Affinity Biologicals™ INC.

REPRESENTATIVE DATASHEET*

VisuCon™-F Frozen Coag Screen ABN

Product #: FCSAB0125
FCSAB0181
FCSAB0481

Store at -60°C or lower.

For *in vitro* diagnostic use.

Intended Use

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 instruments in conjunction with appropriate commercial reagents.

Summary and Principle

Good laboratory practice requires that assays be calibrated over the relevant range and that controls be performed regularly to confirm assay calibration. The VisuCon-F Frozen Coag Screen ABN plasma is a pool of normal citrated human plasma collected from a minimum of 20 donors, diluted to defined concentrations, buffered with 0.02M HEPES buffer, dispensed and rapidly frozen. This control plasma is intended for use in the monitoring of the performance of PT and APTT assays in the mid-level abnormal range.

Reagents

A. Description:

Coag Screen ABN:

Box containing 25 x 1mL vials of frozen plasma, Prod. # FCSAB0125
OR
Box containing 81 x 1mL vials of frozen plasma, Prod. # FCSAB0181
OR
Box containing 81 x 4mL vials of frozen plasma, Prod. # FCSAB0481

B. Reagent Preparation/Handling:

Thaw each 1 mL vial for 5 minutes and each 4 mL vial for 7 minutes in a 37°C (+/- 1°C) waterbath. Invert gently before use.

C. Storage and Stability:

Vials are stable until the expiration date stated on the vial when stored at –60°C or lower.

Once thawed, the plasma is stable for 8 hours on-board (15 - 22°C) or at 2-8°C in original vial. Thawed material should be discarded after use and not be refrozen.

D. Precautions and Warnings:

This product is intended for use by personnel trained in laboratory procedures and universal precautions for the use of potentially biohazardous substances. This product contains human source material. Each unit of source plasma used in the preparation of this product has been tested by FDA approved methods and found non-reactive for Hepatitis B surface antigen (HbsAg), negative for the presence of Human Immunodeficiency Virus (HIV-1/2, rDNA) as well as for Hepatitis C (HCV). As no test can offer complete assurance that products derived from human blood will not transmit infectious diseases, this product should be handled as potentially infectious material.

Procedure

A. Materials Required (but not provided)

Waterbath
Coagulation Instrument or assay system
Assay Reagents
Calibrator Plasma (e.g. VisuCal-F Frozen Calibrator Plasma)
Common clinical laboratory equipment and material (pipettes, etc.)

B. Assay Procedure

After thawing the VisuCon-F Frozen Coag Screen ABN Plasma, use on coagulation instrument or assay system with corresponding reagents in accordance with established coagulation assay procedures.

Quality Control

Each laboratory should establish and maintain its own quality control ranges for each particular instrument-reagent system used. If appropriate control values are not obtained, assess the components of the assay system including reagents, substrate plasmas, calibrator plasma or instrumentation to identify potential sources of error. QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

Limitations of the Procedure

The results obtained with the VisuCon-F Frozen Coag Screen ABN plasma will be subject to the limitations of the assay system including types of reagents and instrumentation.

Expected Values

The results obtained for the VisuCon-F Frozen Coag Screen ABN plasma will depend on various factors including assay method, types of reagents and instrumentation. Therefore, each laboratory should establish its own mean values and expected reference ranges for quality control purposes using their particular instrument-reagent system. The results presented in the supplied Certificate of Analysis were determined from data specific to the instrument-reagent system used for internal quality control testing. Lot specific results may vary when using different instrument and reagent combinations.

Performance Characteristics

Within-run (intra-assay), between day (inter-assay), between-run and within device precision were assessed for three lots of the VisuCon-F Frozen Coag Screen ABN using various instrument-reagent systems. Controls were tested in duplicate, 2 times per day for 20 days as per CLSI guideline EP5-A2[3]. The coefficients of variation (% CV) obtained in these precision studies are presented in the tables below.

STA Compact, HemosIL™ PT-Fib, HemosIL™ APTT-SP				
	Within Run	Between Day	Between Run	Within Device Precision
PT	0.8 - 1.7%	1.0 - 1.7%	0 - 0.9%	1.6 - 2.2%
APTT	1.8 - 3.5%	2.1 - 3.7%	0 - 2.0%	4.1 - 4.5%

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STA Compact, Stago Neoplastine® CI+, STA® PTT-Automate				
	Within Run	**Between Day**	**Between Run**	**Within Device Precision**
PT	1.2 - 2.5%	1.2 - 1.9%	0 - 1.3%	2.4 - 3.0%
APTT	1.3 - 2.7%	2.1 - 2.9%	2.5 - 3.4%	3.8 - 4.9%

BCS, Siemens Innovin®, Siemens Actin FSL®				
	Within Run	**Between Day**	**Between Run**	**Within Device Precision**
PT	0.9 - 2.0%	0 - 2.6%	0.4 - 2.0%	2.0 - 3.2%
APTT	2.0 - 3.5%	0 - 1.1%	0 - 2.5%	2.2 - 3.5%

Bibliography

1. "Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays, Approved Guideline, Fifth Edition. H21-A5, CLSI, Vol. 28. No. 5, 2008.

2. "Graphical Symbols for Use in the Labelling of Medical Devices", EN 980:2003, European Committee for Standardization, April 2003.

3. "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition". EP5-A2, CLSI, Vol. 24, No. 25, 2004.

Symbol Legend[2]

For in vitro diagnostic use

Batch code


Expiry date

Catalogue Number


Upper limit of temperature


Manufacturer


Consult instructions for use


Biological Risks

Limited Warranty:

This product is warranted to perform in accordance with its labeling and literature. Affinity Biologicals Inc. disclaims any implied warranty of merchantability or fitness for any other purposes, and in no event will Affinity Biologicals Inc. be liable for any consequential damages arising out of aforesaid express warranty.

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