

**BIOPHEN  
PLASMA CALIBRATOR  
Ref A222101**

Normal Human Plasma for the calibration of some coagulation factors.

For in vitro diagnostic use only



Last revision: 30/06/2006

**INTENDED USE:**

BIOPHEN Plasma Calibrator is normal citrated human plasma used as the calibrator in the assay methods for coagulation factors Antithrombin III and Protein C.

The following table shows the various parameters, which are measured using assays from HYPHEN BioMed or from other manufacturers, and according to the package inserts:

Assays	Reagents	Manufacturers	Reference
<b>ATIII</b>	Biophen Antithrombin	Hyphen BioMed	A221102 A221105
<b>Protein C</b>	Biophen Protein C	Hyphen BioMed	A221202 A221205
<b>Lupus Anticoagulant</b>	DVVtest®	American Diagnostica	810
	DVVconfirm®		815 / 815L

DVVtest, DVVconfirm are registered trade marks from American Diagnostica Inc.

The BIOPHEN Plasma Calibrator is tested for the absence of Lupus Anticoagulant and can be used for this investigation.

**REAGENTS SUPPLIED:**

12 vials of 1 ml of normal citrated human pooled plasma, lyophilised.

**Note:**

- BIOPHEN Plasma Calibrator contains an antibiotic as preservative (ciprofloxacin)
- Each donor unit used for the preparation of BIOPHEN Plasma Calibrator is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HVC) and antibodies to HIV 1 and 2 and was found negative. However, no test can completely exclude the presence of infectious agents. Any product of human origin, and more especially plasma, must be considered as being potentially infectious and must be handled with all the required cautions for this kind of material.

**STORAGE CONDITIONS:**

Unopened reagents, must be stored at 2–8 °C, in their original packaging box.

They are then stable until the expiration date printed on the label.

**Note:** The stability studies at 30°C show that the reagents can be shipped at room temperature without damage.

**PREPARATION AND STABILITY OF REAGENTS:**

Reconstitute each vial with exactly 1 mL of distilled water. Shake thoroughly until complete dissolution of the content (vortex). Incubate at room temperature (18-25°C) for 30 min, while shaking the vial from time to time.

Homogenise the content before each use.

Stability of plasma calibrator, kept in its original vial:

- 8 hours at room temperature.
- 24 hours at 2-8°C.
- Do not freeze.

**Cautions:**

- In order to improve stability, reagents must be closed with their original screw caps following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.

It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.

**APPLICATIONS:**

BIOPHEN Plasma Calibrator can be used for the calibration of some coagulation assays (especially Antithrombin III and Protein C). The exact concentration is reported for each parameter tested on the flyer provided within the kit.

The various parameters reported (Antithrombin III, Protein C) are accurately determined by reference to the corresponding NIBSC (National Institute for Biological Standards and Controls, UK) International Standards, when available.

For each parameter, the concentration may present variations from lot to lot, but it is exactly measured for each lot and reported on the flyer.

The following table shows the usual ranges expected for the BIOPHEN Plasma Calibrator.

Assays	Reagents	Acceptance range
<b>ATIII</b>	Biophen Antithrombin	> 85%
<b>Protein C</b>	Biophen Protein C	> 85%
<b>Lupus Anticoagulant</b>	DVVtest/DVVconfirm	≤ 1.2

**PERFORMANCE CHARACTERISTICS:**

The following values, obtained for one lot of BIOPHEN Plasma Calibrator, are provided as an example only.

Parameter	[C]	N	CV (%)
ATIII	100%	18	1.50
Protein C	96%	18	1.45
DVVtest/DVVconfirm ratio	1.01	2	/

For each parameter, the concentration may present variations from lot to lot, but it is exactly measured for each lot and reported on the flyer provided within the kit.

When the BIOPHEN Plasma Calibrator is used for calibrating the assay of some coagulation factors, the BIOPHEN quality control plasmas (BIOPHEN Normal Control Plasma, ref A223201, and BIOPHEN Abnormal Control Plasma, ref A223301) can be used in order to obtain an homogeneous quality control system. The values obtained for quality control plasmas must be within the acceptance ranges reported for the lot used, in order to validate the test series. Should the value be out of these ranges, the results for the corresponding series must be considered as invalid. It is then recommended to rerun the series and to check all the assay parameters.

**CAUTIONS:**

- Like all lyophilised plasmas, the plasmas from the BIOPHEN Plasma Calibrator are more or less cloudy after reconstitution. This is due essentially to the lipids that, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial stand 10 minutes at room temperature and shake gently before use in order to homogenise the content.
- Reagents must be handled with care, in order to avoid any contamination or activation during use. Any plasma containing a coagulum or contamination must be rejected.

