

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

A. 510(k) Number:

k110432

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

PT, APTT, and Fibrinogen

D. Type of Test:

Quality Control Material, Assayed

E. Applicant:

Affinity Biologicals Inc.

F. Proprietary and Established Names:

VisuCon-F Frozen Coag Screen N

VisuCon-F Frozen Coag Screen ABN

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, Plasma, Coagulation Control

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

VisuCon-F Frozen Coag Screen N:

The VisuCon-F Frozen Coag Screen N plasma is an assayed normal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT), Activated partial thromboplastin time (APTT) and fibrinogen, in the normal range. The VisuCon-F Frozen Coag Screen N plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

VisuCon-F Frozen Coag Screen ABN:

The VisuCon-F Frozen Coag Screen ABN plasma is an assayed abnormal control plasma intended for use in the quality control of quantitative coagulation assays, including Prothrombin Time (PT) and Activated partial thromboplastin time (APTT), in the mid-level abnormal range. The VisuCon-F Frozen Coag Screen ABN plasma may be used with mechanical and photo-optical coagulation instruments in conjunction with appropriate commercial reagents.

2. Indication(s) for use:

Same as Intended use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Diagnostica Stago Inc. STA Compact Hemostasis System and Dade Behring Inc. BCS™ System.

I. Device Description:

VisuCon-F Frozen Coag Screen N is a pool of normal citrated human plasma collected from a minimum of 20 donors, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen. The product is packaged in box containing 25 x 1 mL vials or 81 x 1 mL vials or 81 x 4 mL vials.

VisuCon-F Frozen Coag Screen ABN is a pool of normal citrated human plasma collected from a minimum of 20 donors, diluted to a defined concentration, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen. The product is packaged in box containing 25 x 1 mL vials or 81 x 1 mL vials or 81 x 4 mL vials.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):
HemosIL™ Routine Control Level 1, 2, and 3, k082859
2. Comparison with predicate:

Similarities		
Item	Device VisuCon-F Frozen Coag Screen N and ABN	Predicate HemosIL™ Routine Control Level 1, 2, and 3
Intended Use	Quality controls of Prothrombin Time (PT), Activated partial thromboplastin time (APTT), and fibrinogen in the normal and abnormal ranges.	Same
Matrix	Citrated normal human plasma	Same

Differences		
Item	Device VisuCon-F Frozen Coag Screen N and ABN	Predicate HemosIL™ Routine Control Level 1, 2, and 3
Manufacturing process	Frozen pooled normal citrated human plasma buffered with 0.02 M HEPES buffer. The plasma is diluted to defined concentration in the creation of the abnormal control.	Lyophilized pooled human citrated plasma from healthy donors containing buffers and stabilizers. Normal plasma is modified to simulate an abnormal sample.
Storage	≤ -60°C	2-8°C
Open vial stability	8 hours at 2-8°C or on-board the coagulation instrument (15 - 22°C)	8 hours at 2-8°C in the original vial
Analyzers	STA Compact Hemostasis System; BCS™ System	ACL Classic System (100 – 7000)
Final Product Form (per control level)	25 x 1 mL or 81 x 1 mL or 81 x 4 mL vials Two levels: normal and low abnormal range	10 x 1 mL vials Three levels: normal, low abnormal, and high abnormal range

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

Not applicable

L. Test Principle:

Not applicable

M. Performance Characteristics:

1. Analytical performance:

a. *Precision/Reproducibility:*

System #1: Precision studies on two STA Compact analyzers were performed using three lots for both the VisuCon-F Frozen Coag Screen N plasma and the VisuCon-F Frozen Coag Screen ABN plasma. The control plasmas were assayed in duplicate, with 2 runs per day for 20 days, giving a total of 80 determinations per lot of control plasma. HemosIL™ PT-Fib, HemosIL™ APTT-SP and Stago Fib-5 reagents were used for the precision studies. The acceptance criteria, set by the sponsor, are as follows:

- %CV ≤ 5 for PT and APTT
- %CV ≤ 15 for fibrinogen (Coag Screen N plasma only).

The following table summarizes precision results for the VisuCon-F Frozen Coag Screen N plasma:

Coag Screen N Control		PT	APTT	Fibrinogen
Within-device Precision (Reproducibility)	Lot #1	2.3%	2.4%	3.2%
Intra-Assay Precision (Repeatability)		1.7%	1.2%	2.2%
Within-device Precision (Reproducibility)	Lot #2	2.4%	3.7%	3.9%
Intra-Assay Precision (Repeatability)		1.2%	2.0%	2.9%
Within-device Precision (Reproducibility)	Lot #3	1.9%	1.9%	4.2%
Intra-Assay Precision (Repeatability)		1.1%	1.2%	3.4%

The following table summarizes all precision results for the VisuCon-F Frozen Coag Screen ABN:

Coag Screen ABN Control		PT	APTT
Within-device Precision (Reproducibility)	Lot #1	2.2%	4.3%
Intra-Assay Precision (Repeatability)		1.4%	1.9%
Within-device Precision (Reproducibility)	Lot #2	1.6%	4.5%
Intra-Assay Precision (Repeatability)		0.8%	1.8%
Within-device Precision (Reproducibility)	Lot #3	1.9%	4.5%
Intra-Assay Precision (Repeatability)		0.9%	2.1%

System #2: Precision studies on two STA Compact analyzers were performed using three lots for both the VisuCon-F Frozen Coag Screen N plasma and the VisuCon-F Frozen Coag Screen ABN plasma. The control plasmas were assayed in duplicate, with 2 runs per day for 20 days, giving a total of 80 determinations per lot of control plasma. Stago Neoplastine Cl+ and APP-Automate reagents were used in the precision studies. The acceptance criteria, set by the sponsor, are as follows:

- %CV ≤ 5 for PT and APTT

The following table summarizes precision results for the VisuCon-F Frozen Coag Screen N:

Coag Screen N Control		PT	APTT
Within-device Precision (Reproducibility)	Lot #1	1.6%	2.3%
Intra-Assay Precision (Repeatability)		1.0%	1.5%
Within-device Precision (Reproducibility)	Lot #2	1.8%	2.7%
Intra-Assay Precision (Repeatability)		1.2%	1.4%
Within-device Precision (Reproducibility)	Lot #3	1.5%	2.2%
Intra-Assay Precision (Repeatability)		1.0%	1.1%

The following table summarizes all precision results for the VisuCon-F Frozen Coag Screen ABN:

Coag Screen ABN Control		PT	APTT
Within-device Precision (Reproducibility)	Lot #1	2.4%	4.6%
Intra-Assay Precision (Repeatability)		1.2%	1.8%
Within-device Precision (Reproducibility)	Lot #2	2.5%	4.1%
Intra-Assay Precision (Repeatability)		1.7%	1.3%
Within-device Precision (Reproducibility)	Lot #3	3.0%	3.8%
Intra-Assay Precision (Repeatability)		1.9%	1.3%

System #3: Precision studies on two BCS™ System analyzers were performed using three lots for both the VisuCon-F Frozen Coag Screen N plasma and the VisuCon-F Frozen Coag Screen ABN plasma. The control plasmas were assayed in duplicate, with 2 runs per day for 20 days, giving a total of 80 determinations per lot of control plasma. Siemens Innovin and Actin FSL reagents were used in the precision studies. The acceptance criteria, set by the sponsor, are as follows:

- %CV ≤ 5 for PT and APTT

The following table summarizes precision results for the VisuCon-F Frozen Coag Screen N:

Coag Screen N Control		PT	APTT
Within-device Precision (Reproducibility)	Lot #1	1.3%	1.5%
Intra-Assay Precision (Repeatability)		0.4%	0.8%
Within-device Precision (Reproducibility)	Lot #2	2.2%	2.1%
Intra-Assay Precision (Repeatability)		0.7%	1.3%
Within-device Precision (Reproducibility)	Lot #3	1.5%	1.4%
Intra-Assay Precision (Repeatability)		0.7%	0.9%

The following table summarizes all precision results for the VisuCon-F Frozen Coag Screen ABN:

Coag Screen ABN Control		PT	APTT
Within-device Precision (Reproducibility)	Lot #1	2.6%	2.2%
Intra-Assay Precision (Repeatability)		1.1%	2.0%
Within-device Precision (Reproducibility)	Lot #2	2.1%	2.5%
Intra-Assay Precision (Repeatability)		1.0%	2.4%
Within-device Precision (Reproducibility)	Lot #3	2.0%	2.5%
Intra-Assay Precision (Repeatability)		0.9%	2.0%

b. *Linearity/assay reportable range:*

Not applicable

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

Value assignment: For each of three lots of the VisuCon-F Frozen Coag Screen N and VisuCon-F Frozen Coag Screen ABN controls the mean values were assigned to fibrinogen, PT, and APTT by testing 20 vials over 4 days with 5 vials tested per day (n = 20). Fibrinogen values were generated for the VisuCon-F Frozen Coag Screen N control only. Ranges were then assigned by calculating the mean ±2 standard deviations (SD). System #1 (STA Compact, HemosIL™ PT-Fib, HemosIL™ APTT-SP, Stago Fib-5), System #2 (STA Compact, Stago Neoplastine CI+ and APP-Automate) and System #3 (BCS™ System, Siemens Innovin, Actin FSL) were used and all testing was performed internally. Acceptance criteria set by the sponsor, for the mean value for each assay within each platform/reagent system are as follows:

System #1		
VisuCon-F Frozen Coag Screen N		
PT (sec)	APTT (sec)	Fibrinogen (g/L)
8 -16	20 - 39	1.5 – 4.5
VisuCon-F Frozen Coag Screen ABN		
PT (sec)	APTT (sec)	Fibrinogen (g/L)
≥ 19	≥ 60	not applicable
System #2		
VisuCon-F Frozen Coag Screen N		
PT (sec)	APTT (sec)	
8 -16	20 - 39	
VisuCon-F Frozen Coag Screen ABN		
PT (sec)	APTT (sec)	
≥ 19	≥ 60	
System #3		
VisuCon-F Frozen Coag Screen N		
PT (sec)	APTT (sec)	
8 -11	20 - 39	
VisuCon-F Frozen Coag Screen ABN		
PT (sec)	APTT (sec)	
≥ 12	≥ 60	

All mean values for the three lots of VisuCon-F Frozen Coag Screen N and Frozen Coag Screen ABN fell within the acceptance criteria listed for each platform/reagent system.

Open Vial Stability: Open-vial stability of the VisuCon-F Coag Screen N and VisuCon-F Coag Screen ABN control plasmas was performed using System #1 (STA Compact, HemosIL™ PT-Fib, HemosIL™ APTT-SP, Stago Fib-5), System #2 (STA Compact, Stago Neoplastine CI+ and APP-Automate) and System #3 (BCS™ System, Siemens Innovin, Actin FSL). After initial thawing for the recommended time at 37°C the control plasmas were tested for PT, APTT and fibrinogen then stored at 2-8°C and on-board the instrument (15-22°C) in the original vial and re-tested at 4 hours and 8 hours. Acceptance criteria are as follows:

- Results at 4 and 8 hour time points:
 - Within ±10% of the time 0 result for PT and APTT
 - Within ±15% of the time 0 result for Fibrinogen

A minimum of two lots of control plasma were included in the study. All results fell within the above stated acceptance criteria. The data supports an open-vial 8 hour stability at 2-8°C or on-board the instrument (15-22°C).

Closed Vial Stability: The closed vial shelf-life stabilities of the VisuCon-F Frozen Coag Screen N and VisuCon-F Frozen Coag Screen ABN controls were assessed through real-time stability studies. The instrument and reagents used for the closed vial stability testing were as follows: System #1 (STA Compact with reagents HemosIL™ PT-Fibrinogen, HemosIL™ APTT-SP, and Stago Fib-5). The VisuCon-F Frozen Coag Screen N study included

five lots of control and the VisuCon-F Frozen Coag Screen ABN tested three lots. All controls were stored at their recommended storage temperature of $\leq -60^{\circ}\text{C}$ and tested internally at the indicated time points for PT and APTT. Fibrinogen was assessed on the normal control only. Acceptance criteria set by the sponsor, are as follows:

- $\pm 10\%$ of the original assigned value for PT and APTT
- $\pm 15\%$ of the original assigned value for Fibrinogen

The study data for the VisuCon-F Frozen Coag Screen N and VisuCon-F Frozen Coag Screen ABN supports a closed vial stability of 30 and 36 months respectively when stored at $\leq -60^{\circ}\text{C}$.

- 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:*
Not applicable
4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
Expected values are provided in the Package Insert accompanying the product.

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.