BIOPHEN™ Dabigatran Control

CE
IVD

REF 225001 CI CII 6 x 1 mL
REF 224701 C1 C2 6 x 1 mL

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

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INTENDED USE:

The BIOPHEN™ Dabigatran Control kits consist of lyophilized human plasmas, spiked with Dabigatran at various concentrations, for the quality control of Dabigatran assays. They are titrated and optimized for the assay of Dabigatran by anti-IIa method.

SUMMARY AND EXPLANATION:

Technical:
These controls are proposed for the quality control of anti-IIa clotting and chromogenic assays of Dabigatran in plasma (HEMOCLOT™ Thrombin Inhibitors and BIOPHEN™ DTI, low range / standard range).
Clinical:
Dabigatran is the active moiety of the oral direct anticoagulant anti-thrombin pro-drug, Dabigatran etexilate (Pradaxa®), used for both curative and preventive purposes. Though monitoring is not needed in treated patients, measurement in human plasma may be of use in certain cases, particularly in the event of emergency surgery or of suspected overdosage (bleeding risk).

REAGENTS:

CI **Control I:** Lyophilized human plasma containing a titrated quantity of Dabigatran of approximately 25 ng/mL.
CII **Control II:** Lyophilized human plasma containing a titrated quantity of Dabigatran of approximately 75 ng/mL.
C1 **Control 1:** Lyophilized human plasma containing a titrated quantity of Dabigatran of approximately 100 ng/mL.
C2 **Control 2:** Lyophilized human plasma containing a titrated quantity of Dabigatran of approximately 300 ng/mL.

The control plasmas contain stabilizing agents.

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

BIOPHEN™ Dabigatran Control Low
REF **225001** ➔ CI **6 vials of 1 mL**
CII **6 vials of 1 mL**

BIOPHEN™ Dabigatran Control Plasma
REF **224701** ➔ C1 **6 vials of 1 mL**
C2 **6 vials of 1 mL**

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Use only the reagents from the same batch of kits.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

CI CII C1 C2 Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.
For manual method, allow to stabilize for 10 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

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.

CI CII C1 C2 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **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 and use immediately.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:
- Distilled water.

Materials:
- Calibrated pipettes.

TRACEABILITY:

The Dabigatran control plasmas are titrated relative to a Reference Internal Standard, whose qualification is linked to the reference method by LC-MS/MS.

QUALITY CONTROL:

The BIOPHEN™ Dabigatran Control kits are used for the quality control of Dabigatran assays by anti-IIa method (low range or standard range), such as those provided by the HEMOCLOT™ Thrombin Inhibitors (CK002K/CK002L) kits.
The control 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.
If the controls fall outside of the acceptable range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

LIMITATIONS:

- If the controls 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 controls in its own analytical system.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

REFERENCES:

1. Douxfils J. *et al.* Impact of Dabigatran on a large panel of routine or specific coagulation assays. Thrombosis and Haemostasis. 2012.
2. Antovic J.P. *et al.* Evaluation of coagulation assays versus LC-MS/MS for determinations of dabigatran concentrations in plasma. Eur J Clin Pharmacol. 2013.
3. Kyrle P.A. et al. Dabigatran :patient management in specific clinical settings. Wien Klin Wochenschr. 2014.
4. Amiral J. *et al.* An update on laboratory measurements of Dabigatran: Smart specific and calibrated dedicated assays for measuring anti-IIa activity in plasma. Transfusion and Apheresis Science. 2016.
5. Gosselin R.C. *et al.* International council for standardization in haematology (ICSH) recommendations for laboratory measurement of direct oral anticoagulants. Thrombosis and Haemostasis. 2018.

SYMBOLS:

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