

Dabigatran Plasma Calibrator

REF 222801-RUO

CAL1 CAL2 CAL3 4 x 1 mL

Human plasmas for the calibration of Dabigatran assays
by anti-IIa method.

FOR RESEARCH USE ONLY.

DO NOT USE IN DIAGNOSTIC PROCEDURES.



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INTENDED USE:

The Dabigatran Plasma Calibrator kit is a set of human plasma calibrators, lyophilized, supplemented with Dabigatran, for the calibration of Dabigatran assay in human plasma.

It is titrated and optimized for the anti-IIa clotting assay of Dabigatran, and more especially with the HEMOCLOT™ Thrombin Inhibitors kit (CK002K-RUO/CK002L-RUO), with the standard range protocol.

This kit is for research use only and must not be used for patient diagnosis or treatment.

REAGENTS:

CAL1 Calibrator 1: Human plasma supplemented with Dabigatran, lyophilized, containing a titrated quantity of Dabigatran of approximately 50 ng/mL (level 1). Contains BSA.

4 vials of 1 mL.

CAL2 Calibrator 2: Human plasma supplemented with Dabigatran, lyophilized, containing a titrated quantity of Dabigatran of approximately 250 ng/mL (level 2). Contains BSA.

4 vials of 1 mL.

CAL3 Calibrator 3: Human plasma supplemented with Dabigatran, lyophilized, containing a titrated quantity of Dabigatran of approximately 500 ng/mL (level 3). Contains BSA.

4 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.
- Biological products must be handled with all necessary precautions and considered as being potentially infectious.
- The human plasma used to prepare the calibration plasma has been tested by approved methods and found negative for HIV 1/2 antibodies, HCV and HBs antigen.
- This material contains substances of animal origin and must be handled as a carrier and a potential transmitter of diseases.
- 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 calibrators may have been transferred, depending on the protocol used.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device is intended for professional use in the laboratory.
- For *in vitro* use.

REAGENT PREPARATION AND STABILITY:

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

CAL1 CAL2 CAL3 Calibrators 1, 2, 3: Human plasma supplemented with Dabigatran

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:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **Up to 6 months** frozen 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, 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:

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 to the reference method by LC-MS/MS.

PROPERTIES:

The Dabigatran Plasma Calibrator kit is used to establish a calibration curve to measure Dabigatran levels in plasma by anti-IIa methods, such as those provided by HEMOCLOT™ Thrombin Inhibitors (CK002K-RUO/CK002L-RUO), with the standard range protocol.

The calibrator target values are determined from multi-instrument (Sysmex CS-series or equivalent) 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 acceptance 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.

The results obtained should be for research use only and must not be used for patient diagnosis or treatment.

SYMBOLS:

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