EASYPLASMA™ Calibrator

REF 226601

CAL 6 x 1 mL

IVD

Normal human plasma for the calibration of coagulation assays.

HYPHEN BioMed

www.hyphen-biomed.com

155, rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE
Tel. : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
info@hyphen-biomed.com

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INTENDED USE:

The EASYPLASMA™ Calibrator kit is normal citrated human plasma, lyophilized, intended for the calibration of several coagulation factors assays. It may also be used as normal control plasma.

SUMMARY AND EXPLANATION:

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

Parameter	Method
PT/INR/% and aPTT	Clotting
Fibrinogen (Fbg)	Clotting
Thrombin Time (TT)	Clotting

REAGENTS:

CAL **Plasma Calibrator:** Normal citrated human plasma, lyophilized.
6 vials of 1mL.

The calibrator values 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.

CAUTIONS AND WARNINGS:

- 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 take 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-weeks 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 of lyophilized reagents, gently remove the freeze-drying stopper.

CAL **Plasma Calibrator**

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 Fibrinogen, PT/INR/% and aPTT:
  - **24 hours** at 2-8°C.
  - **8 hours** at room temperature (18-25°C).
  - Frozen at -20°C or less*
- For Thrombin Time:
  - **8 hours** at 2-8°C.
  - **4 hours** at room temperature (18-25°C).
  - Frozen at -20°C or less*

*Thaw only once, as rapidly as possible at 37°C, adapting the incubation period to the volume of reagent. The stability of the thawed reagent should be checked under laboratory work conditions.

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 Standard.

PROPERTIES:

The EASYPLASMA™ Calibrator is used to establish a calibration curve for several coagulation assays.
The calibrator target values are determined from multi-reagent and multi-instrument tests.
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.

SYMBOLS:

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