

DABIGATRAN CONTROL PLASMA

Ref 224701

Human plasmas at two levels of Dabigatran for the quality control of Dabigatran measurements with anti-IIa method

For in vitro research use only (RUO)

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ENGLISH

INTENDED USE:

Dabigatran Control Plasma Kit is a set of control plasmas for the quality control of Dabigatran measurements, using anti-IIa clotting assay. This kit is optimised for being used with the **HEMOCLOT THROMBIN INHIBITORS assay** (low range protocol)(#CK002K/CK002L).

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 (6 sets of 2 vials) of 1 mL of human plasma supplemented at 2 different concentrations of Dabigatran (6 vials for each concentration).

C1 : Control 1

Human plasma, freeze-dried, supplemented with Dabigatran (level 1 at about 0.10 µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

C2 : Control 2:

Human plasma, freeze-dried, supplemented with Dabigatran (level 2 at about 0.30µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

The Dabigatran concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

Note:

- Control plasmas contain an antibiotic as preservative (ciprofloxacin).
- Each donor unit used for the preparation of control 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 after reconstitution:

- 7 days at 2-8°C.
- 48 hours at room temperature (18-25°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.

TRACEABILITY ON CONTROL MATERIALS:

Dabigatran Controls 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.

CONCENTRATION:

Each Dabigatran Control Plasma kit contains 2 sets of 6 vials with 2 different concentrations of Dabigatran (low and high). The exact concentrations may present variations from lot to lot, but they are exactly determined for each lot.

The Dabigatran concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

The following example shows the Dabigatran concentrations indicated for one lot of Dabigatran Control Plasma (obtained on water bath, ACL and/or STAR):

Dabigatran Control	Dabigatran (µg/ml)	Acceptance range (µg/ml)	Intra-Assay		Inter-Assay	
			N	SD	N	SD
Level 1	0,12	0,07-0,17	20	0,003	11	0,007
Level 2	0,30	0,22-0,38	20	0,008	11	0,012

The control **C1** has usually a concentration of 0.10 ± 0.05 µg/mL.

The control **C2** has usually a concentration of 0.30 ± 0.08 µg/mL.

QUALITY CONTROL:

Dabigatran Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for the measurements of Dabigatran in plasma. They allow validating these calibration curves. They are especially useful for controlling the stability of the calibration curves, from run to run, when using a same lot of reagents.

If controls are out of the acceptance range, the test series can be invalid, and the assay should be rerun. Check all the components of the test system, before rerunning the assay.

The Dabigatran control kit, which contains plasmas at 2 different Dabigatran concentrations, can be used in association with **Dabigatran Plasma Calibrator (#222801)** for assaying Dabigatran concentration in plasma, especially with the **HEMOCLOT Thrombin Inhibitors kit (#CK002K/ CK002L)**.

PERFORMANCE CHARACTERISTICS:

Dabigatran Control plasmas allow validating the calibration curve for the measurements of Dabigatran in plasma, especially with Anti-IIa method. The results are determined with the **HemoClot Thrombin Inhibitors (ref. CK002K/CK002L)** assay (**low range protocol**).

The results obtained could present little variation, when these controls are used with other kits according to the assay reactivity and its standardization. These controls can nevertheless be used with different kits for quality control and testing run to run variability, but the acceptable values must be determined by each laboratory.

The HemoClot Thrombin Inhibitors anti-IIa method, used for the measurement of Dabigatran in plasma, offers a sensitivity threshold of about 0.02 µg/mL.

CAUTIONS:

- Like all lyophilised plasmas, the control plasmas from the Dabigatran Control 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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