

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k100103

B. Purpose for Submission:

Change of manufacturing location for a currently marketed device

C. Measurand:

Abnormal control for Prothrombin Time (PT), activated Partial Thromboplastin Time (aPTT), Factors II, V, VII, X, VIII, IX, XI, XII, Fibrinogen, von Willebrand Factor Antigen, Ristocetin Cofactor, Protein C, Protein S (total and free)

D. Type of Test:

Hemostasis quality control

E. Applicant:

Helena Laboratories Corporation

F. Proprietary and Established Names:

Specialty Assayed Control-2 (S.A.C.-2)

G. Regulatory Information:

1. Regulation section:
21 CFR 864.5425, Multipurpose system for in vitro coagulation studies
2. Classification:
II
3. Product code:
GGC, Control, plasma, abnormal
4. Panel:
81 Hematology

H. Intended Use:

1. Intended use(s):
The S.A.C.-2 is an assayed abnormal control plasma intended for use in clinical laboratories when testing human plasma for the following coagulation deficiencies: Prothrombin time (PT), activated Partial Thromboplastin Time (aPTT), Factor II, V, VII, VIII, IX, X, XI, XII deficiencies, Fibrinogen, von Willebrand Factor antigen, Ristocetin cofactor, Protein C activity, and Protein S activity (total and free). The control material can be used with manual assays, electro-mechanical, or photo-optical clot detection methods.
2. Indication(s) for use:
Same as Intended Use
3. Special conditions for use statement(s):
Prescription use only
4. Special instrument requirements:
Mechanical and photo-optical instrumentation

I. Device Description:

The S.A.C.-2 is an assayed abnormal control plasma from normal human donors intended for use in clinical laboratories when testing human plasma for the following coagulation deficiencies: Prothrombin time (PT), activated Partial Thromboplastin

Time (aPTT), Factor II, V, VII, VIII, IX, X, XI, XII deficiencies, Fibrinogen, von Willebrand Factor antigen, Ristocetin cofactor, Protein C activity, and Protein S activity (total and free).

The control is prepared from a normal pool of human plasma collected in 4% sodium citrate. The pool has 0.03M Hepes buffer and is lyophilized to ensure stability of all plasma coagulation factors. All factors are adjusted to be in the abnormal range.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Specialty Assayed Control-2 (S.A.C.-2)
2. Predicate 510(k) number(s):
k941872
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The S.A.C.-2 is an assayed abnormal control plasma intended for use in clinical laboratories when testing human plasma for the following coagulation deficiencies: Prothrombin time (PT), activated Partial Thromboplastin Time (aPTT), Factor II, V, VII, VIII, IX, X, XI, XII deficiencies, Fibrinogen, von Willebrand Factor antigen, Ristocetin cofactor, Protein C activity, and Protein S activity (total and free). The control material can be used with manual assays, electro-mechanical, or photo-optical clot detection methods.	The S.A.C.-2 is an assayed abnormal control plasma which may be used in many facets of testing in the coagulation laboratory
Analytes	Prothrombin time (PT), activated Partial Thromboplastin time (aPTT), Factor II, V, VII, VIII, IX, X, XI, XII deficiencies, fibrinogen, von Willebrand Factor antigen, Ristocetin cofactor, Protein C activity, and Protein S activity (total and free).	Same
Reagent	Lyophilized, buffered human plasma collected in 4% sodium citrate	Same
Stability (reconstituted)	4 hours at 2 - 8°C	Same
Packaging	10 x 1 mL vials	Same
Instrumentation	Mechanical and photo-optical instruments	Same

Differences		
Item	Device	Predicate
Analytes (Kinetic)	Analytes no longer available in control F VIII, X, plasminogen, antithrombin III, protein C, a2-antiplasmin	Included in control F VIII, X, plasminogen, antithrombin III, protein C, a2-antiplasmin
Analytes (Immunological RID)	Analytes no longer available in control Plasminogen, antithrombin III	Included in control Plasminogen, antithrombin III

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

CLSI, EP5-A2-Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines-Second Edition

L. Test Principle:

The control plasma may be used when performing tests on manual assays, mechanical or photo- optical coagulation instruments in conjunction with suitable commercial reagents.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were performed at Helena Laboratories with three operators, using various reagent systems and analyzers. Duplicate determinations of all analytes were made on five vials from four lots of control, as described in CLSI, EP5-A2. All parameters fell within acceptance criteria (CV of $\leq 15\%$).

b. *Linearity/assay reportable range:*

Not applicable

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

Assays are acceptable if the mean values are as follows:

Assay	Mean Value
Prothrombin Time (PT)	≥ 14.0 seconds
Activated Partial Thromboplastin Time (aPTT)	> 35.0 seconds
Factor Assays	$\leq 50\%$
Fibrinogen	≤ 140 mg/dL
Rocket vonWillebrand Factor Antigen	$\leq 50\%$
Rocket Protein C	$\leq 50\%$
Rocket Protein S	$\leq 50\%$
Rocket Protein S (Free)	$\leq 50\%$
Ristocetin Cofactor	$\leq 50\%$
ELISA Protein C	$\leq 50\%$
ELISA Protein S, S (Free), Monoclonal Free S	$\leq 50\%$
ELISA vonWillebrand Factor Antigen	$\leq 50\%$

Stability studies were performed on each analyte using duplicate determinations on three vials from each of three lots of control. Each analyte was tested at 0 hours and at 4.5 hours with storage at 2 to 8°C. Acceptance criteria for the studies was defined as falling within assigned range and for the 4.5 hour data point to be within 20% of the 0 hour data point. All parameters fell within acceptable performance.

d. *Detection limit*

Not applicable

e. *Analytical specificity:*

Not applicable

f. *Assay cut-off:*

Not applicable

N. Proposed Labeling:

The labeling is sufficient and 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.