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CE

BIOPHEN ARIXTRA® CALIBRATOR Ref 222501

Calibration plasmas for the assay of Arixtra® with anti-Xa method

For in vitro diagnostic use only

Not for Sale in the US

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ENGLISH

INTENDED USE:

BIOPHEN Arixtra® Calibrator is a set of calibration plasmas for Arixtra® (Fondaparinux) measurements, titrated and optimised using the anti-Xa colorimetric assay BIOPHEN HEPARIN 3 and 6.
BIOPHEN Arixtra® Calibrator allows calibrating the assays of Arixtra® using chromogenic anti-Xa method especially when BIOPHEN Heparin kit is used.

SUMMARY AND EXPLANATION:

Arixtra® can be used as an anticoagulant for curative or preventive indications in thromboembolic contexts. When required, measuring the Arixtra® concentration in patients' plasma allows monitoring the therapy and adjusting drug dosage. BIOPHEN Arixtra® calibrators are used to establish the calibration curve for Arixtra® with Anti-Xa chromogenic assay.

REAGENTS SUPPLIED:

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

CAL 1: ***Calibrator 1:*** 1mL 3 vials.
Human plasma, lyophilised, without any addition of Arixtra® (level 1 at 0 µg/ml) (to be restored with 1 mL distilled water).

CAL 2: ***Calibrator 2:*** 1mL 3 vials.
Human plasma, lyophilised, supplemented with Arixtra® (level 2 at about 0.5 µg/ml) (to be restored with 1 mL distilled water).

CAL 3: ***Calibrator 3:*** 1mL 3 vials.
Human plasma, lyophilised, supplemented with Arixtra® (level 3 at about 1.0 µg/ml) (to be restored with 1 mL distilled water).

CAL4 : Calibrator 4: 1mL 3 vials.
Human plasma, lyophilised, supplemented with Arixtra® (level 4 at about 1.50 µg/ml) (to be restored with 1 mL distilled water).

The exact concentration of Arixtra® in each vial is indicated on the flyer provided in each kit. The calibration curve covers the range from 0 to about 1.5 µg/ml.

Note:
- Calibrator plasmas contain an antibiotic as preservative..
- 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.

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 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:

Lyophilised: Kept in the original packaging, the reagents are stable until the expiration date indicated on the labels.

Reconstituted:
- 7 days at 2-8°C.
- 48 hours at room temperature (18-25°C).

Do not freeze.

***Cautions*:**
- In order to improve stability, reagents must be closed with their original screw caps 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.

CALIBRATION RANGE:

Each BIOPHEN Arixtra® calibrator kit contains 3 sets of 4 vials supplemented with increasing concentrations of Arixtra®.
The following values, obtained for one lot of BIOPHEN Arixtra® Calibrator (lot 92601, determined using Biophen Heparin assay on 1 series water bath, 1 series ACL7000, 7 series STAR for inter assay), are provided as an **example only.**

Calibrator	Arixtra® concentration (µg/ml)	Intra assay (ACL7000)			Inter assay (WB/ACL7000/STAR)		
		N	SD	CV	N	SD	CV
CAL 1	0	15	na	na	9	na	na
CAL 2	0.53	15	0.02	3.8	9	0.03	6.4
CAL 3	1.06	15	0.02	1.2	9	0.03	3.1
CAL 4	1.56	15	0.02	1.7	9	0.06	3.7

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.
This concentration is exactly defined against an Internal reference Standard, initially validated against a reference preparation of fresh Arixtra® diluted into a normal human plasma pool.
The concentrations have been determined using Biophen Heparin 3 or 6 kits .
The calibration curve covers the range from 0 to about 1.5 µg/ml.

PERFORMANCE CHARACTERISTICS:

BIOPHEN Arixtra® calibrator plasmas allow establishing the calibration curve for the measurement of Arixtra® in plasma, especially with anti-Xa method **BIOPHEN Heparin 3 (ref. 221003) or BIOPHEN Heparin 6 (Ref. 221006**). The assay is then linear up to about 1.5µg/ml using the manual method or the STA-R instrument.
The calibration curve obtained covers the usual concentrations currently observed during Arixtra® therapy.
BIOPHEN **Arixtra® Control Plasma (ref 224001)** can be used in order to obtain an homogeneous quality control system.
The BIOPHEN Heparin anti-Xa method, used for the measurement of Arixtra® concentrations in plasma, offer a sensitivity threshold of about 0.05 µg/ml.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas from the BIOPHEN Arixtra® Calibrator 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.

REFERENCES:

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3. "Selective factor Xa inhibition with fondaparinux:from concept to clinical benefit", Alexander G.G.Turpie, European Heart Journal Supplements(2008) 10 (SupplementC),C1–C7.
4. Laboratory monitoring of new anticoagulants", Donna D.Castellone, and Elizabeth M.VanCott, Am.J.Hematol.85:185–187,2010.