

BIOPHEN RIVAROXABAN® PLASMA CALIBRATOR Ref 222701



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Calibration plasmas for Rivaroxaban® measurements with anti-Xa method

For in vitro diagnostic use only

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ENGLISH

INTENDED USE:

Rivaroxaban® Plasma Calibrator is a set of calibration plasmas for Rivaroxaban® measurements, titrated and optimised for anti-Xa colorimetric assays, and more especially for **Biophen DiXal** (Hyphen BioMed # 221030)

Rivaroxaban® Plasma Calibrator allows calibrating the assays of Rivaroxaban® using chromogenic anti-Xa methods, especially when the BIOPHEN DiXal kit is used.

SUMMARY AND EXPLANATION:

Rivaroxaban® is an oral anticoagulant drug, used for curative or preventive indications. Although monitoring of this treatment is not necessary, when required, measuring the Rivaroxaban® concentration in patients' plasma is helpful when overdosage is suspected (bleeding risk). Rivaroxaban® Plasma Calibrators are used to establish the calibration curve for Rivaroxaban® Anti-Xa chromogenic assays.

REAGENTS SUPPLIED:

12 vials of 1 ml human plasma supplemented with different concentrations of Rivaroxaban® (3 levels, 4 vials for each concentration).

CAL 1: Calibrator 1:

Human plasma, freeze-dried, with a Rivaroxaban concentration of about 0.00 µg/ml; (4 vials; each vial has to be restored with 1 mL distilled water).

CAL 2: Calibrator 2:

Human plasma, freeze-dried, with a Rivaroxaban concentration of about 0.25 µg/ml; (4 vials; each vial has to be restored with 1 mL distilled water).

CAL 3: Calibrator 3:

Human plasma, freeze-dried, with a Rivaroxaban concentration of about 0.50 µg/ml; (4 vials; each vial has to be restored with 1 mL distilled water).

The exact concentration of Rivaroxaban® can present slight variations from lot to lot, but its exact concentration is indicated on the flyer provided in the kit. The calibration curve covers the range from 0.00 to about 0.50 µg/ml.

Note:

- Calibrator plasmas contain an antibiotic as preservative, and stabilizers.
- Each donor unit used for the preparation of calibration plasmas is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HVC) and antibodies to HIV 1 and 2 and was found negative. However, no test can completely exclude the presence of infectious agents. Any product of human origin, and more especially plasma, must be considered as being potentially infectious and must be handled with all the required cautions for this kind of material.

TRACEABILITY TO THE REFERENCE MATERIAL:

These calibrators have Rivaroxaban concentrations accurately established against an Internal Standard for Rivaroxaban®, which concentrations have been exactly determined using the reference HPLC method.

STORAGE CONDITIONS:

Unopened reagents, must be stored at 2–8 °C. Kept in their original packaging they are then stable until the expiration date printed on the kit.

Note: Stability studies for 3 weeks at 30°C show that the reagents can be shipped at room temperature for a short period without damage.

PREPARATION AND STABILITY OF REAGENTS:

Preparation:

- Reconstitute each vial with exactly 1 mL of distilled water.
- Shake thoroughly until complete dissolution of the content (vortex).
- Incubate at room temperature (18-25°C) for 30 min, while shaking the vial from time to time.
- Homogenise the content before each use.

Stability of reconstituted reagents, in their original vial:

- 7 days at 2-8 °C.
- 48 hours at room temperature (18-25 °C).
- Up to 6 months frozen at -20 °C or below

Cautions:

- Reagents vials are closed under vacuum. Remove carefully the stopper, in order to avoid any loss of powder when opening the vials.
- In order to improve stability, reagents must be closed with their original screw cap following each use.
- Reagents must be handled with care, in order to avoid any contamination during use.
- It is recommended to homogenize each vial before use, in order to have a good reproducibility, all the time.
- Incubating the reconstituted vials at RT allows stabilizing the reagents, and obtaining a homogeneous reactivity.
- Take care to limit as much as possible any evaporation of the reagents during use, eg. by using chimneys.

EXAMPLE OF VALUES:

Each Rivaroxaban® Plasma Calibrator kit contains 4 sets of 3 vials supplemented with increasing concentrations of Rivaroxaban®.

The following values, obtained for one lot of Rivaroxaban® Plasma Calibrator (using the STAR instrument), are provided as an example only:

Calibrator	Rivaroxaban® concentration (µg/ml)	Intra assay		Inter assay	
		N	SD	N	SD
CAL 1	0.05	10	0.003	6	0.008
CAL 2	0.25	10	0.008	6	0.010
CAL 3	0.50	10	0.014	6	0.021

The exact concentration may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit.

The concentrations have been established with the Biophen DiXal kit is used.

The calibration curve covers the range from 0.00 to about 0.50 µg/ml.

PERFORMANCE CHARACTERISTICS:

Rivaroxaban® Plasma Calibrators allow establishing the calibration curve for the measurement of Rivaroxaban® in plasma, especially with Anti-Xa methods. Using **BIOPHEN DiXal (ref. 221030)** kit, the assay is linear up to about 0.50 µg/ml, when using the manual method or the STA-R instrument.

The calibration curve obtained covers the usual concentrations currently observed during Rivaroxaban® therapy.

The **Rivaroxaban® Control Plasma (ref 224501)** can be used in order to obtain a homogeneous quality control system.

The BIOPHEN DiXal kit, used for the measurement of Rivaroxaban® concentrations in plasma, offers a sensitivity threshold of about 0.02 µg/ml.

If used with other kits, results can vary according to the assay reactivity and its standardization: each laboratory must then determine and validate the suitability for use in its specific test conditions.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas are more or less cloudy after reconstitution. This is due essentially to the lipids that, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial 10 minutes at room temperature and shake gently before use in order to homogenise the content.
- Reagents must be handled with care, in order to avoid any contamination or activation during use. Any plasma containing a coagulum or contamination must be rejected.

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