal range.	Same	K021023 HemosIL Normal Control, K021022 HemosIL Low Abnormal Control, K021024 HemosIL High Abnormal Control Same
Matrix	Human Plasma	Same
Form	Lyophilized	Same

Differences		
Item	Device	Predicate
Assayed Control	Assayed Control	Unassayed Control

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

N/A

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within run precision was assessed over multiple runs using the three levels of HemosIL Routine Control with specific lots of reagents on representative coagulation systems: ACL 9000, ACL Advance, ACL 300, ACL 6000. ACL Advance, and ACL 300 for PT, APTT and Fibrinogen. Reagents used in the analysis included HemosIL PT-Fibrinogen Recombinant, HemosIL PT-Fibrinogen, HemosIL PT-Fibrinogen HS Plus, HemosIL APTT-SP, HemosIL SynthAFax, and HemosIL SynthASil. Within Run and Between Run %CVs were within the specifications.

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

A real-time shelf-life study was performed using three lots of HemosIL Routine Control Level 1, 2, and 3. Vials of the control were tested in quadruplicate at Day 0 and stored at 2-8°C in the original vials for the duration of testing. At each time interval, the three lots of control were tested at a minimum in duplicate on a representative coagulation system using representative reagents. The data presented supports the real-time stability claim of 36 months for HemosIL Control Level I and 24 months for Level 2 and 3.

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:

The reported Acceptance Ranges were determined over multiple runs on an ACL Classic System (100-7000) using specific reagents.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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

