

CE IVD BIOPHEN™ Plasma Calibrator

REF 222101

C1 12 x 1 mL

Normal Human Plasma for the calibration of some coagulation factors.

English, Last revision: 11-2021

INTENDED USE:

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

SUMMARY AND EXPLANATION:

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
Antithrombin	BIOPHEN™ Antithrombin	Hyphen BioMed	221102
	Antithrombin		221105
Protein C	BIOPHEN™ Protein C	Hyphen BioMed	221202
	Protein C		221205

REAGENTS:

CAL Normal citrated human plasma, lyophilized.
 12 vials of 1 mL.

Calibrators contain stabilizing agents.

The calibrator concentrations may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

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

Assays	Reagents	Expected level
Antithrombin	BIOPHEN™ Antithrombin	> 85%
Protein C	BIOPHEN™ Protein C	> 85%

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.
- This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

CAL Reconstitute the contents of each vial with exactly 1 mL of distilled water.

Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.

For manual method, allow to stabilize for 30 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

CAL Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- 24 hours at 2-8°C.
- 8 hours at room temperature (18-25°C).
- 2 months at -20°C or less*
- Stability on board of the analyzer: see the specific application.**

*Thaw only once, as rapidly as possible at 37°C and use immediately.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:

- Distilled water.

Materials:

- Calibrated pipettes.

TRACEABILITY:

The value assignment of the various parameters reported is related to the corresponding International Standards, when available, or against an internal reference.

QUALITY CONTROL:

BIOPHEN™ Plasma Calibrator can be used for the calibration of some coagulation assays (especially Antithrombin and Protein C).

The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents.

Include the quality controls with each series, as per good laboratory practice, in order to validate the test.

A new calibration curve should be defined, preferably for each test series, and at least for each new reagent batch, or after analyzer maintenance, or when the measured quality control values fall outside the acceptable range for the method.

PERFORMANCES:

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

Parameter	Concentration	N	CV (%)
Antithrombin	100%	18	1.50
Protein C	96%	18	1.45

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 223201, and BIOPHEN™ Abnormal Control Plasma, ref 223301) 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 or within range defined by the end user, 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.

LIMITATIONS:

- If the calibrators are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these calibrators in its own analytical system.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- If necessary, let each vial stand 10 minutes at room temperature and shake before use in order to homogenize the contents.

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions document.

Changes compared to the previous version.