

BIOPHEN™ Edoxaban Control

REF 225401-RUO C1 CII 6 x 1 mL

REF 225501-RUO C1 C2 6 x 1 mL

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

FOR RESEARCH USE ONLY.

DO NOT USE IN DIAGNOSTIC PROCEDURES.



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INTENDED USE:

The BIOPHEN™ Edoxaban Control kits consist of lyophilized human plasmas, spiked with Edoxaban at various concentrations, for the quality control of Edoxaban assays.

They are titrated and optimized for the assay of Edoxaban by anti-Xa chromogenic technique.

This kit is for research use only and must not be used for patient diagnosis or treatment.

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).

REAGENTS:

C1 Control I: Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 25 ng/mL.

CII Control II: Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 75 ng/mL.

C1 Control 1: Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 150 ng/mL.

C2 Control 2: Lyophilized human plasma containing a titrated quantity of Edoxaban of approximately 300 ng/mL.

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™ Edoxaban Control Low

REF 225401-RUO → C1 6 vials of 1 mL
CII 6 vials of 1 mL

BIOPHEN™ Edoxaban Control

REF 225501-RUO → 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* 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.

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.

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.

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.
- 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 control 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 Control kits are used for the quality control of Edoxaban assays by chromogenic methods (low range or standard range), such as those provided by BIOPHEN™ Heparin LRT (221011-RUO, 221013-RUO and 221015-RUO) and BIOPHEN™ DiXal (221030-RUO).

The controls 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.

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.

The results obtained should be for research use only and must not be used for patient diagnosis or treatment.

REFERENCES:

- Bathala MS *et al.* Pharmacokinetics, biotransformation, and mass balance of edoxaban, a selective, direct factor Xa inhibitor, in humans. *Drug Metab Dispos.* 2012.
- Bounameaux H and Camm AJ. Edoxaban: an update on the new oral direct factor Xa inhibitor. *Drugs.* 2014.
- Furugohri T *et al.* DU-176b, a potent and orally active factor Xa inhibitor: in vitro and in vivo pharmacological profiles. *J Thromb Haemost.* 2008.
- 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

SYMBOLS:

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

Changes compared to the previous version.