

BIOPHEN RIVAROXABAN® CONTROL PLASMA Ref 224501



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Human plasmas at two levels of Rivaroxaban® for the quality control of Rivaroxaban® measurements with anti-Xa methods

For in vitro diagnostic use only

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ENGLISH

INTENDED USE:

Rivaroxaban® Control Plasma Kit is a set of control plasmas for the quality control of Rivaroxaban® measurements, using anti-Xa colorimetric assays, and more especially **Biophen DiXal** (Hyphen BioMed # 221030)

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). These control plasmas are then used for the quality control of Rivaroxaban® chromogenic assays.

REAGENTS SUPPLIED:

12 vials of 1 mL of human plasma supplemented at 2 different concentrations of Rivaroxaban® (6 vials for each concentration).

C1 : Control 1

Human plasma, freeze-dried, supplemented with Rivaroxaban® (level 1 of about 0.10 µg/mL): 6 vials each vial to be restored with 1 mL distilled water).

C2 : Control 2:

Human plasma, freeze-dried, supplemented with Rivaroxaban® (level 2 of about 0.30 µg/mL): 6 vials; each vial to be restored with 1 mL distilled water).

The Rivaroxaban® concentrations and the acceptance ranges can slightly vary from lot to lot and are indicated for each lot on the flyer provided within the kit.

Note:

- Control plasmas contain an antibiotic as preservative, and stabilizers.
- Each donor unit used for the preparation of control plasmas is 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 ON CONTROL MATERIALS:

These controls are calibrated against an Internal Standard for Rivaroxaban®, which concentrations have been accurately 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 label.

Note: The stability studies for 3 weeks at 30°C show that the reagents can be shipped at room temperature 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 after reconstitution, in their original vial:

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

Cautions:

- Reagents vials are closed under vacuum. Remove carefully the stopper, in order to avoid any lost 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® Control Plasma kit contains 2 sets of 6 vials with 2 different concentrations of Rivaroxaban®. The exact concentration may present variations from lot to lot, but it is exactly determined for each lot.

The Rivaroxaban® concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

The following example shows the Rivaroxaban® concentrations indicated for one lot of Rivaroxaban® Control Plasma:

Rivaroxaban® Control	Rivaroxaban® (µg/ml)	Acceptance range (µg/ml)	Intra assay		Inter assay	
			N	SD	N	SD
Level 1	0.10	[0.05-0.15]	10	0.007	6	0.007
Level 2	0.30	[0.22-0.38]	10	0.013	6	0.012

C1 has a concentration of about 0.10 µg/mL.

C2 has a concentration of about 0.30 µg/mL.

PERFORMANCES:

Rivaroxaban® Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for the measurements of Rivaroxaban® in plasma. They allow validating these calibration curves. They are especially useful for controlling the stability of the calibration curves, from run to run, when using a same lot of reagents.

If controls are out of the acceptance range, the test series can be invalid, and the assay should be rerun. Check all the components of the test system, before rerunning the assay.

The Rivaroxaban® Control Plasma kit, which contains plasmas at 2 different Rivaroxaban® concentrations, can be used in association with **BIOPHEN Rivaroxaban® Calibrator (#222701)** for testing Rivaroxaban® in plasma.

CHARACTERISTICS:

Rivaroxaban® Control plasmas allow validating the calibration curve for the measurement of Rivaroxaban® in plasma, especially when using Anti-Xa methods. The results are guaranteed and optimised for being used with **BIOPHEN DiXal (ref. 221030)** assay.

The **BIOPHEN DiXal** anti-Xa method, used for the measurement of Rivaroxaban® in plasma, offers a sensitivity threshold of about 0.02 µg/mL.

If used with other kits, measured values 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 control 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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