

**BIOPHEN™ Edoxaban****Calibrator**

REF 226501



IVD

CAL 1 CAL 2 CAL 3 4 x 1 mL

Set of plasma calibrators for Edoxaban measurements by chromogenic method.

**Not for Sale in the US**

English, Last revision: 05-2017

**INTENDED USE:**

The BIOPHEN™ Edoxaban Calibrator kit is a set of human plasmas supplemented with Edoxaban at 3 different levels intended for the calibration of Edoxaban measurements, and lyophilized. They are titrated and optimized for anti-Xa chromogenic assays such as BIOPHEN™ Heparin LRT (221011, 221013 and 221015) and BIOPHEN™ DiXal (221030).

**SUMMARY AND EXPLANATION:**

Edoxaban is an oral anticoagulant drug, used for curative or preventive indications. Although monitoring of this treatment is not necessary, when required, measuring the Edoxaban concentration in patients' plasma is helpful in some clinical cases: emergency surgery, adherence to treatment... BIOPHEN™ Edoxaban Calibrator is proposed to establish the calibration curve for Edoxaban measurements in plasma using anti-Xa chromogenic assays.

**REAGENTS:**

**CAL 1 Calibrator 1:** Lyophilized human plasma containing no Edoxaban.  
4 vials of 1 mL.

**CAL 2 Calibrator 2:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 250 ng/mL  
4 vials of 1 mL.

**CAL 3 Calibrator 3:** Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 500 ng/mL  
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.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be taken when handling and disposing of plasma.
- 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 plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-weeks period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- For *in vitro* diagnostic use.

**REAGENT PREPARATION AND STABILITY:**

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

**CAL 1 CAL 2 CAL 3**

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.
- 24 hours at room temperature (18-25°C).
- 2 months frozen at -20°C or less\*

\*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:**

The Edoxaban calibration plasmas are qualified against an Internal Standard Reference, whose qualification is linked to the reference method by HPLC-MS/MS.

**PROPERTIES:**

The BIOPHEN™ Edoxaban Calibrator is used to establish a calibration curve to measure Edoxaban levels by chromogenic methods, such as those provided by BIOPHEN™ Heparin LRT (221011, 221013 and 221015) and BIOPHEN™ DiXal (221030).

The calibrators target values are determined from multi-reagent (BIOPHEN™ Heparin LRT and BIOPHEN™ DiXal) 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 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 acceptable 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.

**REFERENCES:**

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6. Ogata K et al. Clinical safety, tolerability, pharmacokinetics, and pharmacodynamics of the novel factor Xa inhibitor edoxaban in healthy volunteers. *J Clin Pharmacol.* 50(7):743-53. 2010
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8. Zaipeur A and Oo TH. Update on Edoxaban for the Prevention and Treatment of Thromboembolism: Clinical Applications Based on Current Evidence. *Adv Hematol.* 920361. 2015

**SYMBOLS:**

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