



IVD

BIOPHEN™ Edoxaban Calibrator Low

REF 226401

CAL I CAL II CAL III 4 vials x 1 mL

BIOPHEN™ Edoxaban Calibrator

REF 226501

CAL 1 CAL 2 CAL 3 4 vials x 1 mL

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INTENDED USE:

For calibration of Edoxaban assays, using a quantitative automated method. This device of in vitro diagnostic use is intended for professional use in the laboratory.

Technical:

These calibrators are used to establish the calibration curve for anti-Xa chromogenic assays of Edoxaban in plasma (BIOPHEN™ DiXal and BIOPHEN™ Heparin LRT, low range / standard range).

Though Edoxaban 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 Lyophilized human plasma without Edoxaban.

CAL II Lyophilized human plasma containing approximately 50 ng/mL of Edoxaban.

CAL III Lyophilized human plasma containing approximately 100 ng/mL of Edoxaban.

CAL 1 Lyophilized human plasma without Edoxaban.

CAL 2 Lyophilized human plasma containing approximately 250 ng/mL of Edoxaban

CAL 3 Lyophilized human plasma containing approximately 500 ng/mL of Edoxaban

Calibrator 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.

The product is classified as non-hazardous and is not subject to labeling according to EC Regulation No. 1272/2008 [CLP].

- 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
- Waste should be disposed of in accordance with applicable local regulations.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public https://ec.europa.eu/tools/eudamed or on request to HYPHEN BioMed).

REAGENT PREPARATION:

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

CALI CALII CALII 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.

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

- 7 days at 2-8°C.
- 60 days frozen at -20°C or less*
- Stability on board of the analyzer: see the specific Application Guide.

*Thaw only once, as rapidly as possible at 37°C and use immediately

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Laboratory material.

Lot to lot variability measured on 3 lots is: %CV ≤ 10%.

HYPHEN BioMed 155 rue d'Eragny, 95000 Neuville-sur-Oise, France Calibrators are traceable to internal standard of reference using the LC-MS/MS reference measurement procedure for Edoxaban.

Certificate of traceability and uncertainty is available on the HYPHEN BioMed website:

Uncertainty			
CALI	± 0.0 ng/mL	CAL1	± 0.0 ng/mL
CALII	± 3.5 ng/mL	CAL2	± 10 ng/mL
CALIII	± 3.9 ng/mL	CAL3	± 13 ng/mL

QUALITY CONTROL:

For calibration of Edoxaban assays by chromogenic methods (low range or standard range), with BIOPHEN™ Heparin LRT (221011, 221013 and 221015) and BIOPHEN™ DiXal (221030) kits.

The target values are determined from multi-reagent and multi-instrument tests.

The use of quality controls serves to validate method compliance, along with betweenseries 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 acceptance 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 no limpid appearance or showing signs of contamination must be rejected.

REFERENCES:

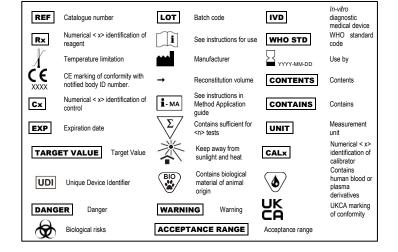
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e-IFU (other languages) are available on www.hyphen-biomed.com.
For customer support or Application Guides, please contact your local provider or distributor (see www.hyphen-biomed.com).

Changes compared to the previous version.

The following symbols may appear on the product labeling:



D750-02/BI/6401-6501/v3