

**\*\*REPRESENTATIVE DATASHEET\*\***

## VisuCal™ Antigen Calibrator Plasma

**Product #** EIA-CSA-1  
EIA-CSA-5

Store at 2-8°C

For Research Use Only. Not for use in diagnostic procedures.

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### Product Description

The VisuCal™ Antigen Calibrator Plasma is a lyophilized reference plasma intended for use in the calibration of Antigen assays for coagulation factor II, factor VII, factor X, factor XI, factor XIII, Protein C, Protein S, Antithrombin III, von Willebrand Factor and fibrinogen by ELISA. This product is intended for Research Use Only and must not be used for diagnostic applications or the calibration of coagulation activity assays.

The VisuCal™ Antigen Calibrator plasma is prepared from a pool of normal citrated human plasma collected from a minimum of 20 donors, buffered with HEPES and stabilizers and lyophilized.

### Materials Provided

**A. Description:**

Bag containing 1 x 1 mL vials of lyophilized plasma, Prod. #EIA-CSA-1 OR

Bag containing 5 x 1 mL vials of lyophilized plasma, Prod. #EIA-CSA-5

The VisuCal™ Antigen Calibrator Plasma contains a lot-specific Certificate of Analysis with the assigned antigen reference values for each analyte, which were determined against the SSC/ISTH secondary coagulation standard. For those analytes where antigen assignments have not been determined, activity value assignments have been used, assuming 1 U/mL activity = 1 U/mL antigen.

**B. Reagent Preparation/Handling:**

Reconstitute each vial with 1 ml of reagent grade water. Mix gently and allow to stand for 15 minutes at room temperature prior to use. Shake gently once more before use.

**C. Storage and Stability:**

Vials are stable until the expiration date stated on the vial when stored at 2-8°C. Once reconstituted, the plasma is stable for 2 hours at 18-25°C or 30 days at -20°C in the original vial. **EXCEPTION:** Frozen plasma should not be used for determination of Protein C antigen; use a freshly reconstituted vial for this analyte. Thaw frozen plasma at 37°C for 5 minutes. Discard thawed plasmas after 2 hours at 18-25°C.

**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 negative for the presence of Human Immunodeficiency Virus (HIV)

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Type 1 and Type II. Hepatitis B surface antigen (HbsAg) 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.

### Materials Required but not Provided

ELISA assay system

Quality Control Material

Common clinical laboratory equipment and material (pipettes, etc.)

### Procedure

After reconstituting the VisuCal™ Antigen Calibrator Plasma, use in Antigen ELISA assay (Research Use Only) in accordance with established assay procedures for the quantitative determination of the desired antigen.

### Expected Values

Refer to the lot specific Certificate of Analysis for the assigned values for each parameter. Values stated on the Certificate of Analysis are lot specific and vary from one lot to another.

### Quality Control

Each laboratory should establish and maintain its own quality control ranges for the particular ELISA assay used. If appropriate control values are not obtained, the test sample antigen values should be considered suspect.

### Limitations of the Procedure

The results obtained with the VisuCal™ Antigen Calibrator Plasma will be subject to the limitations of the ELISA assay system. Test samples should be of the same matrix and anticoagulant as the calibrator plasma (citrated plasma).

### Related Products

Cat. #: <b>FG-EIA</b>	Paired Antibody set for ELISA of Fibrinogen, 5 x 96 wells
Cat. #: <b>FII-EIA</b>	Paired Antibody set for ELISA of Factor II, 5 x 96 wells
Cat. #: <b>FVII-EIA</b>	Paired Antibody set for ELISA of Factor VII, 5 x 96 wells
Cat. #: <b>FX-EIA</b>	Paired Antibody set for ELISA of Factor X, 5 x 96 wells
Cat. #: <b>FXI-EIA</b>	Paired Antibody set for ELISA of Factor XI, 5 x 96 wells
Cat. #: <b>FXIII-EIA</b>	Paired Antibody set for ELISA of Factor XIII, 5 x 96 wells
Cat. #: <b>PC-EIA</b>	Paired Antibody set for ELISA of Protein C, 5 x 96 wells
Cat. #: <b>PS-EIA</b>	Paired Antibody set for ELISA of Protein S, 5 x 96 wells
Cat. #: <b>VWF-EIA</b>	Paired Antibody set for ELISA of VWF, 5 x 96 wells
Cat. #: <b>ATIII-EIA</b>	Paired Antibody set for ELISA of ATIII, 5 x 96 wells
Cat. #: <b>EIA-PAK-1</b>	VisuLize™ Buffer Pak

**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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