

DABIGATRAN PLASMA CALIBRATOR Ref 222801

Calibration plasmas for the assay of Dabigatran with anti-IIa method

For in vitro research use only (RUO)

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ENGLISH

INTENDED USE:

Dabigatran Plasma Calibrator is a set of calibration plasmas for Dabigatran measurements, titrated and optimised using the anti-IIa clotting assay **HEMOCLOT THROMBIN INHIBITORS (CK002K/CK002L)**.

Dabigatran Plasma Calibrator allows calibrating the assays of Dabigatran using clotting anti-IIa method, especially when HEMOCLOT Thrombin Inhibitors kit is used, with the **low range protocol**.

SUMMARY AND EXPLANATION:

Dabigatran is the active component of the oral anticoagulant pro-drug, Dabigatran Etxilate. When required, Dabigatran can be measured in plasma for some studies or in case of suspicion of overdosage or emergency.

REAGENTS SUPPLIED:

12 vials (4 sets of 3 vials) of 1 ml human plasma supplemented with different concentrations of Dabigatran (4 vials for each concentration).

CAL 1: Calibrator 1: 1mL 4 vials.

Human plasma, freeze-dried, supplemented with Dabigatran (level 1 at about **0.05 µg/ml**) (to be restored with 1 mL distilled water).

CAL 2: Calibrator 2: 1mL 4 vials.

Human plasma, freeze-dried, supplemented with Dabigatran (level 2 at about **0.25 µg/ml**) (to be restored with 1 mL distilled water).

CAL 3: Calibrator 3: 1mL 4 vials.

Human plasma, freeze-dried, supplemented with Dabigatran (level 3 at about **0.50 µg/ml**) (to be restored with 1 mL distilled water).

The exact concentration of Dabigatran in each vial is indicated on the flyer provided in each kit. The calibration curve covers the range from about 0.1 to 0.5 µg/ml.

Note:

- Calibrator plasmas contain an antibiotic as preservative.
- Each donor unit used for the preparation of calibration plasmas 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. Kept in their original packaging 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:

Preparation:

- 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:

Lyophilised: Kept in the original packaging, the reagents are stable until the expiration date indicated on the labels.

Reconstituted:

- 7 days at 2-8°C.
 - 48 hours at room temperature.
- 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.

CALIBRATION RANGE:

Each Dabigatran Plasma Calibrator kit contains 4 sets of 3 vials supplemented with increasing concentrations of Dabigatran.

The following values, obtained for one lot of Dabigatran Plasma Calibrator lot (on water bath, ACL and/or STAR), are provided as an example only.

Calibrator	Dabigatran Concentration [µg/ml]	Intra-Assay		Inter-Assay	
		N	SD	N	SD
CAL 1	0,04	20	<0,001	11	0,006
CAL 2	0,25	20	0,007	11	0,010
CAL 3	0,50	20	0,010	11	0,014

The exact concentration may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit.

These concentrations are accurately determined against an Internal Reference Standard, initially validated against fresh reference preparations of Dabigatran, spiked into a normal human citrated plasma pool, and confirmed by physico-chemical method.

The concentrations have been determined using HEMOCLOT Thrombin Inhibitors kit.

The calibration curve covers the range from about 0.10 to 0.50 µg/ml.

PERFORMANCE CHARACTERISTICS:

Dabigatran Plasma Calibrators allow establishing the calibration curve for the measurement of Dabigatran in plasma, especially with Anti-IIa method. Using the **HEMOCLOT Thrombin Inhibitors (ref. CK002K/L)** kit, Dabigatran is measured with the **low range protocol**, and the assay is linear up to about 0.5 µg/ml using the manual method or the STA-R instrument.

The calibration curve obtained covers the usual concentrations currently observed during Dabigatran therapy.

Dabigatran Control Plasma (ref 224701) can be used in order to obtain an homogeneous quality control system.

The HEMOCLOT Thrombin Inhibitors anti-IIa method, used according to the **low range protocol**, for the measurement of Dabigatran concentrations in plasma, offers a sensitivity threshold of about 0.02 µg/ml.

If used with other kits, results can vary according to the assay reactivity and its standardization: each laboratory must then determine and validate the suitability for use in its specific test conditions.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas from the Dabigatran 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 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.

REFERENCES:

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