BIOPHEN™ Plasma Calibrator

REF 222101

CAL 12 x 1 mL

IVD

Normal Plasma for the calibration of coagulation assays.

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INTENDED USE:

BIOPHEN™ Plasma Calibrator kit contains normal citrated human plasma, lyophilised. It can be used as calibrator for the assay of some coagulation factors.

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:

Parameters	Method
Fibrinogen (Fbg)	Activity / Antigen
Lupus Anticoagulant (LA)	Activity
α2 – Antiplasmin (α2-AP)	Activity
Antithrombin (AT)	Activity / Antigen
Prothrombin (FII)	Activity
Factor V (FV)	Activity
Factor VII (FVII)	Activity
Factor VII + X (FVII + X)	Activity
Factor VIII:C (FVIII)	Activity
Factor IX (FIX)	Activity
Factor X (FX)	Activity
Factor XI (FXI)	Activity
Factor XII (FXII)	Activity
Factor XIII (FXIII)	Activity
Plasminogen (Plg)	Activity
Protein C (PC)	Clotting activity
Protein C (PC)	Chromogenic activity
Protein S (PS)	Clotting activity
Free Protein S (Free PS)	Antigen
von Willebrand Factor Antigen (vWF: Ag)	Antigen

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 as negative control for this investigation.

REAGENTS:

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

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

WARNINGS AND PRECAUTIONS:

- Calibrator plasmas contain stabilizing agents.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be taken when handling and disposing of plasma.
- 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.
- For *in vitro* diagnostic use.

REAGENT PREPARATION AND STABILITY:

The reagents are lyophilized under a vacuum in their vials. To avoid any product loss when opening the vial, gently remove the freeze-drying stopper.

CAL Normal citrated human plasma

Reconstitute the contents of each vial with exactly **1 mL distilled water**, shake vigorously until fully dissolved.
Allow to stabilize for 30 min. at room temperature (18-25°C), shaking occasionally.
Homogenize prior to use.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- For AT, PC; FVII-X, Plasminogen, FII, FVII, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag and LA:
  - **24 hours** at 2-8°C.
  - **8 hours** at room temperature (18-25°C).
  - **Do not freeze.**
- For FVIII:C, FV and PS:
  - **8 hours** at 2-8°C.
  - **4 hours** at room temperature (18-25°C).
  - **Do not freeze.**

STORAGE CONDITIONS:

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.

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.

PROPERTIES:

The BIOPHEN™ Plasma Calibrator is proposed for calibrating the assay of some coagulation assays.
The calibrator target values are determined from multi-reagent and multi-instrument test.
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.

LIMITATIONS:

- Like all lyophilized plasmas, calibration plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- 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.
- If necessary, let each vial 10 minutes at room temperature and shake before use in order to homogenize the content.

SYMBOLS:

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

Changes compared to the previous version.