

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

A. 510(k) Number:

K050661

B. Purpose for Submission:

To seek clearance of a new assay

C. Measurand:

Factor II

D. Type of Test:

Clotting

E. Applicant:

Instrumentation Laboratory Co.

F. Proprietary and Established Names:

HemosIL Factor II Deficient Plasma

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7290

2. Classification:

Class II

3. Product code:

GJT

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

HemosIL Factor II Deficient Plasma is human plasma immunodepleted of Factor II for the quantitative determination of Factor II activity in citrated plasma, based on the prothrombin time (PT) assay, on IL Coagulation and ELECTRA™ Systems.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The HemosIL Factor II Deficient Plasma kit consists of 5-1 mL vials of lyophilized human plasma that has been artificially depleted of Factor II and containing buffer and stabilizers. Residual Factor II activity is less than or equal to 1%, all other coagulation factors have normal levels.

J. Substantial Equivalence Information:

1. Predicate device name(s):

HemosIL Factor II Deficient Plasma on ACL Family of Analyzers

Hemoliance Factor II Deficient Plasma on ELECTRA Series Analyzers

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

K002400

K900133

3. Comparison with predicate:

Similarities			
Item	Device	Predicate 1	Predicate 2
Sample type	Citrated plasma	same	same
Storage	2-8° C	same	same
Composition	Lyophilized human plasma immunoadsorbed on a column of antibody specific for human factor II	Same	same
Intended use	Quantitative determination of Factor II activity based on the PT assay	Same	same

Differences			
Item	Device	Predicate 1	Predicate 2
Instrumentation	IL ACL and ELECTRA	IL Coagulation Systems	ELECTRA
Manufacturer	IL, Orangeburg, NY	Trinity Biotech, Wicklow, Ireland	Trinity Biotech Wicklow, Ireland

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

NCCLS EP5-T2, User Evaluation of Precision Performance of Clinical Chemistry Devices

L. Test Principle:

Factor II (prothrombin), is a vitamin K-dependent plasma protein that is synthesized in the liver and circulates in plasma as an inactive molecule. During coagulation FII is converted to the active form, factor IIa (thrombin), by Factor Xa.

Congenital deficiency of factor II is a very rare inherited disorder that causes in general a mild to moderate bleeding tendency. Factor II deficiencies may also be acquired secondarily due to other diseases such as hyperfibrinolysis, DIC and liver disease.

Factor II activity in a patient's plasma is determined by performing a modified prothrombin time test. Patient plasma is diluted with Owren's Buffer and mixed with a substrate plasma deficient in factor II. The mixture is assayed by the PT clotting procedure. The clotting time is dependent upon the concentration of factor II in the patient plasma. The clotting time is compared to a standard curve prepared prior to assay from dilutions of normal pooled plasma or commercial reference plasma mixed with the same factor II deficient plasma.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was performed on an ACL Advance (K002400), the ACL Futura Coagulation Analyzer (K951891), the ACL 9000 (K000053), ACL 300 (K881367), ACL 3000 (K912087), ACL TOP (K033414), ELECTRA 1400C (K944227), ELECTRA 1600 (K931206), and the ELECTRA 1800C (K962664) using HemosIL RecombiPlasTin (K012768) PT reagent and 2 levels of controls: HemosIL Normal Control (K021023) and the HemosIL Special Test Control Level 2 (K040359). On the ACL 9000, ACL Futura, ACL TOP, and ELECTRA 1600C, each control was run in replicates of four twice a day for 10 days (n=80). On the ACL 300, ACL 3000, ACL Advance, ELECTRA 1400C, and ELECTRA 1800C, each control was run in replicates of four twice a day for five days (n=40). Within run, between run and total %CV was calculated per NCCLS EP5-T2. %CV were within the acceptance criteria (Normal <10%, Special Test Level 2 <17%).

b. Linearity/assay reportable range:

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

d. Detection limit:

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies:

a. *Method comparison with predicate device:*

An in-house study was conducted using 60 patient citrated plasma samples with the HemosIL Factor II Deficient Plasma versus the predicate devices. Each sample was run in duplicate using HemosIL RecombiPlasTin reagent.

New HemosIL Factor II Deficient Plasma vs. Predicate HemosIL Factor II Deficient Plasma on ACL Family			
IL System	Slope	Intercept	r
ACL 300	1.0357	1.0196	0.9921
ACL 6000	1.0464	-2.1396	0.9954
ACL 9000	1.0458	-1.6123	0.9953
ACL TOP	1.0582	-4.6831	0.9855
New HemosIL Factor II Deficient Plasma vs. Predicate Hemoliance Factor II Deficient Plasma on ELECTRA			
E1600C	1.063	-0.2821	0.9917

A field study was conducted using 61 patient citrated plasma samples with the HemosIL Factor II Deficient Plasma versus the predicate HemosIL Factor II Deficient Plasma on an ACL Futura. HemosIL RecombiPlasTin reagent was used in the testing. ($y = 1.0602x - 3.6113$, $r = 0.9946$)

b. *Matrix comparison:*

3. Clinical studies:

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

- c. Other clinical supportive data (when a. and b. are not applicable):

The following studies were presented to demonstrate the equivalent performance of HemosIL Factor II Deficient Plasma with various PT reagents on representative IL instruments:

1. 49 patient samples spanning in range from 7 – 171% were test on an ACL Advance using HemosIL RecombiPlasTin (reference) vs. HemosIL PT-Fibrinogen HS (test) (K923921) reagent. Results are statistically similar ($y = 0.8916x - 18.676$, $r = 0.9653$).
2. The same testing pool was also run on an ACL Advance using HemosIL RecombiPlasTin (reference) vs. HemosIL PT-Fibrinogen HS Plus (test) (K933252) reagent. Results are statistically similar ($y = 1.1194x - 13.560$, $r = 0.9846$).
3. The same testing pool was also run on an ACL Advance using HemosIL RecombiPlasTin (reference) vs. HemosIL PT-Fibrinogen Recombinant (K981479) reagent. Results are statistically similar ($y = 1.0551x - 1.2247$, $r = 0.9796$).
4. 40 patient samples spanning in range from 15 – 215% were test on an ELECTRA using HemosIL RecombiPlasTin (reference) vs. Hemoliance Brain Thromboplastin reagent. Results are statistically similar ($y = 0.9650x - 2.1467$, $r = 0.9633$).

Results demonstrated that the performance of HemosIL Factor II Deficient Plasma is statistically equivalent between PT reagents.

4. Clinical cut-off:
5. Expected values/Reference range:

N. Proposed Labeling:

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

O. Conclusion:

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