

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

**A. 510(k) Number:**

K043451

**B. Purpose for Submission:**

The is a bundled submission for the clearance of 3 devices

**C. Measurand:**

Antithrombin III (ATIII), Protein C, and Lupus Anitcoagulant

**D. Type of Test:**

Assayed Quality Control Material

**E. Applicant:**

Hyphen BioMed

**F. Proprietary and Established Names:**

Biophen Plasma Calibrator

Biophen Normal Control Plasma

Biophen Abnormal Control Plasma

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.5425 Multipurpose Systems for In Vitro Coagulation Studies

2. Classification:

Class II

3. Product code:

GGN

4. Panel:

81

**H. Intended Use:**

1. Intended use(s):

The Biophen Plasma Calibrator is normal citrated human plasma used as the calibrator in the assay methods for coagulation factors such as ATIII and Lupus Anticoagulant.

The Biophen Normal Control Plasma is a set of 12 vials of normal citrated human plasma for the quality control of ATIII and Lupus Anticoagulant.

The Biophen Abnormal Control Plasma is a set of 12 vials of normal citrated human plasma for the quality control of ATIII and Lupus Anticoagulant.

2. Indication(s) for use:

3. Special conditions for use statement(s):

4. Special instrument requirements:

**I. Device Description:**

Biophen Plasma Calibrator reagent is composed of citrated normal human plasma, lyophilized in the presence of additives and preservatives. Each kit contains 12 vials of lyophilized reagent to be reconstituted with 1 ml distilled water. The concentration of the various coagulation factors is determined from the international standard.

The Biophen Normal and Abnormal Control Plasmas are lyophilized control material prepared from pooled plasma from selected health donors. Each control is calibrated for each parameter against a normal citrated human plasma pool and against

international standard when available. ATIII and Protein C is confirmed against SSC/ISTH Secondary Coagulation Standard (lot #2), which has an assigned value of 96% activity and 97% antigen for Protein C and 92% activity and 93% antigen for ATIII. Both controls are negative for lupus anticoagulant, and the Biophen Normal Control Plasma is also tested for the absence of activated protein C resistance (APC-r).

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Dade Behring Control Plasma N

Bio-Rad Lyphochek Hemostasis Control

HemosIL Calibration Plasma

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

K001256

K020878

K041905

3. Comparison with predicate:

<b>Similarities- Control Plasma N</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Matrix	Stabilized reagent prepared from pooled human plasma	same
Intended Use	To provide quality control in the normal range	same
Form	Lyophilized	same
Instrumentation	Mechanical and photo-optical	same

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Analytes	ATIII, Protein C, Lupus Anticoagulant	PT, aPTT, TT, Batroxobin Time

<b>Differences</b>		
Item	Device	Predicate
		Fibrinogen, coagulation factors II, V, VII, IX, X, XII, ATIII, Pro C, $\alpha$ -2 antiplasmin, plasminogen, ProC, APC
Stability	8 hrs- RT/24 hrs 2-8° C	4 hrs-RT/4 weeks -20- -30°C

<b>Similarities- Lyphochek Hemostasis Control</b>		
Item	Device	Predicate
Intended Use	To provide quality control in the normal range	same
Matrix	Stabilized pooled human plasma	same
Form	Lyophilized	same

<b>Differences</b>		
Item	Device	Predicate
Analytes	ATIII, Protein C, Lupus Anticoagulant	PT, aPTT, TT, Fibrinogen, coagulation factor II, V, VII, VIII, IX, X, XI, XII, ATIII, Pro C (functional), Protein S (functional), plasminogen,
Stability	8 hrs- RT/24 hrs 2-8° C	8 hrs-RT except Protein S-8 hrs at 2-8° C

<b>Similarities- HemosIL Calibration Plasma</b>		
Item	Device	Predicate
Matrix	Stabilized reagent prepared from pooled human plasma	same
Intended Use	For the calibration of coagulation assays	same
Form	Lyophilized	same

Similarities- HemosIL Calibration Plasma		
Item	Device	Predicate
Volume	1 ml	same

Differences		
Item	Device	Predicate
Analytes	ATIII, Protein C,	Coagulation factor VII, ATIII, Pro C, Pro S, plasminogen, von Willebrand factor, Plasma inhibitor

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

**L. Test Principle:**

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

The following values were obtained for one lot of Calibrator, Normal Control, and Abnormal Control.

	%CV		
	Calibrator	Norm Control	Abnormal Control
ATIII	1.5	1.4	1.5
Pro C	1.45	1.8	1.4

*b. Linearity/assay reportable range:*

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

The values assigned to the Biophen plasma calibrator are determined over multiple runs against a calibration standard which is traceable to the international standard, SSC/ISTH Secondary Coagulation standard lot#2. The value of the SSC/ISTH Secondary Coagulation standard lot#2 is determined against NIBSC 1<sup>st</sup> International standard for Protein C and against the NIBSC 2<sup>nd</sup> International standard for Antithrombin.

The Biophen Normal and Abnormal Control Plasma are calibrated for each parameter against a normal citrated human plasma pool and against internal standards, when available

- d. Detection limit:*
  
  - e. Analytical specificity:*
  
  - f. Assay cut-off:*
2. Comparison studies:
- a. Method comparison with predicate device:*
  
  - b. Matrix comparison:*
3. Clinical studies:
- a. Clinical Sensitivity:*
  
  - b. Clinical specificity:*
  
  - c. Other clinical supportive data (when a. and b. are not applicable):*

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.