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BIOPHEN
ARIXTRA® CONTROL PLASMA
Ref 224001-RUO

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

FOR RESEARCH USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.

Last revision: 24/06/2014

INTENDED USE:

Biophen Arixtra® Control Kit is a set of control plasmas for the quality control of Arixtra® (Fondaparinux) measurements, using anti-Xa colorimetric assay, optimised using BIOPHEN HEPARIN 3 and 6 assays. **This kit is for research use only and should not be used for patient diagnosis or treatment.**

REAGENTS SUPPLIED:

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

C1 : ***Control 1:***
Human plasma, lyophilised, supplemented with Arixtra® (level 1 at about 0.40 µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

C2 : ***Control 2:***
Human plasma, lyophilised, supplemented with Arixtra® (level 2 at about 1.20 µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

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

Note:
- Control plasmas contain an antibiotic as preservative.
- Each donor unit used for the preparation of control 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 after reconstitution:

- 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.

TRACEABILITY ON CONTROL MATERIALS:

BIOPHEN Arixtra® Controls are calibrated against an Internal Standard for Arixtra®, initially validated against a fresh reference preparation of Arixtra®, diluted in a normal human citrated plasma pool.

CONCENTRATION:

Each BIOPHEN Arixtra® Control kit contains 2 sets of 6 vials with 2 different concentrations of Arixtra®. The exact concentration may present variations from lot to lot, but it is exactly determined for each lot.

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

The following example shows the Arixtra® concentrations indicated for one lot of BIOPHEN Arixtra® Control (lot 91801, tested using Biophen Heparin with 1 series water bath, 1 series ACL7000, and 7 series STAR for inter assay) as an **example only:**

BIOPHEN Arixtra® Control	Arixtra® (µg/ml)	Acceptance range (µg/ml)	Intra assay (ACL7000)			Inter assay (WB/ACL7000/STAR)		
			N	SD	CV	N	SD	CV
Level 1	0.44	0.34-0.54	20	0.02	3.5	9	0.02	4.4
Level 2	1.18	1.03-1.33	20	0.03	2.1	9	0.04	3.0

The control **C1** has usually a concentration of 0.40 ± 0.10 µg/mL.
The control **C2** has usually a concentration of 1.20 ± 0.15 µg/mL.

QUALITY CONTROL:

BIOPHEN Arixtra® Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for the measurements of Arixtra® 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 BIOPHEN Arixtra® control kit, which contains plasmas at 2 different Arixtra® concentrations, can be used in association with **BIOPHEN Arixtra® Calibrator (#222501-RUO)** for testing Arixtra® in plasma.

PERFORMANCE CHARACTERISTICS:

BIOPHEN Arixtra® Control plasmas allow validating the calibration curve for the measurements of Arixtra® in plasma, especially with Anti-Xa method, are determined using **BIOPHEN Heparin 3 (ref. 221003) or BIOPHEN Heparin 6 (Ref. 221006)** assays.

The BIOPHEN Heparin anti-Xa method, used for the measurement of Arixtra® in plasma, offers a sensitivity threshold of about 0.05 µg/mL.

CAUTIONS:

- Like all lyophilised plasmas, the control plasmas from the BIOPHEN Arixtra® Control 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.

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

REFERENCES:

1. J. Hirsch, "Fondaparinux", BC Decker Inc., Hamilton, 2007.
2. J.M. Walenga, J. Fareed, W.P. Jeske, F.X. Frapaise, R.L. Bick, M.M. Samama, "Development of a Synthetic Heparin Pentasaccharide: Fondaparinux*", Turk J Haematol*, 2002; 19(2):137-150.