

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

A. 510(k) Number:

K150144

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Fibrinogen

D. Type of Test:

Quality Control Material, Assayed

E. Applicant:

Affinity Biologicals Inc.

F. Proprietary and Established Names:

VisuCon-F Low Fibrinogen Control Plasma

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):

The VisuCon-F Low Fibrinogen Control Plasma is an assayed control plasma prepared from de-fibrinated human plasma intended for use in the quality control of quantitative fibrinogen assays in the low abnormal range. The VisuCon-F Low Fibrinogen Control Plasma may be used with mechanical instruments in conjunction with appropriate commercial reagents for determining fibrinogen levels in plasma by the clotting method of Clauss. This plasma is intended “For *In Vitro* Diagnostic Use”.

The intended users of the VisuCon-F Low Fibrinogen Control Plasma are trained laboratory personnel working in clinical laboratories.

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Not applicable

I. Device Description:

The VisuCon-F Low Fibrinogen Control Plasma is a pool of de-fibrinated citrated human plasma collected from a minimum of 10 donors, buffered with 0.02 M HEPES buffer. The VisuCon-F Low Fibrinogen Control Plasma is packaged frozen in boxes containing: 5 x 1mL vials, 25 x 1mL vials or 81 x 1mL vials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Precision Biologic Inc., Cryocheck Low Fibrinogen Control

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

K951823

3. Comparison with predicate:

| Similarities | | |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item | Device VisuCon-F Low Fibrinogen Control Plasma | Predicate Cryo Check Low Fibrinogen Control |
| Intended Use | <p>The VisuCon-F Low Fibrinogen Control Plasma is an assayed control plasma prepared from de-fibrinated human plasma intended for use in the quality control of quantitative fibrinogen assays in the low abnormal range. The VisuCon-F Low Fibrinogen Control Plasma may be used with mechanical instruments in conjunction with appropriate commercial reagents for determining fibrinogen levels in plasma by the clotting method of Clauss. This plasma is intended “For <i>In Vitro</i> Diagnostic Use”.</p> <p>The intended users of the VisuCon-F Low Fibrinogen Control Plasma are trained laboratory personnel working in clinical laboratories.</p> | <p>The Cryo[√] Check™ Low Fibrinogen Control is a citrated normal human source plasma recommended for use as an abnormal control in monitoring the precision and accuracy of quantitative clottable fibrinogen assays.</p> |
| Analyte | Fibrinogen | Same |
| Matrix | Citrated human plasma | Same |
| Differences | | |
| Item | Device | Predicate |
| Storage | ≤ -60°C | -40°C to -80°C |
| Open-Vial Stability | 72 hours at 2–8°C or 8 hours on-board instrument (19–22° C) | 72 hours at 2–8°C |
| Packaging | 5 x 1.0 mL 25 x 1.0 mL 81 x 1.0 mL | 25 vials x 1.0 mL 80 vials x 1.0 mL |

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

CLSI EP05-A2; Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, 2nd Edition

L. Test Principle:

The VisuCon-F Low Fibrinogen control is to be utilized to monitor the performance of

fibrinogen assays in the low abnormal range using the Clauss clotting method in mechanical instruments.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility/Precision Study:

A reproducibility study was conducted at three sites (one internal and two external), testing three individual lots at each site, two runs per day in triplicate for five non-consecutive days. At each testing site, each of the three VisuCon Low Control lots were tested by one operator using one lot of Diagnostica STA-Fibrinogen Assay (K840211) on STA Compact Analyzer (K093167).

All data points from the study were pooled and analyzed in a mixed effect model with lot, test site, day and run treated as random effects. The coefficient of variation (CV) and the standard deviation (SD) for each of the random effects (variance): lot-to-lot, site-to-site, between-day, between-run, within-run and total reproducibility precision was calculated.

Results show that data met pre-determined acceptance criteria and demonstrated reproducibility of the VisuCon Low Control under tested conditions. Results of the pooled data are presented below:

Instrument: STA Compact Analyzer

| Source of Variance | Standard Deviation (SD) | %CV (SD/mean)*100 |
|----------------------------|-------------------------|-------------------|
| Lot-to-lot | 0.059 | 7.2% |
| Site-to-site | 0.013 | 1.5% |
| Between-Day | 0.006 | 0.7% |
| Between-Run | 0 | 0% |
| Within-Run (Repeatability) | 0.025 | 3.0% |
| Total Variability | 0.07 | 8.0% |

Repeatability study/Within-Laboratory Precision Study: Three lots of VisuCon-F Low Fibrinogen Control Plasma were tested on two different Diagnostica Stago STA-Compact Analyzers using the Diagnostica Stago STA-Fibrinogen 5 assay. Testing was conducted in duplicate, two runs per day over a period of 20 days. Data from the repeatability study was pooled (n=480) and analyzed in a mixed effect model with the lot, instrument, day and run treated as random effects.

Results show the data met pre-determined acceptance criteria, and are summarized below:

Instrument: Diagnostica Stago STA Compact Analyzer

| Source of Variance | SD | %CV |
|----------------------------|-------|------|
| Lot-to-Lot | 0.066 | 7.8% |
| Instrument-to-Instrument | 0.004 | 0.5% |
| Between-Day | 0.005 | 0.5% |
| Between-Run | 0.00 | 0% |
| Within-Run (Repeatability) | 0.027 | 3.2% |
| Within-Device (total) | 0.072 | 8.4% |

b. *Linearity/assay reportable range:*

Not applicable

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

Stability Study:

Open Vial Stability Study: The open vial stability study was conducted at the refrigerated temperature of 2°C to 8°C and on-board temperature of 19°C to 22°C, on two lots of VisuCon-F Low Fibrinogen Control plasma. The study demonstrated the VisuCon-F Low Fibrinogen Control Plasma is stable up to 72 hours when stored at 2-8°C and up to 8 hours at 19-22°C. The study met the pre-determined acceptance criteria.

Closed Vial Stability Study: The closed vial stability study was conducted at the storage temperature of $\leq -60^\circ\text{C}$ using three lots of the VisuCon-F Low Fibrinogen Control Plasma. The study demonstrated that the VisuCon-F Low Fibrinogen Control Plasma is stable up to 36 months when stored at or below -60°C . The study met the pre-determined acceptance criteria.

Value Assignment: The value assignment for VisuCon-F Low Fibrinogen Control Plasmas were assigned to fibrinogen by testing 20 vials, 5 vials per day over 4 days (n=20). The ranges for the controls were assigned to fibrinogen by calculating and applying ± 2 standard deviations (SD) from the mean. Three lots were tested using the Diagnostica Stago Fibrinogen-5 Assay, which was calibrated against SSC/ISTH Secondary Coagulation Standard. The mean values assigned to each lot met the acceptance criteria and is as follows:

| Lot 1 | | | | |
|----------------|-------------|-------------|-------------|-----------------|
| Vial | Day 1 (g/L) | Day 2 (g/L) | Day 3 (g/L) | Day 4 (g/L) |
| 1 | 0.81 | 0.81 | 0.81 | 0.80 |
| 2 | 0.78 | 0.78 | 0.77 | 0.77 |
| 3 | 0.82 | 0.80 | 0.77 | 0.76 |
| 4 | 0.79 | 0.78 | 0.77 | 0.82 |
| 5 | 0.77 | 0.81 | 0.79 | 0.81 |
| Overall Mean | | | | 0.79 g/L |
| Overall SD | | | | 0.019 |
| Overall %CV | | | | 2.41% |
| Assigned range | | | | 0.75 – 0.83 g/L |
| Lot 2 | | | | |
| Vial | Day 1 (g/L) | Day 2 (g/L) | Day 3 (g/L) | Day 4 (g/L) |
| 1 | 0.82 | 0.82 | 0.82 | 0.83 |
| 2 | 0.82 | 0.84 | 0.80 | 0.78 |
| 3 | 0.80 | 0.80 | 0.77 | 0.79 |
| 4 | 0.80 | 0.86 | 0.79 | 0.78 |
| 5 | 0.82 | 0.82 | 0.82 | 0.81 |
| Overall Mean | | | | 0.81 g/L |
| Overall SD | | | | 0.022 |
| Overall %CV | | | | 2.72% |
| Assigned range | | | | 0.77 – 0.85 g/L |
| Lot 3 | | | | |
| Vial | Day 1 (g/L) | Day 2 (g/L) | Day 3 (g/L) | Day 4 (g/L) |
| 1 | 0.93 | 0.92 | 0.93 | 0.93 |
| 2 | 0.96 | 0.92 | 0.85 | 0.91 |
| 3 | 0.80 | 0.90 | 0.90 | 0.87 |
| 4 | 0.87 | 0.91 | 0.88 | 0.90 |
| 5 | 0.96 | 0.91 | 0.92 | 0.88 |
| Overall Mean | | | | 0.90 g/L |
| Overall SD | | | | 0.037 |
| Overall %CV | | | | 4.11% |
| Assigned range | | | | 0.83 – 0.97 g/L |

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:

A lot-specific Certificate of Analysis with an assigned reference value is 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.