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BIOPHEN™ Edoxaban Control Low

REF 225401 C1 CII 6 vials x 1 mL

BIOPHEN™ Edoxaban Control

REF 225501 C1 C2 6 vials x 1 mL



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English, revision: 08-2023

INTENDED USE:

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

SUMMARY AND EXPLANATION:

Technical:

These controls are proposed for the quality control of anti-Xa chromogenic assays of Edoxaban in plasma (BIOPHEN™ DiXal and BIOPHEN™ Heparin LRT, low range / standard range).

Clinical:

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:

- C1 Lyophilized human plasma containing approximately 25 ng/mL of Edoxaban.
- CII Lyophilized human plasma containing approximately 80 ng/mL of Edoxaban.
- C1 Lyophilized human plasma containing approximately 150 ng/mL of Edoxaban.
- C2 Lyophilized human plasma containing approximately 300 ng/mL of Edoxaban.

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.

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

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.
- 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 website: <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 vial.

C1 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.

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.

C1 CII C1 C2 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.

TRACEABILITY:

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

Controls 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 | | | |
|-------------|-------------|----|------------|
| C1 | ± 3.5 ng/mL | C1 | ± 10 ng/mL |
| CII | ± 3.9 ng/mL | C2 | ± 10 ng/mL |

QUALITY CONTROL:

For quality control 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 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 acceptance 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 no limpid appearance or showing signs of contamination must be rejected.

REFERENCES:

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- Patel MR, Washam JB. Edoxaban and the need for outcomes-based NOAC dosing. Lancet. 2015.
- Honda Y and Morishima Y. Thrombin generation induced by tissue factor plus ADP in human platelet rich plasma: A potential new measurement to assess the effect of the concomitant use of an oral factor Xa inhibitor edoxaban and P2Y12 receptor antagonists. Thromb Res. 2015.
- Ogata K *et al.* Clinical safety, tolerability, pharmacokinetics, and pharmacodynamics of the novel factor Xa inhibitor edoxaban in healthy volunteers. J Clin Pharmacol. 2010.
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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:

| | | | | | |
|--------------|--|------------------|---|----------|---|
| REF | Catalogue number | LOT | Batch code | IVD | In-vitro diagnostic medical device |
| Rx | Numerical < x> identification of reagent | | See instructions for use | WHO STD | WHO standard code |
| | Temperature limitation | | Manufacturer | | Use by |
| CE | CE marking of conformity with notified body ID number. | | Reconstitution volume | CONTENTS | Contents |
| Cx | Numerical < x> identification of control | i-MA | See instructions in Method Application guide | CONTAINS | Contains |
| EXP | Expiration date | | Contains sufficient for <n> tests | UNIT | Measurement unit |
| TARGET VALUE | Target Value | | Keep away from sunlight and heat | CALx | Numerical < x> identification of calibrator |
| UDI | Unique Device Identifier | BIO | Contains biological material of animal origin | | Contains human blood or plasma derivatives |
| DANGER | Danger | WARNING | Warning | UK CA | UKCA marking of conformity |
| | Biological risks | ACCEPTANCE RANGE | Acceptance range | | |