

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

A. 510(k) Number:

k092113

B. Purpose for Submission:

New device

C. Measurand:

Free Protein S

D. Type of Test:

Quantitative immuno-turbidimetric method

E Applicant:

DIAGNOSTICA STAGO, INC.

F. Proprietary and Established Names:

STA[®] - Free PS Calibrator

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1150, Calibrator
2. Classification:
Class II
3. Product code:
JIX, Calibrator, Multi-Analyte Mixture
4. Panel:
Hematology (81)

H. Intended Use:

1. Intended use(s):
STA[®] - Free PS Calibrator kit is a set of calibrator plasmas intended for use with analyzers of the STA[®] line suitable to these reagents for the calibration of free protein S assays by the immuno-turbidimetric method, STA[®] - Liatest[®] Free PS.
2. Indication(s) for use:
Same as Intended Use
3. Special conditions for use statement(s):
For Prescription Use Only
4. Special instrument requirements:
STA[®] - Free PS Calibrator kit is for use with the STA[®] - Liatest[®] Free PS kit and STA[®] product line of IVD analyzers (STA-R[®] and STA Compact[®]).

I. Device Description:

The STA[®] - Free PS Calibrator kit is a set of lyophilized human plasmas used to create the calibration curve on an IVD instrument performing the immuno-turbidimetric method for free protein S assay, STA[®] - Liatest[®] Free PS. Such IVD instruments being the STA[®] product line of medical device analyzers such as STA-R[®] and STA Compact[®]. The calibrator kit consists of four (4) calibrators. Each calibrator is composed of lyophilized human plasma containing a well defined quantity of free protein S, buffer, and stabilizers.

Substantial Equivalence Information:

1. Predicate device name(s):
HemosIL™ Calibration Plasma
2. Predicate K number(s):
k041905
3. Comparison with predicate:

Similarities		
<i>Item</i>	STA® - Free PS Calibrator	HemosIL™ Calibration Plasma
Intended Use	STA® - Free PS Calibrator kit is a set of calibrator plasmas intended for use with analyzers of the STA® line suitable to these reagents for the calibration of free protein S assays by the immuno-turbidimetric method, STA® - Liatest® Free PS	HemosIL Calibration Plasma is intended for the calibration of coagulation assays on IL and ELECTRA coagulation systems.
Parameters	Free Protein S	Protein S
Design	Lyophilized human plasma reconstituted with water used in IVD analyzers	Same
Storage	2-8°C	Same

Differences		
Item	Device	Predicate
Instrumentation	STA-R® and STA Compact®	IL and ELECTRA coagulation systems.
Parameters		Antithrombin, Single Factors, Fibrinogen, Plasmin Inhibitor, Plasminogen, von Willebrand Factor, Protein C, PT, APTT, TT

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

Not applicable

L. Test Principle:

Protein S is a physiological inhibitor of the coagulation process. It acts as the cofactor of activated protein C. The congenital or acquired deficiency of protein S increases the risk of thrombo-embolism. The STA® - Free PS Calibrator kit is a set of lyophilized human plasmas used to create the calibration curve on an IVD instrument performing the immuno-turbidimetric method for free protein S assays.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. Precision/Reproducibility:
The free protein S level determinations were performed in eight different series on each calibrator level with the same instrument (STA-R®) using two different lots of STA® - Liatest® Free PS kit. Concurrently, the free protein S level determinations were also performed in eight different series on each

calibrator level with two different instruments (STA Compact[®] and STA-R[®]) using one lot of STA[®] - Liatest[®] Free PS kit. All tests were run within two to three weeks. A target value was established for each calibrator level; Reagent 1: 14%, Reagent 2: 29%, Reagent 3: 57%, Reagent 4: 95%. Total CV% for both studies is as follows:

Inter-Assay Lot Reproducibility Data for STA[®] - Free[®] PS Calibrator

STA [®] - Liatest [®] Free PS	Free Protein S Level (%)			
	Reagent 1	Reagent 2	Reagent 3	Reagent 4
Lot 1 CV (%)	6.7	3.7	1.7	2.6
Lot 2 CV (%)	5.0	3.7	2.5	1.9

Inter-Instrument Reproducibility Data for STA[®] - Free[®] PS Calibrator

Instrument	Free Protein S Level (%)			
	Reagent 1	Reagent 2	Reagent 3	Reagent 4
STA-R [®] CV (%)	6.7	3.7	1.7	2.6
STA Compact [®] CV (%)	7.6	3.6	2.8	2.6

- b. *Linearity/assay reportable range:*
Not applicable
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Value assignment: For each calibrator level, the free protein S value corresponds to the mean of a minimum of 24 determinations performed with a minimum of 3 instruments, using at least two different lots of STA[®] – Liatest[®] Free PS. The determinations are carried out by a minimum of two laboratory technicians.

Traceability: The STA[®] - Free PS Calibrators are determined against a secondary standard, International Standard 03/228 for free protein S established in 2006 by the National Institute for Biological Standards and Control (NIBSC).

Stability: Three different lots of calibrators (Reagent 1, 2, 3, and 4) were used in the stability studies. Three vials each of Reagent 1, 2, 3, and 4 were reconstituted and stored for 4 hours on both analyzers (STA Compact and STA-R). In addition, freshly reconstituted reagents from the same three lots were run using the STA[®] – Liatest[®] Free PS assay. The reconstituted stability study result supports the claim of remaining stable for 4 hours on board the STA line of IVD analyzers. In the lyophilized state, the calibrator plasmas remain stable for a duration of 18 months from the date of manufacture when stored at 2-8°C.
 - 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):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected values are manufacturing lot specific. An Assay Value Insert (AVI) is provided with each box of calibrators. Target values are as follows: Reagent 1: 15%, Reagent 2: 31%, Reagent 3: 61%, Reagent 4: 101%.

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.