BIOPHEN™ Edoxaban Calibrator

CE

IVD

REF 226401 CAL I CAL II CAL III 4 x 1 mL

REF 226501 CAL 1 CAL 2 CAL 3 4 x 1 mL

Human plasmas for the calibration of Edoxaban measurements by anti-Xa chromogenic method.

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INTENDED USE:

The BIOPHEN™ Edoxaban Calibrator kits consist of lyophilized human plasmas, spiked with Edoxaban at various concentrations, for the calibration of Edoxaban assays.
They are titrated and optimized for the assay of Edoxaban by the anti-Xa chromogenic technique.

SUMMARY AND EXPLANATION:

Technical:
These calibrators are used to establish the calibration curve for anti-Xa chromogenic assays of Edoxaban in plasma (BIOPHEN™ DiXaI and BIOPHEN™ Heparin LRT, low range / standard range).
Clinical:
Edoxaban is an oral anticoagulant 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:

CAL I **Calibrator I:** Lyophilized human plasma containing no Edoxaban.

CAL II **Calibrator II:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 50 ng/mL.

CAL III **Calibrator III:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 100 ng/mL.

CAL 1 **Calibrator 1:** Lyophilized human plasma containing no Edoxaban.

CAL 2 **Calibrator 2:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 250 ng/mL

CAL 3 **Calibrator 3:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 500 ng/mL

Calibrators plasmas contain stabilizing agents.

The calibrator 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™ Edoxaban Calibrator Low

REF 226401 ➔ CALI **4 vials of 1 mL**
CALII **4 vials of 1 mL**
CALIII **4 vials of 1 mL**

BIOPHEN™ Edoxaban Calibrator

REF 226501 ➔ CAL1 **4 vials of 1 mL**
CAL2 **4 vials of 1 mL**
CAL2 **4 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.

CALI CALII CALIII CAL1 CAL2 CAL3 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.

CALI CALII CALIII CAL1 CAL2 CAL3 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **7 days** at 2-8°C.
- **24 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 Edoxaban calibration plasmas are qualified against an Internal Standard Reference, whose qualification is linked to the reference method by HPLC-MS/MS.

QUALITY CONTROL:

The BIOPHEN™ Edoxaban Calibrator kits are used to establish a calibration curve to measure Edoxaban levels by chromogenic methods (low range or standard range), such as those provided by BIOPHEN™ Heparin LRT (221011, 221013 and 221015) and BIOPHEN™ DiXaI (221030).
The calibrators target values are determined from multi-reagent (BIOPHEN™ Heparin LRT and BIOPHEN™ DiXaI) and 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 established, 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:

- 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.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

REFERENCES:

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SYMBOLS:

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

Changes compared to the previous version.